

Vitae Pharmaceuticals, Inc. (VTAE)

Initiating Coverage at Market Outperform; Conquering Disease with the Assistance of Computational Chemistry

MARKET DATA

Price	\$6.30
52-Week Range:	\$5.41 - \$8.47
Shares Out. (M):	17.4
Market Cap (\$M):	\$109.6
Average Daily Vol. (000):	41.0
Cash (M):	\$59
Cash/Share:	\$3.39
Enterprise Value (M):	\$225
LT Debt (M):	\$2

Source: Thomson Reuters and JMP Securities LLC

MARKET OUTPERFORM | Price: \$6.30 | Target Price: \$15.00

INVESTMENT HIGHLIGHTS

Initiating coverage on Vitae Pharmaceuticals with a Market Outperform rating and \$15 price target after the company recently completed its IPO transaction on September 24. 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, we believe they have potential to be first- or best-in-class, 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). We arrive at our 12-month \$15 price target based on a synthesis of our discounted cash flow (DCF) and sum-of-the-parts (SOTP) analyses.

Structure-based drug design (SBDD) is a tried and true pathway to successful drug development and value creation in the biotechnology space. Some of the biotechnology industry's earliest successes, such as Vertex (VRTX, MO, \$115 PT, Bayko) and Agouron, now part of Pfizer (PFE, NC), were SBDD companies that originally began developing HIV protease inhibitors, leveraging targeted structural information via the use of X-ray crystallography. More recently, Plexxikon, now part of Daiichi Sankyo (DSKYF, NC), was acquired for over \$900MM in 2011. While not strictly SBDD companies, two of our covered companies, Karyopharm (KPTI, MO, \$50 PT) and Epizyme (EPZM, MO, \$50 PT) utilize both structural and computational methodologies in their respective discovery processes. KPTI is currently valued at \$1.02 billion and the market cap of EPZM is ~\$800MM. We believe VTAE has similar potential for market cap multiplication, particularly in light of its \$500MM in future milestone opportunities.

It's all about the BACE for Alzheimer's disease. While the Alzheimer's disease space has seen more than its share of failed clinical development programs, many companies are still toiling to come up with therapies that could affect the course of the disease even modestly. Many approaches have been taken, but those that target beta amyloid, which appears to be the culprit protein leading to the disease, hold the greatest promise. In the small molecule arena, therapies directed against BACE, also known as beta-secretase appears to have strong validation from both human genetic and knock-out animal studies. The key issue facing the pharmaceutical industry has been the design of molecules that combine high potency and selectivity, properties that have eluded other drug developers. With the assistance of CONTOUR and funding from BI, we believe Vitae may have finally opened the door to what is expected to be the biggest drug category ever to hit the pharmaceutical industry.

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



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FOR DISCLOSURE AND FOOTNOTE INFORMATION, REFER TO JMP FACTS AND DISCLOSURES SECTION.

Covering a broad spectrum of the ills of metabolic disease by interdiction against 11 β HSD1. By our reckoning, Vitae is one of the few remaining companies with active programs against this notoriously difficult-to-drug target. The attractiveness of hitting 11 β HSD1 is its pleiotropic effects. In both animal and human studies, 11 β HSD1 inhibitors have been shown to have beneficial effects on weight, glucose, lipids, and blood pressure. The difficulty with the development of this class has been the ability to find highly selective, well-tolerated compounds. This combination of attributes has eluded the pharmaceutical industry to date. For the company that can get it right, a large commercial market awaits.

CONTOUR has created a rich product development pipeline for Vitae. In addition to the two aforementioned programs, Vitae has created a proprietary pipeline of development candidates across four distinct therapeutic areas - autoimmune disorders, acute coronary syndromes, atopic dermatitis and immuno-oncology. Over time, we would anticipate CONTOUR spinning out additional candidates on a regular basis.

Modest market cap relative to achievable milestones warrants Market Outperform rating on shares of Vitae. As we mentioned, under the terms of the agreement with BI, Vitae stands to gain upwards of \$500MM in milestones, assuming success. This amount pales in comparison to VTAE's modest technology value of \$44MM. In addition, each of the company's pipeline programs represents a significant commercial opportunity, success for any of which could drive the shares to higher levels. For now, we have only factored VTP-37948 and VTP-34072 into our valuation assumptions.

INVESTMENT THESIS

Traditionally, structure-based drug design (SBDD) has been a successful strategy for compound development when used by the groups who know how best to wield its power - such as Vitae. The company was founded on the principles of SBDD in 2001, and has successfully validated its approach to drug discovery no fewer than three times. Two of these programs are VTP-37948 and VTP-34072, directed against 11 β HSD1 and BACE, respectively. A former product candidate, VTP-27999, was discovered by VTAE and developed by GlaxoSmithKline (GSK, NC) for hypertension. While the compound hit all of its clinical objectives, the program was returned to Vitae in 2009 when a competitor molecule failed to achieve a meaningful benefit in risk reduction in a population of dialysis patients.

The company bounced back nicely from this setback and rebounded with two lucrative development agreements with BI on 11 β -HSD1 and BACE. Further, as an example of the efficiency of CONTOUR, Vitae was able to move from target declaration of these two compounds to patentable chemistry solutions in two and six months, respectively. Proof-of-principle was then achieved in 16 and 14 months, respectively. From a business point of view, this kind of efficiency has enabled Vitae to minimize the dilution hit required by shareholders. To its credit, the company has been able to survive strictly on funds raised from corporate partners rather than investors since 2007 when it raised its last venture round. The company has generated \$150MM in payments from BI on the 11 β HSD1 and BACE to date.

Based on its capital-efficient model, the proceeds of the company’s IPO (~\$48.4MM net of fees) should enable the company to generate two IND filings (VTP-38443 and VTP-38543), drive VTP-43742 through Phase Ib proof-of-concept for VTP-43742 in autoimmune disease, and the identification of a clinical candidate for its unnamed immuno-oncology drug candidate. Finally, we expect Phase I data in normal volunteers from the BACE program between now and the end of the year, while the 11βHSD1 program should provide data from a Phase IIa proof-of-concept trial in 2015.

KEY UPCOMING EVENTS

FIGURE 1. Upcoming 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

VALUATION

We arrive at our 12-month \$15 price target based on a synthesis of our discounted cash flow (DCF), and sum-of-the-parts (SOTP) analyses. Each approach is built upon our forecast of sales of VTP-34072 sales in diabetes and VTP-37948 in Alzheimer's. Our model relies on the continued collaboration revenue royalty with Boehringer Ingelheim (BI) with respect to the global marketing and commercialization of both products. We exclude the RORyt, LXRβ, and the immune-oncology programs from our analysis, as they are preclinical or discovery stage assets, and while we find the concepts and biology behind the development of these assets exciting, the probability of success is unclear at this point.

FIGURE 2. Price Target Derivation

Synthesis of Valuation Approaches	
Approach	Valuation
DCF Analysis	\$ 13.80
SOTP	15.74
Price Target	\$ 15.00

Source: JMP Securities LLC

Discounted cash flow methodology

We have constructed a discounted cash flow (DCF) model (Figure 3) utilizing contributions of revenue streams derived from continued development of VTP-34072 and VTP-37948 by BI, factoring in milestone payments for regulatory and clinical development and marketing and commercialization. We assume approval in diabetes for VTP-34072 in 2018 and Alzheimer's approval in 2020. We project cash flows from these indications out to 2025 and assume a blended royalty rate to Vitae of 12.5% for each product.

We apply an initial tax rate of 0% that reaches 35% as the company attains profitability. We derive a blended discount rate of 38%, given the early clinical nature of the compounds and their unique mechanisms of action. We project peak revenues of \$1.79B in 2025. This equates to \$13.80 on a per share basis.

FIGURE 3. Discounted Cash Flow Model

Vitae Pharmaceuticals (VTAE)												
Discounted Cash Flow Model	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Total Revenues												
US Sales					-	21.7	108.1	179.6	286.7	427.5	629.5	715.8
Ex-US Sales					-	-	126.5	262.1	443.1	637.6	790.0	962.2
Milestones	6.0	20.0	-	46.0	70.0	20.0	60.0	50.0	145.0	75.0	-	107.0
Total Revenues	\$ 20.0	\$ -	\$ 46.0	\$ 70.0	\$ 41.7	\$ 294.5	\$ 491.7	\$ 874.8	\$ 1,140.2	\$ 1,419.6	\$ 1,785.0	
Cost of product sales												
COGS as a % of revenue					#DIV/0!	0%	0%	0%	0%	0%	0%	0%
Gross Profit	0.0	20.0	0.0	46.0	70.0	41.7	294.5	491.7	874.8	1,140.2	1,419.6	1,785.0
R&D expense	19.3	23.8	26.7	29.3	58.6	65.7	82.1	105.1	120.9	139.0	159.8	183.8
R&D as a % of revenue					84%	157%	28%	21%	14%	12%	11%	10%
SG&A expense	6.4	10.8	13.0	19.4	26.2	30.2	37.7	60.4	84.5	118.3	159.7	215.6
SG&A as a % of revenue					37%	72%	13%	12%	10%	10%	11%	12%
Total operating expenses	25.8	34.6	39.6	48.8	84.9	95.9	119.8	165.4	205.4	257.3	319.5	399.4
% Margin					121%	230%	41%	34%	23%	23%	23%	22%
Operating income (EBIT)	(25.8)	(14.6)	(39.6)	(2.8)	(14.9)	(54.1)	174.7	326.2	669.4	882.9	1,100.0	1,385.5
Taxes	0.0	0.0	0.0	0.0	0.0	0.0	45.9	97.9	234.3	309.0	385.0	484.9
Tax rate	0%	0%	0%	0%	0%	0%	26%	30%	35%	35%	35%	35%
After tax operating income	(25.8)	(14.6)	(39.6)	(2.8)	(14.9)	(54.1)	128.9	228.3	435.1	573.9	715.0	900.6
					-21%	-130%	44%	46%	50%	50%	50%	50%
Discount year	0.00	1.00	2.00	3.00	4.00	5.00	6.00	7.00	8.00	9.00	10.00	11.00
Discount factor	1.0	1.4	1.9	2.6	3.6	5.0	6.9	9.5	13.1	18.1	25.0	34.5
PV	(25.8)	(10.6)	(20.8)	(1.1)	(4.1)	(10.8)	18.7	24.0	33.2	31.7	28.6	26.1
Residual value of cash flow	\$183									Terminal Value	93.5	
+Cash and Cash equivalents	59											
Company value	242											
-Long-term debt on 6/30/2014	2											
Value of equity	\$240											
Fully diluted shares outstanding on 06/30/14	17.37											
Price/share	\$13.80											
Discount Rate	38.0%											
Terminal growth rate	10%											

Source: JMP Securities LLC

Sum-of-the-parts methodology

We value VTAE shares at \$15.74 on a per share basis using a sum-of-the-parts methodology (Figures 4 & 5). We project VTP-34072 and VTP-37948 revenues in anticipated approval indications, diabetes and Alzheimer's, in the U.S., EU, and Japan. As per the agreement with BI, VTAE receives tiered royalties from the high-single digits to the low-double digits on sales in these partnered programs. We subsequently discount revenues using rates of 35% for diabetes and 40% for Alzheimer's given the early stage clinical nature. We attribute an NPV of \$82MM on peak royalty revenues of \$431MM U.S. and \$73.2MM ex-U.S. for VTP-37948 in diabetes and an NPV of \$106MM on peak royalty revenues of \$284MM U.S. and \$708MM ex-U.S. related to sales of VTP-34072 in Alzheimer's, for a \$4.72 and \$6.14 per share valuation, respectively.

FIGURE 4. Sum-of-the-Parts Analysis

NPV Sum-of-the-Parts			
	WW	US	Ex-US
Diabetes VTP-37948	\$ 4.72	\$ 4.10	\$ 0.63
Alzheimer's VTP-34072	\$ 6.14	\$ 1.76	\$ 4.38
Milestones	\$ 1.49		
Cash and Equivs on Hand	\$ 3.39		
Total NPV	\$ 15.74	\$ 5.85	\$ 5.00

Source: JMP Securities LLC

FIGURE 5. Sum-of-the-Parts Valuation

VTP-37948, Diabetes NPV	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
US Sales (\$MM)					-	174	567	823	1,342	1,946	3,175	3,453
Royalty rate					13%	13%	13%	13%	13%	13%	13%	13%
Royalty to VTAE					0.0	21.7	70.9	102.8	167.7	243.3	396.8	431.6
Contribution Margin					100%	100%	72%	68%	58%	48%	42%	38%
Operating Margin					0.0	21.7	51.1	69.9	97.3	116.8	166.7	164.0
Terminal Value												497.0
Discount Period					4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0
PV of CF to VTAE					0.0	4.8	8.4	8.6	8.8	7.8	8.3	24.4
Discount Rate												35%
Terminal Growth												2%
NPV												\$ 71.14
# Shares outstanding (mm)												17.4
Incremental price per share												\$ 4.10
Ex-US Sales (\$MM)					\$0	\$0	\$34	\$154	\$276	\$389	\$484	\$585
Royalty rate					13%	13%	13%	13%	13%	13%	13%	13%
Royalty to VTAE					0.0	0.0	4.2	19.2	34.5	48.6	60.5	73.2
Contribution Margin					100%	100%	72%	68%	58%	48%	42%	38%
Operating Margin					0.0	0.0	3.1	13.1	20.0	23.3	25.4	27.8
Terminal Value												84.2
Discount Period					4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0
PV of CF to VTAE					0.0	0.0	0.5	1.6	1.8	1.6	1.3	4.1
Discount Rate												35%
Terminal Growth												2%
NPV												\$ 10.87
# Shares outstanding (mm)												17.4
Incremental price per share												\$ 0.63
VTP-34072, Alzheimer's NPV	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
US Sales (\$MM)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 297	\$ 614	\$ 951	\$ 1,474	\$ 1,862	\$ 2,274
Royalty rate							13%	13%	13%	13%	13%	13%
Royalty to VTAE							0.0	37.1	76.7	118.9	184.3	232.7
Contribution Margin							100%	100%	72%	68%	58%	48%
Operating Margin							0.0	0.0	26.7	52.2	69.0	88.5
Terminal Value												284.2
Discount Period					4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0
PV of CF to VTAE					0.0	0.0	3.6	4.9	4.7	4.3	3.4	9.7
Discount Rate												40%
Terminal Growth												2%
NPV												\$ 30.52
# Shares outstanding (mm)												17.4
Incremental price per share												\$ 1.76
Ex-US Sales (\$MM)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 740	\$ 1,530	\$ 2,370	\$ 3,674	\$ 4,640	\$ 5,666
Royalty rate							13%	13%	13%	13%	13%	13%
Royalty to VTAE							0.0	92.6	191.2	296.3	459.2	579.9
Contribution Margin							100%	100%	72%	68%	58%	48%
Operating Margin							0.0	0.0	66.6	130.0	171.9	220.4
Terminal Value												243.6
Discount Period					4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0
PV of CF to VTAE					0.0	0.0	8.9	12.3	11.6	10.7	8.4	24.1
Discount Rate												40%
Terminal Growth												2%
NPV												\$ 76.06
# Shares outstanding (mm)												17.4
Incremental price per share												\$ 4.38
Milestone Revenue	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
Milestone Payments (\$MM)	\$ -	\$ 10.00	\$ -	\$ 26.00	\$ -	\$ 20.00	\$ 60.00	\$ -	\$ -	\$ -	\$ -	\$ 60.00
Contribution Margin	100%	95%	100%	95%	100%	100%	72%	68%	58%	48%	42%	38%
Operating Margin	0.0	9.5	0.0	24.7	0.0	20.0	43.2	0.0	0.0	0.0	0.0	22.8
Discount Period	0.0	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0
PV of CF to VTAE	0.0	6.8	0.0	9.0	0.0	3.7	5.7	0.0	0.0	0.0	0.0	0.6
Discount Rate												38%
Terminal Growth												0%
NPV												\$ 25.81
# Shares outstanding (mm)												17.4
Incremental price per share												\$ 1.49

Source: JMP Securities LLC

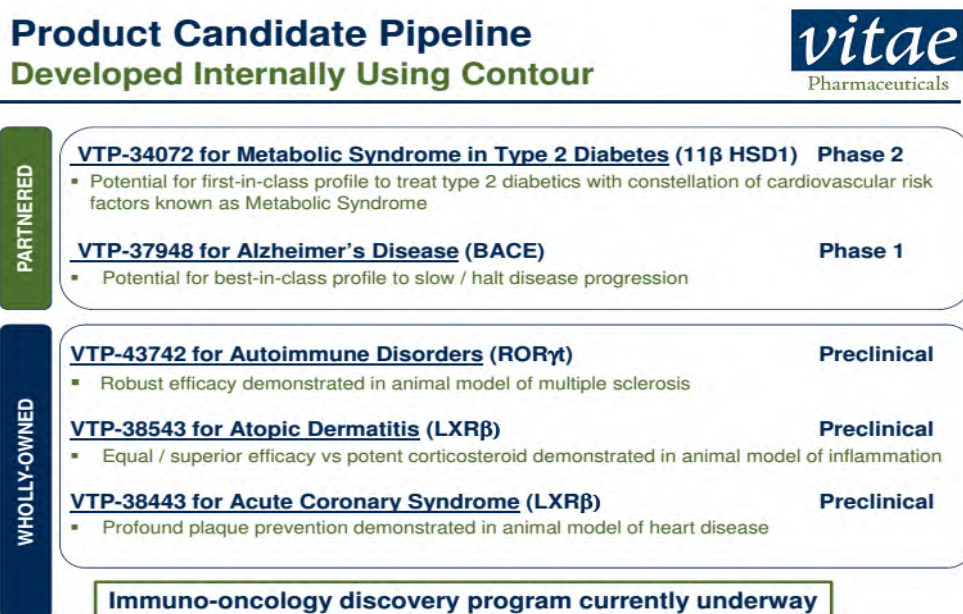
COMPANY DESCRIPTION

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 development efforts on two targets that treat the 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 preclinical 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 read-outs by the end of 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 ROR γ t 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 LXR β receptor. Vitae is also developing an as-yet unnamed program to develop preclinical compounds for immune-oncology applications.

FIGURE 6. Vitae Pipeline Overview



Source: Company presentations

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 suffers from safety and tolerability issues, Vitae and Boehringer Ingelheim (BI) may choose to end development in any of the current indications. Additionally, if the FDA and EMEA do not approve VTP-34072 or VTP-37948, Vitae's 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 becomes 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 commercialization 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 first. 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 projecting to finish 3Q14 with ~\$53.5MM in cash, equivalents, and marketable securities. We expect this funding to be able to carry the company through to 2016. Like most non-profitable biotechnology companies, VTAE will likely need to seek additional financing, exposing current investors to dilutive risk.

PIPELINE OVERVIEW

Vitae has focused its efforts to develop inhibitors to validated but difficult-to-inhibit targets. These small molecule therapeutics address large markets and unmet clinical needs. The company's pipeline is developed around six specific programs, two of which are partnered with Boehringer Ingelheim (BI), and one where it discontinued development. In 2005, Glaxosmithkline (GSK) initiated a partnership with Vitae to develop renin inhibitors for cardio-renal conditions. Targeting renin was highly attractive, in light of the success in the development of ACE inhibitors and ARB's, small molecules targeting a similar signaling axis for hypertension. Renin had proven difficult to target because of its similarity to other proteases and the poor pharmacokinetics of first and second generation peptide-based inhibitors. Vitae quickly advanced its program and by leveraging Contour, its key technological platform, was able to develop preclinical candidates within 7 months, generated animal proof-of-concept in 14 months.

In 2009, GSK ended the collaboration as it scaled down efforts in the primary care segment and cardio-renal in general. In 2012, Vitae decided to discontinue development in light of FDA requirements for outcomes research in cardio-renal development that would make further clinical development cost-prohibitive. In 2007, BI struck its first deal with Vitae Pharmaceuticals to develop inhibitors targeting 11- β -HSD1, a difficult-to-target enzyme for the treatment of metabolic syndrome and type 2 diabetes. VTP-34072 is currently in Phase II clinical trials for the treatment of mild-to-moderate Alzheimer's.

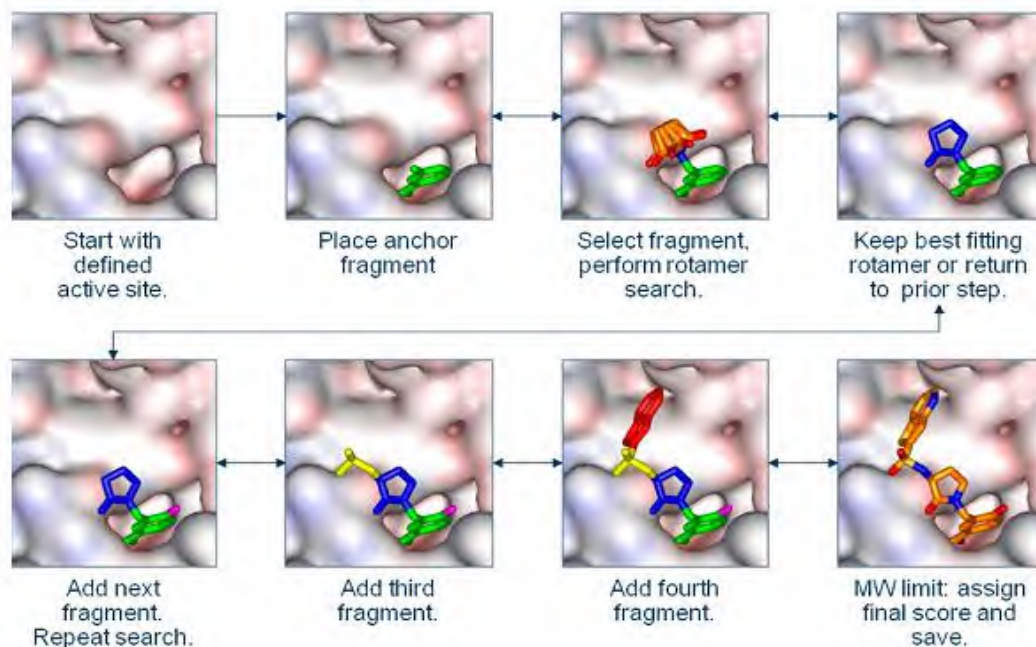
Also in 2009, BI struck a second partnership with Vitae, with the goal of discovering inhibitors of BACE-1, an exciting target for the treatment of Alzheimer's. VTP-37948, the resulting BACE-1 inhibitor, is currently in Phase I clinical trials. These two deals total nearly \$500MM in milestones and upfront payments. Additionally, Vitae has developed three programs surrounding two targets, ROR γ t and LXR β . The resulting compounds, VTP-43742 for the treatment of autoimmune disease, VTP-38543 for the treatment of atopic dermatitis, and VTP-38443 for the treatment of acute coronary syndrome have advanced from discovery to preclinical development. Finally, Vitae has initiated programs to develop inhibitors to an as-of-yet undisclosed target in the immune-oncology space (Figure 6).

TECHNOLOGY PLATFORM

CONTOUR- Technology that gives life to Vitae

Vitae is a pharmaceutical company leveraging a structure-based drug discovery platform to design lead compounds with optimized properties. Structure-based drug discovery has been a significant driver of drug development for over 20 years. Major biotechnology and pharmaceutical companies such as Merck and Vertex were early pioneers of the combined use of medicinal chemistry and structural methods (e.g., x-ray crystallography, NMR) in rational drug design. The utility of structure-based drug design is best exemplified by the development of kinase inhibitors in oncology indications.

Almost every major kinase-targeted therapy, including Gleevec (imatinib) for the treatment of bcr-abl fusions in chronic myeloma leukemia, has been accomplished with the aid of rational drug design. Antivirals, in particular, hepatitis C targeting drugs such as Incivek (telaprevir), have led to durable near-cures for patients. Other major therapeutics whose development was influenced by structure-based drug design include: Sprycel (dasatinib) (BCR-ABL; oncology), Sutent (sunitinib) (VEGFR/PDGFR/KIT; oncology), Zolinza (vorinostat) [histone deacetylase (HDAC); oncology], Prezista (darunavir) (HIV protease; HIV/AIDS), and Januvia (sitagliptan) [dipeptidyl peptidase-4 (DPPIV); type 2 diabetes.

FIGURE 7. Contour Software Iterative Drug Design

Source: Company publications

Capital investment in structure-based drug design has occurred at countless levels from infrastructure (synchrotrons and NMR magnets), to advancements in protein handling and crystal growth (G-protein coupled receptors). Intense efforts have also focused on software development and structure informed *in silico* drug design and this is where Vitae has focused its efforts. The company believes that small molecule drug discovery is hampered by the use of low affinity small molecule libraries, the inefficient docking of these small molecules *in silico*, and the lack of a high-quality scoring function to triage molecules of interest.

Vitae has developed the Contour platform, a structural biology powered software suite that combines proprietary software for drug design and modeling with a directional model-based rapid scoring algorithm referred to as the Contour scoring function. Through the efficient use of x-ray crystallography, molecular modeling, medicinal chemistry, and biology, Contour leverages cutting edge developments in software to rapidly develop therapeutics for difficult-to-drug high value targets.

The Contour algorithm begins by utilizing a high resolution structure of a protein target. Contour uses proprietary algorithms to model the binding site of interest and utilizes many more parameters than typical software suites. Where the target is typically modeled either in a Newtonian fashion (balls and springs) or in a quantum chemical fashion (based on electron orbitals), the drug configuration and search space can result in trillions of calculations - an inefficient and unreasonable method to develop small molecules. In contrast, Contour models the binding site, taking the shape and chemical hydrogen bonding nature of the binding cavity into account. Contour then identifies drug fragments that are compatible sterically and chemically. Contour then “grows” the drug molecule into the binding site (Figure 7). Contour software performs these calculations in a processor and calculation-load distributed manner, taking advantage of advances in microchip design.

FIGURE 8. Accelerated Discovery and Preclinical Development

-- Cumulative time to event --

'Difficult-to-drug' biologic target	Patentable chemistry solutions	Animal PD proof-of-principle	Value realization via deal	Upfront committed deal cash*	Success-based milestones + extensions	Remaining milestones
11 β -HSD1	2 mos.	16 mos.	21 mos.	\$37 MM	\$43 MM**	\$272 MM
BACE	6 mos.	14 mos.	18 mos.	\$42 MM	\$36 MM	\$326 MM
ROR γ t	2 mos.	10 mos.	-	-	-	-
LXR β	6 mos.	12 mos.	-	-	-	-
Renin	7 mos.	14 mos.	-	-	-	-

Source: Company Reports

Another key aspect of the Contour program is its ability to intelligently choose the molecules it grows utilizing desired biological and biochemical constraints. Utilizing an informed understanding of drug pharmacokinetics and pharmacodynamics (PK/PD), Contour can build an optimized target molecule. This parameter, in particular, can reduce inherent risks in drug development. A significant number of lead molecules fail in preclinical and clinical development because of the inefficient application of desired PK/PD. Typically, a molecular lead will be identified from high throughput screening or *in silico* docking and then advanced through iterative medicinal/biochemical methods. If the starting compound is devoid of idealized PK/PD parameters, the resulting molecules will likely not be ideal. Contour begins the process of rational design with these parameters in mind, resulting in high affinity lead molecules with low biological lability. The combination of high selectivity and improved PK potentially results in higher efficacy and an improved side effect profile. These molecules are more likely to succeed in discovery and preclinical studies, drastically reducing development time frames (Figure 8).

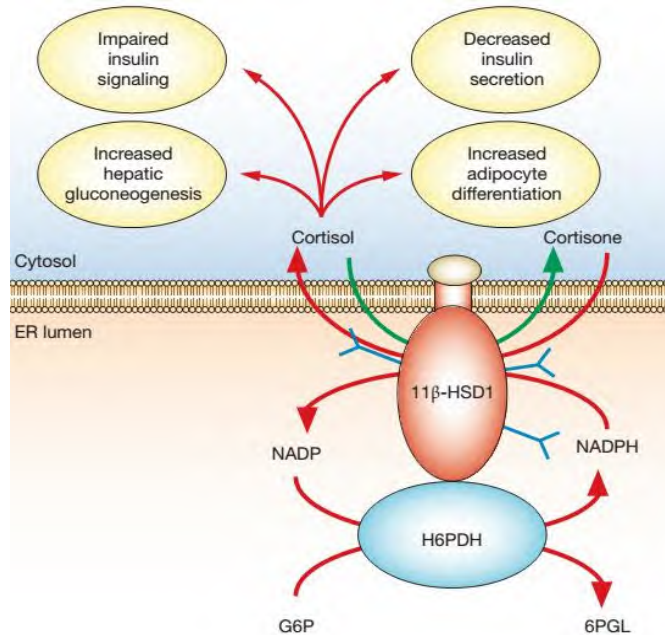
PARTNERED PROGRAMS

11 β -Hydroxysteroid Dehydrogenase Type I and VTP-34072

VTP-34072 is being developed for type 2 diabetes (T2DM). Current therapies for diabetes involve the injection of insulin or incretin mimetics, oral diabetes drugs, and life style interventions with the goal of treating the metabolic syndrome that arises from an inability to process and modulate glucose levels in the blood. In spite of the variety of methods available for the control of diabetes, over 60% of type-2 diabetics do not have glucose levels under adequate control, while at the same time and metabolic disease is increasing in prevalence. The dysregulation of metabolism results in positive feedback mechanisms involving multiple endocrine signaling systems. This includes the hypothalamic-pituitary-adrenal axis that results in the production of plasma cortisol. Cortisol levels increase in response to metabolic stress, and, through activation of the glucocorticoid receptor, results in increased expression of genes involved in gluconeogenesis (glucose synthesis), and adipogenesis (fat cell growth), further exasperating diabetic co-morbidities (Figure 9).

Cortisol levels are highly regulated by the HPA signaling axis and serum-binding proteins and inactivation of cortisol through the concerted activities of 11 β -Hydroxysteroid Dehydrogenase Type 1 and 2 (11 β -HSD1, 11 β -HSD2). 11 β -HSD2 converts cortisol to inactive cortisone and back to cortisol by 11 β -HSD1.

FIGURE 9. 11 β -HSD Control of Metabolism



Source: *Nature Clinical Practice*, Dec 2005 vol1 no 2

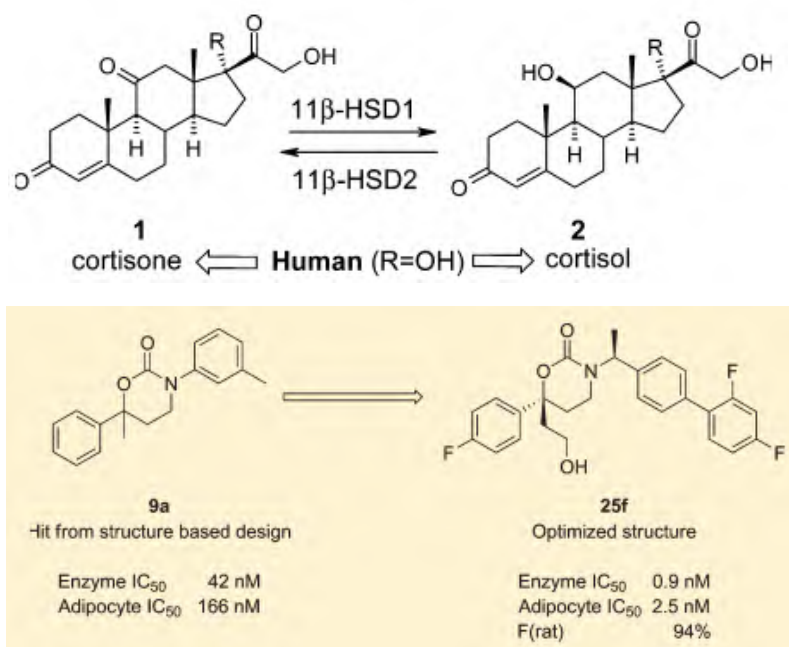
Major pharmaceutical companies have launched programs to develop inhibitors to 11 β -HSD1, but have fallen short in advancing beyond safety/efficacy studies (Figure 7). In many cases, the nature of the binding site led to difficulties in developing a molecule that maintained good pharmacokinetics and pharmacodynamics. These large, “greasy” molecules were also difficult to formulate and were poorly bioavailable (AMG-221, PF-915275). Additionally, many of these compounds were unable to target adipose tissue, or proved to be hepatotoxic (AZD-4017, AMG-221, MK-0736). In a few cases, good selectivity between isoforms 1 and 2 were not achieved, leading to undesired side effects (BMS-770767, INCB013739).

FIGURE 10. 11 β -HSD Inhibitors in Development

11 β -HSD inhibitor	Company	11 β -HSD1 IC ₅₀	11 β -HSD2 IC ₅₀	Clinical Phase	Comments/Issues
VTP-34072/ BI 187004	Boehringer Ingelheim/Vitae	single digit nM	1000-fold	Phase II in Europe	
AMG-221	Amgen	13 nM	>10 μ M	PI/Suspended	Poor PK, poor adipose distribution
PF-915275	Pfizer	Ki<1nM	>10 μ M	PII/Suspended	Poor PK/ tablet formulation
AZD-4017	AstraZeneca	7 nM	>10 μ M	PI/Suspended	Elevated liver enzymes, lack of efficacy in adipose tissue
MK-0736	Merck	3 nM	>4 μ M	PII/Suspended	No efficacy in humans, off target CYP inhibition
BMS-770767	Bristol Myers Squibb	12 nM	2.52 μ M	PII/Suspended	
INCB013739	Incyte	1.1 nM		PII/Suspended	Concentration did not reach IC ₉₀ in patients

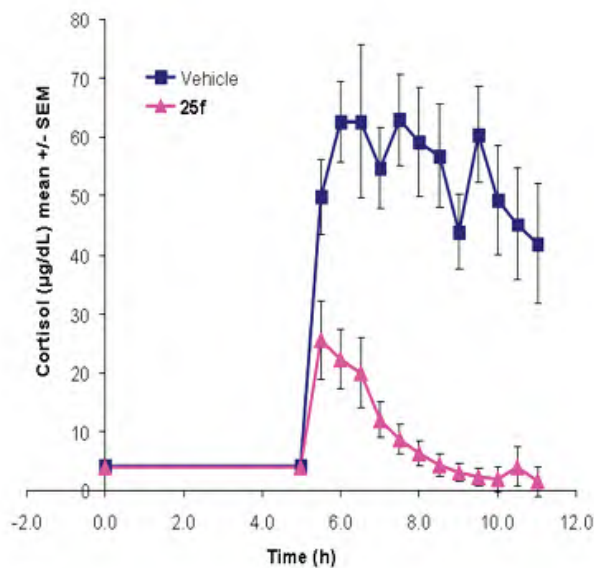
Source: Various medicinal chemistry publications and reviews, *J. Med. Chem.* 2011, 54, 6050–6062

Vitae has been able to use its Contour scoring function and structure-informed medicinal chemistry efforts to advance a number of lead candidates, culminating in molecules with optimized characteristics, examples of which are provided (Figure 11). The initial structure based hit molecule from this Vitae study had surprisingly good efficacy with IC₅₀'s of 42 nM in enzymatic assays and 166 nM in adipocyte cellular assays. Further optimization resulted in a molecule with a high degree of efficacy, (0.9 nM and 2.5 nM) and selectivity (over 1,000 fold over for 1 over 2) with optimized bio-distribution resulting in 94% oral bioavailability in a rat model. Furthermore this molecule demonstrated over 60-fold reduction cortisol levels in a cynomolgus monkeys (Figure 12). The structure of the company's lead molecule, VTP-34072, has not been disclosed, but is likely to have arisen from this medicinal chemistry campaign, and the molecule in Figure 11 exemplifies the power of the Contour platform.

FIGURE 11. Vitae 11- β -HSD1 Inhibitor Development

Source: *J. Med. Chem.* 2014, 57, 4466–4486; *J. Med. Chem.* 2011, 54, 6050–6062

FIGURE 12. Pharmacodynamics of 12f from Figure 11 in Cynomolgus Monkeys



Source: J. Med. Chem. 2011, 54, 6050–6062

In a single dose escalating trial, VTP-34072 was tested in 72 healthy overweight volunteers and was found to be safe and well tolerated. Adipose biopsies demonstrated greater than 90% inhibition at 24 hours in multiple dose groups. In a second Phase I, VTP-34072 was tested in a multiple ascending dose trial in 70 overweight diabetic patients. Plasma cortisol levels and ACTH levels remained unchanged, indicating no inhibition of 11 β -HSD2. In contrast, adipose biopsies showed greater than 90% inhibition of 11 β -HSD1 activity.

In July 2014, VTP-34072 initiated a Phase II (EudraCT Number: 2013-003646-16) randomized, placebo-controlled trial in 126 overweight type 2 diabetic patients. According to the trial structure, patients will discontinue their current diabetic medications, excluding metformin, and patients will be dosed once a day for four weeks. Primary endpoints include safety, tolerability, and secondary endpoints include glucose lowering. Data is expected in the first half of 2015.

FIGURE 13. Type-2 Diabetes Revenue Model

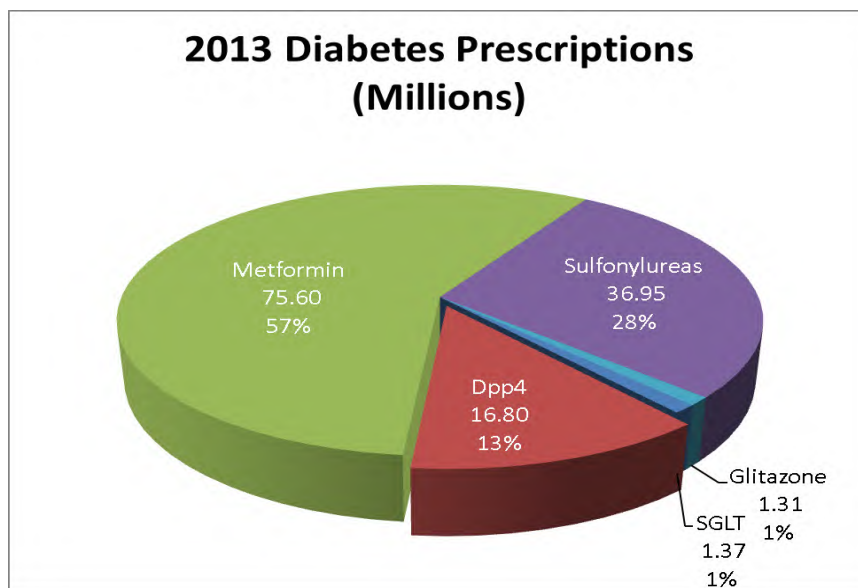
Vitae Pharmaceuticals (VTAE)												
VTP-34072 Revenue Build (\$MM)	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
T2-DM - US					\$0.0	\$173.9	\$378.2	\$617.0	\$894.7	\$1,946.0	\$3,174.6	\$3,452.6
T2-DM - EU					-	-	271.5	413.3	642.2	1,047.6	1,367.2	1,652.1
T2-DM - JPN					-	-	-	94.7	147.2	240.1	313.4	378.7
Total VTP-34072 Sales WW					\$ -	\$173.9	\$ 650	\$ 1,125	\$ 1,684	\$ 3,234	\$ 4,855	\$ 5,483
Royalties to Vitae					0.0	21.7	81.2	140.6	210.5	404.2	606.9	685.4
Royalties to VTAE as % of WW sales					13%	13%	13%	13%	13%	13%	13%	13%

Source: JMP Securities LLC

Commercial opportunity in type-2 diabetes

Globally the type-2 diabetes is similar in scope to the Alzheimer's market, if not larger, at nearly 70 million people worldwide. About 60 percent of the type-2 diabetes population does not have their glucose under control. In 2013, there were over 132 million prescriptions written for oral non-insulin medications. Although this market may seem huge it is dominated by generic mass produced drugs like metformin and sulfonylureas at \$4B. We conservatively expect that a novel type-2 diabetes medication would receive a market adoption capping at ~3% after several years. In our revenue model we assume Phase II data read-out in 2015, and Phase III read-out and filing in 2017, with subsequent approval in 2018. Peak sales are expected to reach \$5.4B in 2025

FIGURE 14. U.S. Oral Diabetes Market



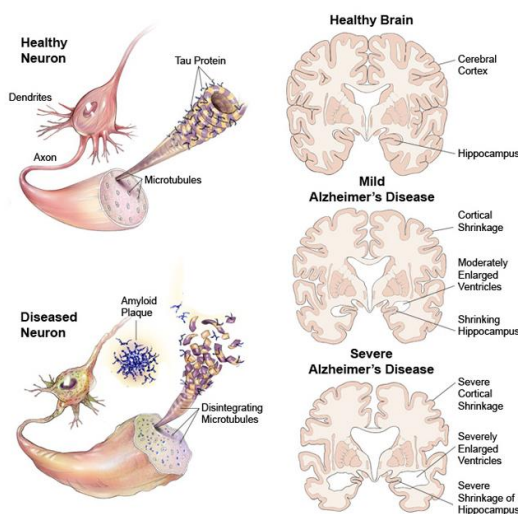
Source: IMS Health

BACE-1 inhibitors and VTP-34072

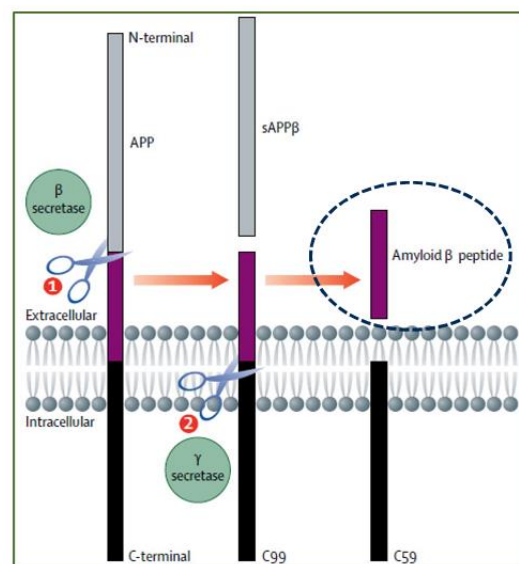
Alzheimer's disease is a debilitating condition affecting over 17 million people worldwide. The Alzheimer's Association has estimated that the 2014 costs associated with this disease amount to over \$214B in Medicare, Medicaid, and out-of-pocket expenses. Alzheimer's spending is on the rise and currently stands at 19 times the average per-senior person spend by Medicaid. While death rates from other diseases have seen a dramatic drop from 2000-2010 (e.g., -42% for HIV, -23% for stroke), deaths from Alzheimer's have increased over 68%. This effect is primarily due to an aging population, coupled with a lack of efficacious therapies to treat disease pathology.

Alzheimer's disease is a form of dementia that occurs when toxic cellular bio-products begin to build-up and accumulate as amyloid plaques composed of A β peptides and neurofibrillary Tau protein tangles. A β peptides are derived from the processing of a protein on the surface of neurons known as amyloid precursor protein (APP) (Figures 15 & 16). Genome studies have identified predictive polymorphisms that result in increased degradation of APP to A β that accelerate the disease. Additionally, genetic variations have been identified that result in APP proteins that are less prone to cleavage by BACE-1, one of the rate limiting factors in the production of A β peptides, resulting in a 40% reduction in A β production. Individuals that have this variation have approximately 7.5x decreased risk of developing Alzheimer's.

Multiple therapeutic interventions have been developed but failed to achieve efficacy in Alzheimer's. Currently approved therapies focus on modulation of neuronal activity to prevent or enhance cognitive performance without addressing the underlying cause of the disease (Aricept/donepezil, Eisai) (Figure 17). Focus has also been placed on lowering the levels of amyloid A β protein through both antibody and small molecule means. Notable failures in this space include the anti-amyloid biologics (Solanezumab, Eli Lilly; Bapineuzumab, Pfizer; Crenezumab, Roche) that have largely failed to show significant effects in both early and late-stage patients. Small molecules targeting an alternative A β -processing pathway, the γ -secretase family (semagacestat, Eli Lilly) have also failed to generate efficacious therapy, mainly because of the significant proteolytic substrate overlap with the processing of Notch, a signaling pathway that when inhibited, can cause skin cancer.

FIGURE 15. Alzheimer's Pathology

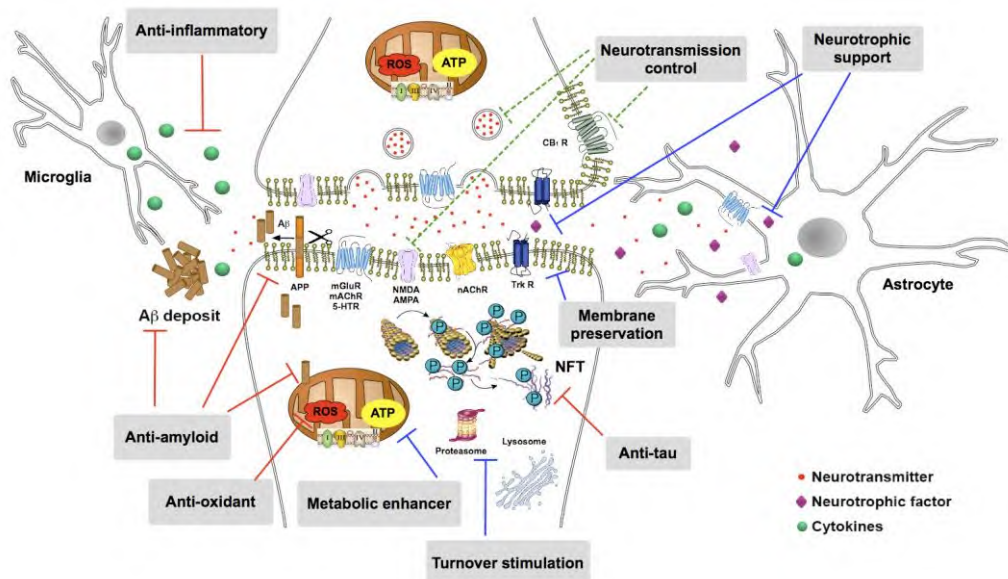
Source: Brightfocus

FIGURE 16. APP Proteolysis-forming A β Peptides

Source: Company presentations

VTP-34072 is being developed to treat Alzheimer's by targeting a secondary step in the A β producing pathway BACE-1. BACE-1 has also been extensively studied and pursued by major pharmaceutical companies (Figure 18). These programs have largely resulted in mixed progression through clinical development, with a number of failures due to off-target toxicology (LY2811376, LY2886721, Eli Lilly) and on-target toxicology from inhibition of BACE-2 or lack of efficacy due to suboptimal, blood-brain-barrier penetration (CTS-21166, Astellas/CoMentis).

FIGURE 17. Targets of Therapeutics Approved and in Development for Alzheimer's Treatment Modalities



Source: <http://dx.doi.org/10.5772/54783>

In contrast, several clinical programs have shown promise, notably the Merck/Ligand partnered compound MK-8931, which has advanced into Phase III clinical development. In the Phase II trials, patients achieved greater than 75% reduction in CSF A β 40 levels in the highest cohort tested. Another compound in continued clinical development is AZD32923 partnered between AstraZeneca, Eli Lilly, and Otsuka, which has completed a Phase I trial and demonstrated up to 75% decreased A β levels in patients.

VTP-37948 has demonstrated a high level of preclinical efficacy with inhibition of A β production of up to 95%. Vitae was able to quickly develop candidate molecules and advance them into animal studies within 14 months of program inception primarily by incorporating an understanding of target behavior, honing in on developing high affinity compounds (~4 nM IC₅₀) and maintaining brain penetrance and stability of the compound. The resulting compound, VTP-37948, is currently in two Phase 1 clinical trials involving a total of 68 healthy volunteers. The first trial will study the safety, tolerability, and pharmacokinetics of VTP-37948. The second study will focus on measuring A β levels in patients, a key biomarker that will greatly inform the further clinical development of VTP-37948. Results from this study are expected by the end of 2014.

FIGURE 18. BACE-1 Inhibitors in Development

BACE-1 inhibitor	Company	Clinical Phase	BACE-1 IC50	Comments/Issues
VTP-37948	Boehringer Ingelheim/Vitae	Phase I	~4nM	
CTS-21166	Astellas/CoMentis	Phase I/Suspended		No effect on CNS abeta
LY2886721	Eli Lilly	Phase II/Suspended	20 nM	Off-target Hepatotoxicity
LY2811376	Eli Lilly	Suspended	250 nM	Retinal and neuronal toxicity
E2609	Eisai	Phase II initiation EOY14	7 nM	Average decrease of 79% in CSF AB 200 mg cohort
MK-8931	Merck/Ligand	Phase III	1.7 nM	95% of patients achieved >75% of CSF Aβ40 reduction in the 60 mg cohort
AZD32923	AstraZeneca, Eli Lilly, Otsuka	Completed Phase I		Up to 75% decreased Aβ

Source: Company reports

Commercial opportunity in Alzheimer's

Alzheimer's disease affects nearly 17 million worldwide and is expected to between 22 and 30 million patients by 2025. In the U.S. market there is currently 5.1 million patients with Alzheimer's. Current estimates suggest there are nearly 4 million patients in the U.S. with mild-to-moderate Alzheimer's, the patient population estimated to benefit the most from anti-amyloid treatment. Looking at IMS tracking data for therapeutics used to treat this patient population, we estimate at least 33 million prescriptions are filled in the U.S. in 2013 alone. The major therapies used in this indication are donepezil and memantine (Namenda). Donepezil is an acetylcholinesterase inhibitor that was marketed exclusively by Eisai as Aricept up until it came off patent in November 2012. At its peak, sales of Aricept reached over \$4.2B and it continues to dominate the market as a generic, with major manufactures combining with donepezil. The Alzheimer's disease market is large enough to support and reward such a therapy.

We expect Phase III read-outs for Alzheimer's disease in 2019 with approval to follow in 2020. We conservatively model a peak penetration rate of 9% in 2023 with royalty revenue of \$3B in 2025.

FIGURE 19. Alzheimer's Revenue Model

Vitae Pharmaceuticals (VTAE)												
VTP-3794 Revenue Build (\$MM)	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Alzheimer's - US				\$0.0	\$0.0	\$0.0	\$297.1	\$613.8	\$951.2	\$1,474.2	\$1,861.8	\$2,273.9
Alzheimer's - EU				-	-	-	603.2	1,246.2	1,931.2	2,992.9	3,779.8	4,616.4
Alzheimer's - JPN				-	-	-	137.2	283.4	439.2	680.7	859.7	1,050.0
Total VTP-3794 Sales WW				\$ -	\$ -	\$ -	\$ 1,038	\$ 2,144	\$ 3,322	\$ 5,148	\$ 6,501	\$7,940.3
Royalties to VTAE				0.0	0.0	0.0	129.7	267.9	415.2	643.5	812.7	992.5
Royalties to VTAE as % of WW sales				13%	13%	13%	13%	13%	13%	13%	13%	13%

Source: JMP Securities LLC

OVERVIEW OF THE BOEHRINGER INGELHEIM PARTNERSHIP

11 β -HSD

Vitae entered into its first partnership with BI over the 11 β -HSD program in October 2007. This agreement granted BI worldwide exclusive rights to develop and commercialize compounds arising from the research agreement for patients with type-2 diabetes and related metabolic diseases. Vitae retains the rights to develop 11 β -HSD1 inhibitors outside of the agreed upon indications, pursuant to approval of the joint steering committee.

The collaborative research portion of this program has ended, with Vitae having received \$59.2MM in non-equity financing, including success-based milestones and upfront licensing fees. These include \$15MM on execution of the agreement, quarterly payments of \$0.8MM over 27 months, and \$37MM in substantive milestone payments. Vitae expects to receive a \$6MM milestone payment in 3Q14 for dosing the first patient in the Phase II VTP-34072 trial. Vitae is eligible to receive up to \$272MM in additional milestone payments based on the achievement of pre-specified events, including up to \$147MM in development and regulatory milestone payments and up to \$125MM in commercialization milestone payments.

Additionally, the royalty agreement allows Vitae to receive tiered royalties from the high-single digits to the low-double digits with the option to participate in funding Phase 3 clinical trials in exchange for increased royalties. We model this royalty as a blended 12.5% under the assumption that Vitae participates in the buy-up to increase royalties.

BACE-1

Vitae entered into its second partnership with BI over the BACE program in June 2009. Vitae has granted worldwide exclusive rights to BI to develop and commercialize BACE inhibitors for the treatment of certain indications, including Alzheimer's. Under the BACE Agreement, Vitae has received \$63.2MM in non-equity funding, including an upfront license fee from BI of \$15MM upon execution of the BACE Agreement. Additionally, BI has made quarterly payments of \$1MM over the 36-month collaborative research program period and \$0.8MM over an additional 36-month extension period, for a total of \$15.2MM. Pursuant to certain amendments to the agreement to incorporate additional indications for BACE inhibition, including metabolic disease, a \$4MM fee was paid to Vitae.

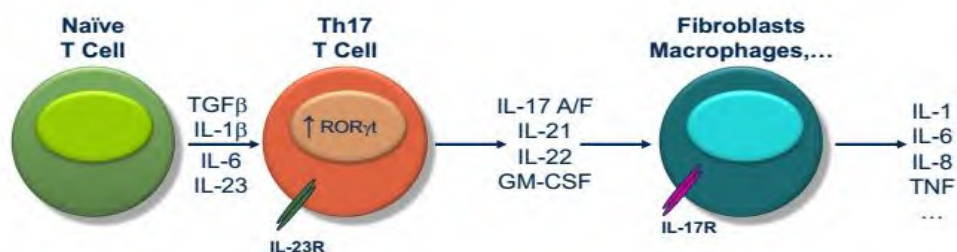
For the years ended December 31, 2013 and 2012, Vitae has earned \$18MM and \$9MM, respectively, for achieving substantive development milestones related to BACE inhibitors. Milestone revenue for the year ended December 31, 2013 includes \$14MM related to the advancement of its most advanced compound in the BACE program, VTP-37948, into Phase I clinical studies. Vitae is eligible to receive an additional \$326MM in milestone payments based on the achievement of pre-specified events, including up to \$176MM in development and regulatory milestone payments and up to \$150MM in commercialization milestone payments. Vitae is eligible to receive tiered royalties from the high-single digits to the low-double digits with the option to buy up to increased royalties in exchange for participation in funding Phase II clinical trials. We model this royalty as a blended 12.5%, under the assumption Vitae participates in the buy-up to increase royalties.

PROPRIETARY PRODUCTS

Autoimmune disease and VTP-43742

Vitae has developed the preclinical compound VTP-43742 for the treatment of various autoimmune related diseases, including multiple sclerosis, psoriasis, and rheumatoid arthritis. Dysregulation of the immune system can arise at a number of checkpoints and controls inherently built into immunity. Disease can arise when a number of cells are incorrectly triggered or conversely suppressed, causing the immune system to begin recognizing self as non-self. Th17 cells are a specific subset of white blood cells that stimulate the activity of effector cells, such as macrophages, through the secretion of various cytokines (Figure 20).

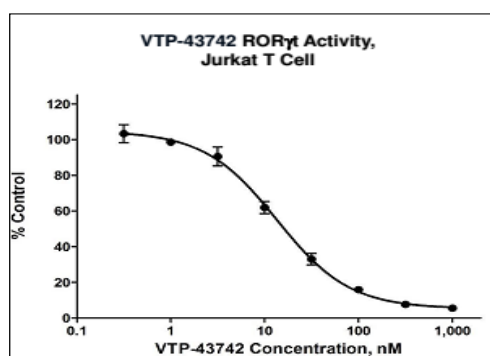
FIGURE 20. Th17 Immune Regulation



Source: Company presentations

Suppression of Th17 cells has become a potent and validated mechanism supported by several marketed and in development products (Stelara/ustekinumab, Centocor; secukinumab, Novartis; brodalumab, Amgen; ixekizumab, Eli Lilly). The central signaling pathway that is activated in stimulated Th17 cells is the RAR-Related Orphan Receptor γ -t (ROR γ t) receptor. VTP-43742 was developed to inhibit signaling at this receptor (Figure 21) while maintaining an ideal balance of selectivity, efficacy, and bioavailability. Preclinical studies of VTP-43742 have demonstrated activity in a mouse model of multiple sclerosis, EAE, and also demonstrated a high degree of oral bioavailability and long half-life. Figure 21 demonstrates that animals treated with VTP-43742 showed improvement in clinical score and a high degree of myelination compared to control mice, suggesting significant efficacy. Vitae plans to advance these compounds in Phase I trials after IND submission in 2015.

FIGURE 21. VTP-43742 Biochemical Activity

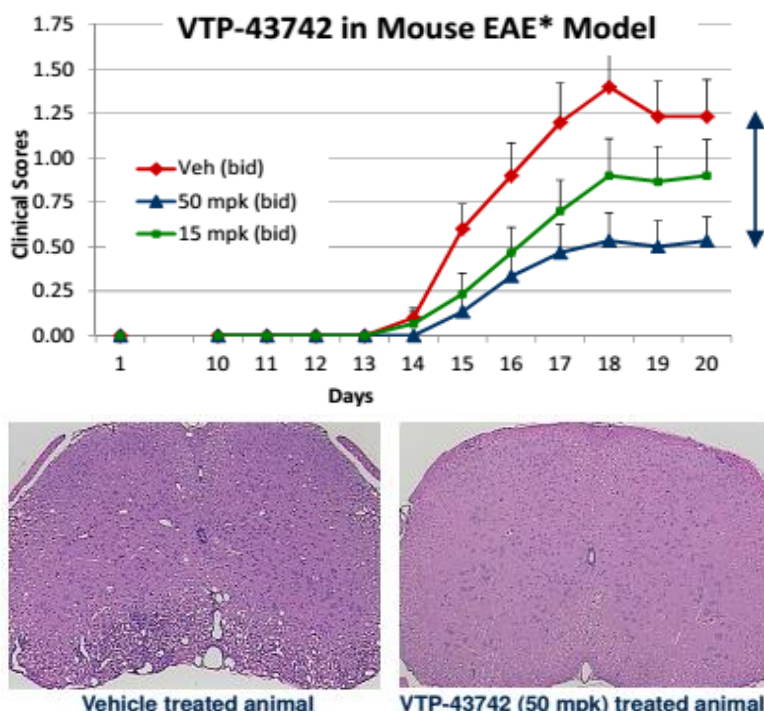


Source: Company presentations

Assay	VTP-43742
hROR γ t Ki (nM)	3.7 nM
hROR α Ki (nM)	4,712 nM
hROR β Ki (nM)	3,914 nM

Parameter	VTP-43742
Dog oral bioavailability	66%
Dog half life (t _{1/2})	15 hrs

Parameter	VTP-43742
Human ROR γ t binding K _i	3.7 nM
Jurkat T cell assay: ROR γ t IC ₅₀	17 nM

FIGURE 22. VTP-43742 Preclinical *in vivo* Efficacy

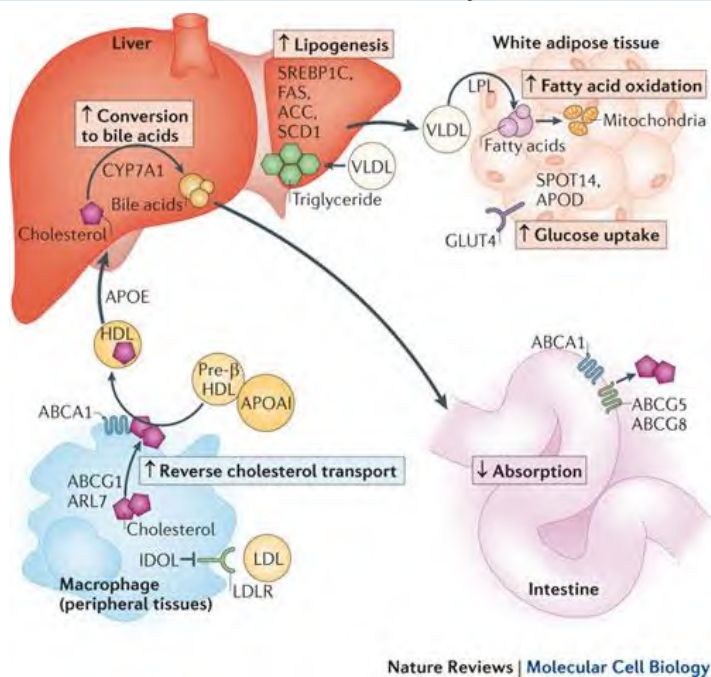
Source: Company reports

Liver X Receptor: VTP-38443 and VTP-38543

Vitae has also focused on the development of preclinical candidates targeting the Liver X Receptor (LXR), a potent modulator of metabolism and autoimmunity. The importance of LXR is underscored by the number of direct gene targets regulated by LXR isoforms, including cholesterol transport genes *ABCA1* and *ABCG1*; cholesterol transport genes *APOC1*, *APOE*, *CETP*, and *GLUT4*, *VEGFA*. Cholesterol transport, in particular, plays a key role in macrophage attraction to and deposition within the vasculature and plays a key role in atherosclerotic disease and liver disease (Figure 22). Because of the potential pleiotropic effects of LXR agonism, pharmaceutical companies have found this target significantly recalcitrant to small molecule stimulation. A key feature of the Vitae program has been the focus on developing efficacious but selective agonists towards the β isoform while sparing the α isoform.

LXR α and LXR β are expressed differentially throughout the body, with the α isoform preferentially expressed in the liver, kidneys, and intestines, while the β isoform is expressed more ubiquitously. LXR α stimulation results increase reverse cholesterol transport into the liver and fatty acid production resulting in elevated serum triglycerides. Treatment with LXR agonists has shown beneficial cardiovascular effects and alterations in the cellular composition of atherosclerotic plaques, with reductions in inflammation and adhesion molecules and changes in fibrous cap thickness in *ApoE*-null mice, one of the most common animal models of atherosclerosis.

FIGURE 23. FXR Role in Inflammation and Immunity



Source: Nature Reviews Molecular Cell Biology 13, 213-224 (April 2012)

VTP-38443

Vitae has developed VTP-38443 for the treatment of acute coronary syndrome, a condition which the company believes can be additive to the current antiplatelet, anticoagting, and cholesterol inhibitory regimens. VTP-38443 is selective for LXR β with biochemically derived 22-fold selectivity for β over α and a 17-fold selectivity in cells (Figure 24). In preclinical animal models, VTP-38443 reduced inflammation and cholesterol levels in atherosclerotic vessels, suggesting good systemic exposure and target activity. Additionally VTP-38443 showed no effect on circulating triglycerides in cynomolgus monkeys, suggesting its selectivity for LXR β was effective in avoiding unwanted side effects.

FIGURE 24. Selectivity Profile VTP-38443

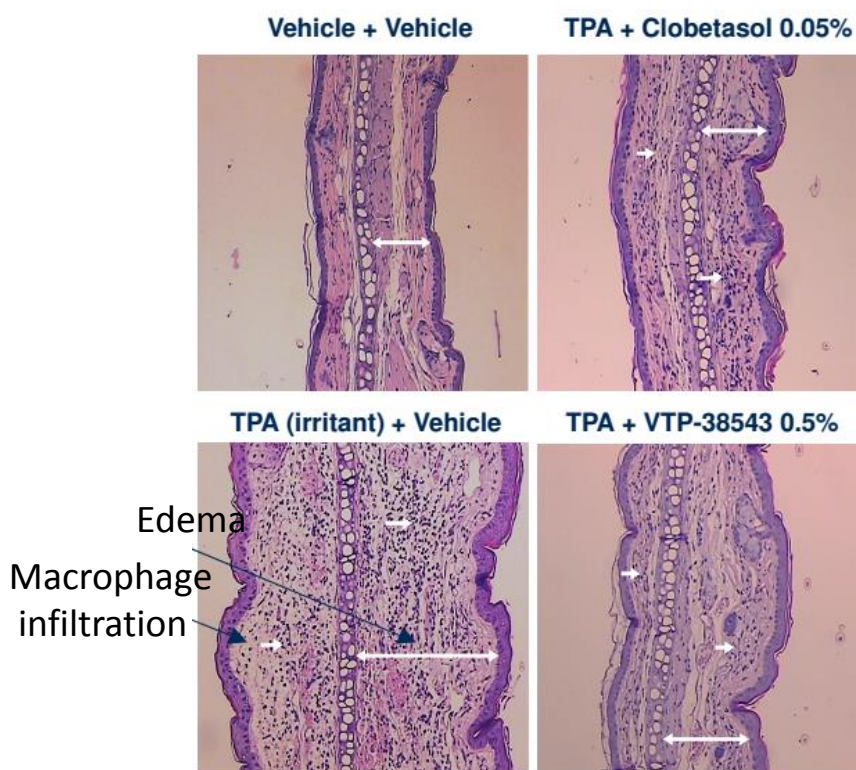
ASSAY	RECEPTOR	VTP-38443
Binding Ki (nM)	LXR α	262
	LXR β	12
	LXRβ Selectivity Ratio	22x
Cell based reporter assay EC ₅₀ nM	LXR α	320
	LXR β	19
	LXRβ Selectivity Ratio	17x

Source: Company reports

VTP-38543

Vitae has seen significant preclinical effects in developing its LXR targeting program, one of which is the beneficial effects of LXR β agonism on the skin. The transport of lipids and cholesterol and the effect on inflammation poses an opportunity to intervene in dermatologic conditions such as atopic dermatitis (eczema). Preclinical studies with VTP-38543, a lead molecule borne out of the LXR program, shows beneficial stimulation of mature skin cells to secrete synthesized triglycerides and improve barrier function. When comparing VTP-38543 in a mouse model of skin inflammation (Figure 25), agonism of LXR β proved to be superior in efficacy to a topical corticosteroid clobetasol. Vitae expects to file an IND and commence clinical trials in the second half of 2015.

FIGURE 25. Topical VTP-38543 Anti-Inflammatory



Source: Company presentations

PATENTS

11 β -HSD—Type-2 Diabetes

VTP-34072 has been issued a patent in the United States, one pending patent application in the United States, two issued patents in foreign jurisdictions, and 37 pending patent applications in foreign jurisdictions including Europe, Japan, Taiwan, Canada, Australia, Brazil, China, and India. These patents are set to expire in November 2030. The patent claiming methods of treating type 2 diabetes mellitus is set to expire September 2031.

BACE—Alzheimer's disease

VTP-37948 patents include one pending patent application in the United States, one pending international application filed under the PCT, and six pending patent applications in foreign jurisdictions. Patents that arise from these applications will likely expire in August 2033, not including possible extensions due to patent office or regulatory delay.

ROR γ t—Autoimmune Disease

VTP-43742 is claimed in a U.S. provisional application filed in February 2014. The U.S. provisional application includes claims to VTP-43742 as a member of a class of related compounds and methods of using these compounds to treat various indications. The U.S. provisional application will allow for the filing of patent applications and pursuit of patents on a worldwide basis. Patents arising from these applications will likely expire in February 2035.

LXR—Acute Coronary Syndrome

VTP-38443 is claimed in a published PCT application. Patents arising from these applications will likely expire in March 2033, not including possible extensions due to patent office or regulatory delay.

LXR—Atopic Dermatitis

VTP-38543 is claimed in a published PCT application. Patents arising from these applications will likely expire in March 2033, not including possible extensions due to patent office or regulatory delay.

MANAGEMENT TEAM AND BOARD OF DIRECTORS

Jeffrey S. Hatfield, President & Chief Executive Officer. Mr. Hatfield joined Vitae Pharmaceuticals as President, Chief Executive Officer and a member of the Board of Directors in March 2004. Prior to joining Vitae Pharmaceuticals, Mr. Hatfield worked at Bristol-Myers Squibb in a variety of executive positions, including: Senior Vice President of BMS's Virology and Immunology Divisions, where he was responsible for all aspects of the \$1 billion business; President and General Manager, Canada; and, Vice President, U.S. Managed Health Care. While at BMS, Mr. Hatfield was directly associated with several product successes, including Pravachol®, Plavix®, Avapro®, Abilify®, Reyataz® and Atripla®. Mr. Hatfield holds an M.B.A. from The Wharton School, University of Pennsylvania and a bachelor's degree in Pharmacy from Purdue University, where he is a Distinguished Alumni. He is a member of the Board of Directors of the Biotechnology Industry Organization (BIO), serving on the Executive Committee of the Emerging Company Section. He is a board member of Ambit Biosciences, and is also a member of the Advisory Committees for Purdue University's College of Pharmacy, Drexel University's LeBow College of Business and the Chapman-KGI School of BioPharmacy.

Richard Gregg, M.D. Chief Scientific Officer. Dr. Gregg spent 19 years leading various groups at Bristol-Myers Squibb Research and Development before joining Vitae Pharmaceuticals. Most recently, he was Vice President of Clinical Discovery, responsible for Early Clinical Development, Clinical Pharmacology, Translational Medicine and Biomarker Technologies. Dr. Gregg developed and led the Bristol's efforts in the application of cutting edge science and analytical technologies to the clinical investigation of new drugs. He also served as Vice President of Metabolic and Cardiovascular Drug Discovery, focusing on the discovery of new drugs for diabetes, dyslipidemia, and atherosclerotic vascular disease. Before coming to Bristol, Dr. Gregg spent 10 years at the National Heart, Lung and Blood Institute, where he studied disorders of lipid and lipoprotein metabolism. He has more than 120 publications in leading medical and research journals, and has presented his research findings at national and international meetings. Dr. Gregg earned his B.S. and M.S. from Iowa State University and his M.D. from Stanford University School of Medicine. He did his internship and residency in Internal Medicine at Strong Memorial Hospital in Rochester, New York, and completed his fellowship in Endocrinology and Metabolism at the National Institutes of Health.

Richard Morris, Chief Financial Officer. Richard Morris, CPA has served as Chief Financial Officer since May 2014. Prior to joining Vitae, Mr. Morris worked at ViroPharma Incorporated, which he joined in 2001, in a variety of positions, including Vice President, Financial Planning and Strategic Analysis from 2012 to 2014, Vice President, Chief Accounting Officer from 2011 to 2014, Controller and Chief Accounting Officer from 2008 April 2011 and Controller from 2005 through 2008. Prior to joining ViroPharma, Mr. Morris worked for KPMG LLP in its Healthcare Assurance practice. Mr. Morris received a bachelor's degree in Accounting from Saint Joseph's University and has been a CPA since 1999.

Arthur Fratamico, R.Ph. Chief Business Officer. Arthur Fratamico, R.Ph. has served as Chief Business Officer since May 2014. Prior to joining us, Mr. Fratamico served as chief business officer of Flexion Therapeutics, Inc. from June 2012 through 2014. Prior to Flexion, Mr. Fratamico led the business development efforts, including overseeing numerous licensing transactions and acquisitions,

at private biotechnology companies including Trevena, Inc. from 2011 to 2012, Gemin X Pharmaceuticals, Inc. from 2008 to 2011 and MGI Pharma, Inc. from 1999 to 2008. Mr. Fratamico earned a bachelor's degree in pharmacy from the Philadelphia College of Pharmacy and an M.B.A. from Drexel University.

David A. Claremon, Ph.D. Vice President, Chemistry. Dr. Claremon has over 30 years of experience in Medicinal Chemistry, gained at Merck & Co., where he was Senior Director, Medicinal Chemistry, and as head of chemistry at Vitae Pharmaceuticals. While at Merck, his research group successfully identified several development candidates including an anti-arrhythmic, an oral fibrinogen receptor antagonist, and an NR2B selective NMDA receptor antagonist. He has co-authored more than 70 publications and is listed as an inventor on 110 patents. He received a Bachelor's degree in Chemistry from Case Western Reserve University and a Ph.D. from the University of Pennsylvania in Organic Chemistry, where he studied with Professor K.C. Nicolaou.

Gerard M. McGeehan, Ph.D. Vice President, Discovery Biology. Dr. McGeehan was Executive Director of Lead Discovery at the DuPont Pharmaceuticals Company in Wilmington, Delaware before coming to Vitae Pharmaceuticals in 2002. He was also at Glaxo Inc. (RTP), for seven years, last serving as head of the Biochemistry Department. At Rhone-Poulenc Rorer, he was Director of Inflammation and established the Department of Lead Generation. Dr. McGeehan's research interests have included the pharmacology of proteolytic enzymes and receptors, new assay methods and exploration of problems at the biology/chemistry interface. Dr. McGeehan received his Ph.D. in Organic Chemistry from Stanford University and served as an NSF post-doctoral fellow at the ETH-Zurich.

Board of Directors

Peter Barrett, Ph.D. Member of the board of directors since December 2004. Dr. Barrett joined Atlas Venture, an early-stage venture capital fund, in 2002, and currently serves as a partner in the life sciences group. Previously, from 1998 to 2002, he was a co-founder, executive vice president and chief business officer of Celera Genomics. Prior to Celera, from 1979 to 1998, Dr. Barrett held senior management positions at the Perkin-Elmer Corporation, most recently serving as vice president, corporate planning and business development. Dr. Barrett served on the boards of directors of SciClone Pharmaceuticals, Inc. from 2011 to 2013, and Helios BioSciences Corporation from 2003 to 2012. Dr. Barrett currently serves on the boards of directors of the PerkinElmer Inc., Zafgen, Inc., and several other privately held companies. Dr. Barrett is currently vice chairman of the advisory council of the Barnett Institute of Chemical and Biological Analysis at Northeastern University, as well as adjunct professor at the Barnett Institute. He also serves as president of the Autism Consortium, a non-profit institution and is a member of the research council at Boston Children's Hospital. Dr. Barrett holds a B.S. in chemistry from Lowell Technological Institute (now known as the University of Massachusetts, Lowell) and a Ph.D. in analytical chemistry from Northeastern University. He also completed Harvard Business School's Management Development Program.

Robert V. Gunderson, Jr. has served as a member of the board of directors since January 2002. Mr. Gunderson is a founding partner of the law firm of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, where he has practiced since 1995. Mr. Gunderson currently serves as a director of Theravance Biopharma, Inc., as well as a number of private companies. Mr. Gunderson previously served on the board of Theravance, Inc. Mr. Gunderson holds a J.D. from the University of Chicago, where he was Executive Editor of The University of Chicago Law Review. Mr. Gunderson also received an M.B.A. in Finance from The Wharton School, University of Pennsylvania and an M.A. from Stanford University.

Donald Hayden, Jr. has served as a member of the board of directors since 2006 and the Chairman of the board of directors since 2006. Mr. Hayden previously served as the Executive Chairman of Transave, a biotechnology company, from 2006 until 2010, when Transave was acquired by Insmed, a biotechnology company. From 1981 to 2006, Mr. Hayden was an executive with Bristol-Myers Squibb Company, where he served in key executive roles including President of Global Pharmaceuticals; Executive Vice President and President, Americas; Executive Vice President of the Health Care Group; President of Oncology and Immunology; and Senior Vice President of Worldwide Franchise Management and Business Development. Mr. Hayden currently serves as lead independent director of Amicus Therapeutics Inc., a biopharmaceutical company, and as non-Executive Chairman of the board of directors of Insmed. Mr. Hayden is also a director of Otsuka America Pharmaceuticals, Inc., the U.S. subsidiary of Otsuka Pharmaceutical Company, Limited, a manufacturer of pharmaceuticals and nutraceutical products. Mr. Hayden also serves on the boards of directors for four privately-held companies: Alvine Pharmaceuticals; Nora Therapeutics; ReGenX Biosciences; and Dimension Therapeutics. Mr. Hayden is also a senior advisor to Prospect Venture Partners, a venture capital firm. Mr. Hayden holds a Bachelor of Arts degree in general studies from Harvard University and a Masters of Business Administration degree from Indiana University.

Charles W. Newhall, III has served as a member of the board of directors since August 2001. In 1977, Mr. Newhall co-founded New Enterprise Associates, or NEA, a venture capital firm that focuses on the medical and life sciences and information technology industries, from which he retired effective December 31, 2012. To date, Mr. Newhall has served as a director of over 50 venture-backed companies. In addition to being a director on our board, some of his current Board memberships include NeuroPace, Inc. and Interfusio. In 1986, he founded the Mid-Atlantic Venture Association, or MAVA, which now has over 80 venture capital firms that are members, and is one of the most active regional venture associations in the country. He is Chairman Emeritus of MAVA. Before NEA, Mr. Newhall was a Vice President of T. Rowe Price. He served in Vietnam commanding an independent platoon including an initial reconnaissance of Hamburger Hill. His decorations include the Silver Star and Bronze Star V (1st OLC). He earned an Honors Degree in English from the University of Pennsylvania and an MBA from Harvard Business School.

Bryan Roberts, Ph.D. has served as a member of our board of directors since 2001. Dr. Roberts joined Venrock, a venture capital investment firm, in 1997, and he currently serves as a partner. From 1989 to 1992, Dr. Roberts worked in the corporate finance department of Kidder, Peabody & Co., a brokerage company. Dr. Roberts serves on the board of directors of Achaogen Inc., Castlight Health, Inc., Ironwood Pharmaceuticals, Inc. and ZELTIQ Aesthetics Inc., as well as on the board of several private companies. Dr. Roberts previously served on the board of directors of athenahealth, Inc. and Sirna Therapeutics, Inc. Dr. Roberts holds a B.A. in Chemistry from Dartmouth College and a Ph.D. in Chemistry and Chemical Biology from Harvard University.

Charles A. Rowland, Jr. has served as a member of the board of directors since September 2014. Mr. Rowland is currently acting as a strategic consultant. Mr. Rowland was Vice President and Chief Financial Officer of ViroPharma Incorporated, an international biopharmaceutical company, from October 2008 until it was acquired by Shire plc in January 2014. Prior to joining ViroPharma, Mr. Rowland was the Executive Vice President and Chief Financial Officer, as well as the interim Co-Chief Executive Officer, for Endo Pharmaceuticals Inc., a specialty pharmaceutical company with a primary focus in pain management, where he served from December 2006 to September 2008. From 2004 to 2006, Mr. Rowland was the Senior Vice President and Chief Financial Officer of Biovail Corporation, an international pharmaceutical company. Mr. Rowland previously held positions of increasing responsibility at Breakaway Technologies, Inc., Pharmacia Corporation, Novartis AG and Bristol-Myers Squibb Co. Mr. Rowland currently serves on the board of directors of BIND Therapeutics, Inc. and Aurina Pharmaceuticals Inc., and previously served on the board of directors of Idenix Pharmaceuticals, Inc. from 2013 until its acquisition by Merck & Co., Inc. in August 2014. He is also a board member of the Philadelphia chapter of Financial Executives International. Mr. Rowland received a bachelor of science degree in Accounting from St. Joseph's University and a M.B.A. from Rutgers University.

Gino Santini has served as a member of the board of directors since September 2014. From 1983 until his retirement in December 2010, Mr. Santini held a variety of commercial and operational roles at Eli Lilly and Company, a public pharmaceutical company, serving most recently, from April 2007 to December 2010, as Senior Vice President, Corporate Strategy and Business Development, where he led corporate strategy and long-range planning, mergers and acquisitions, new product licensing and the expansion of Lilly Ventures in the United States and China. During his tenure at Eli Lilly, Mr. Santini held various leadership positions of increasing responsibility, including manager of various international regions, Senior Vice President of Corporate Strategy and Policy from 2004 to 2007, President of U.S. operations from 1999 to 2004 and President of the women's health franchise from 1997 to 1999. Mr. Santini currently serves on the board of directors of Horizon Pharma, Inc., AMAG Pharmaceuticals Inc. and Sorin S.p.A., a global public medical device company, as well as a number of private companies. He also served on the Board of Directors for United Way and the Executive Committee and Board of Directors of the Indianapolis Chamber of Commerce. He holds an undergraduate degree in mechanical engineering from the University of Bologna and an M.B.A. from the Simon School of Business, University of Rochester.

Source: Company website

FIGURE 26. Vitae Pharmaceuticals Income Statement

Vitae Pharmaceuticals (VTAE)	2013E	1Q 2014	3Q14E	4Q14E	2014E	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Income Statement (\$MM)																				
Total Product Sales and Royalties	0.0	0.0	0.0	0.0	0.0					0.0	0.0	0.0	0.0	21.7	268.5	512.5	876.6	1,243.6	1,629.6	1,931.8
Collaborative Revenue	22.5	2.3			0.0															
Milestone Revenue	0.0		6.0	0.0	6.0				20.0	20.0	0.0	46.0	70.0	20.0	60.0	50.0	145.0	75.0	0.0	107.0
Total Revenue	22.5	2.3	6.0	0.0	6.0				20.0	20.0	0.0	46.0	70.0	41.7	328.5	562.5	1,021.6	1,318.6	1,629.6	2,038.8
Cost of Goods Sold											0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Gross Profit	22.5	2.3	6.0	0.0	8.3					0.0	0.0	46.0	70.0	41.7	328.5	562.5	1,021.6	1,318.6	1,629.6	2,038.8
Operating Expenses:																				
Research and Development	14.9	9.4	4.9	5.0	19.3	5.4	5.8	6.2	6.4	23.8	26.7	29.3	58.6	65.7	82.1	105.1	120.9	139.0	159.8	183.8
General and administrative	5.4	2.6	1.8	2.0	6.4	2.4	2.6	2.8	3.0	10.8	13.0	19.4	26.2	30.2	37.7	60.4	84.5	118.3	159.7	215.6
Total operating expenses	20.3	12.1	6.7	7.0	25.8	7.8	8.4	9.0	9.4	34.6	39.6	48.8	84.9	95.9	119.8	165.4	205.4	257.3	319.5	399.4
Operating income (loss)	2.2	(9.7)	(0.7)	(7.0)	(17.4)	(7.8)	(8.4)	(9.0)	(9.4)	(34.6)	(39.6)	(2.8)	(14.9)	(54.1)	208.7	397.1	816.3	1,061.3	1,310.1	1,639.4
Other income (expense):																				
Interest income	0.1	0.00	0.0	0.0	0.01	0.0	0.0	0.0	0.0	0.0	0.0	0.7	0.7	0.5	0.0	1.5	4.3	9.7	16.6	25.2
Interest expense	(1.4)	(0.54)	(0.20)	(0.20)	(0.94)	(0.20)	(0.20)	(0.20)	(0.20)	(0.80)										
Other income	0.3	0.22	0.3	0.4	0.92					-										
Total other income, net	(1.0)	(0.3)	(0.2)	(0.2)	(0.9)	(0.2)	(0.2)	(0.2)	(0.2)	(0.8)	0.0	0.7	0.7	0.5	0.0	1.5	4.3	9.7	16.6	25.3
Pretax income (loss)	1.2	(10.0)	(0.9)	(7.2)	(18.1)	(8.0)	(8.6)	(9.2)	(9.6)	(35.4)	(39.6)	(2.1)	(14.2)	(53.6)	208.7	398.7	820.6	1,071.0	1,326.7	1,664.7
Income tax benefit (provision)					0.0					0.0	0.0	0.0	0.0	0.0	(54.8)	(119.6)	(287.2)	(374.8)	(464.4)	(582.6)
Tax Rate					0%					0%	0%	0%	0%	0%	26%	30%	35%	35%	35%	35%
Comprehensive income (loss)	1.2	(10.0)	(0.9)	(7.2)	(18.1)	(8.0)	(8.6)	(9.2)	(9.6)	(35.4)	(39.6)	(2.1)	(14.2)	(53.6)	153.9	279.1	533.4	696.1	862.4	1,082.0
Accretion of redeemable convertible preferred stock																				
Net income (loss) attributable to common stockholder	0.0	(10.0)	(0.9)	(7.2)	(18.1)	(8.0)	(8.6)	(9.2)	(9.6)	(35.4)	(39.6)	(2.1)	(14.2)	(53.6)	153.9	279.1	533.4	696.1	862	1,082
Basic EPS to common stockholder	\$ -	\$ (0.96)	\$ (0.05)	\$ (0.41)	\$ (1.04)	\$ (0.46)	\$ (0.49)	\$ (0.52)	\$ (0.54)	\$ (2.00)	\$ (1.84)	\$ (0.09)	\$ (0.64)	\$ (2.40)	\$ 6.8	\$ 12.2	\$ 23.1	\$ 29.8	\$ 36.4	\$ 45.2
Diluted EPS to common stockholder	\$ -	\$ (0.96)	\$ (0.05)	\$ (0.41)	\$ (1.04)	\$ (0.46)	\$ (0.49)	\$ (0.52)	\$ (0.54)	\$ (2.00)	\$ (1.84)	\$ (0.09)	\$ (0.64)	\$ (2.40)	\$ 6.7	\$ 12.0	\$ 22.6	\$ 29.2	\$ 35.7	\$ 44.3
Basic shares outstanding	10.1	10.5	17.4	17.4	17.4	17.5	17.6	17.7	17.8	17.7	21.5	21.8	22.0	22.3	22.6	22.8	23.1	23.4	23.7	23.9
Diluted shares outstanding	10.7	10.5	17.4	17.4	17.4	17.5	17.6	17.7	17.8	17.8	21.5	21.8	22.0	22.3	23.0	23.3	23.6	23.8	24.1	24.4
Diluted S/O as a percentage of basic		2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%

Source: Company filings and JMP Securities LLC

JMP FACTS AND DISCLOSURES

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Market Outperform (MO): JMP Securities expects the stock price to outperform relevant market indices over the next 12 months.

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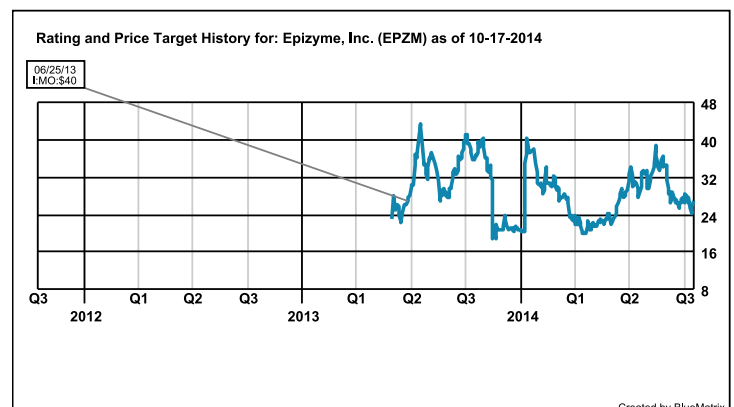
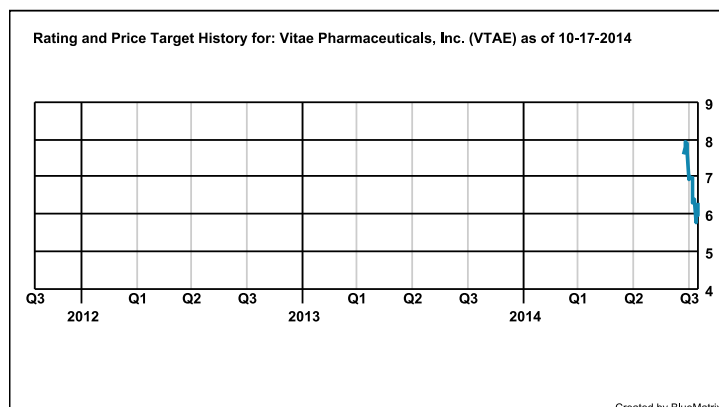
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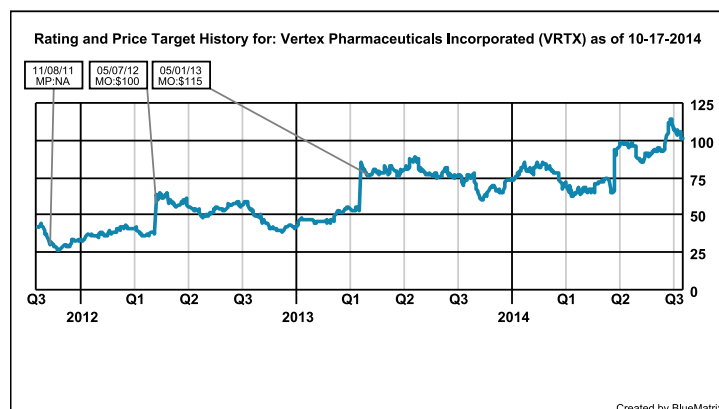
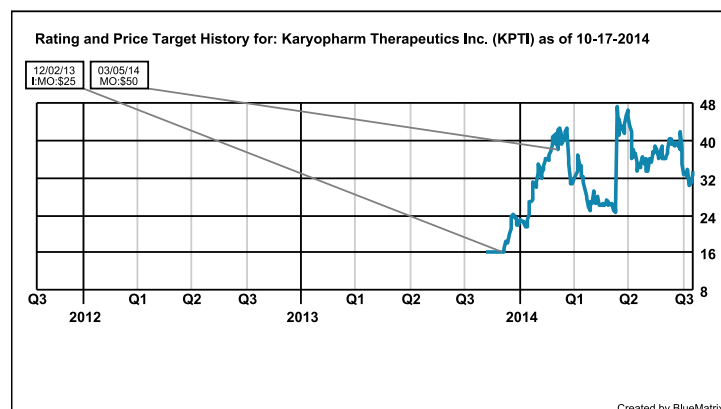
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JMP Rating	Regulatory Equivalent	# Co's Under Coverage	% of Total	Regulatory Equivalent	# Co's Under Coverage	% of Total	# Co's Receiving IB Services in Past 12 Months	% of Co's With This Rating
MARKET OUTPERFORM	Buy	282	61.30%	Buy	282	61.30%	105	37.23%
MARKET PERFORM	Hold	138	30.00%	Hold	138	30.00%	16	11.59%
MARKET UNDERPERFORM	Sell	3	0.65%	Sell	3	0.65%	0	0%
COVERAGE IN TRANSITION		36	7.83%		36	7.83%	0	0%
TOTAL:		460	100%		460	100%	122	26.52%

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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