

# Enanta Pharmaceuticals, Inc. (ENTA)

Initiating Coverage with Market Outperform Rating; Nearing Finish Line for All Oral HCV Therapy

## MARKET DATA

Price	\$19.68
52-Week Range:	\$14.31 - \$22.17
Shares Out. (M):	17.4
Market Cap (\$M):	\$342.4
Average Daily Vol. (000):	32.0
Cash (M):	\$45
LT Debt (M):	\$0

Source: Thomson Reuters and JMP Securities LLC

**MARKET OUTPERFORM** | Price: \$19.68 | Target Price: \$25.00

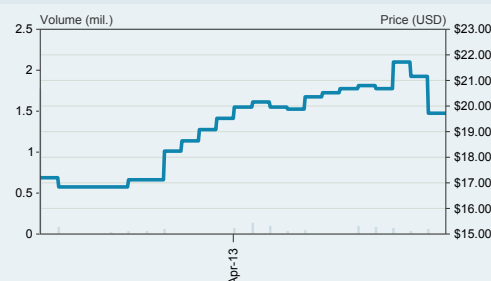
## INVESTMENT HIGHLIGHTS

**Nearing the finish line for all oral HCV therapy; initiating coverage of Enanta Pharmaceuticals with a Market Outperform rating and \$25 price target** based on a risk-adjusted, discounted cash flow analysis. Enanta is a biotechnology company poised to be first to market with an all oral regimen that could cure the majority of HCV patients. We believe Enanta shares could climb this year as Phase 3 data generated by Enanta's protease inhibitor, ABT-450, the backbone of partner AbbVie's triple HCV regimen sets a high bar for forthcoming regimens. Treatment of HCV will initially be a duopoly between AbbVie (ABBV, NC) and Gilead (GILD, NC), vying for share of the bolus of warehoused patients awaiting therapy. Our analysis of Street sentiment suggests that expectations are high for Gilead's domination, giving Enanta, vis-a-vis AbbVie, a chance to surprise. The data behind AbbVie's regimen may be slightly less enticing than Gilead's 100% cure with one pill, once daily; however, we believe AbbVie's data is more realistic, as it was generated in a broader population. The final pill burden and duration of therapy will not be known until after Phase 3 studies readout. We think shares of ENTA will continue to rise after a successful IPO last month, as data flows from the Phase 3 program and the company heads towards profitability in 2014, driven by near-term milestones of \$195 million and royalties.

FY SEP	2012A	2013E	2014E
Revenue (\$M) 1Q	--	\$27.9	--
2Q	--	\$1.4	--
3Q	--	\$1.4	--
4Q	--	\$26.4	--
<b>FY</b>	<b>\$41.7</b>	<b>\$57.1</b>	<b>\$48.8</b>
EPS 1Q	--	\$1.53	--
2Q	--	(\$0.35)	--
3Q	--	(\$0.30)	--
4Q	--	\$0.94	--
<b>FY</b>	<b>\$1.13</b>	<b>\$1.99</b>	<b>\$0.59</b>
<b>CY</b>	<b>\$2.38</b>	--	--

Source: Company reports and JMP Securities LLC

## STOCK PRICE PERFORMANCE



**AbbVie combination could beat expectations.** HCV is undergoing a revolution to (DAA) therapy, which we expect to bring many more patients to the table. AbbVie/Enanta's and Gilead's combinations should be first to the market, though we believe AbbVie will likely be the first to report Phase 3 data this year in the genotype 1 population - the majority of U.S. infections. Until now, the Street has largely supported the notion that the Gilead combination will dominate given the perception that it has a 'magic bullet'. However, we think Phase 3 programs for each regimen will include more real world patients, that commercial products will be more similar than not, and that each regimen will find its own niche. Therefore, we think adoption of AbbVie/Enanta's combination could surpass expectations.

**Royalties should make Enanta cash flow positive beginning in 2014.** Ahead of Phase 3 data, which will roll out during 2013-2014, we assume AbbVie/Enanta can capture 30% of the genotype 1 market. With double-digit royalties on its one-third share of the AbbVie combination, plus developmental and commercial milestones, we estimate 2014-2017 revenue could reach \$48M, \$189M, \$265M, and \$224M, respectively, driving earnings of \$0.59, \$5.75, \$7.40, and \$4.91.

## INVESTMENT THESIS

AbbVie/Enanta are poised to be the first to market in GT1

### First mover advantage

The HCV market is transitioning from interferon-based regimens to all oral interferon-free regimens (IFN), known as direct-acting antiviral (DAA) therapy. AbbVie and partner Enanta are poised to be the first to market for genotype 1 population which comprises about 85% of cases in the U.S., followed closely by Gilead. AbbVie's offering is effectively a triplet built around the Enanta protease inhibitor (PI) ABT-450, boosted with ritonavir/r (ABT-450/r), combined with AbbVie's NS5a (ABT-267), and a non-nucleotide inhibitor (ABT-333) dosed for 12 weeks. Gilead's offering in genotype 1 is built around its nucleotide inhibitor, sofosbuvir, combined with Gilead's NS5a, ledipasvir, dosed for either 12 or 24 weeks. Both offerings are being explored with and without ribavirin.

Given a confluence of science and expectations for at least a doubling of diagnosed cases, there is a plethora of compounds in development positioned to reach the market a couple of years after AbbVie/Enanta and Gilead's offerings (Figure 1). Our due diligence with HCV-treating physicians suggests significant warehousing of patients holding out for these simpler DAA regimens, with fewer side effects and higher cure rates. We assert that most patients diagnosed today are symptomatic given that recommended CDC screening, which would capture asymptomatic patients, has yet to be widely implemented.

AbbVie/Enanta could benefit from being first movers into the bolus of advanced patients motivated to treat, where its regimen could have advantages

Today's pool of diagnosed patients is mostly captured because they present with symptoms and are more advanced, with about 30% of presenters cirrhotic. We think AbbVie/Enanta could benefit from being first movers due to the growing bolus of advanced patients warehoused for interferon-free combinations, where the motivation to treat is high and competition will likely be limited to AbbVie/Enanta and Gilead for the first few years. The AbbVie/Enanta protease-based regimen could, in theory, have advantages in the cirrhotic population over Gilead's nucleotide pro-drug strategy, which would require conversion to the active form in the liver.

**FIGURE 1. HCV DAA Competitive Landscape**

	Protease Inhibitors Simiprevir (Medivir/J&J)	Nucleosides/tides Sofosbuvir (Gilead) (GT2/3 and with IFN)	Non-Nucleosides	NS5A
Registration				
Phase 3	BI 201335 (Boehringer Ingelheim) BMS-650032 (BMS) Vaniprevir (Merck)	RG7128 (Gilead/Roche) GS-7977 (Gilead) (GT1)	ABT-333 BI-207127 (Boehringer Ingelheim)	BMS-790052 (BMS) ABT-267 (Abbott) GS5885 (Gilead)
Phase 2	ACH-1625 (Achillion) Danoprevir (Roche) ABT-450 (Abbott/Enanta) GS-9451 (Gilead) SCH 900518 (Merck) BMS-650032 (BMS) Vaniprevir (Merck) MK-5172 (Merck)	VX-135 (Vertex)	GS9190 (Gilead) ANA598 (Roche) ABT-072 (Abbott) BMS-791325 (BMS) VX-222	IDX719 ACH-3102
Phase 1	ACH-2684 (Achillion) ABT next generation		GS9669 (Gilead)	MK-8742 (Merck) PPI-668 (Presidio) EDP-239 (Enanta/Novartis)

Source: Company reports and JMP Securities LLC

In November 2012, AbbVie initiated development of Enanta's 2<sup>nd</sup> generation PI

### Second generation in the wings

In our opinion, a key disadvantage of the AbbVie combination versus other DAA regimens is a greater potential for drug-drug interactions because of its metabolism by CYP enzymes and required co-administration with ritonavir to boost its bioavailability. In November 2012, AbbVie initiated clinical development of a second generation PI from Enanta. This compound has fewer drug-drug interactions, does not require boosting by ritonavir, and has shown efficacy against mutations known to confer resistance to first generation PIs. Moreover, with fewer drugs in the regimen, Enanta is poised to capture a greater share of the economics (a royalty on 50%) than with the first generation regimen (a royalty on 33%). We believe this program could reach the market in 2018, in time to be competitive with the second wave of DAA combinations.

AbbVie is conducting a Phase 2 study in GT1b without ABT-333, which would reduce the daily pill count

### Doublet

AbbVie is conducting a Phase 2 study in patients with genotype 1b (~30% of the genotype 1 population) without the non-nucleotide component ABT-333, which would reduce the pill count to two or three pills in the morning or just two pills once daily, depending on the need for ribavirin. Not only is this advantageous because of lower pill burden, but the economics to Enanta are more favorable as the company would be eligible for a double-digit royalty on 50% of the regimen, greater than the royalty on 33% of the regimen that Enanta would receive for the leading "triplet" regimen.

We model profitability in 2015

### Profitability in sight

We believe the AbbVie/Enanta regimen will reach the U.S. market in 2014 and provide an instant boost to Enanta revenue as it hits key development and commercial milestones, as well as receipt of double-digit royalties on worldwide sales. This revenue stream, coupled with low expenses and about \$100 million in cash after the recent IPO, should drive a clear path to profitability in 2015, in our opinion; though we note that the onslaught of second generation HCV DAA regimens beginning in 2016 could slow earnings growth until AbbVie's own second generation regimen bears fruit in 2018. We do not anticipate any shareholder dilution ahead of reaching the profitability mark in 2015.

Enanta has a preclinical antibiotic program funding by government contracts means potential upside at no expense to investors.

### Free flyer into antibiotics

Enanta has a preclinical novel macrolide antibiotic program (bicyclolides) slated to begin clinical evaluation in 2014. Preclinical and early clinical development is funded by contracts with NIAID; therefore, we see this program as potential upside with no cost to investors. The lead compound, pro-drug EDP-788, is currently undergoing preclinical toxicology studies.

Data coming this year from both the AbbVie/Enanta and Gilead regimens will set the stage for the 2-3 year duopoly between these players

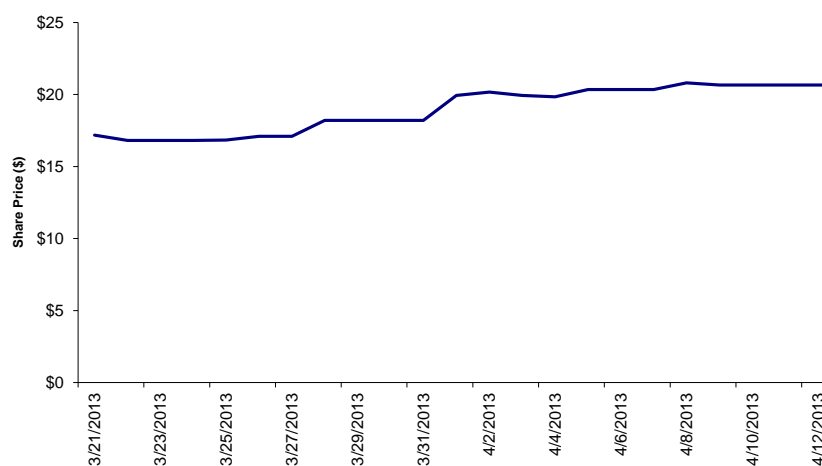
### Defining data coming this year

2013 marks a key year for data flow for Enanta, with defining data for its HCV platform (Figure 2), a source of additional value creation for the program. Specifically, data coming this year from both the AbbVie/Enanta and Gilead regimens should set the stage for the 2-3 year duopoly between these players and establish a bar for forthcoming combinations. Beyond key Phase 3 data read outs from at least two of the six registration studies (likely SAPPHERE 1 and 2) anticipated for the second half of this year, proof of concept for AbbVie/Enanta's second generation PI will also read out, as well as data from PEARL I, which will establish a potential doublet approach for genotype 1b patients.

**FIGURE 2. Upcoming Catalysts**

Timing	Upcoming Catalyst	Product	Indication - Mechanism	Stage
2H13	SAPPHIRE Phase 3 Results	ABT-450	HCV - PI	Phase 3
2H13/1H14	PEARL Phase 3 Results	ABT-450	HCV - PI	Phase 3
2013	POC data	EDP-239	HCV - NS5a	Phase 1
2013	POC data	Next Gen PI	HCV - PI	Phase 1
2H13	PEARL study (2 drug combination GT1b,4)	ABT-450	HCV - PI	Phase 2
1H14	IND, P1 study	EDP-546	HCV - Cyclophilin	Preclinical
2013	Lead identification	Nuc	HCV- Nuc	Preclinical
1H14	IND, P1 study	EDP-788	MRSA	Preclinical

Source: Company reports and JMP Securities LLC

**FIGURE 3. ENTA Price Chart**

Source: Thompson Reuters and JMP Securities LLC

## KEY POINTS OF DEBATE

KOLs describe the magic HCV bullet as one pill, once per day, with cures for all; some believe Gilead's regimen fits this description.

### Does Gilead have the magic bullet?

Key opinion leaders describe the magic HCV bullet as one pill, once per day, with cures for all. Given the simplicity of its regimen and high cure rate, many believe Gilead's sofosbuvir-based regimen fits this description. With the \$11 billion acquisition of Pharmasset, Gilead has made a big bet on sofosbuvir, which we believe is an excellent nucleotide. This opinion is shared by many and reflected in the high expectations for the sofosbuvir combination (Figure 4), with revenue estimates ranging from \$750M to \$7.2B in the first year on the market.

**FIGURE 4. Consensus Range (number of estimates)**

	2015	2016	2017	2018
Sofosbuvir	\$750-\$7286M (12)	\$1000-9071M (7)	\$1143-7233 (6)	\$5290-\$8616M (2)
ABT-450 combo	\$458-600M (3)	\$1119-1750M (3)	\$1567-2500 (2)	\$1567-2600M (2)

Source: Bloomberg

We see opportunities for AbbVie/Enanta to surpass expectations - efficacy in subpopulations, pill burden, and duration of therapy

That said, there is much to learn from the forthcoming Phase 3 studies which will ultimately set the stage for the 2-3 year duopoly that will likely exist between AbbVie/Enanta and Gilead. We see several opportunities for AbbVie/Enanta to surpass expectations:

- **Efficacy.** Key opinion leaders continue to point to efficacy as the most important factor for choosing a regimen. In our opinion, the AbbVie data had been more extensively tested and therefore are more likely to correlate to forthcoming Phase 3 data than Gilead. The AbbVie Phase 2b studies were run in close to 100 sites, with over three times the number of patients exposed in the Gilead Phase 2 ELECTRON study which was run in a single site in New Zealand. As a reminder, SVR for the AbbVie/ Enanta "triplet" was in the high-80% to mid-90% range, whereas Gilead was at 100% (Figure 5). We anticipate cure rates will decline as the combination is tested in a more "real world" environment at various sites around the world.

**FIGURE 5. AbbVie and Gilead Phase 2 Data**

Compounds	Mechanism	n	# sites	Duration	Subtype	SVR
Treatment Naïve						
ABT-450/r	PI	79	96	12 Weeks	GT1	98%
ABT-267	NS5a				GT1a	96%
ABT-333, RBV	Non Nuc				GT1b	100%
ABT-450/r	PI	79	96	12 Weeks	GT1	87%
ABT-267	NS5a				GT1a	83%
ABT-333	Non Nuc				GT1b	96%
Sofosbuvir	Nuc	25	2	12 Weeks	GT1	100%
Ledipasvir	NS5a					
Treatment Experienced						
ABT-450/r	PI	45	96	12 Weeks	Nulls	93%
ABT-267	NS5a				GT1a	89%
ABT-333, RBV	Non Nuc				GT1b	100%
Sofosbuvir	Nuc	9	2	12 Weeks	GT1	100%
Ledipasvir	NS5a					

Source: Company reports and JMP Securities LLC

- **Pill burden.** In our view, concerns over the pill burden for the AbbVie combination may be overdone. A criticism of the AbbVie combination is that it contains five drugs - PI ABT-450 boosted with ritonavir, NS5a ABT-267, non-nuc ABT-333, and ribavirin. However, AbbVie's Phase 3 studies utilize a fixed dose combination (FDC) of boosted ABT-450, ritonavir, and ABT-267, simplifying the regimen to four pills in the morning, plus two pills in the evening, if ribavirin is included. The dose without ribavirin is three pills and one pill once daily (Figure 6). Phase 3 data will tell us if and when ribavirin will be necessary. We see the latter as an advantage for Gilead given the simplicity of once daily therapy. However, if ribavirin is required for the Gilead regimen, this would level the playing field for AbbVie on the pill burden front.

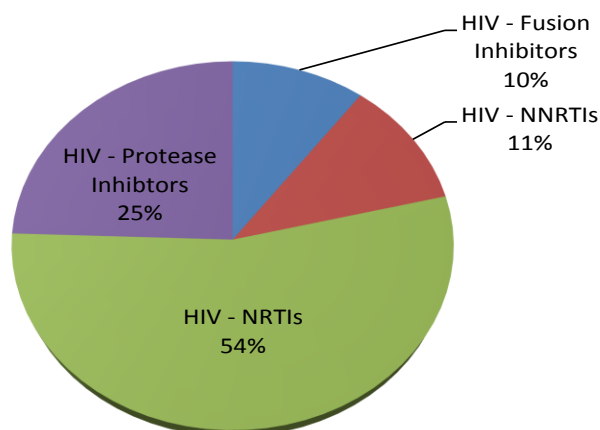
**FIGURE 6. Pills in AbbVie Regimen**



Source: Company reports

- **Duration of therapy.** AbbVie's Phase 3 program is centered on a 12-week regimen, with both 12 and 24 weeks also being explored for cirrhotics and HIV co-infected patients. On the other hand, the Gilead program is evaluating both 12 and 24 weeks of therapy across its programs. The data this year will inform us as to the optimal duration of therapy and in the meantime, we see a shorter duration of therapy as another potential source of competitive advantage for AbbVie.
- **Patient sub-types.** AbbVie is segmenting its Phase 3 campaign to specifically address GT1a, GT1b, cirrhotic, treatment experienced, and treatment naïve patients, as well as a study in HCV/HIV co-infected patients, whereas Gilead is conducting a treatment naïve and experienced study, respectively, with embedded cirrhotics. The Phase 3 data will describe the relative efficacy and we see upside for AbbVie if the ABT-450/r regimen demonstrates numerically higher efficacy than the Gilead combination in any patient sub-type.

To this point, in theory, the AbbVie/Enanta protease based regimen could work better in cirrhotic patients than the Gilead nucleotide pro-drug regimen given the need for conversion to the active form for the latter by the liver. At a recent conference we attended, we learned that there is a sense of urgency to treat cirrhotics patients amongst community HCV physicians. Moreover, our due diligence with HIV doctors suggests that they are comfortable using ritonavir given its history in HIV and that the most commonly prescribed HIV regimens today are not protease inhibitor based (Figure 7), thus we do not see as much concern for drug-drug interaction in this segment as anticipated.

**FIGURE 7. HIV Market Share (in dollars) by class**

Source: Bloomberg, Wolters Kluwer, and JMP Securities LLC

We see the commercial landscape as highly competitive; we believe AbbVie/Enanta may be a leading player

### Fierce competition

AbbVie/Enanta represent just the tip of the iceberg in terms of the HCV revolution and we see the final commercial landscape as a mosaic of various different portfolios (Figure 7), among which we believe Enanta, vis-à-vis AbbVie may be a leading player with both its first and second generation protease inhibitor programs.

The U.S. and European HCV markets are finite

### Sustainability of the Market

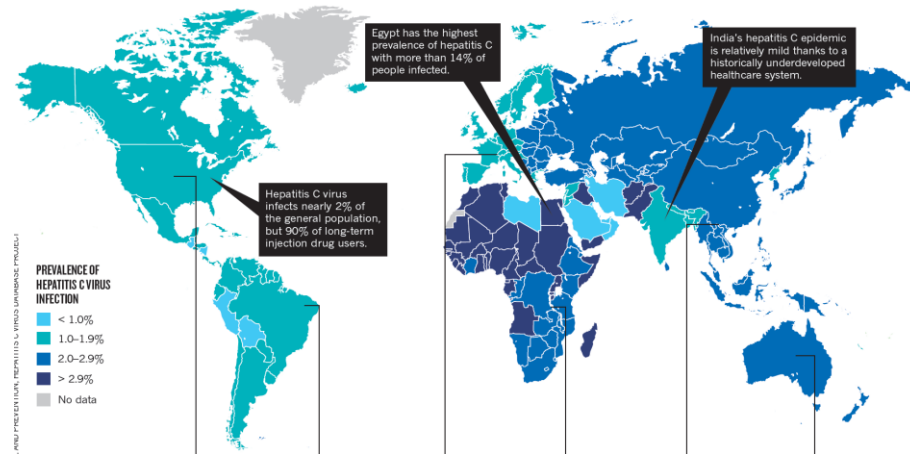
The U.S. and European HCV markets are finite. In the U.S., one million patients are diagnosed with HCV. What is unknown, is how many patients are not yet diagnosed. At a recent Clinical Care Options (CCO) conference we attended, experts estimated that between 45-85% of cases may be undiagnosed today. CDC estimates this number to be 75%. This translates to about 820,000-5,600,000 undiagnosed cases – a wide range for this future pool of patients where the low end of this range would be significantly below expectations and would not be sufficient to sustain the U.S. market beyond the pool of one million diagnosed patients. Unfortunately, this is a risk that is difficult to mitigate since we will not definitively know how many could be diagnosed until after the fact.

Industry will promote age-based screening in an effort to replenish the patient supply, once it has made a reasonable dent in treating the existing diagnosed patient pool.

The CDC has recommended age-based screening, targeting the high-risk baby boomer population; however, our due diligence on this front suggests that these programs have yet to be widely implemented. Our contacts suggest that the industry will promote screening, in an effort to replenish the patient supply, once it has made a reasonable dent in treating the existing diagnosed patient pool.

HCV is a global pandemic, with 170M people chronically infected (Figure 8). Thus, we see a massive opportunity beyond the U.S. and Europe, which may be more sustainable given higher incidence due to the continued use of contaminated blood and the lack of education on transmission. Clearly, pricing will be significantly lower in many of these regions, which is easily justified by the number of patients. Moreover, in many of these regions, factors such as price trump efficacy, convenience, and even tolerability, such that there may be a different preference outside of the U.S. for alternative HCV regimens.



**FIGURE 8. Global HCV Prevalence**

Source: Nat. Rev. HCV issue

## VALUATION

Our \$25 price target is based on a discounted cash flow (DCF) analysis, where we risk-adjust the products in Enanta's clinical stage pipeline. Key assumptions for our risk-adjusted, DCF model include an 11% cost of capital based on a CAPM analysis and 3% terminal value. We assign the ABT-450/r-based combinations an 80% chance of success and the next-generation combinations, a 20% chance of success. We also discount milestone revenue by 20%. We add in cash of \$109M *pro forma*, following the IPO and 17.4M shares outstanding, with no additional dilution expected.

### ABT-450

We model 25% GT1 market share out of the gate in 2015 for the AbbVie combination, peaking in 2016 at 30%, and then leveling off to 20% by 2018 when we estimate the next generation compound will enter the market. We estimate the Enanta is entitled to 12-18% royalties on one-third of revenue associated with the AbbVie combination, as ABT-450/r is one of three novel DAAs in the regimen. Under these assumptions, we reach peak revenue of \$224M in 2017 for the ABT-450/r combination. We note there is potential upside to our estimates if AbbVie also markets ABT-450/r/ABT-267 alone to targeted parts of the HCV population, as Enanta would receive royalties on half the sales in this case. We assume pricing of \$85,000 WAC (\$74,000 net of adjustments) per course of therapy for the combination with 80% compliance and assign an 80% probability of approval ahead of Phase 3 data.

### Next generation combination

We assume the next-generation AbbVie combination is launched in 2018, comprised of the Enanta next-generation PI and a next-generation AbbVie NS5a. We assume this combination enters the market at the same price as the first AbbVie combination and that Enanta receives royalties ranging from 12-18% on one-half of the revenue. We believe this combination will cannibalize the first-generation combination and that the effective duopoly will be broken in 2017, with the entrance of



numerous other regimens. With 80% compliance, peak penetration of 20%, and an 18% royalty, we arrive at ~\$143M in revenue in 2025. We currently assign a 20% probability of approval for this next-generation protease inhibitor.

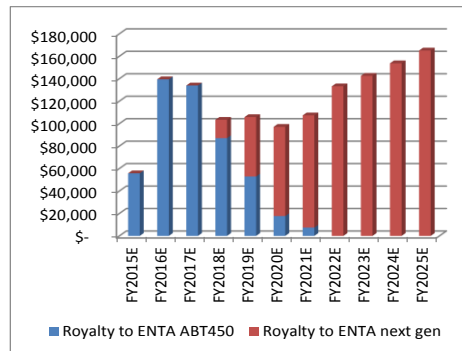
As a reminder, Enanta has the option to co-promote this combination and would retain a 40% royalty if this option was exercised. Phase 2a data triggers this decision. Considering the anticipated level of competition and resources required to compete in the future HCV market, we currently assume Enanta will not exercise this option.

### Milestone payments

Enanta's arrangements with AbbVie and Novartis come with a robust royalty stream for regulatory and commercial milestones. We believe Enanta will receive about \$195M in milestones for ABT-450 over the next 2-3 years and \$80M for approval of a next generation combination. Enanta can also collect ~\$400M in milestones for EDP-239 from Novartis. We discount this milestone revenue by 20% considering the uncertainty in the next-generation PI and NS5a programs.

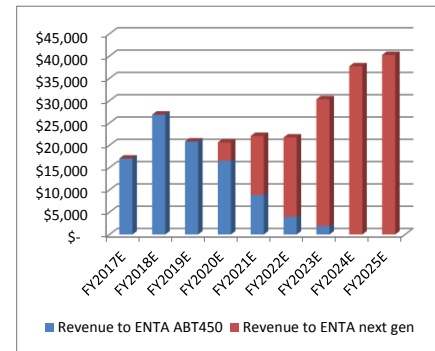
Enanta will likely receive \$195M milestones for ABT-450 in the next 2-3 years

**FIGURE 9. U.S. Projected Rev. (000's)**



Source: JMP Securities LLC estimates

**FIGURE 10. Ex-U.S. Projected Revenue (000's)**



Source: JMP Securities LLC estimates

**FIGURE 11. Discounted Cash Flow Analysis**

Discounted Cash Flow Valuation										
	2013	2014	2015	2016	2017	2018	2019	2020	2021	
Revenues	57,068	48,821	189,348	264,561	224,427	251,585	215,948	122,488	107,144	
ABT450 royalty	0	0	62,319	177,532	224,427	156,310	93,173	47,524	21,235	
ABT next gen	0	0	0	0	0	15,275	42,775	74,964	85,909	
milestones	57,068	48,821	127,029	87,029	0	80,000	80,000	0	0	
other	-	-	-	-	-	-	-	-	-	
COGS	-	-	6,232	17,753	22,443	13,727	10,876	9,799	8,572	
SG&A	5,852	8,464	9,141	9,872	10,662	11,515	12,436	13,431	14,506	
R&D	20,548	27,000	29,700	32,670	35,937	39,531	43,484	47,832	52,615	
Operating Income (EBIT)	30,668	13,357	144,275	204,265	155,385	186,813	149,152	51,426	31,452	
Weighted Risk	80%	80%	80%	80%	80%	76%	68%	43%	32%	
Tax	0%	0%	0%	0%	5%	15%	25%	30%	35%	
Risk adjusted Net Income	-	10,685	115,420	163,412	118,092	121,248	76,196	15,580	6,520	
Year for discounting	0	1	2	3	4	5	6	7	8	
	\$ -	\$ 9,628	\$ 93,711	\$ 119,550	\$ 77,847	\$ 72,020	\$ 40,782	\$ 7,514	\$ 2,833	
NPV	\$ 456,836									
+ Current Cash & Equivalent	\$ 45,418.0									
Value of the Company	\$502,253.8									
- L-T Debt	\$ -									
Value of Equity	\$502,253.8									
Value per Share	\$ 25.07									

Source: JMP Securities LLC estimates

FIGURE 12. Income Statement

	FY10A (Sept 30)	FY11A	FY12A	Dec-12A	Mar-13E	Jun-13E	Sep-13E	FY13E	FY14E	FY15E	FY16E	FY17E	FY18E	FY19E	FY20E	FY21E
ABT-450 first combo next generation ABT										62,319	177,532	224,427	156,310	93,173	47,524	21,235
<b>Total product revenues</b>	-	-	-	-	-	-	-	-	-	62,319	177,532	224,427	156,310	93,173	47,524	21,235
Collaboration costs										0	0	0	15,275	42,775	74,964	85,909
Milestones/Contracts	22,763	41,882	41,706	27,859	1,403	1,403	26,403	57,068	48,821	127,029	87,029	-	80,000	80,000	-	-
<b>Total revenue</b>	<b>22,763</b>	<b>41,882</b>	<b>41,706</b>	<b>27,859</b>	<b>1,403</b>	<b>1,403</b>	<b>26,403</b>	<b>57,068</b>	<b>48,821</b>	<b>189,348</b>	<b>264,561</b>	<b>224,427</b>	<b>251,585</b>	<b>215,948</b>	<b>122,488</b>	<b>107,144</b>
Cost of goods sold	-	-	-	-	-	-	-	-	-	6,232	17,753	22,443	13,727	10,876	9,799	8,572
R&D	9,716	11,547	15,115	4,798	5,000	5,250	5,500	20,548	27,000	29,700	32,670	35,937	39,531	43,484	47,832	52,615
General and administrative	6,105	5,036	5,302	1,152	1,200	1,500	2,000	5,852	8,464	9,141	9,872	10,662	11,515	12,436	13,431	14,506
<b>Total operating expenses</b>	<b>15,821</b>	<b>16,583</b>	<b>20,417</b>	<b>5,950</b>	<b>6,200</b>	<b>6,750</b>	<b>7,500</b>	<b>26,400</b>	<b>35,464</b>	<b>45,073</b>	<b>60,296</b>	<b>69,042</b>	<b>64,773</b>	<b>66,796</b>	<b>71,063</b>	<b>75,693</b>
<b>Operating income (loss)</b>	<b>6,942</b>	<b>25,299</b>	<b>21,289</b>	<b>21,909</b>	<b>(4,797)</b>	<b>(5,347)</b>	<b>18,903</b>	<b>30,668</b>	<b>13,357</b>	<b>144,275</b>	<b>204,265</b>	<b>155,385</b>	<b>186,813</b>	<b>149,152</b>	<b>51,426</b>	<b>31,452</b>
<b>Total other expense, net</b>	<b>805</b>	<b>(1,989)</b>	<b>110</b>	<b>48</b>	<b>72</b>	<b>69</b>	<b>82</b>	<b>259</b>	<b>66</b>	<b>107</b>	<b>195</b>	<b>286</b>	<b>373</b>	<b>458</b>	<b>509</b>	<b>531</b>
<b>Net income (loss)</b>	<b>7,904</b>	<b>23,310</b>	<b>21,399</b>	<b>21,957</b>	<b>(4,725)</b>	<b>(5,278)</b>	<b>18,986</b>	<b>30,940</b>	<b>13,423</b>	<b>144,382</b>	<b>204,461</b>	<b>147,887</b>	<b>159,108</b>	<b>112,207</b>	<b>36,354</b>	<b>20,789</b>
<b>Net income (loss) to stockholders</b>	<b>216</b>	<b>1,565</b>	<b>1,369</b>	<b>1,868</b>	<b>(4,725)</b>	<b>(5,278)</b>	<b>18,986</b>	<b>10,851</b>	<b>13,423</b>	<b>144,382</b>	<b>204,461</b>	<b>147,887</b>	<b>159,108</b>	<b>112,207</b>	<b>36,354</b>	<b>20,789</b>
<b>EPS basic</b>	<b>\$ 0.04</b>	<b>\$ 1.40</b>	<b>\$ 1.26</b>	<b>\$ 1.71</b>	<b>\$ (0.35)</b>	<b>\$ (0.30)</b>	<b>\$ 1.08</b>	<b>\$ 2.14</b>	<b>\$ 0.72</b>	<b>\$ 7.36</b>	<b>\$ 9.92</b>	<b>\$ 6.84</b>	<b>\$ 7.04</b>	<b>\$ 4.75</b>	<b>\$ 1.48</b>	<b>\$ 0.81</b>
<b>EPS diluted</b>	<b>\$ 0.04</b>	<b>\$ 1.32</b>	<b>\$ 1.13</b>	<b>\$ 1.53</b>	<b>\$ (0.21)</b>	<b>\$ (0.27)</b>	<b>\$ 0.94</b>	<b>\$ 1.99</b>	<b>\$ 0.59</b>	<b>\$ 5.75</b>	<b>\$ 7.40</b>	<b>\$ 4.91</b>	<b>\$ 4.88</b>	<b>\$ 3.20</b>	<b>\$ 0.97</b>	<b>\$ 0.52</b>
Shares outstanding - basic	4,873	1,119	1,089	12,815	13,582	17,415	17,615	15,357	18,615	19,615	20,615	21,615	22,615	23,615	24,615	25,615

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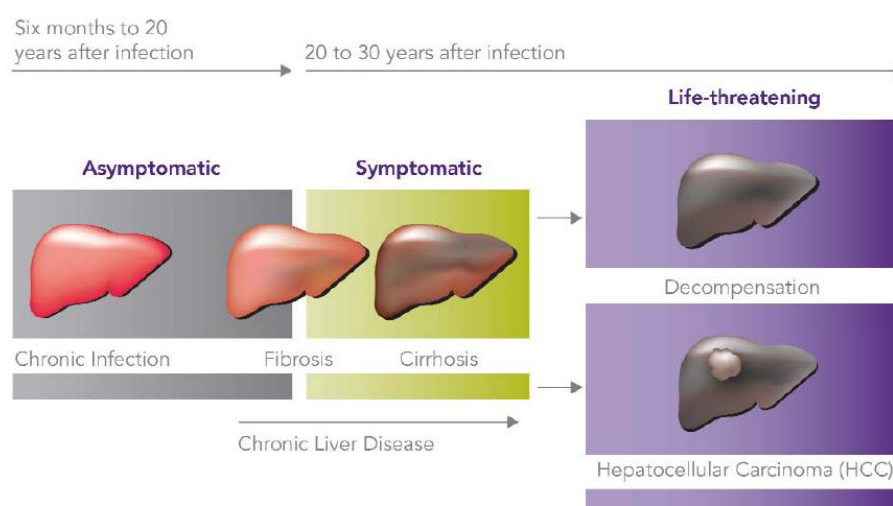
Source: Company reports and JMP Securities LLC

## HCV INFECTION AND MARKET DYNAMICS

While infection with HCV can ultimately result in liver cancer, the disease typically progresses in a slow fashion, allowing patients to delay treatment.

Identified in 1989, HCV infection causes hepatitis, a disease characterized by inflammation of the liver. HCV is contracted through contact with blood or other body fluids from an infected person and is primarily transmitted via injection drug use, tainted blood transfusion (low risk since 1995 due to implementation of screening procedures in many countries), organ transplant, or sexual contact. The virus resides in hepatocytes in the liver, where it uses the cells' own machinery to replicate. HCV has a high replicative capacity, with up to one trillion virus particles produced each day in an individual infected with the virus. While infection with HCV can ultimately result in liver cancer, the disease typically progresses in a slow fashion (Figure 13), allowing patients to delay treatment.

**FIGURE 13. Progression of HCV to HCC**



Source: Progression of HCV to HCC

In Western countries, the HCV-infected population is sizable, but is experiencing negligible growth

In Western countries, the HCV-infected population is sizable, but is experiencing negligible growth. On a global basis, HCV is a pandemic, with 170M people chronically infected. In the United States, there are approximately 3.2M chronically infected people, of which about 2.5M are from the baby boomer generation. Based on the NHANES database, approximately 1.4M cases of chronic infection occurred in people born in the 1950s and 800K in people born in the 1960s and infected in the 1980s (Figure 14). This creates a large bolus of infected patients moving through diagnosis, disease progression, and treatment in a somewhat predictable fashion.

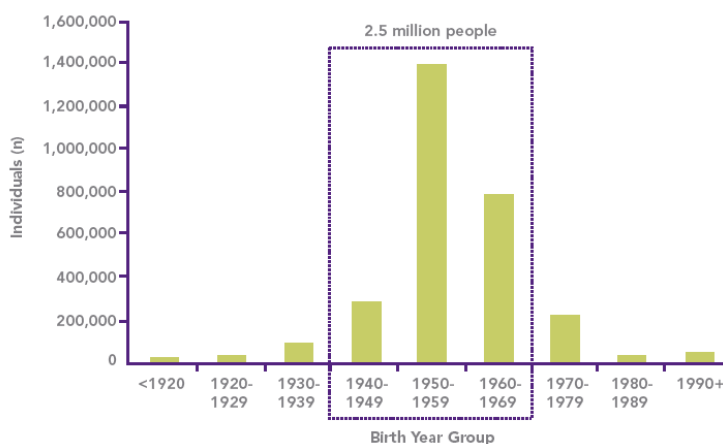
In the early 1990s, healthcare officials increased awareness of HCV and took measures in preventing transmission such as screening blood transfusions, resulting in a particularly sharp drop in infection rates. Since then, new infections have declined year after year, with infection rates hitting a low of 17,000 cases in 2007. With only 13,600 of these new infections progressing to chronic infection and an estimated 12,000 annual deaths from viral hepatitis C, we assert that the HCV infection has entered a state of stagnancy.

Given that the bolus of HCV patients was infected in the 1980s, the majority are currently asymptomatic, but are expected to become symptomatic in this decade.

On the other hand, given the lag between infection and the onset of symptoms, we believe many patients may be on the cusp of diagnosis, priming the market for significant growth. Cirrhosis is characterized by severe fibrosis of the liver, resulting in a decline in liver function and noticeable physical symptoms such as jaundice, nausea, vomiting, weakness, weight loss, and ultimately more serious complications such as end-stage liver disease and death.

Based on our review of the literature regarding the historical progression of the disease, we estimate that approximately 20% of HCV patients develop cirrhosis within 20 years of infection, another 33% of patients develop cirrhosis within 20 and 30 years of infection, and the majority of remaining patients do not develop cirrhosis prior to death. Given that the bolus of HCV patients was infected in the 1980s, the majority are currently asymptomatic but are expected to become symptomatic in this decade.

**FIGURE 14. HCV Prevalence in the U.S. - by Age Group**



Source: Vertex Media Guide

Near-term growth in the domestic market will be followed by a sharp drop-off once the bolus of baby boomer patients is either cured or dies.

### A first-come, first-served market

In the U.S. and E.U., the HCV market is finite. The current patient population consists largely of aging baby boomers, while new infections comprise a very small portion of the population. As such, HCV is distinct from other diseases in that it is not replenished with new patients. Also, unlike some other infections like HIV, HCV therapy can be curative. As such, we anticipate that near-term growth in the domestic market will be followed by a sharp drop-off once the bolus of baby boomer patients is either cured or dies.

These market characteristics highlight the importance of speed to market as the first new therapies that reach the market will cure a portion of available patients, reducing the pool of patients for the following compounds. Although the first-generation compounds, telaprevir from Vertex and boceprevir from Merck, have captured some patients with first mover advantages, the complexity of the regimens leading to a capacity constraint due to the limited number of experts, the time to manage each patient's care, and the awareness of IFN-free therapies on the horizon, have primed the market for next-generation therapies. Net-net, we believe the HCV market is sustainable for the next two decades due to rapidly increasing diagnosis rates, driven by disease progression.

The current HCV market is limited by a low diagnosis rate and cumbersome treatment options

### Breaking down the barriers to treatment

The current HCV market is limited by a low diagnosis rate and cumbersome treatment options. In our opinion, diagnosis is the greatest barrier to treatment as about 45%-85% of chronically infected patients or about three million Americans are unaware they are infected with HCV. Low diagnosis rates are the result of the asymptomatic nature of the disease and the lack of mandatory screens.

We believe the natural progression of disease will begin to yield symptoms in many patients in the near term, particularly the bolus of aging baby boomers. With peak infection rates occurring in the 1980s, we believe we are on the cusp of significant increases in advanced fibrosis of cirrhosis over the next decade.

CDC recommends age-based screening for HCV, which we believe will eventually lead to greater diagnosis rates

The CDC recommends age-based screening for HCV, which we believe will eventually lead to greater diagnosis rates. The CDC recommends that Americans born between 1945 and 1965 be tested once for HCV. Our discussions with experts involved in writing the affordable care act (ACA) suggest that implementation of the guidelines is a priority and we are hopeful that CDC guidelines may be put into practice over the next five years as new treatment options emerge. Our due diligence with large hospital centers suggests that awareness of the CDC recommendation is still relatively low but we think this will change as biopharmaceutical companies initiate campaigns to raise awareness upon the launch of the all oral treatment options.

### Treatment options today

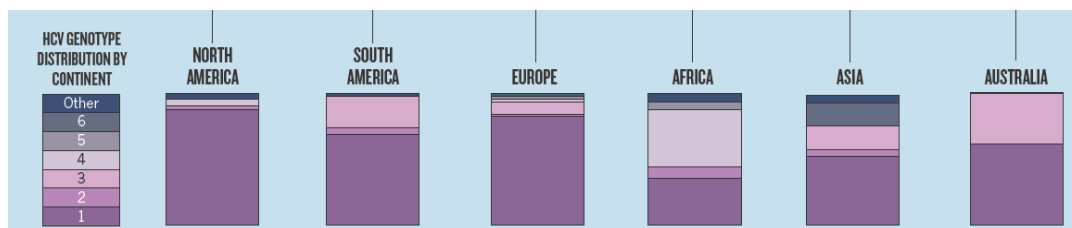
Patients today essentially have two treatment options: a choice of either telaprevir (a PI marketed as Incivek from Vertex/JNJ) or boceprevir (a PI marketed as Victrelis from Merck/Schering-Plough), on a background of pegylated interferon (IFN, available in two forms pegylated interferon alpha 2a (marketed as Pegasys by Roche) or pegylated interferon alpha 2b (marketed as PegIntron by Merck/Schering-Plough)).

Telaprevir and boceprevir approvals were revolutionary for HCV treatment due to the potential to double the cure rate from the prior treatment paradigm; yet marketplace success has been hindered by poor tolerability

The approvals of telaprevir and boceprevir were revolutionary for HCV treatment because of the potential to double the cure rate from the prior treatment paradigm, yet marketplace success has been hindered by poor tolerability. While each agent has its own side effect issues, the continued need for the use of weekly IFN injections and daily oral RBV leads to combinations plagued with fatigue, flu-like symptoms, depression, nausea, anemia, and rash. As a result, 35-40% of patients have had to utilize lower doses and about 15-20% discontinue therapy altogether, resulting in lower cure rates than anticipated. Approximately 30% of diagnosed patients consist of a particularly dire group of 300,000 patients who receive treatment, but fail to be cured, the so-called "treatment failure" population. This group can be further broken down by response, into relapsers (initial response followed by viral rebound) or null responders (failure to achieve a viral load drop of more than 2 logs).

### HCV is not a one size fits all disease and neither are the potential treatments

IFN/RBV has been used to treat HCV with variable cure rates across genotypes. Geographically, GT1 is the most prevalent strain in the U.S. and EU (Figure 15) and is further broken down into GT1a and GT1b, with GT1a accounting for about 70% of this segment in the U.S. and EU. In Japan, almost all GT1 patients are GT1b. GT1a appears to be a more robust virus with more resistant variants than GT1b. Single-nucleotide polymorphisms (SNPs) in the promoter region of IL28b (the gene that encodes IFN  $\lambda$ 3) are correlated with IFN/RBV response, with the CC patients responding best, followed by the CT and TT genotypes.

**FIGURE 15. Geographic Breakdown of HCV Genotypes (GTs)**

Source: Nat Rev HCV issue

Key opinion leaders suggest the optimal therapy would be a single combination with a high cure rate across genotypes

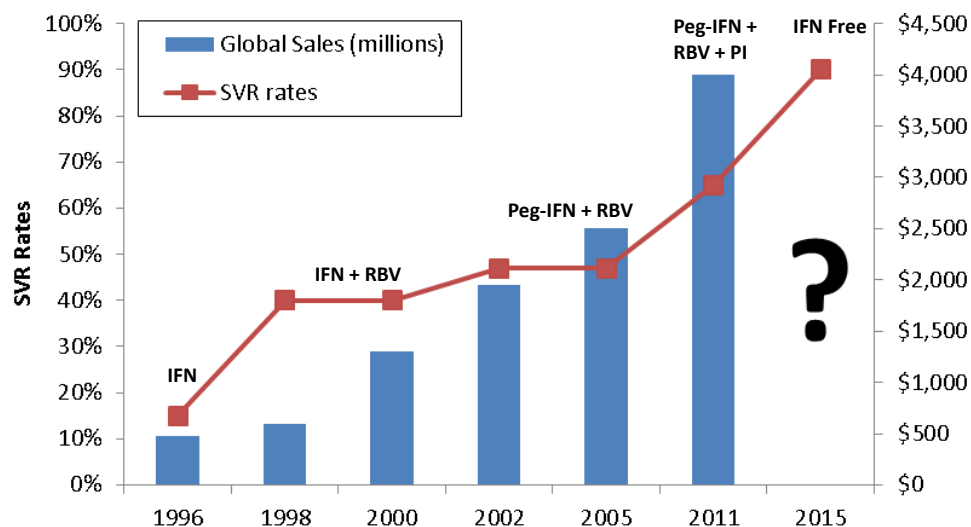
Key opinion leaders suggest the optimal therapy would be a single combination with a high cure rate across genotypes. This is a challenging goal because of the nature of the compounds in development, and the difference in response between genotypes. The only class known to work well across genotypes and, thus the only class considered to be 'pan-genotypic', are the nucleotide/side inhibitors. Most other classes of compounds have only been tested in human GT1 patients so far, given that this is the predominate virus in the U.S. and EU.

The first-generation PIs, telaprevir and boceprevir are specific for GT1 and most of the next-generation PIs are not pan-genotypic, with GT3 being the Achilles heel of the class. That being said, reasonable activity has been shown with higher doses of Merck's MK-5172, Achillion's sovalprevir, and Abbott/Enanta's ABT-450/r, though it is unclear if these fall within an acceptable therapeutic window. In our view, the pan-genotypic attribute is less of a benefit in the U.S. given that 85% of cases are GT1; nonetheless, we do believe is an important source of competitive advantage in other world areas that have a greater mix of genotypes.

### Product introductions drive market growth

The global market reflecting IFN/RBV was ~\$800M in the U.S. and ~\$2.5B worldwide, with \$1.5B of revenue added by the introduction of telaprevir and boceprevir in 2011 (Figure 16). In the next decade, we believe the HCV market is poised to grow significantly as the result of the introduction of new therapies.

In the next decade, we believe the HCV market is poised to grow significantly as a result of the introduction of new therapies

**FIGURE 16. Historical HCV U.S. Sales**

Source: Bloomberg, Wolters Kluwer, and JMP Securities LLC

## MARKET READY IN 2015: ABT-450/R COMBINATIONS

Enanta licensed ABT-450 to Abbott for \$44.7M in upfront cash and \$12.5M in preferred stock, \$250M in milestones and double-digit royalties

In 2009, Enanta licensed ABT-450 to Abbott (now AbbVie) for \$44.7M in upfront cash and \$12.5M in preferred stock, followed by \$250M in potential milestones and double-digit royalties on the Enanta component of future combinations. ABT-450 is a cyclic acyl-sulfonamide protease inhibitor (PI), designed to be more potent against variants that first generation compounds (Figure 17). Early studies indicated that bioavailability of ABT-450 was enhanced by co-administration with ritonavir, a CYP3A4 inhibitor that blocks breakdown of ABT-450. This combination is henceforth referred to as ABT-450/r.

**FIGURE 17. Replicon Values of ABT-450 Against Resistant Mutants**

Replicon	Mutant	EC <sub>50</sub> (nM)	Fold Change	Rep. Capacity
GT 1a	WT	1.19		1
	R155G	19.2	16	0.02
	R155K	51.5	43	0.27
	D168A	70.4	59	0.35
	D168V	136	115	0.04
GT 1b	WT	0.07		1
	D168V	17.5	257	1

Source: Company reports

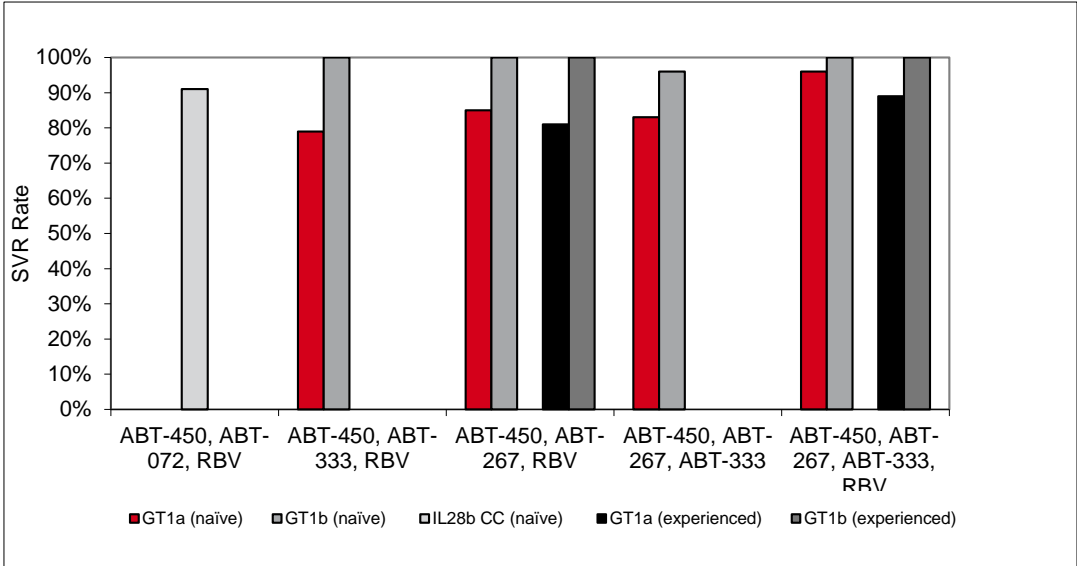


Abbott undertook a large Phase 2b program encompassing 560 patients, 96 centers, and 9 countries

Raising the bar for efficacy

ABT-450/r has been thoroughly tested in combination with other AbbVie molecules with differing mechanisms of action, namely NS5a inhibitor ABT-267 and non-nucleotide inhibitors ABT-333 and ABT-072 in a large multi-arm Phase 2b program referred to as AVIATOR. In total, the study enrolled 560 patients in 96 centers in 9 countries, with about 80 patients each in most treatment-naïve arms and 45 in each treatment-experienced arm. In studies up to 12 weeks, the combinations achieved SVR competitive with the best DAA regimens, and in our view, de-risked the current Phase 3 studies. An overview of these data is shown in Figure 18. As a point of comparison, Gilead nucleotide-based regimens have demonstrated 100% SVR4 in all patients so far; however, we note these data are from a single site with a maximum of 25 patients per arm (Figures 19 & 20).

FIGURE 18. AbbVie DAA Combinations



Source: Company reports and JMP Securities LLC

**FIGURE 19. SVR Rates - Treatment Naïve**

Sponsor	Compounds	Mechanism	Duration	Subtype	SVR
Achillion	ACH-3102 RBV	NS5a	12 Weeks	GT1 IL28bCC	3/3
AbbVie Enanta	ABT-450/r, RBV ABT-072	PI Non Nuc	12 Weeks	GT1 IL28bCC	91%
AbbVie Enanta	ABT-450/r ABT-333 RBV	PI Non Nuc	12 Weeks	GT1 GT1a GT1b	85% 79% 100%
AbbVie Enanta	ABT-450/r ABT-267 ABT-333, RBV	PI NS5a Non Nuc	12 Weeks	GT1 GT1a GT1b	98% 96% 100%
AbbVie Enanta	ABT-450/r ABT-267 ABT-333	PI NS5a Non Nuc	12 Weeks	GT1 GT1a GT1b	87% 83% 96%
Gilead	Sofosbuvir Ledipasvir	Nuc NS5a	12 Weeks	GT1	100%
Gilead	Sofosbuvir RBV	Nuc	12 Weeks	GT1 16% IL28b CC	59%
Gilead	Sofosbuvir RBV	Nuc	24 Weeks	GT1	53%
Gilead	Sofosbuvir RBV	Nuc	12 Weeks	GT1 44% IL28b CC	84%
Gilead	Sofosbuvir RBV	Nuc	24 Weeks	GT1 9 pts	100%
Bristol Gilead	Daclatasvir Sofosbuvir	NS5a Nuc	24 Weeks	GT1	100%
BI	BI201335 TID, RBV BI207127	PI Non Nuc	16 weeks	GT1a GT1b	38% 75%
BI	BI201335 BID, RBV BI207127	PI Non Nuc	28 weeks	GT1a GT1b	43% 83%
Gilead	Ledipasvir, GS-9451 GS-9190, RBV	NS5a, PI Non Nuc	12 weeks	GT1a GT1b	77%* 89%*
Vertex	Telaprevir, RBV VX-222	PI Non Nuc	12 weeks	GT1a GT1b	67%* 100%*
Bristol	Daclatasvir Asunaprevir BMS-791325	NS5a PI Non Nuc	12 Weeks	GT1 (75% GT1a)	94%
Roche	Mericitabine Danoprevir	Nuc PI	24 Weeks	GT1a GT1b	26% 71%

\* Only early responders eligible

Source: Company reports and JMP Securities LLC

**FIGURE 20. SVR Rates - Treatment Experienced**

Sponsor	Compounds	Mechanism	Duration	Subtype	SVR
AbbVie Enanta	ABT-450/r	PI	12 Weeks	Null responders	50%
	ABT-333, RBV	Non Nuc		Null responders	45%
AbbVie Enanta	ABT-450/r	PI	12 Weeks	Null responders	93%
	ABT-267	NS5a		GT1a	89%
	ABT-333, RBV	Non Nuc		GT1b	100%
AbbVie Enanta	ABT-450/r	PI	12 Weeks	Null responders	89%
	ABT-267	NS5a		GT1a	81%
	RBV	Non Nuc		GT1b	100%
Gilead J&J	Sofosbuvir simiprevir	Nuc PI	12 Weeks	GT1	93%
Gilead J&J	Sofosbuvir simiprevir, RBV	Nuc PI	12 Weeks	GT1	96%
Gilead J&J	Sofosbuvir simiprevir	Nuc PI	24 Weeks	GT1	100%
Gilead J&J	Sofosbuvir simiprevir, RBV	Nuc PI	24 Weeks	GT1	67%
Gilead	Sofosbuvir RBV	Nuc	12 Weeks	GT1 Nulls (90% GT1a)	10%
Gilead	Sofosbuvir Ledipasvir	Nuc NS5a	12 Weeks	GT1, 9 patients	100%
Roche	Mericitabine	Nuc	24 weeks	GT1b partial responders	44%
	Danoprevir, RBV	PI		GT1b nulls	72%
Bristol	Daclatasvir	NS5a	24 Weeks	GT1b Nulls	90%
	Asunaprevir	PI		GT1a Nulls	22%
Bristol	Daclatasvir Asunaprevir	NS5a PI	24 Weeks	GT1b IFN intolerant	64%

Source: Company reports and JMP Securities LLC

**Clean Safety Profile**

In the Phase 2 trials, there was one serious adverse event (arthralgia or joint pain) that was possibly related to treatment in a 24-week treatment arm. Two of the 448 subjects discontinued treatment because of a treatment related adverse event (AE), one patient with gallstones had cholestatic hepatitis and one patient had a mouth ulcer, diarrhea, burning sensations, headache, and pruritus. In both cases, the events resolved and patients achieved SVR after 8-10 weeks of therapy. Overall, the side effects were mild (Figures 21 and 22) and similar between treatment naïve and experienced patients. Removal of ribavirin decreased the side effects of the combination. As anticipated, the most frequent lab abnormality was increased indirect bilirubin, consistent with the effect of ABT-450 on a bilirubin transporter. Consistent with prior studies the increase was transient and reversible.

Side effects were mild and  
the removal of ribavirin  
decreased the side effects

**FIGURE 21. Adverse Events**

Duration	Treatment-naïve Patients					Null Responders	
	8 wks	12 wks				12 wks	
Regimen	450/r 267 333 RBV	450/r 333 RBV	450/r 267 333 RBV	450/r 267 333 RBV	450/r 267 333 RBV	450/r 267 333 RBV	450/r 267 333 RBV
<b>Number dosed</b>	80	41	79	79	79	45	45
<b>Any AE, n (%)</b>	20 (25.0)	12 (29.3)	14 (17.7)	10 (12.7)	19 (24.1)	7 (15.6)	11 (24.4)
<b>Fatigue</b>	7 (8.8)	2 (4.9)	3 (3.8)	3 (3.8)	2 (2.5)	1 (2.2)	3 (6.7)
<b>Headache</b>	3 (3.8)	4 (9.8)	3 (3.8)	0	1 (1.3)	0	1 (2.2)
<b>Insomnia</b>	2 (2.5)	1 (2.4)	1 (1.3)	0	4 (5.1)	1 (2.2)	0
<b>Nausea</b>	1 (1.3)	2 (4.9)	1 (1.3)	0	2 (2.5)	0	1 (2.2)
<b>Bilirubin increase</b>	0	0	1 (1.3)	0	2 (2.5)	0	0

Source: Company reports

**FIGURE 22. Grade 3-4 Laboratory Abnormalities**

Event, n (%)	Treatment-Naïve Patients (N = 358)	Null Responders (N = 90)
<b>Clinical Chemistry</b>		
Total bilirubin $\geq$ 2x ULN <sup>a</sup>	24 (6.7)	11 (12.2)
ALT $>$ 5x ULN, $\geq$ 2x BL value	4 (1.1)	1 (1.1)
Triglycerides $>$ 504 mg/dL	4 (1.1)	1 (1.1)
Alkaline Phosphatase $>$ 1.5x ULN	4 (1.1)	0
Creatinine $\geq$ 1.5 mg/dL	4 (1.1)	1 (1.1)
Glucose $>$ 250 mg/dL	3 (0.8)	1 (1.1)
Sodium $<$ 130 mg/dL	3 (0.8)	0
Calculated creatinine clearance <sup>b</sup> $<$ 50 mL/min	2 (0.6)	1 (1.1)
<b>Hematology</b>		
White blood cells $>$ 20 x10 <sup>9</sup> cells/L	4 (1.1)	1 (1.1)
Lymphocytes $<$ 0.5 x10 <sup>9</sup> cells/L	4 (1.1)	0
Platelets $<$ 10 <sup>9</sup> cells/L	2 (0.6)	0
Neutrophils $<$ 10 <sup>9</sup> cells/L	3 (0.8)	1 (1.1)

<sup>a</sup>Predominantly indirect bilirubin    <sup>b</sup>Calculated via Cockcroft-Gault equation

Source: Company reports

In November 2012, AbbVie initiated a comprehensive Phase 3 program for the ABT-450/r based HCV regimen in 2,300 patients, 40 study centers, and at least 11 countries.

**Phase 3 Underway**

In November 2012, AbbVie initiated a comprehensive Phase 3 campaign for the ABT-450/r based HCV regimen in over 40 study centers, in at least 11 countries, with ~2,300 patients.; the program is currently recruiting patients. We expect data from the first of the studies to report out in 2H13, which we see as the beginning of a series of important value drivers for Enanta as the competitive profile of the AbbVie regimens reveals itself.

We like the Phase 3 program because it highlights the potential for the regimen in specific patient subtypes including separate studies for treatment-naïve, treatment-experienced, cirrhotics, HIV-co-infected, and genotype 1b. In contrast, Gilead is utilizing a 'catch all' strategy, perhaps to highlight the simplicity of its regimen. Specifically, the Phase 3 program for Gilead's regimen includes separate GT1

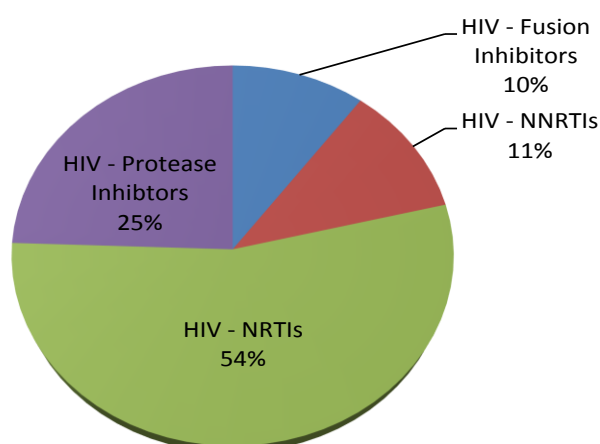
treatment naïve and treatment experienced studies with and without ribavirin for 12 and 24 weeks. Details of the Phase 3 campaign from AbbVie are below and in Figure 23:

- **SAPPHIRE I and II.** These studies are the broadest of the registration studies, evaluating the combination with ribavirin in 600 GT1 (both GT1a and GT1b) naïve and 400 experienced patients, respectively. The studies are placebo controlled and 12 weeks in duration of treatment using SVR12 as the primary endpoint. In our view, these data should be similar to what was already observed in the Phase 2 studies, with SVR rates in the mid-90% range and mid-80% range for treatment naïve and experienced patients, respectively. The study is enrolling and we anticipate data in 2H13.
- **PEARL II and III.** AbbVie is specifically testing the removal of ribavirin in the easier to cure GT1b population. Since ribavirin is difficult to tolerate, this study could carve out a more tolerable regimen for this sub-type. PEARL II is evaluating 200 treatment-experienced patients and PEARL III 400 treatment-naïve patients. Both studies will dose all patients with ABT-450/r, ABT-267 and ABT-333 with patients randomized one to one to receive either ribavirin or placebo. In the Phase 2 studies, SVR rates were 96% without ribavirin in the treatment-naïve population. In our view, this could give AbbVie an edge over Gilead if the latter requires the use of ribavirin for the treatment of GT1b.
- **PEARL IV.** This study is similar to PEARL III, but in GT1a treatment-naïve patients. In Phase 2, treatment-naïve GT1a patients had an 83% SVR rate without ribavirin. Although this regimen will likely be inferior to the ribavirin regimen, we believe it can inform physicians of how to treat patients who may be contraindicated or have to reduce the dose of ribavirin due to side effects.
- **TURQUOISE II.** Cirrhotic patients are an important sub-group, both commercially and to the FDA. To this point, the FDA strongly encourages the inclusion of cirrhotics in Phase 3 HCV programs. In lieu of enrolling cirrhotic patients in each pivotal study, AbbVie is dedicating one trial to compensated cirrhotics. With cirrhosis, the scarring or fibrosis has advanced to the point where the structure of the liver has become altered. Compensated cirrhosis means that the liver is still able to cope with or compensate for the damage and continues to carry out most of its functions. Severe cirrhosis can then progress to decompensated cirrhosis. Cirrhotic patients are among the hardest to treat, leading to lower SVR rates. This study is open label and will evaluate the three-drug, AbbVie combination with ribavirin for both 12 weeks and 24 weeks in 300 patients. In our view, a study dedicated to cirrhotics is a good strategy for AbbVie as it showcases the regimen potential in this difficult to treat population. That said, neither AbbVie nor Gilead has tested their respective regimens in the GT1 cirrhotic population. Gilead took a hit to SVR using sofosbuvir alone in cirrhotic GT2/3 patients in the Phase 3 study, but benefited from a longer duration to 16 weeks of therapy.
- **TURQUOISE I.** Turquoise I is an open-label study testing the three-drug AbbVie combination with ribavirin for 12 and 24 weeks in patients co-infected with HIV. We believe this is important for commercialization given that about 15% of the HCV population is co-infected. As a reminder, PIs, telaprevir and boceprevir, have been tested in HIV co-infected patients and certain regimens are not recommended in combination. About 1/4 of HIV patients are currently on protease inhibitor regimens (Figure 24). HIV specialists have confirmed with us that they are comfortable using ritonavir and do not view this as a limitation to the AbbVie regimen, particularly in the majority of patients not on PI-based HIV therapies. On the other hand, hepatologists and other physicians may not be as comfortable with the potential for drug-drug interactions and therefore may prefer the Gilead regimen. We believe that the more information on the dosing and efficacy of the AbbVie combination in this population that is available, the more likely physicians will be to use the combination.

**FIGURE 23. Phase 3 AbbVie Studies**

Study	Patient Population	Regimen	n	Duration
<b>SAPPHIRE 1</b>	Treatment Naïve	ABT-450/r, ABT-267, ABT-333, RBV	300	12 weeks
		PBO	300	
<b>SAPPHIRE 2</b>	Treatment Experienced	ABT-450/r, ABT-267, ABT-333, RBV	200	12 weeks
		PBO	200	
<b>PEARL II</b>	Treatment Experienced GT1b	ABT-450/r, ABT-267, ABT-333, RBV	100	12 weeks
		ABT-450/r, ABT-267, ABT-333	100	
<b>PEARL III</b>	Treatment Naïve GT1b	ABT-450/r, ABT-267, ABT-333, RBV	200	12 weeks
		ABT-450/r, ABT-267, ABT-333	200	
<b>PEARL IV</b>	Treatment Naïve GT1a	ABT-450/r, ABT-267, ABT-333, RBV	150	12 weeks
		ABT-450/r, ABT-267, ABT-333	150	
<b>TURQUOISE I*</b>	HIV/HCV coinfectd	ABT-450/r, ABT-267, ABT-333, RBV	150	12 weeks
		ABT-450/r, ABT-267, ABT-333, RBV	150	24 weeks
<b>TURQUOISE II</b>	Compensated cirrhotics	ABT-450/r, ABT-267, ABT-333, RBV	150	12 weeks
		ABT-450/r, ABT-267, ABT-333, RBV	150	24 weeks

Source: Company reports and JMP Securities LLC

**FIGURE 24. HIV Treatment Mix (share by dollars)**

Source: Bloomberg, Wolters Kluwer, and JMP Securities LLC

The three-drug combination entitles Enanta to receive royalties on one third of net revenue, whereas Enanta would receive royalties on half of the net revenue from the two-drug combination.

### PEARL I is potential upside

AbbVie is also running a Phase 2 study investigating the combination of ABT-450/r and ABT-267 (eliminating twice daily ABT-333 and ribavirin) in a study referred to as PEARL I in GT1b treatment naïve and experienced patients, as well as GT1a treatment naïve subjects. Previously, this combination was dosed with ribavirin and demonstrated 100% cure rates in GT1b experienced and naïve patients and 79% and 81% SVR in GT1a treatment naïve and experienced patients, respectively. Although we anticipate that this combination may be less efficacious than AbbVie's three-drug regimen, it does have the advantage of being a once daily option, which would put it on par or possibly in terms of convenience, as compared to the Gilead regimen. We also see the potential for upside for Enanta in this combination because of the deal structure with AbbVie. Enanta will collect future royalties on the AbbVie combination that mirrors the percent of the combination stemming from Enanta. The three-drug combination in Phase 3 development entitles Enanta to receive royalties on one-third of the net revenue from this combination. In contrast, Enanta receives royalties on half of the net revenue from the two-drug combination.

Enanta has 30 U.S. and 39 ex-U.S. patents for the protease inhibitor program

### Solid patent coverage

Our review of the patent estate for Enanta's HCV programs leads us to believe the company has good coverage for all three programs. Specifically, Enanta has 30 U.S. and 39 ex-U.S. issued patents for the protease inhibitor program and patent applications for the next generation protease inhibitor that expire between 2023 and 2031 with a pending composition of matter patent that should protect ABT-450 through 2029 at the earliest. EDP-239, the NS5a inhibitor, has five U.S. issued patents that will expire between 2030 and 2032. We don't know if there is overlap between the next-generation protease, or EDP-239, as the structures are not disclosed.

AbbVie plans to submit an NDA in the U.S. and MAA in Europe in 2014 and assuming accelerated review, we anticipate U.S. approval in early 2015 and later in 2015 in the EU.

### Timeline is set for early 2015 launch

AbbVie expects Phase 3 data to readout this year beginning with the SAPPHIRE studies. Competitor Gilead will likely begin to release its Phase 3 data in 2014. AbbVie plans to submit an NDA in the U.S. and MAA in Europe in 2014 and assuming accelerated review, we anticipate U.S. approval in early 2015 and later in 2015 in the EU. This timeline places AbbVie a couple of months ahead of Gilead in reaching the market; however, we think this advantage will be negligible in the long run, as there is a high level of anticipation for both programs and ultimately efficacy, followed by safety and tolerability/convenience, should trump.

Both AbbVie/Enanta's 2<sup>nd</sup> gen PI and AbbVie's NS5a began clinical development last year

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## NEXT-GENERATION PI PARTNERED WITH ABBVIE

AbbVie is working on a next generation program that features a second Enanta PI. Although we do not know much about the compound, *in vitro*, it is active in various genotypes and resistant variants, is dosed just once a day, and does not require boosting with ritonavir. The compound will be used in combination with a next generation NS5a from AbbVie. Both assets began clinical development in 2012. In the absence of any data for this program, we assign a 20% chance of success in reaching the market, assuming it will be on par with the efficacy and profile of other second-generation combinations and will cannibalize ABT-450/r combination when it reaches the market in 2018.



NOVARTIS PARTNERSHIP IN LIMBO

In 2012, Enanta licensed the NS5a inhibitor EDP-239 to Novartis in anticipation of combination with Novartis’ late stage cyclophilin inhibitor Alisporivir – a combination that had shown in vitro synergy. With \$34.4M upfront and up to \$395M in milestones and tiered royalties from the low double digits up to the high teens, the deal is an attractive one. EDP-239 is liver targeted and its in vitro profile suggests high potency and superior resistance profile to first generation NS5a’s (Figure 25).

Unfortunately, shortly after the agreement was consummated, development of Alisporivir was put on hold upon the death of a patient in the Phase 3 study due to pancreas inflammation or pancreatitis. A small number of patients showed inflammation, although only one case was fatal. Novartis has continued development of EDP-239 as it works to resolve the issues surrounding Alisporivir. However, given the high bar for safety with competitive agents, we see the opportunity for Novartis’ program as limited and without another mechanism to put together with EDP-239, the future path for the compound seems in limbo. Consequently, we currently do not include this compound in our valuation, as we have no visibility into the plans Novartis for HCV with only one viable asset.

We see the opportunity for Novartis’ program as limited and without another mechanism to put together with EDP-239, the future path for the compound seems in limbo.

FIGURE 25. NS5a Potency (pM)

	GT1a	GT1b	GT1b/GT1a	GT2a	GT3a	GT4a	GT5a	GT6a
Daclatas vir	50	9	5.6	71	600	12	33	350
GS-5885	34	4	8.5	20800	35000	110	150	120
ACH-3102	17	9	1.9	200	100	100	100	100
MK-8742	4	3	1.3	3-300	20	3		
IDX719	6.2	2.4	2.6	24	17	2	18	n/a
EDP-239	31	7	8.0	n/a	n/a	n/a	n/a	n/a
PPI-668	100	9	11.1	120	1050	20	20	300

n/a = not available, italics = esti

Source: Company reports and JMP Securities LLC

**FIGURE 26. Comparative in vitro Resistance Profile**

Mutation	Daclatas vir	GS-5885	ACH-3102	IDX719	EDP-239
<i>1a-H77 Replicon</i>					
M28T	682	25	16	150	
Q30H	1477	73	7	24	
Q30E	1641	n/a	41	420	
L31M	93	140	3	310	3
L31V	3386	n/a	4	420	25
Q30R	232	Similar to DCV	24	10	
Y93C	1864	Similar to DCV	63	40	
Y93N	7800	n/a	n/a	14363	
Y93H	5432	3309	n/a	4427	22
P32L	142	n/a	2	170	
L31 + Y93H	2000	n/a	n/a	n/a	
Q30R + L31V	1500	n/a	n/a	n/a	
M28T + Q30R	80	n/a	n/a	n/a	
<i>1b-con-1 Replicon</i>					
Y93H	24	1319	< 3	93	22
Y93C	n/a	n/a	n/a	2.7	
Y93N	n/a	n/a	< 2	160	
L28T	n/a	n/a	n/a	74	
L31M	3	n/a	n/a	3.6	3
L31MY93H	114000	n/a	0.4	n/a	
L31V/Y93H	203000	n/a	11	n/a	
L31V	28	n/a	< 3	15	25
L31F/Y93H	69000	n/a	8	n/a	

Source: Company reports and JMP Securities LLC

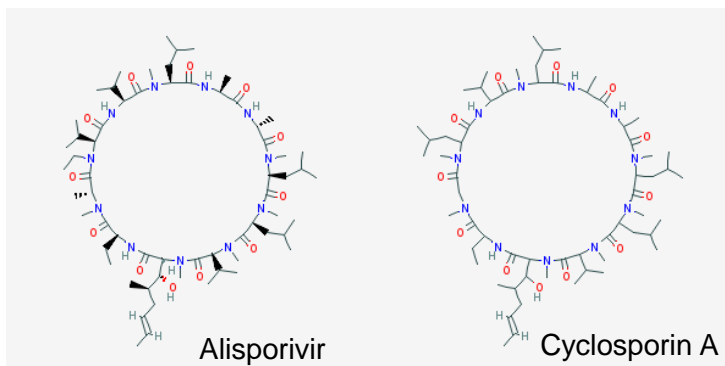
Enanta has cyclophilin and HCV nucleoside inhibitor programs that should be ready to enter clinical development next year

## EARLY STAGE HCV PIPELINE

Enanta has cyclophilin and HCV nucleoside inhibitor programs that should be ready to enter clinical development next year. We point out that each of these classes has been associated with serious toxicities which, in our view, raises the safety bar for these programs. Recall the death observed in the Phase 3 study of Alisporivir described above, and one death and a series of cardiac toxicities in the Phase 2 BMS/Inhibitex nucleotide inhibitor study. Considering these factors, we believe partners will wait on the sidelines until 12-week safety has been established. We note that Enanta is developing the two scarcest assets in the HCV space with the greatest potential to overcome resistance, making them attractive assets if safety hurdles can be cleared. However, due to the timing of development and a crowded, competitive HCV space, we think the commercial opportunity could be limited and therefore, we currently do not include these assets in our valuation.

### Cyclophilin inhibitor

Cyclophilin inhibitors target a human host factor, cyclophilin that is essential to the HCV life cycle and is therefore able to overcome resistance to virus targeted therapies. Novartis's alisporivir is an analogue of cyclosporine A, an immune regulator (Figure 27) optimized to lower the immunosuppressive properties of the compound. Enanta's cyclophilin inhibitors have been optimized to have no immunosuppressive qualities and in vitro, are more potent than alisporivir with a high barrier to resistance, according to the company. Enanta plans to move a clinical candidate forward this year with plans to move into humans in 2014.

**FIGURE 27. Cyclophilin Inhibitor Structures**

Source: Company reports and JMP Securities LLC

### Nucleotide polymerase program

Enanta is developing nucleotides that it believes are structurally distinct from those ahead of it in development by Idenix (IDIX, MP), Gilead (NC), or Vertex (VRTX, MO, \$100 PT). We have no visibility as to the base or pro-drug strategy. The company plans to select a candidate this year for preclinical development.

## ANTIBIOTIC PROGRAM - A FREE OPTION FOR INVESTORS

Enanta is developing a novel series of antibiotics through a grant from the National Institute of Allergy and Infectious Diseases (NIAID). The contract with NIAID is worth up to \$42.7M over five years, which should be sufficient to fund preclinical and clinical development through Phase 2. The compounds are bicyclolides designed to overcome the resistance of other macrolides such as Zithromax. The lead compound is EDP-788, a pro-drug of EDP-322 with broad spectrum activity (gram + and - infections) suited to once a day dosing and is active against vancomycin, daptomycin, and linezolid-resistant MRSA strains. The active species, EDP-322, has been tested in Phase 1 studies in humans with some gastrointestinal side effects that the company expects to disappear when the compound is dosed as a pro-drug. The company is developing both an oral and IV formulations. In our view, this program presents a free option to investors, as the program is funded externally, but could present upside should the profile warrant continued development.

Enanta is developing a series of antibiotics through a grant from NIAID, worth up to \$42.7M over five-years, funding development through Phase 2.

**FIGURE 28. Minimum Inhibitory Concentrations for EDP-322**

Organisms		EDP-322	Zyvox	Vanco
<i>S. aureus</i>	Ery S	0.13	4	2
<i>S. aureus</i>	MLS-Ri	0.13	2	2
<i>S. aureus</i>	MRSA	2	2	2
<i>S. aureus</i>	MRSA-ermC	1	2	2
<i>S. aureus</i>	VRSA	2	2	>32
<i>S. pneumoniae</i>	Ery S	≤ 0.06	0.5	0.5
<i>S. pneumoniae</i>	Ery R-mef	≤ 0.06	0.5	1
<i>S. pneumoniae</i>	Ery R-erm	≤ 0.06	0.5	1
<i>S. pyogenes</i>	Ery S	≤ 0.06	1	1
<i>S. pyogenes</i>	Ery R-mef	≤ 0.06	1	1
<i>S. pyogenes</i>	Ery R-erm	≤ 0.06	1	1
<i>Enterococcus</i>	VRE	Active	Active	Inactive
<i>Atypicals</i>		Active	Inactive	Inactive
<i>H. influenzae</i>		4	8-16	> 64
<i>M. catarrhalis</i>		0.13	4	64

Source: Company reports

## MANAGEMENT TEAM & BOARD OF DIRECTORS

**FIGURE 29. Management Team**

	Position	Joined	Prior experience
Jay R. Luly, Ph.D.	CEO, Director	2003	Oxford Bioscience Partners, Millennium Pharam, LeukoSite
Yat Sun Or, Ph.D.	SVP, R&D, CSO	1999	Abbott, Schering-Plough
Paul J. Mellett	CFO	2003	Essential therapeutics, GelTex Pharma, Marshal Contractors

Source: Company reports and JMP Securities LLC

**FIGURE 30. Board of Directors**

	Affiliation
Jay R Luly, Ph.D.	Enanta
Ernst-Gunter Afting, M.D., Ph.D.	U Goettingen, GSF-National
Stephen Buckley, Jr	Ernst & Yong
Marc E. Goldberg	BioVentures Investors, Mass. Biotech Res. Inst
David Poorvin, Ph.D.	Avaxia Biologics, Oxford Bioscience Partners, Schering-Plough
Helmut Schuhsler, Ph.D.	TVM Capital, Horizonte Venture Management
Terry Vance	Saints Capital, EGS Healthcare, Eagle Advisors
Gregory Verdine, Ph.D.	Harvard University

Source: Company reports and JMP Securities LLC

## Company Description

Enanta is a Watertown, Massachusetts based biotechnology company focused on anti-infectives. The company has partnered a protease inhibitor program with AbbVie Pharmaceuticals and an NS5a program with Novartis, as well as developing fully owned assets. The lead protease inhibitor, ABT-450, partnered with AbbVie, is in Phase 3 development.

## Investment Risks

**Clinical risk.** Drug development is a risky and capital-intensive endeavor. The vast majority of drugs that enter clinical

development fail to reach the market. Enanta's Phase 3 program with AbbVie may experience development setbacks; we point specifically to safety as a source of risk. In addition, Enanta has many early stage assets that may or may not make it to development in humans.

**Regulatory risk.** Enanta is reliant on its pharmaceutical partners, AbbVie and Novartis, to move its drug candidates through registration with the FDA and EMA and it is dependent on the pace of these regulatory entities to approve new drugs. Enanta's early stage HCV assets are from classes that have been placed on clinical hold, leading to increased scrutiny.

**Intellectual Property risk.** Enanta's lead clinical assets are covered by approved patents; however, other assets have patents pending. Patent expirations can result in a negative impact to sales. Additionally, generic companies may file abbreviated new drug applications to challenge current products with patent protection.

**Commercial risk.** Enanta is reliant upon their pharmaceutical partners, AbbVie and Novartis, to successfully commercialize assets. The HCV space is very competitive and Enanta's assets may lose share as new competitors come to market.

**Sector risk.** Valuation of biopharmaceutical stocks is subject to both investor assessments of the prospects of the underlying companies, as well as investor tolerance for risk and confidence in the prospects of pharmaceutical stocks as a group. Therefore, Enanta's stock price may fall, even while the company meets or exceeds investor expectations.

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JMP Securities currently makes a market in the securities of Enanta Pharmaceuticals, Inc., Idenix Pharmaceuticals Inc. and Vertex Pharmaceuticals, Inc.

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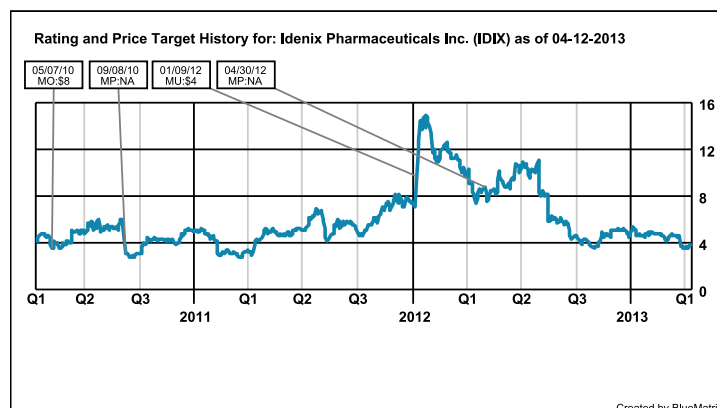
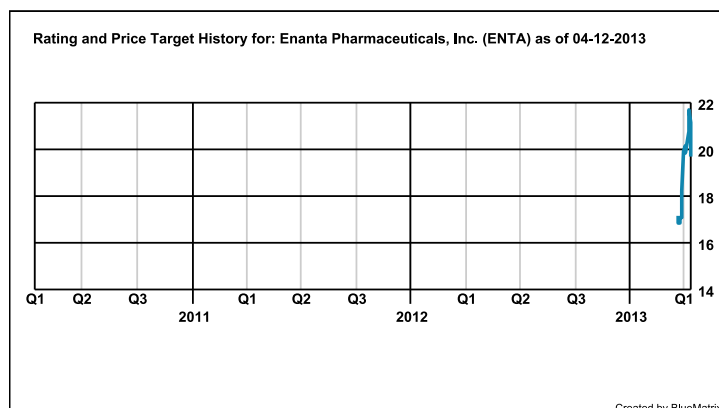
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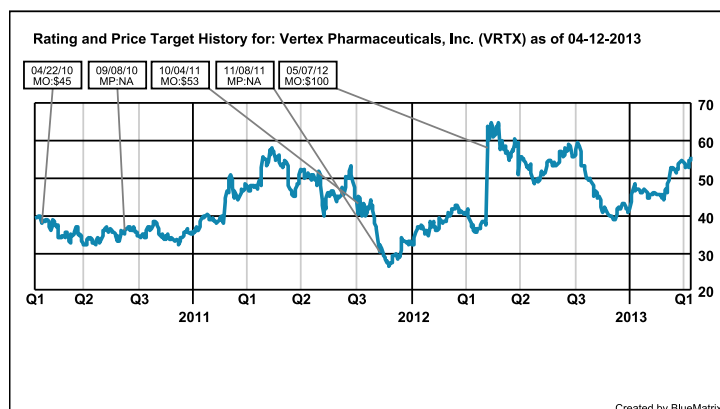
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JMP Rating	Regulatory Equivalent	# Co's Under Coverage	% of Total	Regulatory Equivalent	# Co's Under Coverage	% of Total	# Co's Receiving IB Services in Past 12 Months	% of Co's With This Rating
MARKET OUTPERFORM	Buy	213	59.17%	Buy	213	59.17%	65	30.52%
MARKET PERFORM	Hold	141	39.17%	Hold	141	39.17%	16	11.35%
MARKET UNDERPERFORM	Sell	6	1.67%	Sell	6	1.67%	0	0%
TOTAL:		360	100%		360	100%	81	22.50%

### 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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