Versartis

Equity Research

Company Quick Take

November 7, 2014

Price: $19.34 (11/6/2014)

Price Target: $45.00

OUTPERFORM (1)

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Key Data

Symbol	NASDAQ: VSAR
Market Cap (MM)	$467.9

VRS-317's Profile Remains Exceedingly Attractive As Phase III Start Approaches

The Cowen Insight

VSAR reported Q3 & discussed plans for the VRS-317 Phase III program to begin early next year. We – and our consultants – believe the positive Phase II results indicate a high probability of success in the future study. The bottom-line is VRS-317 has the potential to be the first long-acting pediatric hGH product to reach the market which should drive significant value creation from these levels.

Phase III Program Is De-Risked And VRS-317 Leads Long-Acting hGH Therapies In Development

Versartis reported Q3 results and following interactions with the FDA and EMA, the Company discussed plans for the Phase III trial of VRS-317 in pediatric growth hormone deficient patients to begin early next year. We discuss the proposed Phase III trial design in further detail below, but first, to reiterate our thesis and provide some perspective, recall, our consultants believe that the Phase II efficacy data looks compelling, the adverse event profile is as clean as the currently marketed daily therapies, and this program leads the competitive field in long-acting therapy, which is where the hGH treatment paradigm is moving. Given the unique long-acting dosing profile (only candidate in development with dosing greater than a week in duration), we believe that this program would be exceedingly attractive to various large pharmaceutical players with already established, successful daily hGH franchises. Our consultants continue to suggest that the largest unmet need with respect to current daily hGH therapies is compliance/convenience, as a large percentage of treated patients are significantly non-compliant, resulting in decreased height velocity – or more specifically – a lack of efficacy over time. Furthermore, our consultants continue to indicate that this remains a potentially transformational product and the bottom line is that we continue to believe that VRS-317, if successfully developed as a long-acting product, would alter the standard of care.

As for disclosures about the upcoming Phase III trial design, management has selected semi-monthly dosing – which was as expected – as the commercial formulation is already prepared to move into clinical trials. An interim data disclosure of the 6-month height velocity analysis (means and confidence intervals) is anticipated in mid-2016, while topline 12-month data (primary endpoint) should be available in early 2017. Based upon the positive Phase II data, which was originally presented at the ICE/ENDO conference in June (also discussed further below), we view the VRS-317 program as significantly de-risked as our consultants indicate that the 6-month efficacy profile should be highly predictive of the eventual 12 month results in the soon-to-be-initiated Phase III pivotal study. These time-points and data completion should allow VRS-317 to remain on-track for a mid-2018 FDA approval and launch – which importantly – could allow the Company to be first to market with a long-acting pediatric growth hormone deficiency therapy and provide Versartis with an important first-mover advantage in a treatment area currently fragmented by undifferentiated daily treatment options. A monthly dose will be evaluated as part of the VRS-317 lifecycle expansion strategy and we should receive an update on that program later

next year. Moreover, this trial design should allow for subsequent filings in Canada and Western Europe. The Company has also conducted extensive discussions with the PMDA regulatory agency in Japan and plans to initiate a parallel Phase II/III pediatric trial for VRS-317 in early 2015 for the semi-monthly formulation. Finally, Versartis also expects to initiate a Phase II/III registration study for VRS-317 in adults starting H2:15, which is also a significant additional market opportunity. The bottom-line is that Versartis is aggressively driving forward with multiple programs, should have a first-mover advantage in the long-acting market (with its semi-monthly formulation), and should eventually complement this franchise with a potential once-monthly product. The strategy is sound and the technology is differentiated, and we would be adding at these levels.

The Valuation Suggests Potential Significant Upside

As for the valuation, with the positive 6 month VRS-317 results and subsequent de-risking, we arrive at a base case valuation of $45 per share. While VSAR shares are unlikely to find their way to those levels immediately, we believe that they should approach our price target as the Phase III program progresses and we near both the 6 and 12 month data readouts – and as investors begin to better understand that the risks associated with these events are relatively low. Further de-risking in Phase III for VRS-317 and assuming commercial success should take the value closer to $65-70. We have included peak sales estimates of $400MM+, $400MM+, and approximately $250MM in the target US, EU, and Japanese pediatric GHD markets, respectively. However, we – and our consultants – believe that these peak sales estimates could likely prove conservative if the long-acting profile of VRS-317 holds up (which we believe it will) and no safety issues are observed, as use could spread into other indications. The market potential from the adult GHD indication/program, which is also progressing, is clearly not included in these estimates.

Specifics Of The VRS-317 Pediatric GHD Phase III Program

Versartis expects to initiate the global Phase III pivotal program for VRS-317 in early 2015 with up to 70 clinical sites across the U.S., Canada, and Western Europe (using many of the same sites as in Phase II). The pediatric patient demographics will be similar to the Phase II study (further de-risking the program), which enrolled moderately severe GHD patients with a mean age of 7-8. In our – and our consultants' – view, Versartis is studying VRS-317 in the appropriate patient population and these demographics are representative of typical GHD patients seen in the major markets where Versartis is focusing its commercial efforts. The study will utilize an open-label design with a non-inferiority 12 month height velocity endpoint for 3.5 mg/kg semi-monthly VRS-317 relative to current daily GHD therapy. Of note, the Company has increased the dose from the 2.5 mg/kg used in the Phase II study to 3.5mg/kg based on extensive PK/PD modeling to determine an optimal dose that will provide catch-up growth at the highest tier. Given the clean safety and efficacy profile of the relatively low doses studied in Phase II, we had previously believed Versartis had the ability to take the VRS-317 dose to higher levels, which would have potentially achieved greater HV results**.** And indeed, worth noting, the Company has transitioned 20 VRS-317 patients from Phase II to the 3.5 mg/kg dose in the ongoing safety expansion study with no issues, and the remaining patients will be converted by year-end. We expect this should provide continued valuable insight on safety before heading into Phase III which is anticipated to utilize the 3.5 mg/kg dose, and further de-risks the program. Finally, Versartis is currently in the process of developing a 29-gauge injection device for the product based on feedback from the FDA which is an appropriately competitive gauge and should be well tolerated by patients.

Overview Of Previously Reported Phase II VRS-317 Data

Versartis presented positive 6 month VRS-317 results from a Phase IIa pediatric GHD study at the ICE/ENDO 2014 annual conference in Chicago in late June. VRS-317 demonstrated efficacy and safety comparable to the highest approved doses of market-leading daily growth hormone therapies, Genotropin and Norditropin. Similar to the initial 3 month data, the primary endpoint of repeat weekly, semi-monthly, and monthly dosing of VRS-317 over a 6 month period showed that annualized 6 month height velocity measurements were comparable to age-matched historical controls (on daily injection). Importantly, VRS-317 was safe and well-tolerated in the naive, pre-pubertal children as only mild and transient adverse events, which are typically observed with daily hGH therapy were observed. There were no SAEs or unexpected AEs. There were 5 patients with transient excursions of IGF-I SDS scores above 2 in the 5 mg/kg monthly dosing cohort, but as we stated previously, this is un-concerning to both us and our consultants. We note that the cutoff of 2 is the Company's own stringent requirement and that the FDA is more concerned about levels reaching 3 (per hGH treatment guidelines), which did not occur in the study. Also, as indicated by "transient excursions," these IGF-I SDS scores subsequently returned to normal. The bottom line is that after an additional 3 months of VRS-317 treatment exposure (up to 6 month total), VRS-317 has demonstrated impressive efficacy, a safety profile that appears to be cleaner than previous long-acting therapies in development, and is leading the pack among long-acting hGH therapies in development.

Valuation Methodology And Risks

Valuation Methodology

Pharmaceuticals/Specialty

For our valuation methodology, we arrive at fair value utilizing a discounted cash flow (DCF) approach to derive our 12-month price target.

Investment Risks

Pharmaceuticals/Specialty

Risks include: (1) growing competitive dynamics in the specialty pharmaceuticals space; (2) the ability of management to execute on external growth by successfully acquiring new strategic, accretive products; (3) the ability to grow organically and keep the product pipeline robust; (4) potential regulatory delays, rejections, or failures of pipeline products; (5) economic sensitivity of any self-pay products or weakening consumer demand; (6) domestic or international pricing pressures for marketed products; and (7) failure to execute on new product launches.

Risks To The Price Target

Versartis is an early stage clinical development company with a single product and with that carries risk. Failure of Versartis to successfully develop VRS-317, for which its valuation is solely predicated on, could result in a significant decrease to its valuation and corresponding share price.

Addendum

Stocks Mentioned In Important Disclosures

Ticker	Company Name
VSAR	Versartis

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Assumption: The expected total return calculation includes anticipated dividend yield

Cowen and Company Rating System until May 25, 2013

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Assumptions: Time horizon is 12 months; S&P 500 is flat over forecast period

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Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	440	59.95%	105	23.86%
Hold (b)	278	37.87%	10	3.60%
Sell (c)	16	2.18%	0	0.00%

(a) Corresponds to "Outperform" rated stocks as defined in Cowen and Company, LLC's rating definitions. (b) Corresponds to "Market Perform" as defined in Cowen and Company, LLC's ratings definitions. (c) Corresponds to "Underperform" as defined in Cowen and Company, LLC's ratings definitions.

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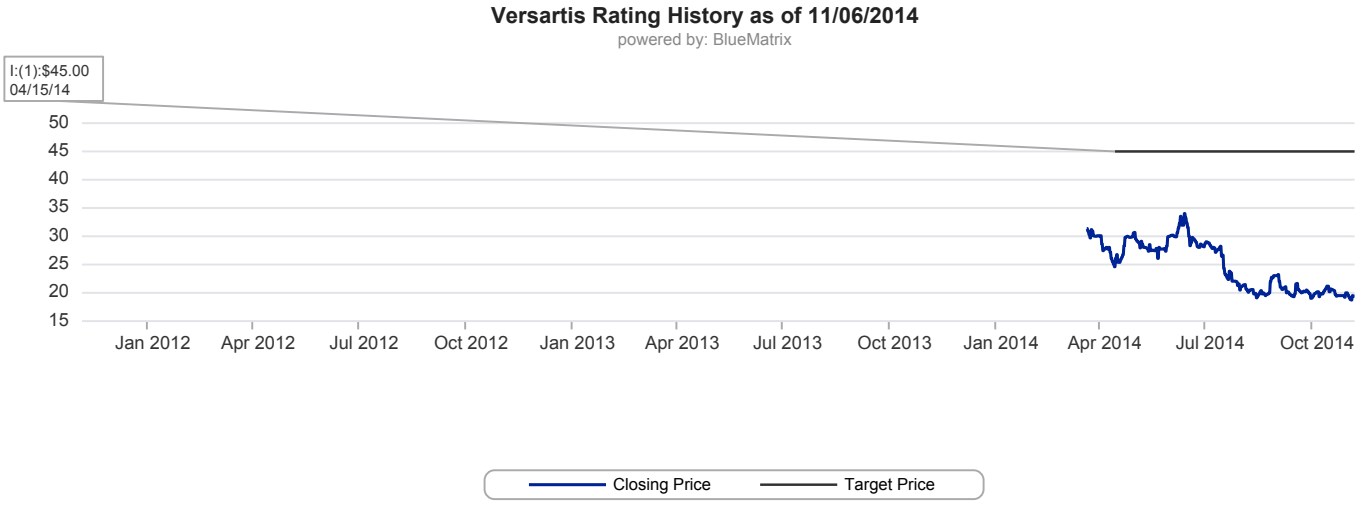

Legend for Price Chart:

I = Initiation | 1 = Outperform | 2 = Market Perform | 3 = Underperform | UR = Price Target Under Review | T = Terminated Coverage | $xx = Price Target | NA = Not Available | S=Suspended

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