

## **Versartis**

**BUY** 

VSAR: NASDAQ: US\$28.85

Target: US\$45.00

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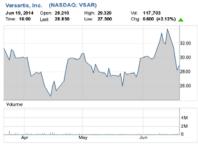
#### **COMPANY STATISTICS:**

Forecast Return:	41.2%
Market Cap (M):	US\$672.2
52-week Range:	23.51 - 36.30
Avg. Daily Vol. (000s):	121.8

#### **EARNINGS SUMMARY:**

D/C Das		00404	00445	004EE
FYE Dec		2013A	2014E	2015E
Revenue (M):		0.0	0.0	0.0
EPS:		(1.99)	(3.00)	(2.34)
Revenue (M):	Q1	0.0	0.0A	0.0
	Q2	0.0	0.0	0.0
	Q3	0.0	0.0	0.0
	Q4	0.0	0.0	0.0
Total		0.0	0.0	0.0
EPS:	Q1	-	(16.13)A	(0.49)
	Q2	-	(0.52)	(0.55)
	Q3	-	(0.60)	(0.64)
	Q4	-	(0.43)	(0.68)
Total		(1.99)	(3.00)	(2.34)

#### **SHARE PRICE PERFORMANCE:**



Source: Interactive Data Corporation

#### COMPANY DESCRIPTION:

Versartis is a development-stage biotechnology company focused on the development and commercialization of its primary drug candidate, VRS-317 for growth hormone treatment. Versartis aims to develop a drug given less frequently in order to decrease injection burden, potentially leading to increased compliance and better treatment outcomes.

All amounts in US\$ unless otherwise noted.

Life Sciences -- Biotechnology

## PROLOR EASTERN EUROPEAN DATA LIKELY INFLATED DUE TO MUCH LOWER BASELINE

### **Investment highlights**

Low baseline for Prolor in Eastern Europe may distort results Prolor's Phase 2 pediatric study for MOD-4023 in Eastern Europe is likely to produce inflated growth velocity data due to severe growth hormone deficiency at baseline. We believe the once-weekly study results are not a relevant or appropriate comparator to Versartis' VRS-317, being tested in the US, where the baseline is more realistic.

Versartis' VRS-317: US geography most reliable and relevant Versartis is testing VRS-317 in US pediatric Growth Hormone Deficient patients, similar to Norditropin and Genotropin, the market leaders. Patients in Versartis' Phase 2 study in pediatrics have a baseline height Standard Deviation Score (SDS) of ~ -2.5, whereas patients in Eastern European trials often enter at -4 to -5. We believe VRS-317's US studies are a more relevant benchmark for real-world commercial uptake.

### Biopartners Eastern Europe study – inflated growth rates

Biopartners' Eastern European Human Growth Hormone study showed very high initial growth velocity, but the magnitude of change for height standard deviation scores (measuring how close a child is to normal height for their age) was the same as US-based studies. We believe companies choose Eastern European geography to "inflate" growth velocity results, even though these patients never catch up to the height of normal children long-term.

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# PROLOR STUDY BASED IN EASTERN EUROPE – EXPECT INFLATED GROWTH RATES

Prolor will present six-month growth velocity data from its Phase 2 study for MOD-4023 given once weekly, which is being tested in Eastern Europe. We would not be surprised to see higher numerical values since the height and IGF-1 SDS are likely to be much lower than that in Versartis' Phase 2 study, which is being run in the US.

# EASTERN EUROPEAN BASELINE DISTORTS GROWTH VELOCITY RESULTS

Prolor and others are testing weekly Human Growth Hormone in pediatric patients in Eastern Europe who are severely growth hormone deficient. As a result, the initial height velocity data often appears numerically higher than US patients, who start at a less deficient level of growth hormone. However, patients in Eastern Europe who start at severely growth hormone deficient do not tend to reach "normal" height for their age even after 12-24 months of Human Growth Hormone therapy.

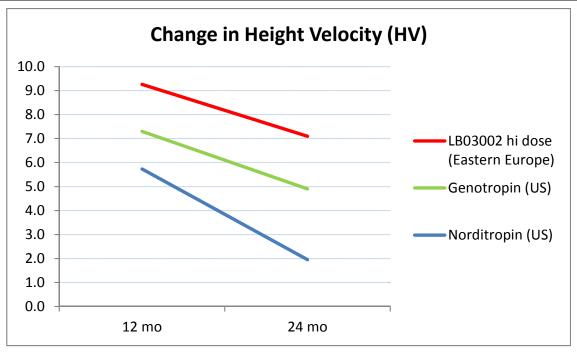
Fast growth velocity for Eastern European patients tends to result in the same magnitude of change for Height Standard Deviation Scores (SDS) – that is how close a child is to normal height for their age. Patients starting at a very low height SDS and who are severely growth hormone deficient do not fare better than less severe patients. Fast growth from a low level improves height, but starting at a very low Height SDS tends to result in a slightly improved but still low height SDS after treatment.

Figure 1: Height velocity data for Norditropin, G	Genotropin, and LB03002
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					Height Velocity (	(cm/yr)	
Drug	Geography	Dose (mg/kg/d)	baseline	12 mo	∆vs baseline	24 mo	<b>Δ</b> vs baseline
Norditropin	US	0.025	4.9	10.7	5.7	6.9	2.0
Genotropin	US	0.04	4.1	11.4	7.3	9.0	4.9
LB03002	Eastern Europe	0.029 0.07 0.1	3.3 3.8 3.2	9.7 11.8 12.4	6.4 8.0 9.3	9.1 9.9 10.3	5.7 6.1 7.1



Figure 2: Change in height velocity for Norditropin, Genotropin, and LB03002





# HEIGHT SDS SCORE MOST IMPORTANT – LOW BASELINE RESULTS IN LOW FINAL RESULT

Height SDS measures how close a child is to normal height at a given age. The goal of Human Growth Hormone Replacement is to increase actual height, but also to move a patient's Height SDS from a negative score closer to zero, which represents a normal child's height at a given age. Importantly, severely growth hormone deficient patients in Eastern Europe tend to grow faster than less severe US patients, but the magnitude of change for Height SDS tends to be the same. That is, severe patients may improve their Height SDS from -4 to -2, a similar magnitude of change for less severe patients moving from -3 to -1.

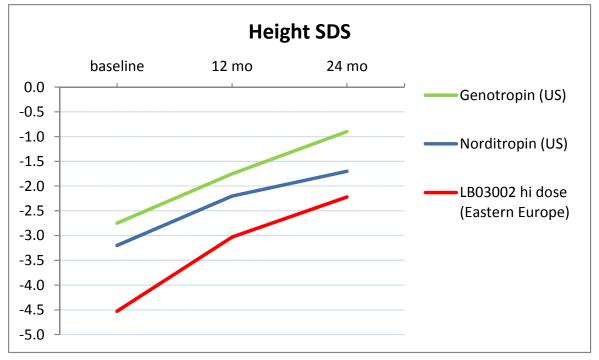
Data from pediatric studies for Norditropin (US study), Genotropin (US study), and LB03002 (European study) show similar magnitude of change for Height SDS even though height velocity is higher for LB03002 (Figure 1, 2). The Eastern European patients receiving LB03002 grew faster than US patients receiving Norditropin, but did not fare any better in terms of magnitude of change for Height SDS. The change in Height SDS for equivalent doses of Norditropin, Genotropin, and LB03002 was 1.0, 1.0, and 1.1 at 12 months, and 1.5, 1.9, and 1.9 at 24 months, showing very little difference in the magnitude of change.

Figure 3: Height SDS	for Norditropin,	Genotropin, LB03002
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					Height SDS		
Drug	Geography	Dose (mg/kg/d)	baseline	12 mo	Δ vs baseline	24 mo	Δ vs baseline
Norditropin	US	0.025	-3.2	-2.2	1.0	-1.7	1.5
Genotropin	US	0.04	-2.8	-1.8	1.0	-0.9	1.9
LB03002	Eastern Europe	0.029 0.07 0.1	-5.0 -3.9 -4.5	-4.0 -2.6 -3.0	1.1 1.4 1.5	-3.1 -1.9 -2.2	1.9 2.1 2.3



Figure 4: Graph of Height SDS for Norditropin, Genotropin, LB03002





# IGF-1 LEVELS MUCH LOWER AT BASELINE IN EASTERN EUROPE

IGF-1 levels can be as low as -7 Standard Deviations at baseline in Eastern European patients, also biasing results towards high growth velocity scores. By contrast, IGF-1 SDS scores were ~ -2 to -3 for US patients in the Norditropin study at baseline. IGF-1 data for the Genotropin study were not available. We believe that the large difference in IGF-1 scores between Eastern European and US patients further skews numerical height velocity results towards Eastern Europe. However, Eastern European patients end up with a poorer result, because they started at a lower IGF-1 SDS (Figure 6).

Figure 5: IGF-1 SDS levels Norditropin, Genotropin

					IGF-1 SDS		
Drug	Geography	Dose (mg/kg/d)	baseline	12 mo	∆ vs baseline	24 mo	Δ vs baseline
Norditropin	US	0.025	-2.8	-0.5	2.3	-0.1	2.7
LB03002	Eastern Europe	0.029	-6.9	-5.5	1.4	-3.5	3.4
		0.07	-5.5	-3.0	2.5	-2.9	2.6
		0.1	-7.4	-3.1	4.3	-3.5	3.9

Source: FDA, Canaccord Genuty

Figure 6: Graph of IGF-1 SDS for Norditropin, LB03002

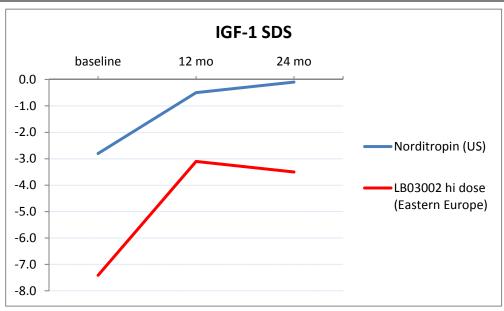




Figure 7: VSAR valuation

Product		ak Sales (\$MM)	Peak Year	Current Value (\$MM)	Probability Adjustment	Value / Share
US						
Pediatrics - GHD	\$	443	2027	\$357	65%	\$10
Adults - GHD	\$	108	2027	\$92	65%	\$2
Turner Syndrome	\$	83	2027	\$69	65%	\$2
ISS + Other	\$	464	2027	\$389	65%	\$10
Total	\$	1,099		\$907		\$24
EU - Co-Promote						
Pediatrics - GHD	\$	203	2027	\$258	65%	\$7
Adults - GHD	\$	60	2027	\$74	65%	\$2
Turner Syndrome	\$	37	2027	\$46	65%	\$1
Other	\$	80	2027	\$99	65%	\$3
Total	\$	381		\$478		\$13
Japan - Royalties						
Pediatrics - GHD	\$	60	2027	\$79	65%	\$2
Adults - GHD	\$	3	2027	\$23	65%	\$1
Other	\$	13	2027	\$18	65%	\$0
Total	\$	75		\$120		\$3
Net Cash						\$100
Total Equity Value						\$978
Shares Outstanding						24
Value Per Share						\$45
Risk-Free		2.0%				
Beta		1.5				
Risk premium		8%				
Total discount rate		14%				
Effective Discount Rate		22%				
Date	,	Jun-14				

Source: Canaccord Genuity, LLC

### **Investment risks**

Primary risks to our rating and price target include the following: VRS-317 may not produce positive Phase 2a data at its six-month readout for monthly, semimonthly, or weekly dosing, even if positive data is produced Phase 3 data may not be positive and the FDA may not approve VRS-317 for any indication, future litigation may delay or reduce revenues, and increased competition may reduce revenues below our current estimates.



20 June 2014

VRS-317 may not show positive Phase 2a data at its six-month readout in June 2014, and even if it does, weekly or semi-monthly dosing may prove to be a more viable treatment option. If dosing is reduced from a monthly treatment to semi-monthly or weekly, VRS-317's competitive advantage versus current and future competitors will be reduced. We see the strength of VRS-317 in its monthly dosing and do not believe patients and doctors will view a semi-monthly treatment option as a very meaningful difference from weekly dosing, should currently in development products be approved.

Litigation from Novo, Roche, or Pfizer may delay VRS-317's entry onto the market, assuming positive data and FDA approval. Depending on the extent of the delay, revenues may be greatly reduced and future cash flows diminished as we expect Versartis' VRS-317 patents will expire in 2030.

Future competition in the growth hormone market may increase, lowering estimated market share for VRS-317 and reducing revenues for Versartis. Should another long-acting growth hormone product be introduced, we expect revenues could be negatively impacted. Growth hormone treatment is a field dominated by several players and new entrants could result in strong competition.



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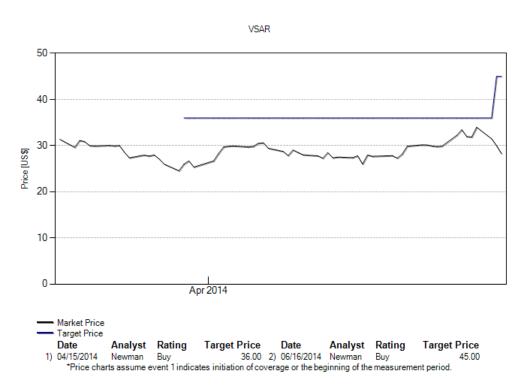
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#### **Site Visit:**

An analyst has not visited Versartis' material operations.

#### **Price Chart:\***



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Coverage Universe					
			IB Clients		
Rating	#	%	%		
Buy	580	58.7%	37.1%		
Speculative Buy	43	4.4%	55.8%		
Hold	317	32.1%	13.2%		
Sell	45	4.6%	4.4%		
	988*	100.0%			

<sup>\*</sup>Total includes stocks that are Under Review



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