

# Enanta Pharmaceuticals, Inc. (ENTA: NASDAQ)

Financial Analysis By: Pamela Juergens-Healthcare

## Company Profile as of 2/18/2015

Market Price: \$34.09  
Industry: Healthcare  
Market Cap: \$636.80 M  
52-Week: \$31.22-52.58  
Beta: 0.543

Source	Target Price	Recommendation
Siena	\$42.80	Buy
Capital IQ	\$41.50	Buy
Yahoo Finance	\$43.00	Buy
Bloomberg	\$42.50	Buy



## Thesis

- Likely approval of Paritaprevir in Japan in early 2015
- Product pipeline
- Contract award from the National Institute of Allergy and Infectious Disease (NIAID) to develop a new antibiotic

## Company Overview

Enanta Pharmaceuticals is a research and development focused biotechnology company, which uses a chemistry driven approach to create small molecule drugs for viral infections and liver diseases. They discover and develop novel inhibitor designed for use against the Hepatitis C Virus, or HCV. These inhibitors include members of the direct acting antiviral (DAA) inhibitor classes- protease, partnered with AbbVie, NS5A, and nucleotide polymerase, as well as host targeted antiviral (HTA) inhibitor class targeted against cyclophilin. Enanta also has a preclinical program in non-alcoholic steatohepatitis (NASH), which is a condition that results in liver inflammation and damage caused by a buildup of fat in the liver.

**Management**

Enanta has an experienced management team with many years combined experience in the biotechnology field. Dr. Jay R. Luly Ph.D. has been the CEO and president of Enanta since July 2003. He has over 20 years of experience in large pharma, mature biopharmaceutical and early-stage biotech environments. Yat Sun Or, Ph.D. is a senior vice president of R&D and the Chief Scientific Officer. He joined Enanta in 1999 and prior to that he worked at Abbot Laboratories. The CFO is Paul J. Mellet; he joined Enanta in September 2003, and prior to that he worked at GelTex Pharmaceuticals. Timothy D. Ocain is the Senior Vice President of New Product Development and Strategy. His focus is on the development activities of Enanta.

**Competitors**

Enanta is engaged in a segment of the pharmaceutical industry that is very competitive and changing rapidly. Many large pharmaceutical and biotechnology companies are commercializing or pursuing the development of products that target viral diseases, including the same viral diseases that they are targeting. Two products, Incivek by Vertex and Victrelis by Merck were approved by the FDA in 2011 for the treatment of HCV, but by mid-2014 Vertex announce they were discontinuing the sale of Incivek, crediting their decision to competing treatments and diminishing market demand. However, even though HCV is now curable multiple products should be able to survive on the market for many years, due to the prevalence of the disease, as long as they have a competitive advantage. Enanta’s main competitor currently is Gilead, with their drug Harvoni. Harvoni is known for it’s effectiveness, but along with that comes very high prices, as high as \$1,000 per day for many patients. Viekira has the ability to take share from Harvoni by being offered at a discount, which it currently is, at 12% lower than Harvoni. Enanta currently has a pipeline of products to treat HCV, but there is a significant number of other product candidates that are under development, and many competitors, other than AbbVie, have product candidates in Phase 2 or later stage clinical trials, including Achillion and Bristol-Myers.

Patient Population	Viekira (ABBV)			Harvoni (GILD)		
	Ribavirin Needed?	Duration	Gross Cost	Ribavirin Needed?	Duration	Gross Cost
Genotype 1a, without cirrhosis	Yes	12 weeks	\$83,319	No	Some Rx naive* = 8 weeks; rest = 12 weeks	\$63,000-\$94,500
Genotype 1a, with cirrhosis	Yes	24 weeks (Partial responders and Relapsers may get 12 weeks, Nulls need 24 wks)	\$83,319-\$166,638	Yes	12 Weeks	\$94,500
Genotype 1b, without cirrhosis	No	12 weeks	\$83,319	No	Some Rx naive* = 8 weeks; rest = 12 weeks	\$63,000-\$94,500
Genotype 1b, with cirrhosis	Yes	12 weeks	\$83,319	Yes	12 Weeks	\$94,500
Contraindications/ Major Warnings:	Ribavirin combo risks, drug interactions with those that are highly dependent of CYP3A or strongly induce CYP3A and 2C8 or inhibit 2C8. (e.g. generic Zocor). ALT elevations.			None.		

**Prevalance of Hepatitis C Virus**

Hepatitis C Virus (HCV) is a small, enveloped, positive-sense single-stranded RNA, and it is the cause of hepatitis C in humans. HCV is commonly spread through sharing of needles or other equipment to inject drugs. Hepatitis C, in combination with hepatitis B, now accounts for 75% of all liver diseases around the world. There is currently no vaccine available to protect against HCV.

Approximately 3.2 million people in the United States have chronic HCV infection. Of those % infected, between 75%-85% develop chronic infection. In the World Health Organization (WHO) European Region an estimated 15 million (2.0%) people are infected. The WHO Health Evidence Network estimates the number of infected people is much higher with prevalence of up to 98% in people who inject drugs. The incidence in Japan was 1.2% of the adult population, or about 2 million people.

**Upcoming FDA Approval**

Enanta currently has one hepatitis C virus product, Paritaprevir (ABT-450), which was approved by the U.S. FDA on December 19, 2014, and in Europe on January 16, 2014. Paritaprevir (ABT-450) is a NS3/4A protease inhibitor and sold as a component of VIEKIRA PAK, which with dasabuvir is a treatment regimen for genotype 1 HCV patients, in partnership with AbbVie. Enanta announced positive phase 3 trial results, in Japan, in early February 2015, and it is expected that it will be approved in Japan in the first

half of 2015. The primary endpoint of the GIFT-1 study was achieved, demonstrating a 95% sustained virologic response rate at 12 weeks post treatment in the sub-group of previously untreated non-cirrhotic adult genotype 1b Japanese patients who were eligible for therapy with interferon and had a high viral load.

Analysts estimate that VIEKIRA PAK could generate approximately 2.9 billion in sales in FY 2015. Enanta's revenues are substantially dependent on the AbbVie collaboration. Enanta can do nothing on the marketing side with the drug, as AbbVie handles that, but AbbVie has proven their ability to sell, with their widely commercially successful drug Humira. Under Enanta and AbbVie's agreement, Enanta stands to earn payments for regulatory and reimbursement milestones as well as annually tiered, double-digit royalties per product on AbbVie's worldwide net sales. Enanta already received \$57 million in connection with signing the collaboration agreement, and \$95 million in subsequent clinical and regulatory and milestone payments, and is eligible to receive an additional \$155 million in payments for regulatory and reimbursement approval milestones. Upon approval in Japan, Enanta is entitled to a \$30 million milestone payment from AbbVie. Enanta's stock price strongly reacts to positive regulatory news. Following FDA approval of VIEKIRA PAK in the US, Enanta's stock rose as much as 15% in one week. Approval in Japan should be a catalyst for Enanta's stock price.

Protease Inhibitor-Containing Regimens	Percentage of Annual Net Sales Used for Enanta Royalty Calculation
ABT-450-containing 3-DAA regimen (ABT-450/r, ombitasvir and dasabuvir)	30%
ABT-450-containing 2-DAA regimen (ABT-450/r, ombitasvir)	45%
For any HCV treatment regimen containing ABT-493, net sales for royalty purposes will be determined by dividing AbbVie's worldwide net sales of the regimen by the number of DAAs in the regimen (e.g. 50% of net sales for a 2-DAA regimen and 33 1/3% of net sales for a 3-DAA regimen).	

## **Pipeline**

Enanta currently has a product pipeline, with several HCV treatment options, as well as treatment for liver disease. IN their pipeline for HCV treatment options, they are looking ahead to the future, where they anticipate resistance developing to the current treatments, giving them an edge against the competition in the future. Their pipeline assets are in varying stages of the approval process.

*ABT-493:* ABT-493 is a next generation protease inhibitor, which is being developed within the Enanta-AbbVie collaboration. AbbVie announced that this protease inhibitor has demonstrated activated in preclinical in vitro testing against a broad range of HCV genotypes, including variants that have shown strong resistance to first generation protease inhibitors. ABT-493 is being developed to be co-formulated with AbbVie's next generation NS5A inhibitor. A Phase 2b clinical trial was initiated in September 2014.

*EDP-239:* EDP-239 is an NS5A inhibitor for HCV infection. Enanta entered into a collaboration with Novartis in February 2012, granting Novartis the exclusive rights to develop, manufacture, and commercialize EDP-239, however Enanta is in the process of regaining the full rights. EDP-239 has demonstrated potent activity against major genotypes in the replicon assay, which is a common in vitro test for determining the potency of an active compound in reducing HCV replication. Preclinical studies support excellent permeability and absorption potentials in humans, with preferential targeting to the liver, which is the target site of the infection. EDP-239 is currently in ongoing proof-of-concept Phase-1b studies.

*Cyclophilin Inhibitors:* Enanta anticipates resistance arising to DAA HCV therapy that targets viral proteins. In response to this they are developing an alternative host-targeted antiviral, or HTA, approach that targets the human host protein, cyclophilin, which is essential for the replication of HCV. They have demonstrated in replicon assays that multiple lead cyclophilin targeting inhibitors are potent

inhibitors of HCV replication and are more potent in these assays than clinical-stage cyclophilin inhibitors under development by others. They are currently advancing their lead candidates in preclinical studies.

*Nucleotide Polymerase Inhibitor:* This is a program to develop nucleotide inhibitors to HCV NS5B polymerase, another DAA mechanism considered to have a high barrier to resistance. They have ongoing discovery in this class, but nothing beginning testing yet.

PRODUCT CANDIDATE (GLOBAL PARTNER)	PRECLIN	PHASE 1	PHASE 2	PHASE 3	APPROVED	STATUS
<b>HCV</b>						
Protease inhibitor: paritaprevir (ABT-450)-containing regimens (AbbVie)	(paritaprevir/r + NS5A + NNuc) ± RBV					Approved in the U.S. and EU for GT1. Marketed by AbbVie
	(paritaprevir/r + NS5A) + RBV					Approved in the EU for GT4. Marketed by AbbVie
	(paritaprevir/r + NS5A) ± RBV					Phase 3 complete in Japan
Next-generation protease inhibitor: ABT-493-containing regimens (AbbVie)	ABT-493 + Next-Gen NS5A					Phase 2b ongoing
NS5A Inhibitor: EDP-239	EDP-239					Proof-of-concept study in HCV patients ongoing
Cyclophilin Inhibitor						Preclinical candidate selection ongoing
Nucleotide polymerase inhibitor						Preclinical candidate selection ongoing
<b>LIVER DISEASE</b>						
Non-alcoholic steatohepatitis (NASH) Primary biliary cirrhosis (PBC)						Preclinical candidate selection ongoing

### Development of New Antibiotic

Enanta is currently developing a new type of antibiotics, the first in 30 years, called bicyclolides. They are a drug class used for the treatment of methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistant Enterococcus (VRE), and other gram-positive infection pathogens. These were previously only a problem for patients treated in hospitals, but now they occurring in the general community, which creates a large need for a new class of antibiotics for use in both the hospital setting and in communities. Enanta's funding partner on the venture is the National Institute of Allergy and Infectious Disease (NIAID). Their partnership with NIAID provides them with the possibility for up to \$42 million in research funding. Pre-clinical research on the bicyclolides revealed activity against MRSA and VRE, even against highly drug-resistant strains. The FDA also began special programs for such drugs through the GAIN Act. This act gives drugs under it a five-year exclusivity extension, as well as an expedited approval process. There is currently an urgent and growing threat of resistant strains of these infections, which along with the added benefits from the GAIN Act make the future of their new antibiotic look promising.

### Conclusion

Enanta is a buy because of their innovative pipeline of products, as well as upcoming approval of Paritaprevir in Japan in the first half of 2015. They are also receiving funding to develop an antibiotic that will be the first new antibiotic in 30 years. There is a growing need for this because many stains of bacteria are demonstrating resistance to current antibiotics, and the new antibiotic has the potential to be a blockbuster for Enanta.

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**Enanta Pharmaceuticals, Inc.** **ENTA**

**Analyst**  
**Pamela Juergens**

**Current Price**  
**\$33.65**

**Intrinsic Value**  
**\$43.95**

**Target Value**  
**\$42.80**

**Divident Yield**  
**0%**

**Target Return**  
**27.2%**

**NEUTRAL**

<u>General Info</u>		<u>Peers</u>		<u>Market Cap.</u>		<u>Management</u>			
Sector	Healthcare	InterMune, Inc				<b>Professional</b>	<b>Title</b>		
Industry	Biotechnology	Vertex Pharmaceuticals Incorporated	\$27,494.05			Luly, Jay	Chief Executive Officer, Presiden		
Last Guidance	(Invalid Identifier)					Mellet, Paul	Chief Financial Officer and Senio		
Next earnings date	5/8/2015					Or, Yat	Chief Scientific Officer and Senio:		
<u>Market Data</u>		Gilead Sciences Inc	\$155,806.06			Gardiner, Nathaniel	Senior Vice President, General Ct		
		Pharmacyclics Inc	\$12,938.85			Ocaín, Timothy	Senior Vice President of New Prt		
		<u>Current Capital Structure</u>				<u>Historical Performance</u>			
		Enterprise value	\$534.39			<u>ENTA</u>		<u>Peers</u>	
		Market Capitalization	\$636.80			<u>Industry</u>		<u>All U.S. firms</u>	
		Daily volume	0.21			Growth	29.1%	27.4%	15.9%
		Shares outstanding	18.68			Retention Ratio	0.0%	94.1%	107.9%
		Diluted shares outstanding	19.52			ROIC		25.4%	17.0%
		% shares held by institutions	59.40%			EBITDA Margin	0.0%	54.7%	19.2%
		% shares held by insiders	9.94%			Revenues/Invested capital	57.4%	80.0%	64.4%
Short interest	14.72%			Excess Cash/Revenue	190.1%	47.3%	82.9%		
Days to cover short interest	6.57			Unlevered Beta	1.19	1.08	0.95		
52 week high	\$52.58			TEV/REV	11.7x	7.8x	6.2x		
52-week low	\$31.22			TEV/EBITDA	33.8x	17.7x	16.1x		
5y Beta	0.00			TEV/EBITDA	34.5x	18.3x	18.9x		
6-month volatility	48.99%			TEV/UFCF		84.5x	43.3x		
<u>Past Earning Surprises</u>				<u>Non GAAP Adjustments</u>					
	<b>Revenue</b>	<b>EBITDA</b>	<b>Norm. EPS</b>	Operating Leases Capitalization	100%	Straightline	10 years		
Last Quarter	-10.5%	0.0%	-42.9%	R&D Exp. Capitalization	100%	Straightline	10 years		
Last Quarter-1	62.0%			Expl./Drilling Exp. Capitalization	0%	N/A	N/A		
Last Quarter -2	1.9%	16.6%	6.4%	SG&A Capitalization	0%	N/A	N/A		
Last Quarter -3	-85.4%	0.0%							
Last Quarter -4	-39.5%								
<u>Proforma Assumptions</u>				<u>Forecasted Profitability</u>					
		<u>Period</u>		<u>Rev. Growth</u>		<u>Adj. Op. Cost/Rev</u>			
						<u>Revenue</u>			
						<u>NOPLAT</u>			
						<u>Invested capital</u>			
						<u>UFCF</u>			
Operating. Cash/Cash	0.0%	LTM	94%	10%	\$124.35	\$95.88	\$135.22		
Unlevered Beta	1.40	LTM+1Y	33%	44%	\$164.83	\$60.95	\$279.97		
Rev/Invested Capital	100.0%	LTM+2Y	19%	46%	\$195.42	\$64.53	\$326.67		
Continuing Period Revenue Growth	5.0%	LTM+3Y	14%	48%	\$221.99	\$67.80	\$368.01		
Long Term ROIC	12.4%	LTM+4Y	9%	49%	\$242.38	\$70.64	\$401.80		
Invested Capital Growth	Equals to Maintenance	LTM+5Y	7%	49%	\$259.35	\$74.25	\$431.92		
Justified TEV/REV	5.0x	LTM+6Y	7%	49%	\$277.51	\$78.63	\$464.48		
Justified TEV/EBITDA	15.0x	LTM+7Y	7%	49%	\$296.93	\$83.71	\$494.77		
Justified TEV/EBITDA	25.0x	LTM+8Y	6%	49%	\$316.14	\$88.85	\$524.19		
Justified TEV/UFCF	18.0x	LTM+9Y	5%	49%	\$331.95	\$93.14	\$550.40		
<u>Valuation</u>									
		<u>ROIC</u>		<u>WACC</u>		<u>EVA</u>			
				<u>Enterprise Value</u>		<u>Total Debt</u>			
				<u>Other claims</u>		<u>Equity</u>			
				<u>Adjusted Price</u>					
LTM	111.3%	10.5%	\$124.80	\$770.22	\$0.18	-\$73.84	\$843.88		
LTM+1Y	39.2%	10.5%	\$78.31	\$843.82	\$0.18	\$36.57	\$807.07		
LTM+2Y	23.1%	10.6%	\$40.59	\$860.54	\$0.18	\$21.97	\$838.38		
LTM+3Y	20.8%	10.7%	\$36.89	\$912.56	\$0.18	-\$2.58	\$914.96		
LTM+4Y	19.2%	10.8%	\$33.58	\$962.31	\$0.18	-\$37.85	\$999.97		
LTM+5Y	18.5%	10.9%	\$32.57	\$1,014.11	\$0.18	-\$80.15	\$1,094.08		
LTM+6Y	18.2%	11.0%	\$33.28	\$1,072.39	\$0.18	-\$123.91	\$1,196.11		
LTM+7Y	18.0%	11.1%	\$34.03	\$1,130.65	\$0.18	-\$174.84	\$1,305.30		
LTM+8Y	18.0%	11.2%	\$35.18	\$1,190.59	\$0.18	-\$231.65	\$1,422.06		
LTM+9Y	17.8%	11.3%	\$35.36	\$1,249.07	\$0.18	-\$296.23	\$1,545.11		
<u>Monte Carlo Simulation Assumptions</u>				<u>Monte Carlo Simulation Results</u>					
		<u>Base</u>		<u>Stdev</u>		<u>Min</u>			
				<u>Max</u>		<u>Distribution</u>			
Revenue Variation	0	10%	N/A	N/A	Normal	Mean est.	\$44.91		
Op. Costs Variation	0	10%	N/A	N/A	Normal	σ(e)	\$0.32		
Market Risk Premium	6%	N/A	5%	7%	Triangular	3 σ(e) adjusted price	\$43.95		
Long term Growth	5%	N/A	3%	29%	Triangular	Current Price	\$33.65		
Terminal Value	0	0.1	N/A	N/A	Normal	Analysts' median est.	\$42.50		

