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LEERINK SWANN

HEALTHCARE EQUITY RESEARCH

ENANTA PHARMACEUTICALS, INC.

Second-Gen HCV Regimen Could Soon Emerge as the Next Driver

• **Bottom Line:** Yesterday, ENTA reported F3Q:13 results, ending the June quarter with a cash balance of \$115M, an increase from a quarter ago. In addition to the progress of the Phase III for its lead HCV regimen, the timeline of the Phase II start of ABBV/ENTA's second-generation interferon-free regimen ABT-493 (protease inhibitor)/ABT-530 (NS5A inhibitor) has recently been moved up from 2014 to 2013. With downside well protected with current cash and anticipated precommercial milestones of ~\$195M (most expected to be earned and paid in 2014/15), which together nearly equal its market capitalization, we believe the 493/530 combination could drive the upside. Although the coming lock-up expiry in September may have been an overhang, at the current levels we believe the risk/reward profile is especially attractive. Our price target on ENTA remains \$28.

• **All 6 registration trials for ABBV/ENTA's three-direct antiviral agent (DAA) combination of ABT-450/r + ABT-267 + ABT-333 have completed enrollment**, with data expected late 2013 or early 2014, regulatory filing in calendar 2Q:14 (moved up slightly from mid-2014), and potential launch in early 2015. These timelines are essentially identical to those for GILD's (OP) regimen.

• **Two-DAA combination of ABT-450/r + ABT-267 is being developed for select populations and could potentially result in improved economics to ENTA depending on pricing.** ABBV is conducting a large Phase II known as PEARL I on the interferon-free, ribavirin-free combination of ABT-450/r + ABT-267 in GT1b and GT4 patients. Additionally, this regimen is being tested in Japan in GT1b and GT2 patients. There is a presentation at AASLD 2013 on ABT-450/r + ABT-267 in treatment-naïve and null responder GT1b patients, although we do not know the details of the study.

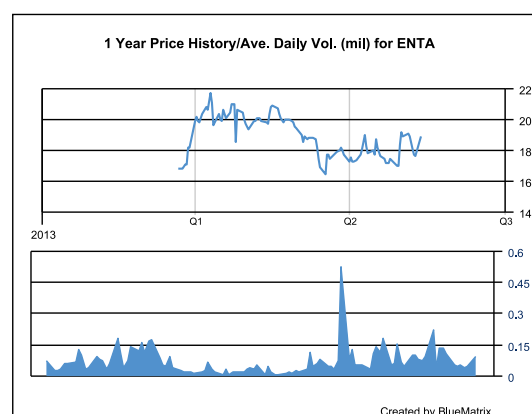
• **The most important development, in our view, would be the second-generation 2-DAA combination** due to a long-term impact, improved economics (ENTA eligible for royalty on half rather than one-third of the regimen and opt-in for co-promotion). ABBV has indicated that ABT-493/530 are once a day without boosting, are pan-genotypic, have good activity against resistant mutants, and can be co-formulated. MRK (MP) data at AASLD on the MK-5172/MK-8742 combination will be interesting to watch both as competition but also as proof of principle. Additionally, partner NVS (OP) on ENTA's NS5A inhibitor EDP-239 has initiated a Phase I study in HCV patients. The FDA has lifted the clinical hold on NVS' lead HCV agent alisporivir.

Key Stats:

(NASDAQ:ENTA)

S&P 600 Health Care Index:	1,118.08
Price:	\$18.87
Price Target:	\$28.00
Methodology:	DCF analysis
52 Week High:	\$22.40
52 Week Low:	\$14.00
Shares Outstanding (mil):	17.8
Market Capitalization (mil):	\$335.9
Cash Per Share:	\$6.44
Net Debt to Total Capital:	0%
Dividend (ann):	\$0.00
Dividend Yield:	0.0%

General: IPO was priced at \$14 on March 20, 2013.



Sep Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2012A	--	--	--	--	\$41.7	--	--	--	--	\$1.26	15.0x
2013E - New	\$27.9A	\$1.2A	\$1.6A	\$1.6	\$32.4	\$1.61A	(\$2.28)A	(\$0.23)A	(\$0.23)	(\$1.17)	NM
2013E - Old	\$27.9A	\$11.0	0.0	0.0	\$38.9	\$1.61A	\$4.36	(\$0.34)	(\$0.34)	(\$0.54)	NM
2014E - New	--	--	--	--	\$40.0	--	--	--	--	\$0.91	20.7x
2014E - Old	--	--	--	--	\$40.0	--	--	--	--	\$0.93	NM

Source: Company Information and Leerink Swann LLC Research
Revenues in \$M; GAAP presentation

Please refer to Pages 6 - 8 for Analyst Certification and important disclosures. Price charts and disclosures specific to covered companies and statements of valuation and risk are available at <https://leerink2.bluematrix.com/bluematrix/Disclosure2> or by contacting Leerink Swann LLC Publishing Department, One Federal Street, 37th Floor, Boston, MA 02110.



INVESTMENT THESIS

ENTA offers an opportunity to participate in the multi-billion HCV market for IFN-free regimen as a small-cap but late-stage player. ENTA is partnered with ABBV on ABT-450, which is the protease inhibitor (PI) in ABBV's all-oral HCV treatment regimen, which is one of the only two late-stage regimens that have broad genotype-1 activity and is anticipated to reach the market in 2015. We are more bullish than the Street on the size of the HCV market. ENTA's valuation is based primarily on the initial market for IFN-free regimens, thus ENTA represents a way to participate in the market upside without taking long-term market risks, in our view. We believe our market share assumption of 70:30 split for GILD:ABBV in GT-1 patients is supported by the most recent example of HCV protease inhibitor market. Though we believe GILD will be a fierce competitor, the market is large enough for multiple players. In comparison to the current HCV protease inhibitor market, which is split approximately 70:30 between VRTX's (OP) Incivek and MRK's Victrelis, the efficacy and convenience advantage for Incivek over Victrelis is arguably bigger than the difference between GILD and ABBV regimens although there does not appear to be a safety/tolerability advantage for ABBV over GILD as Victrelis is at least perceived to hold over Incivek. We believe ENTA's valuation is well supported by potential ABBV milestone payments and royalties on early ABT-450 sales. ENTA is entitled to tiered double-digit royalties on sales attributable to ABT-450, and we believe there is upside to the stock as ABBV HCV numbers rise to reflect the overall market potential. Several upside scenarios exist. We conservatively model no sales for ABT-450 post-2020. The biggest upside for ENTA would be if GILD's HCV program somehow stumbles, although we think this is unlikely. However, the scenario that earlier-stage competitors experience a setback is realistic, in our view. Furthermore, ABBV/ENTA's next-gen PI (in Phase I) could extend the HCV franchise into the next decade. ENTA has a 40% profit share option on this agent. In addition, ENTA is entitled to economics on EDP-239, its NS5A inhibitor partnered with NVS, in Phase I development. We currently attribute limited value to these programs; however, successful advancement and development could create significant royalty and milestone payments for ENTA. Productive medicinal chemistry platform could continue to advance clinical candidates. ENTA currently has three interesting pre-clinical programs that could potentially advance to the clinic in the 2014 timeframe. A MEDACorp key opinion leader (KOL) highlighted the cyclophilin inhibitor (for hepatitis C) as an interesting agent to watch. In addition, given the scarcity in the class, ENTA's nucleotide HCV polymerase inhibitor could generate investor interest as it advances.

Model updates. We are updating our financial model to reflect reported F2Q:13 and F3Q:13 results. The variance of reported results relative to our model was mainly due to the accounting for the milestone payment. ENTA's R&D spending has been slightly lower than our expectations (\$3.9-4.0M vs. our \$4.8M estimate). We updated our F4Q:13 estimates based on reported results, and made a modest change to our F2014E EPS. Management projected that its cash balance of \$115M is sufficient to meet its anticipated cash requirement for at least the next 24 months, although we expect ENTA to receive most of the registration milestone of \$40M and most of the approval milestone of \$155M in 2014/15.



ENTA – Expected Events

Timing	Event
<u>ABT-450/r (protease inhibitor)</u>	
late'13/early'14	Phase III data in GT1
2Q:14	NDA filing for IFN-free regimen containing ABT-450
2015	Potential approval
<u>ABT-493 (Next-Gen protease inhibitor)</u>	
2H:13	Initiation of Phase II combination study
<u>EDP-239 (NS5A inhibitor)</u>	
2014	Possible Phase I and proof of concept data
<u>Cyclophilin inhibitor program</u>	
2H:13	Expect to advance into preclinical studies
<u>Nucleotide polymerase program</u>	
2H:13	Expect to advance into preclinical studies
<u>EDP-788 (Bicyclolide antibiotic)</u>	
1H:14	Expect to initiate Phase I

Source: Company reports and Leerink Swann research

ENTA – Product Pipeline

Candidate	Mechanism	Indication	Status	Partner
ABT-450	NS3/4A protease inhibitor	Hepatitis C	Phase III	AbbVie
Next generation protease inhibitor	NS3/4A protease inhibitor	Hepatitis C	Phase I	AbbVie
EDP-239	NS5A inhibitor	Hepatitis C	Phase I	Novartis
Cyclophilin inhibitor	Cyclophilin inhibitor	Hepatitis C	Preclinical	
Nucleotide polymerase inhibitor	Nucleotide polymerase inhibitor	Hepatitis C	Preclinical	
EDP-788	Biocyclolide antibiotic	MRSA	Preclinical	

Source: Company reports and Leerink Swann research



VALUATION

Our \$28/share 12-month valuation is derived from a probability-adjusted DCF analysis of ABT-450 royalties as well as expected pre-commercialization milestone payments and platform value. We model >\$3B in worldwide sales for ABBV's HCV regimen from 2016 to 2018, with declining revenues in 2019 and 2020 and no revenues afterwards. We model a blended royalty rate of 15-16% for the 1/3 of sales attributable to ABT-450, and apply at 85% probability adjustment. We assume \$195M in milestone payments from ABBV, \$135M in YE:14 cash and \$60M platform value. We use a 12% discount rate on after-tax cash flows as the royalty payments are already probability adjusted.

RISKS TO VALUATION

- ABBV's Phase III HCV regimen may fail due to either efficacy or safety concerns.
- ABBV's HCV program faces competition from GILD, VRTX, BMY (OP), Roche, MRK and other players in the field.
- Ritonavir boosting may limit the usage of ABBV's regimen due to drug-drug interactions.
- Treatment rates for all oral treatments in HCV may be lower than we and the market anticipate.
- Pricing and reimbursement pressures are high in the US, Europe and other geographies and may be a headwind to sales.
- Dependent on partners in clinical development and commercialization and in assembling a portfolio of agents to have a competitive IFN-free regimen.
- EDP-239 currently lacks a combination partner as NVS's alisporivir is on clinical hold.

Enanta Pharmaceuticals, Inc.

All figures in millions of U.S. Dollar, except per share items.

	<u>FY12A</u>					<u>FY13E</u>	<u>FY14E</u>	<u>FY15E</u>
	<u>Sep '12A</u>	<u>1QA</u> <u>Dec '12A</u>	<u>2QA</u> <u>Mar '13A</u>	<u>3QA</u> <u>Jun '13A</u>	<u>4QE</u> <u>Sep '13E</u>	<u>Sep '13E</u>	<u>Sep '14E</u>	<u>Sep '15E</u>
Total revenues	41.7	27.9	1.2	1.6	1.6	32.4	40.0	250.5
SG&A	5.3	1.2	1.3	1.8	1.2	5.5	4.6	5.0
R&D	15.1	4.8	3.9	4.0	4.6	17.3	19.2	20.0
Operating Income	21.3	21.9	(4.0)	(4.2)	(4.2)	9.6	16.2	225.5
Interest income	0.1	0.0	0.0	0.1	0.0	0.1	0.0	0.0
Interest expense	0.0	(0.0)	(0.0)	(0.0)	0.0	(0.0)	0.0	0.0
Change in fair value of warrant liability	(0.0)	0.0	0.2	(0.0)	0.0	0.2	0.0	0.0
Pretax Income	21.4	22.0	(3.7)	(4.1)	(4.2)	9.9	16.2	225.5
Taxes		0.0	0.0	0.0	0.0	0.0	0.0	78.9
Income After Taxes	21.4	22.0	(3.7)	(4.1)	(4.2)	9.9	16.2	146.6
Accretion of redeemable convertible preferred to redemption value	(5.4)	(1.3)	(1.2)	0.0	0.0	(2.5)	0.0	0.0
Net income attributable to participating securities	(14.7)	(18.8)	0.0	0.0	0.0	(18.8)	0.0	0.0
Net income to common shares	1.4	1.9	(5.0)	(4.1)	(4.2)	(11.4)	16.2	146.6
<u>EPS</u>								
Basic	\$1.26	\$1.61	(\$2.28)	(\$0.23)	(\$0.23)	(\$1.17)	\$0.91	\$8.23
Diluted	\$1.13	\$1.45	(\$2.28)	(\$0.23)	(\$0.23)	(\$1.17)	\$0.81	\$7.33
<u>Common shares</u>								
Basic	1.1	1.2	2.2	17.8	17.8	9.7	17.8	17.8
Diluted	2.5	2.6	2.6	20.0	20.0	11.3	20.0	20.0

Source: Company information, Leerink Swann estimates



Disclosures Appendix

Analyst Certification

I, Howard Liang, Ph.D., certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.



Distribution of Ratings/Investment Banking Services (IB) as of 06/30/13				
Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [OP]	103	62.80	30	29.00
HOLD [MP]	61	37.20	2	3.00
SELL [UP]	0	0.00	0	0.00

Explanation of Ratings

Outperform (Buy): We expect this stock to outperform its benchmark over the next 12 months.

Market Perform (Hold/Neutral): We expect this stock to perform in line with its benchmark over the next 12 months.

Underperform (Sell): We expect this stock to underperform its benchmark over the next 12 months. The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.

For the purposes of these definitions the relevant benchmark will be the S&P 600® Health Care Index for issuers with a market capitalization of less than \$2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over \$2 billion.

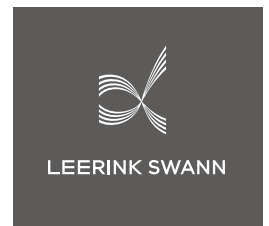
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