

ENANTA PHARMACEUTICALS, INC.

Increasing Valuation Based on Impressive Preclinical Profile of Second-Gen PI

• **Bottom Line:** Based on the first data presented last week at the Conference on Retroviruses and Opportunistic Infections (CROI) showing strong resistance profile as well as pan-genotypic coverage, we believe that ABBV and ENTA's next-generation protease inhibitor (PI) ABT-493 has the potential to be among the best in class and a true "cornerstone" agent when used in combination with an NS5A inhibitor (namely ABBV's ABT-530). We are introducing to our model probability-weighted (at 50%) sales for ABBV/ENTA's second-generation combination and assume that ENTA will decide to opt-in to a 40% profit-sharing agreement with ABBV rather than receive tiered double-digit royalties as it will with its first-generation PI, ABT-450. We raise our price target from \$29 to \$45.

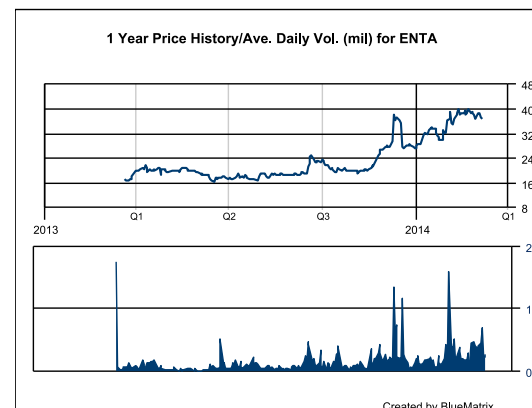
• **Potent in vitro activity against the R155K mutation appears to place ABT-493 among the best PIs in development.** MEDACorp hepatology key opinion leaders (KOLs) and industry executives have suggested that a protease inhibitor's (PI) ability to treat the R155K mutation is the key to becoming a "cornerstone" agent and achieving a high sustained viral response rate (SVR) when used in combination with an NS5Ai inhibitor without a nucleotide in the regimen. Our own analysis appears to support such a correlation. CROI data show high potency of ABT-493 against a broad array of known resistant protease variants including R155K. While MRK's (MP) MK-5172, which has produced the most impressive sustained viral response (SVR) rates in combination with an NS5Ai in our opinion, is slightly less potent against the R155K variant compared to the wild-type (WT), ABT-493 is equally potent against R155K vs. the WT. We are impressed by ABT-493's resistance profile. For a full analysis of PIs and the R155K mutation, see our post-CROI recap note ([LINK](#)).

• **ABT-493 also demonstrated broad coverage against other genotypes, including potent activity against GT3a HCV replicons.** We note that GT3 patients remain difficult to treat, with most other PIs showing poor activity against this genotype. While 24-week treatment with GILD's (OP) Sovaldi (sofosbuvir)+RBV was able to achieve 92-94% SVR12 rates in treatment-naïve GT3 patients in the Phase III VALENCE trial, only 60% of treatment-experienced patients with cirrhosis were able to be cured. Thus, this remains one of the few subsets of patients with a clear unmet need with regards to efficacy.

Key Stats:

(NASDAQ:ENTA)

| | |
|---------------------------------------|----------------------|
| S&P 600 Health Care Index: | 1,310.69 |
| Price: | \$36.80 |
| Price Target: | \$45.00 from \$29.00 |
| Methodology: | DCF analysis |
| 52 Week High: | \$41.10 |
| 52 Week Low: | \$14.00 |
| Shares Outstanding (mil): | 17.9 |
| Market Capitalization (mil): | \$658.7 |
| Cash Per Share: | \$5.92 |
| Net Debt to Total Capital: | 0% |
| Dividend (ann): | \$0.00 |
| Dividend Yield: | 0.0% |



| Sep Yr | 1Q | 2Q | 3Q | 4Q | FY Rev | 1Q | 2Q | 3Q | 4Q | FY EPS | P/E |
|-------------|--------|--------|-------|-------|---------|-----------|----------|----------|----------|----------|-------|
| 2013A | \$27.9 | \$1.2 | \$1.6 | \$1.3 | \$32.1 | \$1.45 | (\$2.28) | (\$0.23) | (\$0.25) | (\$0.67) | NM |
| 2014E - New | \$0.9A | \$40.0 | 0.0 | 0.0 | \$40.9 | (\$0.30)A | \$1.90 | (\$0.33) | (\$0.33) | \$0.93 | 39.6x |
| 2014E - Old | -- | -- | -- | -- | \$40.0 | -- | -- | -- | -- | \$0.90 | NM |
| 2015E - New | -- | -- | -- | -- | \$257.8 | -- | -- | -- | -- | \$8.43 | 4.4x |
| 2015E - Old | -- | -- | -- | -- | \$256.1 | -- | -- | -- | -- | \$8.39 | NM |

Source: Company Information and Leerink Partners 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 Partners Editorial 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, ABT-493, (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 (OP), 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.

ENTA's economics on ABT-493 could improve on opt-in to a profit-sharing with ABBV compared to ABT-450. ABT-493 is being studied in a Phase I/II as monotherapy currently in HCV GT1 patients and in combination with ABT-530 in healthy volunteers. Under its current agreement with ABBV, ENTA is entitled to tiered, double-digit royalties based on ABT-493's sales (which would be 50% of total regimen sales if included in a two-agent combo with ABBV's ABT-530). ENTA also has the option to enter a profit-sharing agreement whereby it would receive 40% of ABT-493's US sales and be responsible for 40% of sales and development expenses (it would still receive royalties on ex-US sales). As the development path has been mapped out by ABT-450,

the registration program could potentially be less complex and costly. ENTA has previously stated that it is conducting an internal analysis and will make a decision on the option prior to Phase IIb.

Model update. We are updating our model to reflect recently reported 4Q:13 financial results. Based on the impressive preclinical profile for ABT-493 reported at CROI, generally good predictability of clinical efficacy of antiviral compounds based on preclinical data, ABBV and ENTA's expertise in development of HCV protease inhibitors, and generally good safety track record of the class, we are including 50% probability of success-weighted sales for an ABT-493+ABT-530 combination in our ENTA model. We assume ENTA will exercise its option for the profit-sharing agreement. Based on a DCF analysis, we are updating our valuation from \$29 to \$45.

Enanta, Inc. Expected Events

| Timing | Event |
|---|--|
| <u>ABT-450/r (protease inhibitor)</u> | |
| Apr-13 | Full results from Phase III trials at EASL |
| 2Q:14 | NDA and MAA filing for IFN-free regimen containing ABT-450 |
| Early '14 | Initiation of Phase III trials of ABT-450+ABT-297 |
| 2015 | Potential approval |
| <u>ABT-493 (Next-Gen protease inhibitor)</u> | |
| 2H:14 | Results of Phase II combination study with ABT-530 |
| 2015 | Decision on profit-sharing option with ABBV |
| 2016 | Potential approval |
| <u>EDP-239 (NS5A inhibitor)</u> | |
| 2014 | Possible Phase I and proof of concept data |
| <u>Cyclophilin inhibitor program</u> | |
| 1H:14 | Expect to advance into preclinical studies |
| <u>Nucleotide polymerase program</u> | |
| 1H:14 | Expect to advance into preclinical studies |
| <u>EDP-788 (Bicyclolide antibiotic)</u> | |
| 2014 | Phase I trial ongoing |

Source: Company reports, Leerink Partners analysis

Enanta Pipeline

| Candidate | Mechanism | Indication | Status | Partner | Comments |
|---------------------------------|---|-------------|-------------|----------|---------------------------------|
| ABT-450 | NS3/4A protease inhibitor | Hepatitis C | Phase III | AbbVie | Part of an all oral HCV regimen |
| ABT-493 | NS3/4A protease inhibitor (next generation) | 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, Leerink Partners analysis

VALUATION

We are raising our 12-month valuation to \$45 from \$29, derived from a probability-adjusted DCF analysis of ABT-450 royalties, ABT-493 US profit-sharing revenues and ex-US royalties, as well as expected pre-commercialization milestone payments and platform value. We model a blended royalty rate of 15-16% for the 1/3 of sales attributable to ABT-450, and apply at 90% probability adjustment. For ABT-493, we apply a 50% probability of success. We assume \$195M in milestone payments from ABBV, \$135M in YE:14 cash and \$60M platform value. We use a 10% 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, BMV (OP), 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.

Enanta Pharmaceuticals, Inc.

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

| | <u>FY12A</u> | | | | | <u>FY13A</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>4QA</u> <u>Sep '13A</u> | <u>Sep '13A</u> | <u>1QA</u> <u>Dec '13A</u> | <u>2QE</u> <u>Mar '14E</u> | <u>3QE</u> <u>Jun '14E</u> | <u>4QE</u> <u>Sep '14E</u> | <u>Sep '14E</u> | <u>Sep '15E</u> |
| Net Sales | 41.7 | 27.9 | 1.2 | 1.6 | 1.3 | 32.1 | 0.9 | 40.0 | 0.0 | 0.0 | 40.9 | 257.8 |
| SG&A | 5.3 | 1.2 | 1.5 | 1.8 | 1.8 | 6.2 | 2.1 | 1.2 | 1.2 | 1.2 | 5.5 | 5.0 |
| R&D | 15.1 | 4.8 | 3.7 | 4.0 | 4.3 | 16.8 | 4.3 | 4.8 | 4.8 | 4.8 | 18.7 | 20.0 |
| Operating Income | 21.3 | 21.9 | (4.0) | (4.2) | (4.7) | 9.0 | (5.5) | 34.1 | (6.0) | (6.0) | 16.7 | 232.8 |
| Interest income | 0.1 | 0.0 | 0.0 | 0.1 | 0.3 | 0.4 | 0.1 | 0.0 | 0.0 | 0.0 | 0.1 | 0.1 |
| Interest expense | 0.0 | (0.0) | (0.0) | (0.0) | 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 | 0.0 | 0.0 | 0.0 | 0.0 |
| Pretax Income | 21.4 | 22.0 | (3.7) | (4.1) | (4.4) | 9.6 | (5.4) | 34.1 | (6.0) | (6.0) | 16.8 | 232.8 |
| Taxes | | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 81.5 |
| Income After Taxes | 21.4 | 22.0 | (3.7) | (4.1) | (4.4) | 9.6 | (5.4) | 34.1 | (6.0) | (6.0) | 16.8 | 151.4 |
| Accretion of redeemable convertible preferred to redemption value | (5.4) | (1.3) | (1.2) | 0.0 | 0.0 | (2.5) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Net income attributable to participating securities | (14.7) | (13.7) | 0.0 | 0.0 | 0.0 | (13.7) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Net income to common shares | 1.4 | 7.0 | (5.0) | (4.1) | (4.4) | (6.6) | (5.4) | 34.1 | (6.0) | (6.0) | 16.8 | 151.4 |
| EPS | | | | | | | | | | | | |
| Basic | \$1.26 | \$6.05 | (\$2.28) | (\$0.23) | (\$0.25) | (\$0.67) | (\$0.30) | \$1.90 | (\$0.33) | (\$0.33) | \$0.93 | \$8.43 |
| Diluted | \$1.13 | \$1.45 | (\$2.28) | (\$0.23) | (\$0.25) | (\$0.67) | (\$0.30) | \$1.90 | (\$0.33) | (\$0.33) | \$0.93 | \$8.43 |
| Common shares | | | | | | | | | | | | |
| Basic | 1.1 | 1.2 | 2.2 | 17.8 | 17.9 | 9.8 | 17.9 | 17.9 | 17.9 | 17.9 | 17.9 | 17.9 |
| Diluted | 2.5 | 1.2 | 2.2 | 17.8 | 17.9 | 9.8 | 17.9 | 17.9 | 17.9 | 17.9 | 17.9 | 17.9 |

Source: Company information, Leerink Partner 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 12/31/13 | | | | |
|---|-------|---------|-----------------------|---------|
| Rating | Count | Percent | IB Serv./Past 12 Mos. | |
| | | | Count | Percent |
| BUY [OP] | 118 | 64.50 | 30 | 25.00 |
| HOLD [MP] | 65 | 35.50 | 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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| Leerink Partners LLC Equity Research | | | |
|--------------------------------------|--|--|--|
|--------------------------------------|--|--|--|

| | | | |
|---|-------------------------------|----------------|-------------------------------|
| Director of Equity Research | John L. Sullivan, CFA | (617) 918-4875 | john.sullivan@leerink.com |
| Associate Director of Research | Alice C. Avanian, CFA | (617) 918-4544 | alice.avanian@leerink.com |
| Healthcare Strategy | John L. Sullivan, CFA | (617) 918-4875 | john.sullivan@leerink.com |
| | Alice C. Avanian, CFA | (617) 918-4544 | alice.avanian@leerink.com |
| Biotechnology | Howard Liang, Ph.D. | (617) 918-4857 | howard.liang@leerink.com |
| | Joseph P. Schwartz | (617) 918-4575 | joseph.schwartz@leerink.com |
| | Marko Kozul, M.D. | (415) 905-7221 | marko.kozul@leerink.com |
| | Michael Schmidt, Ph.D. | (617) 918-4588 | michael.schmidt@leerink.com |
| | Jonathan Chang, Ph.D. | (617) 918-4015 | jonathan.chang@leerink.com |
| | Irene Lau | (415) 905-7256 | irene.lau@leerink.com |
| | Paul Matteis | (617) 918-4585 | paul.matteis@leerink.com |
| | Gena Wang, Ph.D., CFA | (212) 277-6073 | gena.wang@leerink.com |
| | Richard Goss | (617) 918-4059 | richard.goss@leerink.com |
| | | | |
| Life Science Tools and Diagnostics | Dan Leonard | (212) 277-6116 | dan.leonard@leerink.com |
| | Justin Bowers, CFA | (212) 277-6066 | justin.bowers@leerink.com |
| Pharmaceuticals/Major | Seamus Fernandez | (617) 918-4011 | seamus.fernandez@leerink.com |
| | Ario Arabi | (617) 918-4568 | ario.arabi@leerink.com |
| Specialty Pharmaceuticals, Generics | Jason M. Gerberry, JD | (617) 918-4549 | jason.gerberry@leerink.com |
| | Christopher W. Kuehnle, JD | (617) 918-4851 | chris.kuehnle@leerink.com |
| Medical Devices, Cardiology & Orthopedics | Danielle Antalffy | (212) 277-6044 | danielle.antalffy@leerink.com |
| | Richard Newitter | (212) 277-6088 | richard.newitter@leerink.com |
| | Robert Marcus, CFA | (212) 277-6084 | robert.marcus@leerink.com |
| | Ravi Misra | (212) 277-6049 | ravi.misra@leerink.com |
| Healthcare Services | Ana Gupte, Ph.D. | (212) 277-6040 | ana.gupte@leerink.com |
| Healthcare Technology & Distribution | David Larsen, CFA | (617) 918-4502 | david.larsen@leerink.com |
| | Christopher Abbott | (617) 918-4010 | chris.abbott@leerink.com |
| Sr. Editor/Supervisory Analyst Supervisory Analysts | Mary Ellen Eagan, CFA | (617) 918-4837 | maryellen.eagan@leerink.com |
| | Robert Egan | | bob.egan@leerink.com |
| | Amy N. Sonne | | amy.sonne@leerink.com |

New York
299 Park Avenue, 21st floor
New York, NY 10171
(888) 778-1653

Boston
One Federal Street, 37th Floor
Boston, MA 02110
(800) 808-7525

San Francisco
201 Spear Street, 16th Floor
San Francisco, CA 94105
(800) 778-1164