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Vitae Pharmaceuticals (VTAE - OUTPERFORM): Voluntary Clinical Hold on BACE Inhibitor Program a Temporary Setback, in Our Opinion; Reiterate OUTPERFORM and $21 PT

Price: $13.28 **12-Month Price Target: $21**

- **Vitae announced today that its partner Boehringer Ingelheim (BI) has voluntarily placed on temporary clinical hold its Phase 1 trial of its BACE1 inhibitor BI-1181181/ VTP-37948 for the treatment of Alzheimer's disease.** The reason cited was the occurrence of skin reactions in some study participants during the multiple ascending dose (MAD) phase. The company is currently evaluating these patients and once complete BI will decide how to proceed.
- **We view this temporary clinical hold as a minor event given that the hold was voluntary and the adverse events were localized to the skin.** We anticipate BI will make a decision as to whether to reinitiate the program with BI-1181181/ VTP-37948 or a Phase 1 ready back up compound fairly soon. Either way we believe the program is likely to restart. We would caution investors on comparing the relatively benign skin reaction observed in this trial to the liver and retina toxicities observed with previous trials with BACE inhibitors. The company and we believe those toxicities were the result of the compounds and not based on the mechanism of action.
- **We do not believe the temporary clinical hold is likely to have significant impact on our projected launch date in Q3 2020.** We presume that the clinical hold is resolved this year, and BI initiates Phase 2 testing in H1:2016. If that occurs, we believe the program is likely to be on track to initiate Phase 3 in H1:17 and we estimate readout in H1:19, potential approval in Q1:20 and launch Q3:20.
- **NEXT: Top-line Phase 2 results for VTP-34072 in diabetic patients in H1 2015.** We anticipate data release from the single-dose Phase 1 safety and PK trial of VTP-43742/autoimmune by mid:2015 and resolution of the temporary clinical on BI-1181181/ VTP-37948 in 2015.

Figure 1: MILESTONES (*our estimates)

Timing	Milestones	Estimated Probability	Estimated Upside/Downside
H1:15	VTP-34072/T2D-META: PHASE 2 DATA RELEASE	60:40	±10-25%
H1:15	VTP-43742/ AUTOIMMUNE: INITIATE PHASE 1	--	--
Mid:15	VTP-43742/ AUTOIMMUNE: PHASE 1 DATA RELEASE	50:50	± 0-15%
H2:15*	VTP-43742/ AUTOIMMUNE: INITIATE PHASE 1 POC	--	--
YE:15	VTP-43742/ AUTOIMMUNE: PHASE 1 POC DATA RELEASE IN PSORIASIS	50:50	± 5-20%
2015*	RESOLUTION OF VOLUNTARY CLINICAL HOLD ON VTP-37948/ALZ	60:40	±5-15%
Q2:16*	VTP-38543/ADERM: PHASE 1 DATA RELEASE	50:50	± 0-15%

Source: Company data, Wedbush Securities, Inc.

- **We reiterate our OUTPERFORM rating and our price target of $21.** Our 12-month PT is a 365-day projection of our current fair value estimate calculated using a sum-of-parts with each part calculated using a 30% annual discount from peak sales of each drug/disease to present day and applying a 1-10x multiple, depending on stage of development to reflect risk.

INVESTMENT THESIS *Vitae, located in Fort Washington, Pennsylvania, is a clinical-stage emerging pharmaceutical company focused on discovering and developing novel, small molecule drugs for large market diseases with significant unmet medical needs. The company's proprietary structure-based drug design platform called Contour® has provided multiple, high-quality product candidates which have attracted over $150 million in collaboration funding from big pharma. Vitae has two partnered product candidates in the clinic and several wholly-owned product candidates in preclinical development. The most advanced product candidates include VTP-34072, currently being tested in phase 2 for the treatment of type 2 diabetes and VTP-37948 which is in phase 1 for the treatment of Alzheimer's disease. Both products are being developed by Vitae's partner Boehringer Ingelheim GmbH (BI). Earlier-stage product candidates are currently unpartnered and include VTP-43742 for the treatment of autoimmune disorders, VTP-38443 for the treatment of acute coronary syndrome (ACS) and VTP-38543 for the treatment of atopic dermatitis (eczema). Vitae intends to develop and commercialize these programs and/or to strategically partner programs as appropriate. We have projected clinical development and potential regulatory approvals so that the first product could be launched in late 2019. We project the first full year of profitability in 2021 from revenues of about $119 million. With the completion of a follow-on in January of 2015, we project Vitae has $86.4MM in cash and cash equivalents, which we expect to provide cash runway covering transforming clinical data releases from multiple product candidates. On February 26, 2015, Vitae announced that its partner Boehringer Ingelheim placed on temporary clinical hold its Phase 1 trial of VTP-37948 for the treatment of Alzheimer's disease. We believe the BI will decided fairly soon whether to move forward with VTP-37948 or a Phase 1 ready backup compound. Either way we believe the program is likely to be reinitiated. We also anticipate upside potential from additional partnerships around their currently unpartnered product candidates and that Vitae's future clinical success could result in the company's acquisition.*

RISKS TO THE ATTAINMENT OF OUR 12-MONTH PRICE TARGET

Clinical Risks: Despite producing high-quality product candidates and encouraging initial clinical and preclinical data, Vitae has not completed phase-3 testing with any product candidate and, in general, the majority of clinical candidates fail. Vitae with BI are also developing a treatment for Alzheimer's disease in which the vast majority of clinical candidates have failed. Vitae is also dependent on BI for the proper development of their two lead product candidates VTP-34072 and VTP-37948. Both Vitae and BI use third parties to conduct preclinical and clinical testing which we view as higher risk as we believe third parties may be less motivated to reduce execution risk. Near-term clinical risks including data releases from the two lead programs are the highest risks to our price target at this time, in our view. On February 26, 2015, Vitae announced that its partner Boehringer Ingelheim (BI) placed a temporary clinical hold on its Phase 1 trial of VTP-37948/ BACE1 inhibitor due the observation of skin reactions in some patients. There is the risk that BI abandons the program, however we this risk to be low given the apparent benign nature of the adverse event (skin reaction) and possibility for BI to move forward with a Phase 1 ready , structurally distinct, compound.

Regulatory Risks: Despite Vitae's management having big pharma experience, Vitae has not achieved regulatory approval for any product candidate.

Manufacturing Risks: On one hand, we view manufacturing risk to be lower for small molecule drug candidates versus biologics and oligonucleotides; however, Vitae relies on third parties for the manufacture of their product candidates for preclinical, clinical, and potential commercial manufacture and we view third parties as less motivated, in general. Also, if Vitae succeeds at obtaining regulatory approval for a product candidate, the current purchase order supply arrangements will need to be augmented with long-term supply arrangements. Vitae intends to also work with additional manufacturers to provide active pharmaceutical ingredients (APIs) and fill-and-finish services prior to pursuing regulatory approval. BI is responsible for the manufacture of API and fill-and-finish services for both 11β-HSD1 and BACE.

Commercial Risks: For their unpartnered programs, Vitae anticipates retaining US commercial rights in specialty markets and establish regional partnerships to commercialize outside the United States. At this time, Vitae does not have a sales force or marketing capabilities. For the two lead programs, Vitae expects BI to commercialize these products with their sales and marketing group.

Competition Risks: Vitae's product candidates, if approved, will compete with currently marketed treatments and potentially with product candidates currently in development focusing on the same mechanism of action which include: 1) 11β-HSD1 competition from Bristol-Myers Squibb, Eli Lilly & Co., and Roche Holding AG which are also testing their inhibitors in clinical trials; 2) BACE competition from Merck & Co., AstraZeneca PLC and Eisai Co., Ltd. in collaboration with Biogen Idec which are studying BACE inhibitors in clinical trials; 3) RORγt competition from potentially multiple companies which are actively assessing RORγt inhibitors in preclinical studies; and 4) LXRβ competition from Bristol-Myers Squibb which is testing an LXRβ inhibitor in cardiovascular clinical trials and Alexar Therapeutics, Inc., which is developing an LXRβ inhibitor for dermatologic conditions.

Intellectual Property Risks: Due to the nature of Vitae's business model, we consider intellectual property risks to be low as the company discovers its own product candidates and has composition-of-matter protection to 2030 and beyond.

Financial Risks: Vitae is a development-stage emerging pharmaceutical company and, despite receiving substantial partnership income from Boehringer Ingelheim, they have no product sales or royalty income and are unlikely to before late 2019. In January of 2015 Vitae completed a follow-on raising ~ $38.6MM in cash and cash equivalents. With the addition of cash from the follow-on, we project the company has $86.4MM in cash, providing cash runway into Q1 2017.

Analyst Certification
I, Liana Moussatos, Ph.D., certify that the views expressed in this report accurately reflect my personal opinion and that I have not and will not, directly or indirectly, receive compensation or other payments in connection with my specific recommendations or views contained in this report.

Disclosure information regarding historical ratings and price targets is available at http://www.wedbush.com/ResearchDisclosure/DisclosureQ414.pdf

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The Investment Ratings are based on the expected performance of a stock (based on anticipated total return to price target) relative to the other stocks in the analyst's coverage universe (or the analyst's team coverage).*

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Wedbush Equity Research Disclosures as of February 26, 2015

Company	Disclosure
Vitae Pharmaceuticals	1,3,4,5,7

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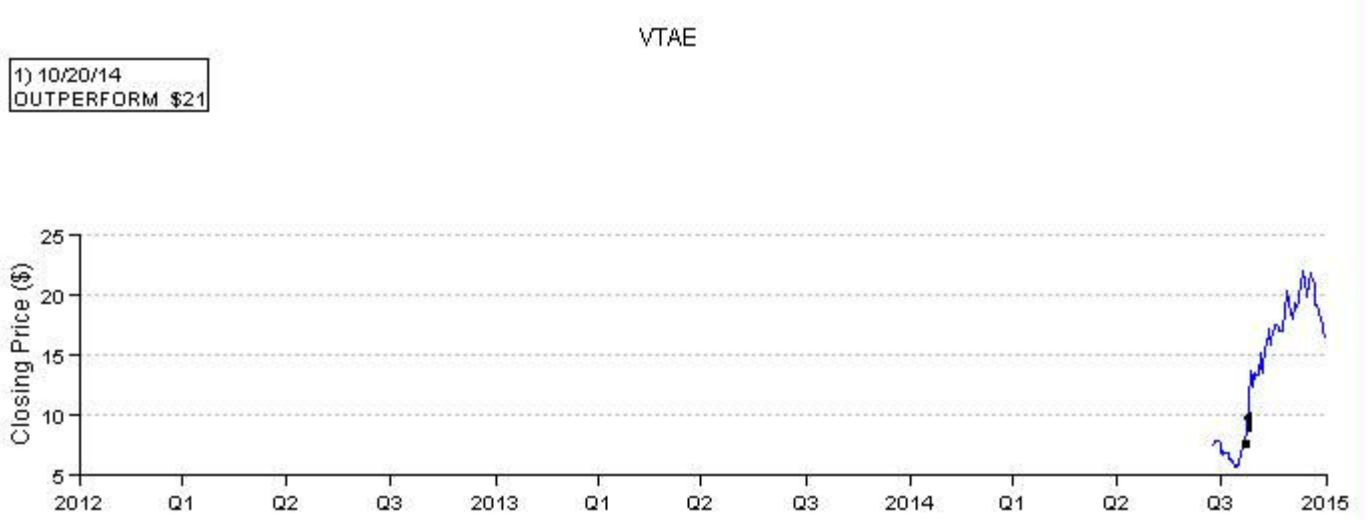

* WS changed its rating system from (Strong Buy/Buy/Hold/Sell) to (Outperform/ Neutral/Underperform) on July 14, 2009.
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