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# Vitae Pharmaceuticals (VTAE)

Q4/2014 Update; Cash Runway Covers Multiple Clinical Drivers and Two Proprietary Candidates in the Clinic by YE; Reiterate OUTPERFORM and \$21 PT.

- Q4/2014 Update. Vitae reported \$0.162MM/\$8.7MM in revenues—in line with our \$0.178MM/\$8.7MM estimates. Reported GAAP EPS (loss) for Q4/2014 were \$(0.40)/\$(3.61). Vitae ended 2014 with about \$65.3MM in cash & short-term investments, which does not include the \$37.8MM raised in a follow-on offer in Q1 2015. Based on the cash in hand, we project runway into Mid-2017.
- Vitae's partner Boehringer Ingelheim (BI) has decided to move forward with a structurally distinct BACE inhibitor, BI-1147560, for the treatment of Alzheimer's disease. Following the voluntary clinical hold and clinical review of the Phase 1 trial of VTP-37948, BI has decided to move forward with a backup Phase 1 ready, structurally distinct, BACE inhibitor, BI-1147560, for the Alzheimer's disease program. The companies anticipate initiating Phase 1 by year-end 2015 and Vitae anticipates receiving a \$7MM milestone payment with its initiation and we have included it in our Q4:15 revenues. While the adverse skin reactions observed in the Phase 1 trial were unexpected, management indicated the skin reactions seen with VTP-37948 were compound related—not seen with other BACE inhibitors. Due to the resulting delay, we have pushed out our potential launch by 6 months. We project BI-1147560 can potentially achieve WW peak sales of over \$3.7BN for treating Alzheimer's disease.
- NEXT: Topline results from the Phase 2 PoC trial for VTP-34072 in Type 2 diabetes (T2D) patients are expected in Q2. The study assesses safety, tolerability and glucose lowering in 126 T2DM patients. We expect positive news is likely to support initiation of a larger Phase 2 trial.
- We also anticipate the topline results from the single dose Phase 1 safety and PK trial of VTP-43742/Autoimmune in healthy volunteers by mid:15 and initiation and readout from the POC study in psoriasis patients in H2:15.
- 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.

April 1, 2015

Price

\$11.89

Rating

## **OUTPERFORM**

12-Month Price Target **\$21** 

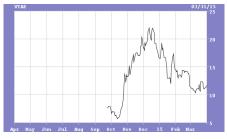
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Company Information	
Shares Outst (M)	21829
Market Cap (M)	\$211
52-Wk Range	\$5.41 - \$23.35
Book Value/sh	\$3.94
Cash/sh	\$3.85
Enterprise Value (M)	\$295
LT Debt/Cap %	0.0
User Input	0.0

## **Company Description**

Vitae is a clinical stage emerging pharmaceutical company discovering and developing small molecule drug candidates to treat large market indications with unmet medical needs.

FYE Dec	2013A	2014A			2015E				
REV (M)	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.		
Q1 Mar	0.98A	1.16A		N/AA	0.16E		0.07E		
Q2 Jun	0.98A	1.16A		N/AA	0.16E		0.07E		
Q3 Sep	10.28A	6.18A		N/AA	0.16E		0.07E		
Q4 Dec	10.28A	0.16A	0.18E	0.09E	7.16E		6.73E		
Year*	22.51A	8.67A	8.68E	8.68E	7.65E		5.20E		
Change									
	2013A		2014A			2015E			
EPS	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.		
Q1 Mar	-0.66A	-0.47A		N/AA	-0.33E		-0.41E		
Q2 Jun	-0.34A	-0.48A		N/AA	-0.34E		-0.43E		
Q3 Sep	0.26A	-1.06A		N/AA	-0.36E		-0.45E		
Q4 Dec	0.46A	-0.40A	-0.43E	-0.40E	-0.06E		-0.46E		
Year*	0.11A	-3.61A	-1.91E	-2.40E	-1.09E		-1.74E		
P/E									
Change									



Source: Thomson Reuters

Consensus estimates are from Thomson First Call.

\* Numbers may not add up due to rounding.

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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. Bl ultimately decided to discontinue development of VTP-37948 and move forward with a structurally distinct, Phase 1 ready BACE1 inhibitor, BI-1147560. We do not believe the switch in compounds is likely to have a material impact on the commercial opportunity for Vitae/Bl's Alzheimer's disease program. 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.

#### A replay of the Q4/2014 financials conference call may be listened to at http://ir.vitaepharma.com/

Figure 1: MODEL UPDATE Vitae, Inc. (VTAE:NASDAQ)
Historical and Projected Income Statement 400,32 1,319.5 2.804.77 4.717.54 otal Revi 1.07 11.1 40.03 131,95 280 47 471.75 tal COGS 10.27 ,524,940 ,246,44 35,042 14,91 4,713 1,315 4,713 1,315 5,08 2,18 19,30 7,91 6,35 30,62 32,16 81,51 1,621,38

Source: Company data, Wedbush Securities, Inc.

**Q4/2014 Update** Vitae reported \$0.162MM/\$8.7MM in revenues—in line with our \$0.178MM/\$8.7MM estimates. Reported GAAP EPS (loss) for Q4/2014 were \$(0.40)/\$(3.61). Vitae ended 2014 with about \$65.3MM in cash & short-term investments, which does not include the \$37.8MM raised in a recent (Q1) follow-on offering. Based on the cash in hand, we project runway into Mid-2017.

Figure 2: MILESTONES (\*our estimates; \*\*Bloomberg estimates)

Timing	Milestones	Estimated Probability	Estimated Upside/Downside
Q2:15	VTP-34072/T2D-META: PHASE 2 DATA RELEASE	60:40	±10-25%
Q2:15	VTP-43742/ AUTOIMMUNE: INITIATE PHASE 1 in HEALTHLY VOLUNTEERS		
Mid:15	VTP-43742/ AUTOIMMUNE: PHASE 1 DATA RELEASE	50:50	± 0-15%
H2:15	VTP-43742/ AUTOIMMUNE: INITIATE PHASE 1 POC		
H2:15	VTP-43742/ AUTOIMMUNE: PHASE 1 POC DATA RELEASE IN PSORIASIS	50:50	± 5-20%
2015*	BI-1147560(BACE) INITIATE PHASE 1 CLINICAL TRIAL	60:40	±5-15%
H1:16*	VTP-38543/ADERM: PHASE 1 DATA RELEASE	50:50	± 0-15%



Source: Company data, Wedbush Securities, Inc.

Vitae's partner Boehringer Ingelheim (BI) has decided to move forward with a structurally distinct BACE inhibitor, BI-1147560, for the treatment of Alzheimer's disease. Following the voluntary clinical hold and clinical review of the Phase 1 trial of VTP-37948, BI has decided to move forward with a backup Phase 1 ready, structurally distinct, BACE inhibitor, BI-1147560, for the Alzheimer's disease program. The companies anticipate initiating the Phase 1 trial by year-end 2015. We note Vitae anticipates receipt of a \$7MM milestone payment with the initiation of the Phase 1. While the adverse skin reactions observed for VTP-37948 treatment in the Phase 1 trial were unexpected, management believes the skin reactions were compound related. However, as a result of the delay, we have pushed out our potential launch date by 6 months. We continue to project WW peak sales of over \$3.7BN for a successful Alzheimer's treatment if approved.

**NEXT:** Topline results from the Phase 2 proof of concept trial of VTP-34072 in Type 2 diabetic (T2DM) patients are expected in Q2 2015. The study will assess the safety, tolerability and glucose lowering efficacy of VTP-34072 in 126 T2DM patients. We expect positive news is likely to support the initiation of a larger trial for VTP-34072 in T2DM.

We also anticipate the topline results from the single dose Phase 1 safety and PK trial of VTP-43742/Autoimmune in healthy volunteers by mid:15 and initiation and readout from the POC study in psoriasis patients in H2:15. Vitae reiterated its plans to file an IND and initiate a Phase 1 study of VTP-43742 in healthy volunteers in Q2:15. We anticipate readout from the trial around mid-2015. If positive we expect the initiation and readout of a Phase 1 POC study in psoriasis patients in H2:15. We believe this study is likely to assess overall clinical improvement for skin manifestations of psoriasis as well as biomarkers from skin biopsies. Management anticipates positive data in psoriasis could lead to the initiation of a larger Phase 2 trial (psoriasis, multiple sclerosis, rheumatoid arthritis or another large market indication) and one small Phase 2 trial in a rare disease.

**Figure 2: VALUATION** 

Vitae Product Pipe	ine Valuation	Eligible #	Pricing	Gross Sales		Net Revs	Peak		Estimated / Actual	Discount	Estimate	Fair Value
Product	Indication	Patients	\$/Patient	(\$000)	Year	(\$000)	Penetration	Multiple	Launch	Rate	Fair Value	per Share
VTP-34072 (WW)	Diabetes / Metabolic Syndrome	67,152,070	\$1,952	\$2,428,129	2025	\$615,346	2%	4	12/4/2019	30%	\$246,835	\$11.31
VTP-37948 (WW)	Alzheimer's Disease	8,730,000	\$5,226	\$3,738,358	2026	\$867,924	10%	3	3/2/2021	30%	\$183,520	\$8.41
VTP-43742 (WW)	Psoriasis	609,167	\$4,978	\$369,925	2027	\$144,635	11%	2	11/4/2020	30%	\$20,296	\$0.93
VTP-43742 (WW)	MS	857,143	\$49,683	\$4,405,808	2025	\$1,830,916	8%	2	11/4/2020	30%	\$130,341	\$5.97
VTP-38443 (WW)	ACS	600,000	\$30,500	\$754,409	2028	\$274,449	4%	1	12/4/2021	30%	\$9,000	\$0.41
VTP-38543 (WW)	Atopic Dermatitis	1,235,000	\$4,978	\$148,850	2028	\$50,055	2%	1	8/4/2021	30%	\$1,738	\$0.08
We use multiples to account for clin various stages of dev	• ,								<u>Stock</u>	MktCap (\$000)	<u>Upside</u>	
1: in preclinical testing	6: in Phase 3					12-n	nonth Price	Target	\$20.64	\$450,650	83%	
2: passed preclinical	7: Phase 3 data						Total Pipeli	ne Value	\$27.11	\$591,730	141%	
3: IND filing/stable mature product	8: regulatory review						Cu	rent Cash	\$4.65	\$83,834		
4: Phase 1 data	9: approved					C	urrent Sto	kprice:	\$11.26	\$202,944		
5: Phase 2 data	10: launched											

Source: Company data, Wedbush Securities, Inc.

We reiterate our OUTPERFORM rating and 12-month 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.

## 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. In March 2015, Vitae announced that BI decided to move forward with a Phase 1 ready, structurally distinct BACE inhibitor, BI-1147560. Although



management has stated that BI-1147560 is comparable to VTP-43742 in preclinical efficacy and safety/tolerability profile, we remain cautious that there is the risk that lower than expected efficacy and safety and tolerability issues may come up in clinical testing.

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. We note that BI observed manufacturing issue(s) with BI-1147560 in preclinical testing which contributed to BI decision to move forward with VTP-37948. Although management has stated that the manufacturing issue(s) have been resolved, we remain cautious that issue(s) or related issues may resurface.

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 Biography

Ms. Moussatos is a Managing Director, Equity Research responsible for the coverage of stocks in the Emerging Pharmaceuticals sector. Liana joined Wedbush from Pacific Growth Equities where she was a Senior Research Analyst. Prior to that she came from UBS Global Asset Management where she was Director and Portfolio Manager of the UBS Global Biotech Funds for five years. Previously Liana was with Bristol-Meyers Squibb where she was a manager in University and Government Licensing External Science and Technology and she also worked with Sloan-Kettering Cancer Institute in the Office of Industrial Affairs and the National Cancer Institute in the Office of Technology Development.

Liana received a B.S. in Entomology and a M.S. in Zoology and Biochemistry from Clemson University and a Ph.D. in Plant Pathology from the University of California Davis and completed a postdoctoral research fellowship in Cellular and Molecular Physiology at the Yale School of Medicine.

Liana's Edge: Liana's industry and buy-side experience provide depth in her understanding of what investors need to know along with her 13 years experience in following healthcare stocks. Her pipeline valuation includes all drug candidates / disease indications in active development and provides investors with a stock value for each program.

#### **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 <a href="http://www.wedbush.com/ResearchDisclosure/Disclo

#### **Investment Rating System:**

Outperform: Expect the total return of the stock to outperform relative to the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.

Neutral: Expect the total return of the stock to perform in-line with the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.

Underperform: Expect the total return of the stock to underperform relative to the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.

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).\*

Rating Distribution (as of December 31, 2014)	Investment Banking Relationships (as of December 31, 2014)
Outperform:58%	Outperform:19%
Neutral: 39%	Neutral: 2%
Underperform: 3%	Underperform: 0%

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#### Wedbush Equity Research Disclosures as of April 1, 2015

Company	Disclosure
Vitae Pharmaceuticals	1.3.4.5.7

#### Research Disclosure Legend

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- 2. WS managed a public offering of securities within the last 12 months.
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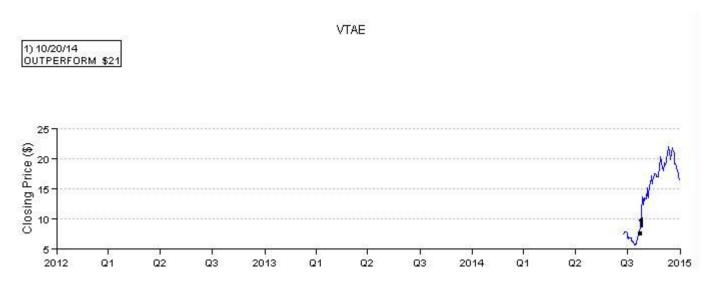
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