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# Vitae Pharmaceuticals (VTAE)

Q1:15 Update: Cash Runway Through 2016 Covers Multiple Catalysts; Next in Q2: Preliminary T2D Phase 2 Results; Reiterate OUTPERFORM and \$21 PT

- Q1:15 financials were in-line. Vitae reported \$0.15MM in revenues--slightly above consensus of \$0.09MM. Reported GAAP EPS (loss) for Q1 was \$(0.47) vs. consensus estimate of \$(0.35). Vitae ended Q1 with \$88.7MM in cash & short-term investments, and guided for runway through 2016. We note that cash runway guidance does not include a potential \$7MM milestone in Q4 from Boehringer Ingelheim (BI) for dosing the first patient in a Phase 1 trial for BI-1147560 (new BACE inhibitor for Alzheimer's disease).
- NEXT in Q2: Initial Phase 2 proof-of-concept (POC) results testing VTP-34072 (11β-HSD-1 inhibitor) treatment of Type 2 diabetes (T2D). Bl plans to release top-line results from the metformin combination arm in Q2 while monotherapy results are expected in H2. Recall, this POC study is a four-week trial designed to assess safety, tolerability and blood glucose management of VTP-34072 in 126 T2D patients. Given the proof-of-concept trial's short duration, we believe a reduction in blood glucose may be sufficient for BI to move forward.
- The Alzheimer's program restart is on track for 2015. Bl is expected to initiate a Phase 1 clinical trial of BI-1147560 for Alzheimer's disease by year-end.
- We anticipate initial clinical data releases from Vitae's proprietary VTP-43742 I autoimmune program in 2015. Results from a single ascending dose Phase 1 safety and pharmacokinetics (PK) study for VTP-43742 in healthy volunteers is expected around mid-year followed by a multiple ascending dose POC study for VTP-43742 treatment of psoriasis, with results expected in H2:15. 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.
- Vitae also plans to initiate clinical testing for their second proprietary candidate in 2015. Initiation of a Phase 1 safety and PK trial for VTP-38543 in atopic dermatitis (eczema) is anticipated in H2:15.
- We reiterate our OUTPERFORM rating and our price target of \$21. Our 12month 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.

May 13, 2015

**Price** 

\$13.38

Rating

# OUTPERFORM

12-Month Price Target \$21

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Company Information	
Shares Outst (M)	20827
Market Cap (M)	\$292
52-Wk Range	\$5.41 - \$23.35
Book Value/sh	\$4.38
Cash/sh	\$4.26
Enterprise Value (M)	\$381
LT Debt/Cap %	0.0
User Input	0.0

## **Company Description**

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	2014A		2015E			2016E	
REV (M)	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	\$1.2A	\$0.2A	0.16E	\$0.1E	\$0.2E		-
Q2 Jun	1.2A	0.2E	0.16E	0.1E	0.2E		
Q3 Sep	6.2A	0.2E	0.16E	0.1E	0.2E		
Q4 Dec	0.2A	7.2E	7.16E	3.6E	0.2E		
Year*	\$8.7A	\$7.6E	7.65E	\$3.9E	\$0.6E		\$2.9E
Change							
	2014A		2015E			2016E	
EPS	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	(\$0.47)A	(\$0.47)A	-0.33E	(\$0.35)E	(\$0.53)E		
Q2 Jun	(0.48)A	(0.47)E	-0.34E	(0.37)E	(0.56)E		
Q3 Sep	(1.06)A	(0.49)E	-0.36E	(0.40)E	(0.58)E		
Q4 Dec	(0.40)A	(0.19)E	-0.06E	(0.33)E	(0.61)E		
Year*	(\$3.61)A	(\$1.61)E	-1.09E	(\$1.44)E	(\$2.28)E		(\$1.66)E
P/E							
Change							



Source: Thomson Reuters

Numbers may not add up due to rounding.

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Consensus estimates are from Thomson First Call.



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 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. 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. We do not believe the switch in compounds is likely to have a material impact on the commercial opportunity for Vitae/BI'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 Q1 financials conference call is available by webcast at http://ir.vitaepharma.com/

Figure 1: MODEL UPDATE Vitae, Inc. (VTAE:NASDAQ) Historical and Projected Income Statement (In thousands except per share data) Wedbush Securities, Inc. 2014A FY:14A 2019E FY:19E 2016E FY:16E 2023E FY:23E Q1A Q4E FY:15E VTP-34072 (T2) 3.66 13.48 46.40 116 55 205.67 203 35 293,353 310,438 133,809 1,830,916 64,010 77,183 667,87 13,087 VTP-43742 (psoriasis VTP-43742 (RMS 1,060 5,982 VTP-38443 (ACS 19,569 4,134 57,995 11,320 123.87 193,097 34,042 847 711 VTP-38543 (Atopic Dermati 22,38 tal Net Product Reve 10.70 111.47 1.319.55 4,717,549 Collaborative Revenues
Total Revenues 60 11.30 601 112.077 .320,151 601 4,718,150 60 2.805.37 otal COGS 8.669 150 150 7.150 601 601 10.233 100.929 60.893 .188.196 2,524,894 4.246.39 7,506 2,111 45 513 Acquired in-process R&I Total Operating Expens 10,973 41,053 49,855 -58.059 41.089 58.07 72.769 77,005 81,519 86,330 91.460 96,932 9.617 9.994 10.469 27,219 Operating Income (Loss)
Other Income / (Expense) (18.550 (9.467) (9.844) (10.319) (3.822 (33,452 (49,254 (57.458 (40.488 (57.33) (62.536 23.924 279.37 1.101.86 2.433.434 4.149.463 (187 (187 (278 (187 (440 (187 (187 2,849 (187) 7,529 45 (108) (36 Total other (exper (1,621,154 19,103 0.0% 39.0 672.30 39.0° 39.0° 2.535.65° 33 94 (0.47)(0.47)(0.49) (2.28)93.73 21,052 \$63,145 \$3.00 22,852 23,45 24,05 24,652 25,852 26,45 \$1,899,101 \$71.80

Source: Company data, Wedbush Securities, Inc.



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

		Estimated	Estimated
Timing	Milestones	Probability	Upside/Downside
Q2:15	VTP-34072/T2D-META: PHASE 2 TOP-LINE DATA RELEASE (METFORMIN ARM)	60:40	±10-20%
Q2:15	VTP-43742/ AUTOIMMUNE: INITIATE PHASE 1 in HEALTHY VOLUNTEERS		
Mid:15	VTP-43742/ AUTOIMMUNE: PHASE 1 DATA RELEASE	50:50	± 0-15%
H2:15	VTP-34072/T2D-META: PHASE 2 DATA RELEASE (MONOTHERAPY ARM)	60:40	±0-15%
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/ATOPIC DERMATITIS: PHASE 1 DATA RELEASE	50:50	± 0-15%

Source: Company data, Wedbush Securities, Inc.

Figure 3: VALUATION

Vitae Product Pipel	ine Valuation	Eligible #	Pricing \$/Patient	Gross Sales (\$000)	Year	Net Revs (\$000)	Peak Penetration	Multiple	Estimated / Actual Launch	Discount Rate	Estimate Fair Value	Fair Value
VTP-34072 (WW)	Diabetes / Metabolic Syndrome	67,152,070	\$1,952	\$2,428,129	2025	\$615,346	2%	4	12/4/2019	30%	\$254,400	\$11.65
BI-1147560 (WW)	Alzheimer's Disease	8,730,000	\$5,226	\$3,738,358	2026	\$867,924	10%	3	3/2/2021	30%	\$189,145	\$8.66
VTP-43742 (WW)	Psoriasis	609,167	\$4,978	\$369,925	2027	\$144,635	11%	2	11/4/2020	30%	\$20,918	\$0.96
VTP-43742 (WW)	MS	857,143	\$49,683	\$4,405,808	2025	\$1,830,916	8%	2	11/4/2020	30%	\$134,336	\$6.15
VTP-38443 (WW)	ACS	600,000	\$30,500	\$754,409	2028	\$274,449	4%	1	12/4/2021	30%	\$9,276	\$0.42
VTP-38543 (WW)	Atopic Dermatitis	1,235,000	\$4,978	\$148,850	2028	\$50,055	2%	1	8/4/2021	30%	\$1,791	\$0.08
We use multiples to account for clini various stages of devi	• ,								Stock	MktCap (\$000)	<u>Upside</u>	
1: in preclinical testing	6: in Phase 3					12-n	nonth Price	Target	\$21.28	\$464,463	59%	
2: passed preclinical	7: Phase 3 data						Total Pipel	ne Value	\$27.94	\$609,866	109%	
3: IND filing/stable mature product	8: regulatory review						Cu	rrent Cash	\$4.06	\$88,693		
4: Phase 1 data	9: approved					С	urrent Sto	ckprice:	\$13.38	\$292,083		
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 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.

## 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. Additionally, we believe there is additional clinical risk in 2015 as BI is expected to make a go/no go decision on whether to continue development of VTP-34072 for type 2 diabetes based on results from the ongoing proof-of-concept trial.

**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

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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. Vitae ended Q1:15 with \$88.7MM in cash and cash equivalents. Management guided to runway through 2016 and we project that with the addition of \$7MM from an anticipated milestone in Q4:15 from BI, we project Vitae has cash runway through 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., 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	1,3,4,5,7

## Research Disclosure Legend

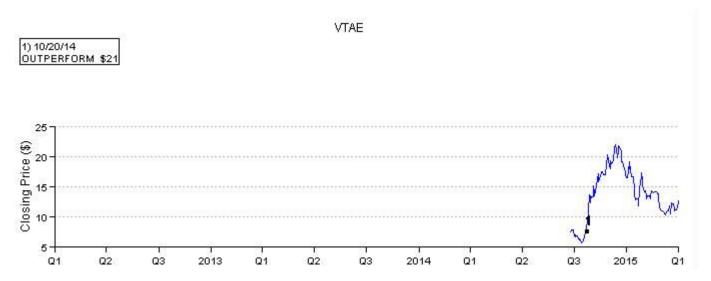
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