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Vitae Pharmaceuticals (VTAE - OUTPERFORM): Promising Phase 1 Results Support Ongoing Proof of Concept Study, In Our View; Reiterate OUTPERFORM and $20 PT

Price: $7.93 **12-Month Price Target: $20**

- **Vitae announced positive top-line results from its single ascending dose study of VTP-43742, its RoRγt inhibitor for autoimmune disorders.** The study evaluated the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of a single oral dose of VTP-43742 in 53 healthy volunteers. Results from the study indicated that VTP-43742 was safe and well tolerated at all doses tested with no serious adverse events, drug related clinical lab or electrocardiogram (EC) abnormalities being reported. Vitae also reported that in an ex-vivo assay using blood taken from study subjects, VTP-43742 showed a dose dependent reduction in RoRγt dependent production of IL-17A by more than 90%. The majority of the effect was continuous over the full 24-hour measurement period of the assay. We note that in preclinical models, continuous inhibition of RoRγt is necessary to achieve fully therapeutic efficacy. Moreover, we believe the ~30 hour half-life observed in this clinical trial is supportive of a once a day dosing regimen and provide further support of the ongoing Phase 1 proof of concept trial for VTP-43742.

- **NEXT: The multiple ascending proof of concept study for VTP-43742 in psoriasis patients is on track to release data by year-end 2015.** The POC study is a four-week trial designed to enroll ~48 healthy volunteers and ~60 moderate-to-severe psoriasis patients and to assess the safety, tolerability, PK and percent change in Psoriasis Area and Severity Index (PASI) from baseline. Given the trial's short duration, we believe that an improvement in PASI score comparable to current treatments at four weeks could be sufficient to warrant further development. The company is planning to develop VTP-43742 for a large market indication (e.g. psoriasis, multiple sclerosis, rheumatoid arthritis) as well as for a rare disease. We believe that VTP-43742 has the potential to achieve blockbuster sales if it follows the path of recently launched psoriasis drugs (Stelara-launched 2009, $2.38BN expected in 2015; Otezla-launched 2014, $1.3BN expected in 2017—source: Bloomberg consensus estimates). We estimate worldwide peak sales for VTP-43742 in psoriasis alone could reach over $1.2BN.

Figure 1: MILESTONES (*our estimates; **Bloomberg estimates)

Timing	Milestones	Estimated Probability	Estimated Upside/Downside
H2:15	VTP-34072/T2D-META: PHASE 2 DATA RELEASE (MONOTHERAPY ARM)	--	--
H2:15	VTP-38543/ATOPIC DERMATITIS: INITIATE PHASE 1 CLINICAL TRIAL	--	--
YE:15	VTP-43742/ AUTOIMMUNE: PHASE 1 POC DATA RELEASE IN PSORIASIS	55:45	± 5-20%
YE:15/H1:16*	VTP-36951(BACE inhibitor) INITIATE PHASE 1 CLINICAL TRIAL	60:40	±5-15%
H1:16*	VTP-38543/ATOPIC DERMATITIS: PHASE 1 DATA RELEASE	50:50	± 0-15%

Source: Company data, Wedbush Securities, Inc.

- **We reiterate our OUTPERFORM rating and $20 price target.** Our 12-month PT uses 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 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 initiated clinical testing of VTP-43742—one of several wholly-owned product candidates from preclinical development and expects to initiate VTP-38543 clinical testing in atopic dermatitis in 2015, as well. The company anticipates release of proof-of-concept results for VTP-43742 in psoriasis by the end of 2015. Earlier-stage product candidates are currently unpartnered and include VTP-38443 for the treatment of acute coronary syndrome (ACS). Vitae intends to develop and commercialize the proprietary programs and/or to strategically partner them as appropriate. We have projected clinical development and potential regulatory approvals so that the first product could be launched in late 2020. We project the first full year of profitability in 2021 from revenues of about $88.5 million. As of the end of Q1:15, Vitae has $88.7MM 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. BI ultimately decided to discontinue development of VTP-37948 and move forward with a structurally distinct, Phase 1 ready BACE1 inhibitor, BI-1147560/VTP-36951. On July 27, 2015, Vitae announced that BI decided to end the collaboration surrounding the BACE/Alzheimer program and their partnership. It is our understanding that the termination of the partnership was a strategic business decision by BI and not related to the compound. We currently believe the costs associated with running a Phase 1 trial for VTP-36951 (~$1-5 million) are not prohibitive, therefore we anticipate Vitae is likely to advance the program forward given the significant unmet medical need for Alzheimer's. 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 uses 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 release from the autoimmune program is the highest risk to our price target at this time, in our view.

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.

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.

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) BACE competition from Merck & Co., AstraZeneca PLC and Eisai Co., Ltd. in collaboration with Biogen Idec which are studying BACE inhibitors in clinical trials; 2) RORγt competition from potentially multiple companies which are actively assessing RORγt inhibitors in preclinical studies; and 3) 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. Vitae ended Q2:15 with $80.3MM in cash and cash equivalents. Management guided to runway through 2016 and we project Vitae has cash runway into Q1 2017.

Analyst Certification
I, Liana Moussatos, Ph.D., Kelechi Chikere, 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.

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Company	Disclosure
Vitae Pharmaceuticals	1,3,4,5

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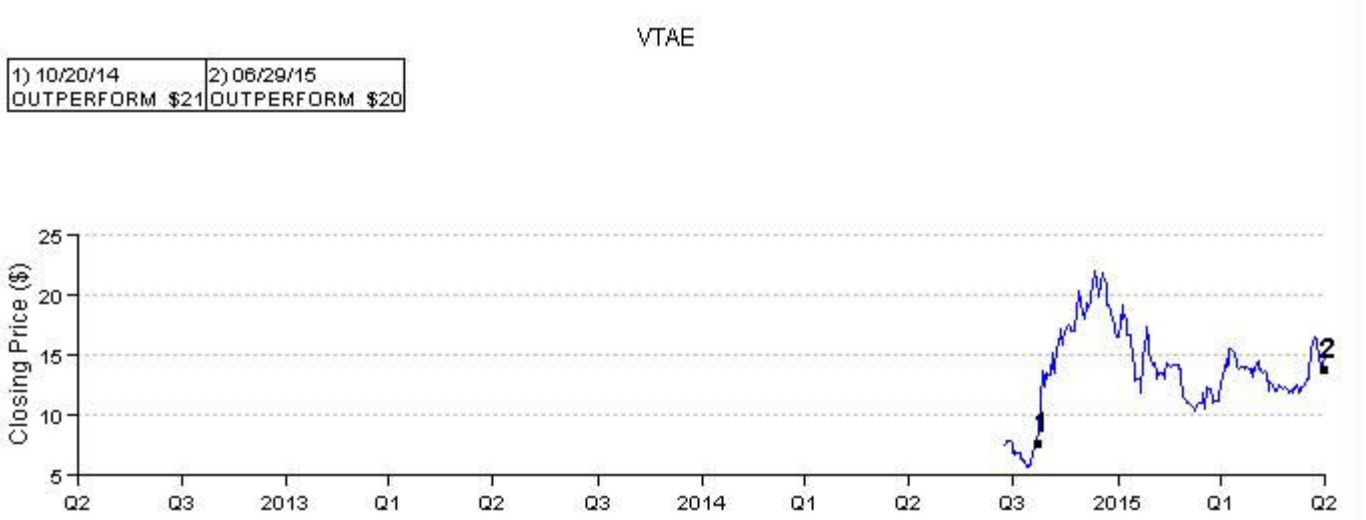

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