October 23, 2014

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Vitae Pharmaceuticals (VTAE - OUTPERFORM): Promising Phase 1 Alzheimer's Biomarker Efficacy Results Reduces Clinical Risk In Our View. Reiterate OUTPERFORM and $21 PT.

Price: $8.65 **12-Month Price Target: $21**

- **Vitae is a clinical-stage emerging pharmaceutical company leveraging its proprietary Contour® structure-based drug design platform to discover and develop optimized orally-dosed small-molecule drug candidates for large market indications.** Partnered with Boehringer Ingelheim (BI), the two lead programs include VTP-34072 for type 2 diabetes and VTP-37948 for Alzheimer's.

- **Vitae announced positive top line results—including preliminary biomarker efficacy--from two phase 1 trials testing VTP-37948 (BI1181181) treatment for Alzheimer's.** In collaboration with BI, Vitae just reported initial results from two ongoing phase 1 trials for VTP-37948 in a total of 68 healthy volunteers. Vitae's first phase 1 clinical trial (NCT02044406 on clinicaltrials.gov) was initiated in January 2014 and had a single dose, randomized, double blind, placebo-controlled design assessing the safety and tolerability of escalating doses of VTP-37948. The primary endpoints included % subjects with drug-related adverse events up to 72 hours and pharmacokinetics including area under the curve (AUC) and Cmax observations. Secondary endpoints included additional pharmacokinetic observations including a half-life of about 16-19 hours—consistent with once daily dosing. Treatment was found to be safe and well-tolerated across all doses tested. The second trial (NCT02106247) design includes single escalating doses of VTP-37498 and addressed the same parameters as the first phase 1 in addition to the primary endpoint of changes in amyloid β in the cerebrospinal up to 24 hours post dosing. In this study, VTP-39748 treatment resulted in more than an 80% reduction in amyloid-β in the cerebral spinal fluid (CSF). We consider this result to support the potential future clinical efficacy of VTP-37948 treatment in which improvement in cognition is likely to be the relevant clinical endpoint. An additional phase 1 study is listed on clinicaltrials.gov (NCT02254161) is intended to further characterize the pharmacokinetic profile of VTP-37948. Data release from this phase 1 is anticipated in H1 2015.

- **VTP-37948 inhibits β-Site Amyloid Precursor Protein Cleaving Enzyme 1 (BACE1) which is associated with the production of amyloid-β-peptide enriched plaques in the brain of Alzheimer's patients.** Amyloid plaques are believed to be an integral part of the Alzheimer's disease process and a recent publication (Choi SH et al Nature 2014 Oct 12 doi: 10.1038/Nature 13800. [Epub ahead of print] PMID: 25307057) supports the amyloid hypothesis that excess amyloid-β-peptide leads to the neurofibrillary tangles. The authors tested the impact of familial Alzheimer's disease (FAD) mutations in β-amyloid precursor protein induce deposition of amyloid-β into plaques and formation of tangles in a new three-dimensional gel-based culture system. In addition, inhibition of amyloid-β production by targeting BACE decreased formation of plaques and tangles in this system. We believe these results strengthen the amyloid hypothesis and the development of BACE inhibitors like VTP-37948 as treatment candidates for Alzheimer's.

- **We project cash runway through 2016 covering material catalysts for the two lead programs.** We estimate Vitae ended Q3:14 with about $78 million in cash covering the phase 2 VTP-34072/type 2 diabetes data release in H1:15 and additional phase 1 (NCT02254161) data for VTP-37948 in the Alzheimer's program.

- **We are reiterating our OUTPERFORM rating and 12-month price target of $21.** Our price target is a 12-month projection of our current fair value calculated using a sum-of-parts with each treatment/indication's value calculated using a 30% annual discount from our net peak sales year to the present day, then applying a 1x-10x premium 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. We estimate Vitae ended Q3 2014 with about $78 million in cash and equivalents which we project can last through 2016. We project cash runway could cover transforming clinical data releases from multiple product candidates. 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.

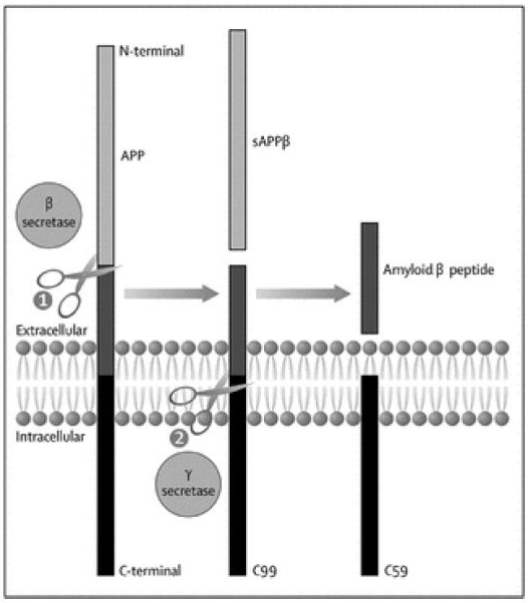
VTP-37948 FOR ALZHEIMER'S DISEASE (BACE INHIBITOR)

ALZHEIMER'S DISEASE

Alzheimer's disease is the most common type of dementia and involves a progressive loss of memory and increasing mental and physical disability leading to disruption in activities of daily living to the point of becoming dependent on caregivers and frequently an early death. The characteristic mark of Alzheimer's disease is the development of large amyloid β plaques in the brain parenchyma which is believed to precipitate neurofibrillary tangles, glutamatergic excitotoxicity, oxidation, inflammation, and cell apoptosis. According to Alzheimer's Association, in 2014, an estimated 5.2 million patients in the US suffer from Alzheimer's and over 500,000 die each year. Due to increasing life expectancy, the prevalence could triple by 2050.

BACE1 AS A DRUG TARGET FOR THE TREATMENT OF ALZHEIMER'S DISEASE

FIGURE 14: GENERATION OF AMYLOID B PEPTIDE



Source: Company data; Wedbush Securities, Inc.

A brain enzyme called β-Site Amyloid Precursor Protein Cleaving Enzyme 1 (BACE1) is thought to play an important role in the neurodegenerative processes leading to Alzheimer's disease. BACE1 activity initiates a proteolytic cascade to convert amyloid precursor protein (APP) into amyloid peptide which aggregates in the brain into amyloid plaques believed to trigger a neurodegenerative cascade. Not only is BACE1 associated with amyloid production, but genetic data also supports its role in the disease process.

Amyloid β is a peptide generated in and secreted by most cell types; however, neurons are the major producers. Amyloid β is produced by the sequential endoproteolytic processing of the amyloid precursor protein (APP) by sequential β and γ-secretase enzymatic activities. APP is initially cut by β-secretase which creates the membrane bound C99 APP peptide and sAPPβ fragment. C99 APP is then cleaved by γ-secretase to generate the 42 amino acid amyloid β peptide fragment.

AMYLOID AND ALZHEIMER'S DISEASE

The deposition of amyloid peptides as plaques in the brain promotes inflammation and neurodegeneration. There are over 200 autosomal dominant mutations observed in familial early-onset disease. The consistent feature across these mutations is that they increase the cleavage efficiency of β and γ secretase. For example, the double mutation in K670N and M671L (the Swedish mutation), and the single mutation A673V, both increase BACE cleavage and Amyloid β peptide production—while the A673T mutation in the B cleavage site of APP decreases cleavage efficiency by 40% and is associated with reduced incidence of Alzheimer disease and increased cognitive faculties in older adults. Together these data support the idea that modification of BACE1 modulates amyloid β production and symptoms of Alzheimer's disease. Currently, there are no approved treatments for Alzheimer's disease that directly target the production or accumulation of amyloid β plaques.

PROSPECTIVE TREATMENTS

ANTI-AMYLOIDβ ANTIBODIES: Recently the results from phase 3 trials examining the use of two anti-amyloid β antibodies, Solanezumab (PFE) and Bapineuzumab (LLY) were published — unfortunately neither met their primary endpoint of an increase in the Alzheimer's disease cooperative study-activities of daily living scale (ADCS-ADL). However, approximately 25% of diagnosed Alzheimer disease participants were negative for amyloid deposition assessed using PET imaging; suggesting that it is likely a majority of PET negative patients did not have Alzheimer's disease. PFE/LLY hopes to exclude these individuals by requiring a positive PET image for acceptance into the third phase 3 trial. In these studies, a subset of early onset patients showed improvement. Patients who show moderate or even mild signs of Alzheimer's may be "too far gone" supporting early diagnosis and treatment in order to prevent or reduce amyloid β plaque formation. It is speculated that amyloid β peptide deposits occur over several years--possibly decades--before the initial clinical symptoms manifest.

GAMMA SECRETASE INHIBITORS: Due to the strong epidemiological association between γ secretase modulation (18-50% of all early onset) and Alzheimer disease, inhibitors of γ secretase activity were tested as a potential treatment. Initial preclinical data demonstrated efficacy in reducing the production of amyloid β peptide in mouse models; however, mutations associated with γ secretase function were lethal--possibly due to the γ secretase role in activating notch—an important factor in fetal development. Despite the adverse event profile seen in mouse models, γ secretase inhibitors were clinically tested; however, there were no signs of improvement in cognitive function and there was an increase in serious adverse events such as melanoma and colitis. We believe safety concerns make further development of γ secretase inhibitors unlikely, in our view.

BETA SECRETASE INHIBITORS (BACE): To date, BACE knockout mice and inhibition of BACE using small molecules has not resulted in lethal effects on mouse physiology and the class is not expected to have the same adverse event profile as γ secretase inhibitors. Consequently, BACE inhibitors may provide a more desirable clinical profile—reducing Aβ without the serious adverse events—and have a larger therapeutic window.

FIGURE 15: BACE INHIBITORS IN DEVELOPMENT

Drug Candidate	Stage of Development
MK-8931 (MRK)	phase 2/3
AZD3293 (AZN/LLY)	phase 2/3 ready
VTP-37948 (VTAE/BI)	phase 2
E2609 (EISAI/BIIB)	phase 2
HPP854	phase 1
LY2886721 (LLY)	phase 2 (Discontinued June 2013 for liver enz's)
RG7129 (RHYYB)	Discontinued 2013

Source: Company data; Wedbush Securities, Inc.

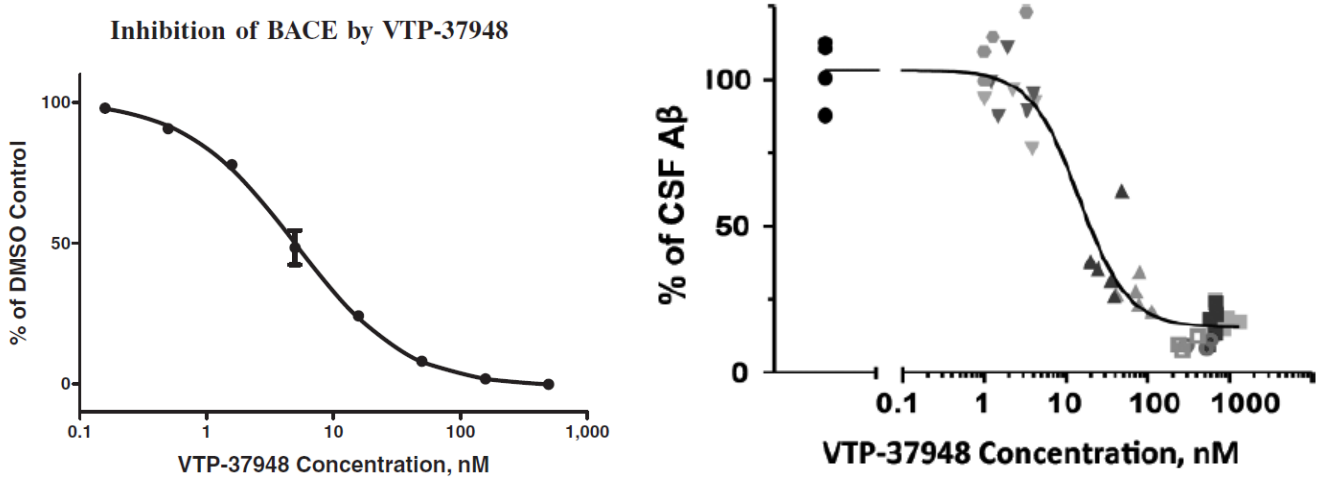
VTP-37948

Vitae discovered and is developing (in a collaboration led by Boehringer Ingelheim (BI)) an orally dosed small molecule drug candidate called VTP-37948 to inhibit BACE1 as a treatment for Alzheimer's disease. In preclinical testing, VTP-37948 demonstrated highly potent and selective inhibition of BACE1 in the brain—associated with up to a 95% reduction in brain amyloid β levels.

PRECLINICAL

In collaboration with BI, Vitae discovered, optimized and selected VTP-37948, a BACE inhibitor for the treatment of Alzheimer's disease using their Contour® platform. Preclinical studies demonstrated that VTP-37948 has a potent low nM inhibition of human BACE activity determined using a cell-free biochemical assay. In addition, VTP-37948 activity is specific in that it has shown no inhibition of pepsin and cathepsin E and a 1000 fold greater preference for BACE compared to renin and cathepsin D.

FIGURE 16: VTP-37948 INHIBITS BACE ACTIVITY AND Aβ



Source: Company data; Wedbush Securities, Inc.

In preclinical studies, orally administered VTP-37948 was shown to be effective in lowering amyloid β in brain and in the cerebral spinal fluid in rat models. Studies in rats and dogs show that VTP-37948 is well absorbed and has a high bioavailability and relatively long plasma half-life. Based on the PK profile, once-daily dosing is likely.

ALZHEIMER'S MARKET

It is estimated that over 5 million Americans (majority over the age of 65 yrs.) are currently suffering with Alzheimer's disease and over 200,000 suffer from early onset disease.

FIGURE 17: APPROVED TREATMENTS FOR ALZHEIMER'S DISEASE

Drug name	Brand name	Approved For	FDA Approved
donepezil	Aricept	All stages	1996
galantamine	Razadyne	Mild to moderate	2001
memantine	Namenda	Moderate to severe	2003
rivastigmine	Exelon	All stages	2000
tacrine	Cognex	Mild to moderate	1993

Source: Company data; Wedbush Securities, Inc.

Currently there are only two classes of FDA-approved treatments for Alzheimer disease, including inhibitors of cholinesterase and N-nitrosodimethylamine (NDMA). Unfortunately, both classes of drugs do not treat the underlying cause of the disease and only address symptoms. Despite limited efficacy, Aricept, a cholinesterase inhibitor, achieved $2.1 billion in its final full year of sales before losing

exclusivity. We believe that VTP-37948 as a BACE inhibitor has the potential to be disease-modifying and could achieve over $5 billion in gross peak annual sales in 2027, by our projections.

INTELLECTUAL PROPERTY

VTP-37948 inhibitor of BACE for Alzheimer's disease—patent expiration in 2033: Vitae's most advanced BACE inhibitor compound for Alzheimer's, VTP-37948, is partnered with BI. Intellectual property protection includes one pending US patent application, one pending PCT application, and six pending patent applications in ex-US jurisdictions. Any patents that may issue from these applications will expire in August 2033, not including possible extensions due to patent office or regulatory delay(s).

For BACE (VTP-37948) Vitae's second research collaboration and license agreement provides BI with an exclusive license to identify, develop and commercialize BACE inhibitors for the treatment of Alzheimer's and other conditions. As of June 30, 2014, Vitae had received $78.2 million from BI related to BACE. This includes a $15 million equity investment, $34.2 in upfront fees and research funding and $29 million for success-based development milestones. In addition, Vitae can receive up to $326 million for additional milestones based on the first product to achieve certain pre-specified events, including up to $176 million for development and regulatory milestone payments and up to $150 million for commercialization milestone payments. Vitae may also receive tiered royalty payments from BI, ranging from upper-single-digit to the low-double-digit percentages, based on the net sales of potential future products. As with VTP-34072 for diabetes, Vitae may opt in to fund phase 3 to increase royalties.

UPCOMING CATALYSTS

With about $78 million in cash estimated at the end of Q3, we project runway through 2016, which covers multiple clinical data releases including: phase-2 data releases from VTP-34072 in diabetes/metabolic syndrome, additional phase 1's for VTP-37948 in Alzheimer's plus phase-1 data releases from VTP-43742 in autoimmune diseases, VTP-38443 in ACS and VTP-38543 in atopic dermatitis.

FIGURE 8: ANTICIPATED MILESTONES (*OUR ESTIMATES)

H1:15	**VTP-37948/ALZ: ADDITIONAL PHASE 1 DATA RELEASE**
H1:15	**VTP-34072/T2D-META: PHASE 2 DATA RELEASE**
YE:15	**VTP-43742/AUTOIMMUNE: PHASE 1 POC DATA RELEASE**
Q2:16	**VTP-38543/ADERM: PHASE 1 DATA RELEASE**
YE:16	**VTP-38443/ACS: PHASE 1 DATA RELEASE**
H2:17*	**VTP-38543/ADERM: PHASE 2 DATA RELEASE**
H1:18*	**VTP-38443/ACS: PHASE 2 DATA RELEASE**
H2:18*	**VTP-34072/T2D-META: PHASE 3 DATA RELEASE**
H1:19*	**VTP-37948/ALZ: PHASE 3 DATA RELEASE**
H1:19*	**VTP-43742/AUTOIMMUNE: PHASE 3 DATA RELEASE**
H2:19*	**VTP-34072/T2D-META: PDUFA/LAUNCH IN US (BI)**
YE:19*	**VTP-38543/ADERM: PHASE 3 DATA RELEASE**
Q1:20*	**VTP-37948/ALZ: PDUFA**
Q3:20*	**VTP-37948/ALZ: LAUNCH IN US (BI)**
MID:20*	**VTP-43742/AUTOIMMUNE: PDUFA**
MID:20*	**VTP-38443/ACS: PHASE 3 DATA RELEASE**
Q4:20*	**VTP-43742/AUTOIMMUNE: LAUNCH IN US**
H1:21*	**VTP-38543/ADERM: PDUFA**
Q3:21*	**VTP-38543/ADERM: LAUNCH IN US**
Q4:21*	**VTP-38443/ACS: LAUNCH IN US**

Source: Company data; Wedbush Securities, Inc.

RISK TO THE ATTAINMENT OF OUR 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.

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. We project that the company is likely to end Q3 2014 with about $78 million in cash and equivalents which we project could last through 2016.

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I, Liana Moussatos, 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	1,3,5,7

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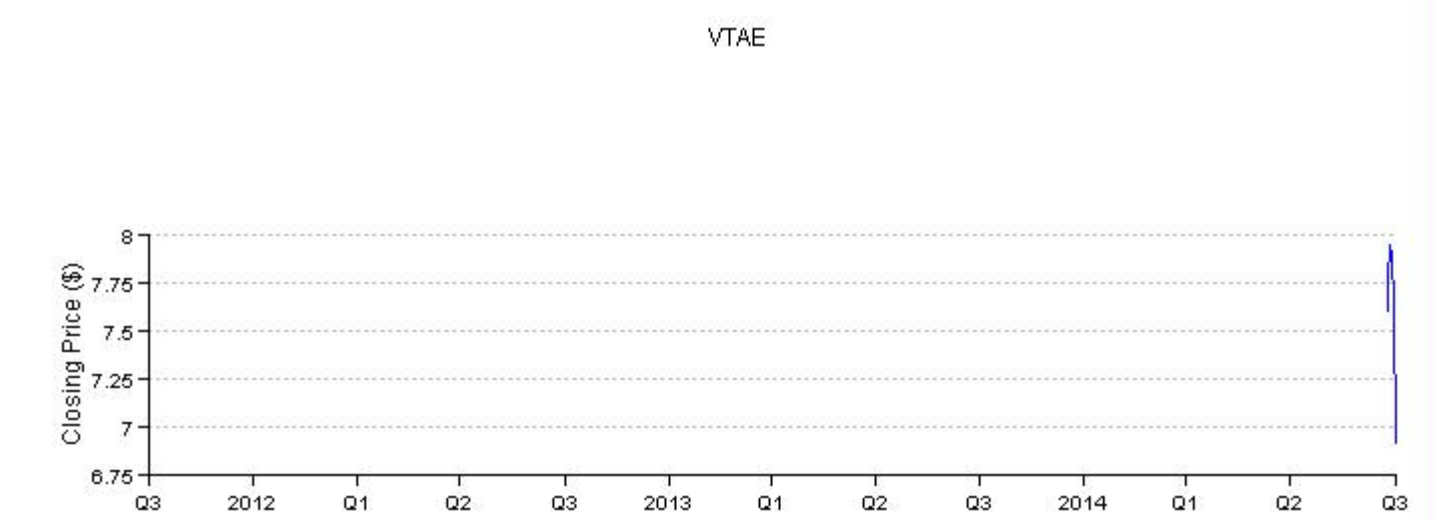

* WS changed its rating system from (Strong Buy/Buy/Hold/Sell) to (Outperform/ Neutral/Underperform) on July 14, 2009.
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