Enanta Pharmaceuticals (ENTA) $22.11 September 2016

Ticker:	ENTA	Current Price:	$22.11
Action:	Long	FD Market Cap (M)	$427.8
Expected Timeframe:	1-3 years	Enterprise Value(M):	$183.2
Target Allocation	2-5%	Target Price:	$39.00
Asset Class:	Common Equity		

Investment Overview/Background

Enanta Pharmaceuticals (Enanta) is a small cap pharmaceutical company focused on liver diseases such as hepatitis C (HCV) and Non-Alcoholic SteatoHepatitis (NASH). Currently Enanta has one product commercially marketed, one in Phase III trials, and a number in earlier stage development. On top of those products, Enanta has a cash rich balance sheet. As of June 1, 2016 Enanta had more than $246 million of cash and liquid investments on the balance sheet, which means that more than half of the current market cap is cash or cash equivalents.

In a sector of near-constant speculative fervor, it would be reasonable to assume that Enanta – a company with an established royalty, an established large cap pharma partner, a robust balance sheet, and a decent pipeline – would have a valuation in line with other pharmaceutical companies. This is not the case and fears about the pipeline continuity along with a potentially crowded hepatitis C market has pushed shares of Enanta down more than 40% in the past twelve months.

Investors would be wise to pay attention to the near-term pipeline, robust royalties, and rich balance sheet. The current myopic assessment of the hepatitis C market will pass and shares of Enanta will re-rate as the market figures out the limited downside thanks to the rich balance sheet.

Hepatitis C Overview

Hepatitis C is a virus that has infected between 130-200 million people around the world. There are seven major genotypes of HCV (1-7). In the United States, Genotype 1 is the most common, with roughly 70% of all cases in the United States diagnosed as Genotype 1, and about 46% of all cases around the world. A few years ago the treatment for HCV was interferon and ribavirin. This combination had a sustained virological response (SVR – effectively the cure rate) of ~40% after weekly injections for 24 to 48 weeks.

While this treatment option often worked, it left a significant percentage of the population sick and the side effects are quite severe. Research worked on identifying new cures that eliminated interferon, increased SVR, and cut down treatment times. The primary focus by pharmaceutical companies and researchers was on direct-acting antivirals that targeted key HCV replication cycle pathways involving

NS3/4a protease and NS5A/B polymerase. The table below shows some of the many drugs available to treat HCV, the manufacturer, and targeted genotype.

Table 1. Hepatitis C drugs by manufacturer and genotype Source: company websites

Drug	Owner	Target	Genotype
Daclatasvir	Bristol-Myers Squibb	NS5A	3
Elbasvir	Merck	NS5A	1,4
Ledipasvir	Gilead	NS5A	1
Ombitasvir	AbbVie	NS5A	1,4
Ravidasvir	Pharco	NS5A	4
Samatasvir	Merck	NS5A	1,2,3,4,5,6
Velpatasvir	Gilead	NS5A	1,2,3,4,5,6
Sofosbuvir	Gilead	NS5B	1,2,3,4
Paritaprevir	AbbVie/Enanta	NS3-4A	1,4
Dasabuvir	AbbVie	NS5B	1
Grazoprevir	Merck	NS3-4A	1,2,3,4,5,6

Combinations of these drugs form the common treatments available today. The most widely prescribed drugs include: sofosbuvir (Sovaldi), ledipasvir/sofosbuvir (Harvoni), paritaprevir/dasabuvir/ ombitasvir/ritonavir (Viekira Pak), and elbasvir/grazoprevir (Zepatier). The selection of a drug requires the doctor to know the genotype, liver condition, possible interactions, previous treatment(s) and insurance coverage. Thus far, Gilead has dominated the competition.

According to the Q2 2016 presentation, sofosbuvir based treatments have treated more than 1 million patients since December 2013. Limited side effects, decent insurance coverage, and excellent SVR's have contributed to this dominance. Gilead's next generation product, Epclusa (sofosbuvir and velpatasvir) is pan-genotypic, can be given to patients with or without cirrhosis, and is almost always ribavirin free.

Pan-genotypic drugs are the next, and likely final wave of HCV drugs. The ability to eliminate genotype testing is a small positive for these drugs, which tend to carry price tags in excess of $50,000 per cure cycle. For a run-of-the-mill HCV patient, Epclusa offers an easier way to get treatment immediately. Drugs that are pan-genotypic also better ensure treatment. It is estimated that between 5-25% of HCV infected patients carry multiple genotypes.

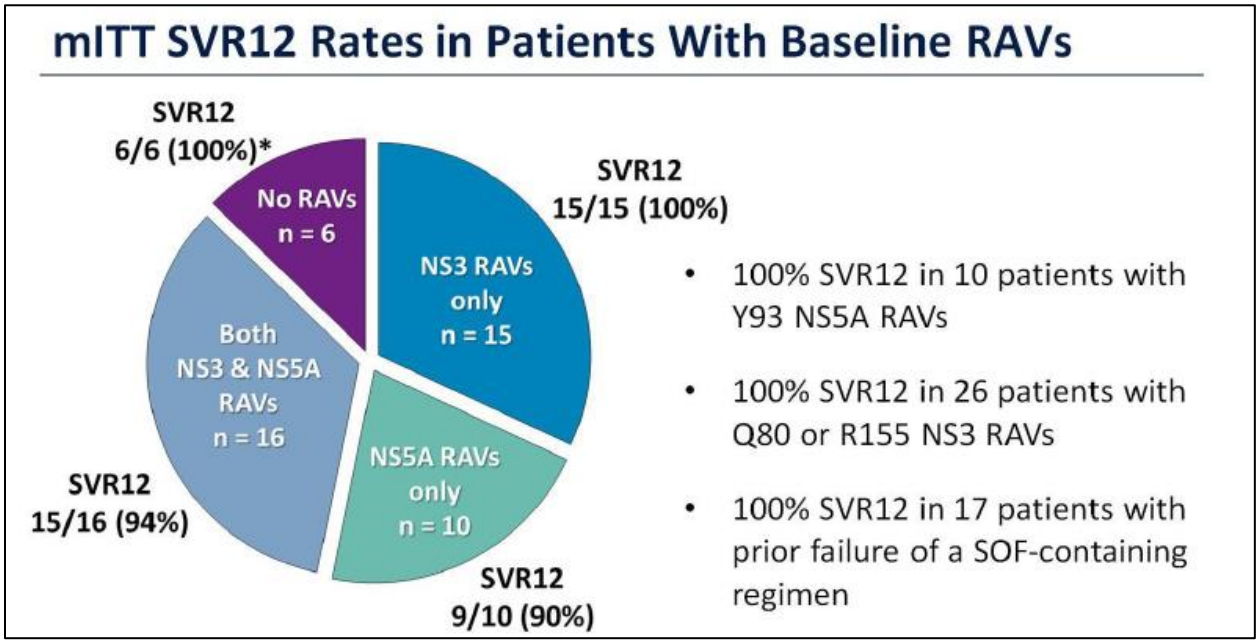
Besides Gilead, AbbVie is also developing a next generation, pan-genotypic HCV drug.

AbbVie

AbbVie has had a mixed entry into the hepatitis C space. While it has been profitable, has preferred status in a number of states, and has a high SVR12 rate, their products have failed to achieve the $3 billion sales goal outlined by management in January 2015. The lofty sales goal was missed for a number of reasons. The biggest was due to a poor safety trial.

AbbVie is finishing up studies on their next generation HCV drug. ABT-493/ABT-530 is an investigational drug that has combines a highly active NS3/4A protease inhibitor with a NS5A inhibitor. ABT-493 is Enanta's internally developed product and ABT-530 is AbbVie's own internally developed drug. Combined, the two drugs show good resistance activity to common NS3A/4A/NS5A variants, as can be seen in the table below. Collectively the drug is being tested in more than 2,000 patients and has shown excellent SVR8 and 12 rates across all genotypes.

Graphic 1. SVR12 Rates ABT-493/ABT-530 Magellan-I EASL Presentation April, 15, 2016



ABT-493/ABT-530 is expected to be approved sometime in 2017. As approval is gained in the United States, Europe, and Japan, Enanta is set to receive up to $80 million of milestone payments. AbbVie is motivated to get 493/530 approved as quickly as possible. The belief is that AbbVie will work towards making 493/530 an 8-week Harvoni competitor that can cure treatment exposed patients, or those with RAVs that Harvoni has trouble going after.

AbbVie would also like to get 493/530 out into the market to shift the perception/reality of their current HCV cocktails. Sales for AbbVie's HCV drugs were increasingly nicely, but in October 2015 the FDA

announced that Viekira Pak and Technivie can cause serious liver injury in patient populations that had advanced liver disease. The contra-indication brought a black cloud over the drugs and many doctors are reluctant to prescribe AbbVie's treatment unless required to by insurance carriers or if the drugs are Medicaid preferred. Gilead's drugs remain the first choice and AbbVie's are in a distant second.

ABT-493/ABT-530 will certainly not change this dynamic, this is Gilead's territory to lose. However, ABT-493/530 will be one of two pan-genotypic treatment options (Merck's pan-genotypic treatment is not expected to receive approval until late 2018 at the earliest) on the market for some time, has good RAV SVR rates, could be an 8-week treatment option for many patients (versus 12 weeks for Epclusa) and provides an option for those who have had prior failure on a sofosbuvir regimen. If 493/530 gets approved, there could be significant upside for Enanta.

Enanta Going Forward

All of the previous analysis was there to simply say: AbbVie has a few drugs that treat HCV, they are seeking approval for a drug that should have a better safety profile along, and the new drug is pan-genotypic. When the old AbbVie HCV cocktail sells, Enanta receives a royalty. When the new HCV cocktail is approved, Enanta is set to receive up to $80 million. When/if the AbbVie sells the new HCV cocktail, Enanta will see increased royalties. Finally, about half the market cap consists of cash and liquid investments.

Enanta received milestone payments of $155 million in late-2014/late-2015 for the regulatory approval of paritaprevir in the United States, Europe, and Japan. The timing and geography of each milestone can be seen in the chart below. While there were other milestones (Phase III milestones, as an example), I am focusing on the regulatory approvals.

Table 1. Milestone Payments for Paritaprevir. Source: Enanta SEC Filings

Country	Amount		Time
Japan	$30,000,000	Reimbursement Approval	Dec-15
United States	$75,000,000	FDA Regulatory Approval	Dec-14
European Union	$50,000,000	EM Regulatory Approval	Dec-14
Total	$155,000,000		

If ABT-493/ABT-530 gains approval Enanta is entitled to more milestone payments. While the exact payout structure is unknown, Enanta will receive $80 million from AbbVie upon regulatory approval in certain geographic areas. According to management it will be roughly in line with paritaprevir milestones. If this is roughly right, Enanta can expect to receive approximately $38 million from FDA approval, $26 million from European approval and $15 million from approval in Japan.

While there is significant uncertainty with any pharmaceutical trial, ABT-493/ABT-530 looks like it will gain approval in 2017. Phase II trials have been largely successful thus far with high cure rates after only eight weeks of treatment. Currently Enanta has $244 million of cash and investments and should ABT-493/530 gain approval in the three major territories, Enanta would see another $80 million of cash.

Cash burn should be kept to a minimum as the current paritaprevir royalty stream is largely offsetting operating expenses. The table below shows AbbVie HCV sales, Enanta royalties received, and a rough idea of Enanta cash burn.

Table 2. Enanta Operating Expenses and Royalties

Quarter Ending	Mar-15	Jun-15	Sep-15	Dec-15	Mar-16	Jun-16
Viekira HCV Sales	$231,000	$385,000	$469,000	$554,000	$414,000	$419,000
Royalties	$6,961	$11,390	$14,334	$17,869	$13,004	$13,978
Royalty Rate	*3.01%*	*2.96%*	*3.06%*	*3.23%*	*3.14%*	*3.34%*
R&D	$5,368	$6,253	$7,049	$9,033	$9,143	$10,785
G&A	$3,438	$3,643	$3,693	$3,818	$4,426	$4,282
OpEx	$8,806	$9,896	$10,742	$12,851	$13,569	$15,067
Stock Comp	$465	$1,584	$1,797	$1,028	$3,319	$2,497
Cash OpEx	-$8,341	-$8,312	-$8,945	-$11,823	-$10,250	-$12,570
Net cash burn	-$1,380	$3,078	$5,389	$6,046	$2,754	$1,408

For the most part, the royalty received from paritaprevir sales are balancing out cash operating expenses. The contra-indication from the FDA was put in place in October 2015, so any significant fallout should be largely baked into sales. Zepatier (Merck's HCV regimen) has been on the market since the beginning of 2016, and has been rather slow to gain acceptance, even with steep discounts.

Even if ABT-493/530 fails to gain approval, it seems likely that Enanta will continue to receive royalties for the next few years, albeit royalties might decrease quicker than the past few quarters. Given the high quality Phase II data that is emerging, I believe that ABT-493/530 will be approved and Enanta will receive $80 million. Assuming modest cash burn of $15 million(in other words, a significant increase in OpEx) and approval of ABT-493/530 before 2018, end of year 2017 cash and equivalents would roughly be $310 million, or more than $16 per share. Compared to a price of $24 per share, the pipeline and remaining royalty stream would be worth $8 per share, or $153 million.

The assumption that there will be $15 million of cash burn may prove to be conservative as royalties are likely to increase if AbbVie can maintain market share. The old AbbVie regimen was three Direct Acting Antivirals (3-DAA). As can be seen in Table 2, Enanta received royalties for roughly 10% their pro rata contribution to sales (30% in this case, with some sales of 2-DAA drugs containing paritaprevir). ABT-493/530 is a 2-DAA regimen and Enanta will see better royalties on their pro rata share of sales.

The new regimen would make Enanta eligible for royalties on 50% of the sales versus 30% for the 3-DAA paritaprevir regimen and 45% of the 2-DAA paritaprevir regimen. Ten percent of ½ sales is an obvious improvement from 10% on 30% of net sales. If we examine historical sales, we can see the impact that a 2-DAA regimen would have on royalties received. The table below shows a hypothetical 50:50 split between 2-DAA and 3-DAA AbbVie sales.

Table 3. Hypothetical 50:50 2-DAA:3-DAA AbbVie HCV Sales Example and the impact on Enanta's royalties Source: Author's calculations

	Sep-15	Dec-15	Mar-16	Jun-16
ABBV HCV Sales	$469,000	$554,000	$414,000	$419,000
Paritaprevir Royalty	$7,817	$9,233	$6,900	$6,983
ABT-493 Royalty	$11,725	$13,850	$10,350	$10,475
Total HCV Royalty	$19,542	$23,083	$17,250	$17,458
Royalty Rate	4.2%	4.2%	4.2%	4.2%

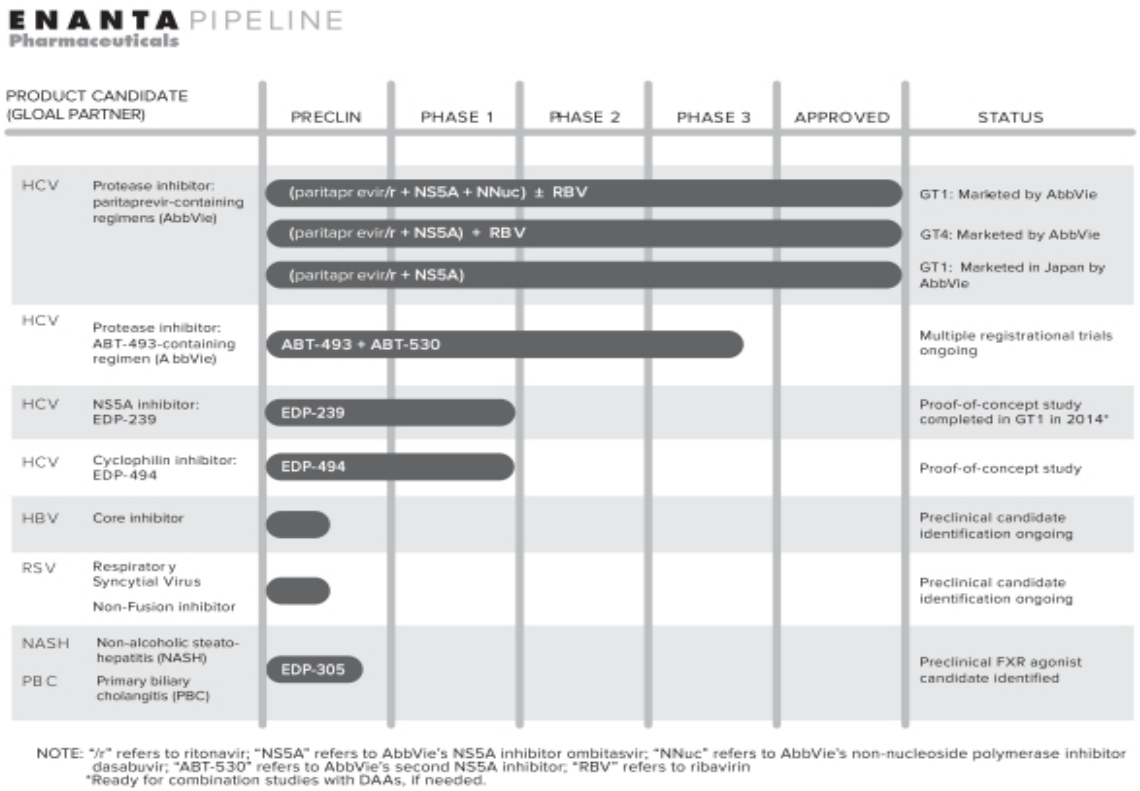
Flipping this over, if we assume ABT-493/530 becomes the only marketed HCV treatment and gains 100% of all HCV sales, AbbVie could see HCV sales drop by 50% and Enanta would still be roughly cash burn neutral. The table below gives an idea for royalty value.

Table 4. Royalty Valuation for Enanta, Royalty in thousands

	TTM Results Steady State	2-DAA Only, current sales are maintained	2-DAA Only, 50% HCV Sales decline
Royalty	$59,000	$90,000	$45,000
Estimated Life in years	6	7	5
Discount Rate	12%	12%	12%
NPV/Share	$12.70	$21.50	$8.49

Obviously there are a myriad of assumptions, guesses, and attempts at calculations in the table above. The bottom line is that between cash and some valuation of the royalty, investors get a pipeline for free with likely accumulation of cash on the balance sheet. The pipeline is focused on HCV and liver diseases. The graphic below shows the pipeline for Enanta

Graphic 2. Enanta Pipeline Source: Company SEC Filings



EDP-239 was a former Novartis collaboration, but Novartis decided to abandon the project back in 2014. Enanta took the product back and it has largely remained dormant since. The main focus of R&D spend is EDP-305 and EDP-494.

EDP-305 is Enanta's NASH candidate and it is expected to advance to phase 1 trials before the end of 2016. NASH is a hot area in pharmaceuticals right now with a number of larger players chasing after treatments. Gilead recently acquired Nimbus Therapeutics lead candidate for a hefty sum. Other preclinical drug candidates have been snapped up as well in the past few years. Like all drug development pathways, there are a number of ways to attack the disease. EDP-305 is a farnesoid X receptor agonist. With a number of potential outcomes, there is no reliable way to estimate EDP-305's potential at the moment. If Enanta can push EDP-305 into Phase I development it is possible that a large player (perhaps AbbVie, which lacks a NASH candidate) could offer a significant sum for the rights to develop this candidate.

EDP-494 is a cyclophilin inhibitor that Enanta spent $3.4 million on developing in 2015. The product is currently in proof-of-concept studies. The goal is to develop a product that is pan-genotypic and has far

better resistance properties. Given the early stage development efforts, no value is assigned to EDP-494 until further data is obtained.

While there is no value ascribed to the pipeline in this report, it does not mean there is no value. If any of the drugs get through phase I trials, there is most certainly value, particularly with EDP-305, which is entering a disease segment that has no FDA-approved therapy and two other farnesoid X receptor agonists in Phase II/III trials.

Summing it all together, investors have the opportunity to buy a cash rich pharmaceutical company with a royalty and a pipeline that is likely worth significantly more than the current market cap. If the HCV market remains robust and AbbVie can get ABT-493/530 to the market, there appears to be plenty of upside for investors and Enanta should accumulate cash even while funding research and development.

Risk Factors

-HCV Vaccine. There are several HCV vaccines in the works right now. The viability of the treatment is unknown as many of these candidates are early stage products. It is also unknown how they would be applied in the real world given the efficacy of current HCV treatments. Vaccines are still several years away from potential commercialization.

-Hepatitis C infections fall off a cliff and the patient population dwindles. Given the rise in heroin usage, HCV rates have started to tick up. This could provide a new patient pool to treat.

-Management could burn cash far quicker or far dumber than expected.

-AbbVie could just walk away. There is significant customer concentration here and if AbbVie decided that they were going to abandon their HCV platform, Enanta would have significant issues.

-Failure of candidate. If one of the pipeline candidates fails it will likely be shrugged off, given the valuation. Failure of ABT-493/530 is a much bigger deal though and would likely cause Enanta to trade down closer to net cash.

Conclusion

Enanta has been beaten over the past year, with shares down 40% thanks to a nearly endless stream of bad news. Investors have ignored the cash rich balance sheet and instead focused on the increasingly competitive HCV market. Hidden in this is Enanta's current royalty, another royalty if AbbVie can get ABT-493/530 approved, and a pipeline to match the balance sheet. Following the potential approval, Enanta would see more cash from milestone payments and another royalty stream. Net-net investors can purchase a pharmaceutical company that has a cash rich balance sheet, multiple royalty streams, and a pipeline of unknown value at a significant discount. I believe shares are worth at least $35 per share and depending on the pipeline, may be worth significantly more.

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