Vitae Pharmaceuticals, Inc. (VTAE)

Reports Top-Line Results from Phase I Studies Supporting Advancement in Alzheimer's Disease

MARKET OUTPERFORM | Price: $8.65 | Target Price: $15.00

MARKET DATA

Price	$8.65
52-Week Range:	$5.41 - $8.47
Shares Out. (M):	17.4
Market Cap ($M):	$150.5
Average Daily Vol. (000):	1,110.0
Cash (M):	$59
Cash/Share:	$3.39
Enterprise Value (M):	$225
LT Debt (M):	$2

Source: Thomson Reuters and JMP Securities LLC

FY DEC		2013A	2014E	2015E
Revenue ($M)	1Q	--	--	$0.0
	2Q	--	--	$0.0
	3Q	--	$6.0	$0.0
	4Q	$1.4	$0.0	$20.0
	FY	**$22.5**	**$6.0**	**$20.0**
EPS	1Q	--	--	($0.46)
	2Q	--	--	($0.49)
	3Q	--	($0.05)	($0.52)
	4Q	($4.66)	($0.41)	($0.54)
	FY	**$0.00**	**($1.04)**	**($2.00)**
	P/E	--	NM	NM

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE

INVESTMENT HIGHLIGHTS

Vitae Pharmaceuticals reported encouraging biomarker results from Phase I studies of VT-39748, which is currently being developed for Alzheimer's disease; reiterate Market Outperform rating and $15 price target, based on a synthesis of discounted cash flow, comparables, and sum-of-the-parts methodologies. Vitae reported encouraging results from a Phase I clinical study of its small molecule BACE-1 inhibitor VT-39748, under development in partnership with Boehringer Ingelheim (BI, Private), to treat Alzheimer's disease (AD). The inhibition of BACE-1 is a well-established, high-value target in AD being pursued by a number of companies with several compounds having entered Phase III (Figure 1). We believe VT-39748 has demonstrated ideal pre-clinical efficacy, and with the current human data in hand, VT-39748 has demonstrated biomarker results that bring it up to par with the most advanced clinical candidates. With a conservative (5-7%) market penetration in 2025E, we estimate sales could reach nearly $8B, shared through a royalty split between Vitae and BI.

VT-39748 exhibits excellent safety, high potency inhibition of BACE-1, and encouraging decreases in Aβ levels in the CSF. Recall, the amyloid hypothesis is currently being pursued among major pharmaceutical companies looking to develop a functional treatment for Alzheimer's disease. Data in the scientific literature strongly suggests Aβ as the most strongly validated target in AD, confirmed by animal studies and human genetic data. The production of β amyloid can be prevented through the inhibition of the proteases that are involved in its production - BACE-1 (β-secretase). BACE-1 inhibitors have progressed considerably through the clinic, and offer significant potential for an efficacious treatment. VT-39748 has demonstrated high biochemical potency against BACE1 (4nM IC50) while retaining negligible BACE-2 activity, inhibition of which creates undesirable off target side effects that have prevented previous compounds from advancing in the clinic (refer to our initiation report here). In this current trial, Vitae reported a greater than 80% reduction in cerebral spinal fluid (CSF) Aβ levels, on par with the effects seen in Phase I clinical trials for the Merck, AstraZeneca, or Eisai compounds (Figure 1). Additionally, VT-39748 was safe and well-tolerated across all doses tested in the separate single rising dose trial, with additional results expected in 2015. The company reported a drug half-life of between 16 and 19 hours, compatible with once-daily dosing. The study also showed no maximum tolerated dose (MTD), which permits a wide therapeutic index for the drug. BI has already begun multiple ascending dose (MAD) studies in normal volunteers in both young and elderly healthy volunteers. We suspect data from the SAD study will be presented at a scientific conference during 2015.

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Vitae is an early stage drug discovery and development company that uses its proprietary CONTOUR structure-based drug design platform for the development of therapeutic candidates directed against validated targets that are difficult-to-drug. While Vitae's programs are early, they are potentially first- or best-in-class for multi-blockbuster opportunities in Alzheimer's disease and type II diabetes. These programs, designated VTP-37948 and VTP-34072, have been validated scientifically and de-risked financially via separate business development agreements with German biopharmaceutical company, Boehringer Ingelheim (private).

FIGURE 1. BACE-1 Clinical Candidates in Development in Alzheimer's

BACE-1 inhibitor	Company	Clinical Phase	BACE-1 IC50	Cohort (mg)	% inhibition in CSF Aβ
VTP-37948	Boehringer Ingelheim/Vitae	Phase I	~4nM		>80%
E2609	Eisai	Phase II initiation EOY14	7 nM	25 50 100 200	46.20% 61.90% 73.80% 79.90%
MK-8931	Merck/Ligand	Phase III	1.7 nM	20 100 550	21% 75% 82%
AZD32923	AstraZeneca, Eli Lilly, Otsuka	Phase III		15 50 70	>75% >75% >75%

Source: JMP Securities LLC, BiomedTracker

FIGURE 2. Upcoming Potential Catalysts

Timing	Program	Catalyst
2H14	VTP-37948 (BACE-1)	Phase I clinical trial and biomarker results expected in Alzheimer's
1H15	VTP-34072 (HSDβ-1)	Phase II clinical results expected in type-2 diabetes
1H15	VTP-43742 (RORγt)	Phase I clinical trials slated to begin in psoriasis
1H15	VTP-38543 (LXRβ)	Phase I clinical trials slated to begin in atopic dermatitis
1H16	VTP-38443 (LXRβ)	Phase I clinical trials slated to begin in acute coronary syndrome

Source: Company Presentations

Company Description

Vitae is a biotechnology company focused on leveraging a discovery and development platform for the advancement of small molecule drugs to treat important unmet clinical diseases. Utilizing the company's proprietary Contour structure based discovery platform, Vitae is able to rapidly discover novel lead molecules with desired target efficacy and biological stability that supports significant derisking at very early stages of drug development. Vitae has initially focused its development on two targets that treat large patient markets: type-2 diabetes and Alzheimer's disease. The company's most advanced clinical asset is VTP-34072, is an inhibitor of 11-β HSD1, a pre-clinically validated target in Diabetes and metabolic disease that is currently in Phase II clinical trials. Data is expected from this trial in the first half of 2015. The second asset, VTP-37948, is an inhibitor of BACE-1, a target of high interest in the treatment of Alzheimer's disease, and has entered Phase I clinical trials with expected biomarker and data readouts by end of year 2014. Both of these clinical candidates target large markets and have been partnered since discovery for further development by Boehringer Ingelheim GmBH, resulting in significant upfront and milestone payments totaling $152.4MM. The company has also used its platform to develop preclinical candidate inhibitors against difficult-to-target pathways in autoimmune disease, cardiovascular disease, and dermatological conditions. These wholly owned assets include VTP-43742, a RORγt inhibitor strongly implicated in autoimmune diseases like multiple sclerosis, psoriasis and rheumatoid arthritis. Additionally, the company has developed VTP-38443 for the treatment of acute coronary syndrome, and VTP-38543 for the treatment of atopic dermatitis, both of which stimulate the LXRβ receptor. Vitae is also developing an as-yet unnamed program to develop preclinical compounds for immune-oncology applications.

Investment Risks

Clinical and Regulatory. If either VTP-34072 in diabetes or VTP-37948 in Alzheimer's is not able to meet any of its primary outcomes or suffer from safety and tolerability issues, Vitae and Boehringer Ingelheim (BI) may choose to end development in any of its current indications. Additionally, if the FDA and EMEA do not approve VTP-34072 or VTP-37948, Vitae stock price would likely suffer.

Partnering. Vitae has partnered with (BI) in the development of VTP-34072 in diabetes and VTP-37948 in Alzheimer's. BI is responsible for the continued clinical and commercial development of both candidates and may decide to end development for one or more indications. If it were necessary for Vitae to develop and market any of its programs due to the loss or inability to retain a partner, it may be difficult to develop an internal commercial structure. Management has limited experience in commercial and marketing activities.

Competitive. The Diabetes market is crowded and saturated with low cost generic manufacturers of metformin and sulfonylureas. It may be difficult for BI and Vitae to garner significant market share. The high bar for safety efficacy differentiation for the Diabetes primary care market may limit adoption. VTP-37948 is not the only BACE-1 inhibitor in development and will not be a first in class therapy if Merck/Ligand are successful in bringing their drug to market. It may be difficult to compete in a market dominated by these therapies.

Financial. Vitae currently derives revenue from research and development funding and from license or collaboration agreements. The company sold ~6,875,000 shares in September 2014, raising net proceeds of ~$51.15MM. As a result, the company is project to finish 3Q14 with ~$53.5MM in cash, equivalents, and marketable securities. We expect this funding to be able to carry the company to 2016. Like most non-profitable biotechnology companies, VTAE will likely need to seek additional financing, exposing current investors to dilutive risk.

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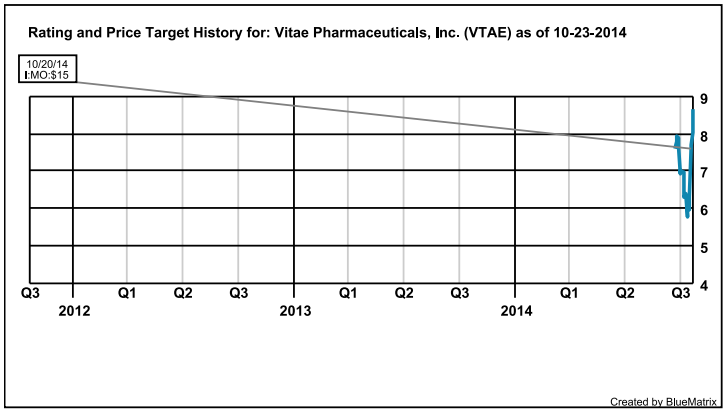
MARKET OUTPERFORM	Buy	284	*61.34%*	Buy	284	*61.34%*	106	*37.32%*
MARKET PERFORM	Hold	140	*30.24%*	Hold	140	*30.24%*	16	*11.43%*
MARKET UNDERPERFORM	Sell	2	*0.43%*	Sell	2	*0.43%*	0	*0%*
COVERAGE IN TRANSITION		36	*7.78%*		36	*7.78%*	0	*0%*
TOTAL:		463	*100%*		463	*100%*	123	*26.57%*

Stock Price Chart of Rating and Target Price Changes:

Note: First annotation denotes initiation of coverage or 3 years, whichever is shorter. If no target price is listed, then the target price is N/A. In accordance with NASD Rule 2711, the chart(s) below reflect(s) price range and any changes to the rating or price target as of the end of the most recent calendar quarter. The action reflected in this note is not annotated in the stock price chart. Source: JMP Securities.



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