# Enanta Pharmaceuticals Reports Financial Results for its Fiscal Fourth Quarter and Year Ended September 30, 2015

November 23, 2015
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***Conference Call and Webcast Today at 4:30 p.m. ET***

- *Royalty revenue of $14.4 million in fourth quarter brings fiscal year total to $34.1 million*
- *AbbVie's phase 3 trial begun for next-generation HCV treatment containing Enanta's protease inhibitor ABT-493*
- *Enanta's cyclophilin inhibitor candidate EDP-494 expected to enter the clinic in the first calendar quarter of 2016*
- *Cash and marketable securities totaled $209 million at September 30, 2015*

WATERTOWN, Mass.--(BUSINESS WIRE)--Nov. 23, 2015-- Enanta Pharmaceuticals, Inc., (NASDAQ: ENTA), a research and development-focused biotechnology company dedicated to creating small molecule drugs for viral infections and liver diseases, today reported financial results for its fiscal fourth quarter and year ended September 30, 2015.

**Fiscal Fourth Quarter and Year Ended September 30, 2015 Financial Results**
Cash, cash equivalents and short-term and long-term marketable securities totaled $209.4 million at September 30, 2015. This compares to a total of $131.8 million in such accounts at September 30, 2014. Enanta expects that its current cash, cash equivalents and marketable securities will be sufficient to meet the anticipated cash requirements of its existing business for the foreseeable future.

Revenue for the three months ended September 30, 2015 was $14.4 million, compared to $2.6 million for the three months ended September 30, 2014. For the 2015 quarter, revenue consisted primarily of royalties earned on contractually specified portions of AbbVie's worldwide net sales of hepatitis C virus (HCV) treatment regimens containing paritaprevir, Enanta's lead protease inhibitor identified within the ongoing AbbVie-Enanta collaboration. Quarterly royalty revenues are all included in accounts receivable at quarter end and then collected in a single payment in the following quarter. For the twelve months ended September 30, 2015, revenue was $160.9 million, compared to revenue of $47.7 million for the same period in 2014. The increase in revenue for the twelve months ended September 30, 2015 was due primarily to a total of $125 million in payments earned from AbbVie for the achievement of U.S. and EU commercialization regulatory approvals of VIEKIRA PAK™ and VIEKIRAX®, respectively, as well as to royalties earned on those products, compared to $40 million in milestone payments and other contractual revenue in the comparable period in 2014. Milestone payments, royalties and other payments from collaborations have varied significantly from period to period, and are expected to continue to do so.

Research and development expenses totaled $7.0 million for the three months ended September 30, 2015, compared to $5.2 million for the three months ended September 30, 2014. For the twelve months ended September 30, 2015, research and development expenses were $23.2 million, compared to $18.7 million for the comparable period in 2014. The increases in the three and twelve month periods over the prior year periods were primarily due to increased internal and external spend on Enanta's proprietary research programs.

General and administrative expenses totaled $3.7 million for the three months ended September 30, 2015, compared to $2.8 million for the three months ended September 30, 2014. For the twelve months ended September 30, 2015, general and administrative expenses totaled $13.5 million, compared to $10.0 million for the comparable period in 2014. The increases in the three and twelve month periods primarily reflected increases in stock-based compensation expense, due principally to increases in Enanta's stock price, as well as additional expenses incurred as Enanta expands its operations.

Net income for the three months ended September 30, 2015 was $5.8 million, or $0.29 per diluted common share, compared to a net loss of $5.0 million, or ($0.27) per diluted common share, for the corresponding period in 2014. For the twelve months ended September 30, 2015, net income was $79.0 million, or $4.09 per diluted common share, compared to $34.4 million, or $1.80 per diluted common share for the comparable period in 2014. The increase in net income during the twelve month ended September 30, 2015 was primarily due to $125 million in milestone payments received, as well as royalty revenue earned from AbbVie. Net income in the 2014 year reflected a total of $40 million in milestone payments for regulatory filings, and the reversal of the entire valuation allowance related to Enanta's deferred tax assets, which resulted in an income tax benefit of $15.2 million in 2014.

"We ended our fiscal year in a position of financial strength and poised for advances in our research pipeline," commented Jay R. Luly, Ph.D., President and Chief Executive Officer. "Our cash and marketable securities balance is strong, and we have royalties on paritaprevir that were running at an annualized rate of approximately $57 million at the quarter ending September 30. Additionally, our second protease inhibitor, ABT-493 has advanced into Phase 3 trials as part of AbbVie's next-generation, fixed-dose combination treatment for HCV, we plan to advance two of our wholly-owned programs – our cyclophilin inhibitor for HCV and an FXR agonist for NASH – into the clinic next year, and we are also advancing other discovery programs."

**Development Program and Business Review**

- In November 2015, Enanta earned a $30 million milestone payment for the reimbursement approval of AbbVie's VIEKIRAX® in Japan, which will be reflected in Enanta's quarter ending December 31, 2015.

- Phase 3 studies have begun on AbbVie's next-generation HCV treatment containing a fixed-dose combination of protease inhibitor ABT-493 and ABT-530, AbbVie's next generation NS5A inhibitor.
- Data from AbbVie's SURVEYOR studies, its investigational hepatitis C virus (HCV) regimen containing Enanta's next-generation protease inhibitor ABT-493 and ABT-530, AbbVie's next generation NS5A inhibitor, demonstrated that after 12 weeks of treatment with doses at or closest to the Phase 3 clinical dose, $SVR_{12}$ rates were 100 percent in genotype 1 HCV patients, 96 percent in genotype 2, and 93 percent in genotype 3. Additional late breaking data from SURVEYOR-I showed that non-cirrhotic genotype 1 HCV patients treated for only 8 weeks with this combination achieved $SVR_{12}$ rate of 97 percent.
- Enanta has selected its cyclophilin inhibitor candidate EDP-494 from its wholly-owned pipeline to advance into a phase 1 clinical study for HCV, which is scheduled to commence in the first quarter of calendar 2016. The cyclophilin inhibitor class may have the highest barrier to resistance of any class because cyclophilin is a human drug target that is non-mutating and may prove valuable in treating resistant forms of HCV.
- AbbVie recently filed a New Drug Application with the FDA for a once-daily, fixed-dose formulation of the 3 DAA's in the VIEKIRA PAK regimen for the treatment of patients with chronic GT1 HCV infection.
- The U.S. Food and Drug Administration granted marketing approval on July 24, 2015 for AbbVie's TECHNIVIE™, the first all-oral, interferon-free, two-direct-acting antiviral (2-DAA) treatment regimen approved in the U.S. for GT4 HCV patients.

**Financial Guidance**

- For the quarter ended September 30, 2015, Enanta's paritaprevir royalties represented approximately 3% percent of AbbVie's reported VIEKIRA sales, and Enanta expects its royalties in the quarter ending December 31, 2015 to continue to be approximately 3% percent of such sales, depending on the amounts and portions of those sales that are 2-DAA or 3-DAA regimen sales. Under its agreement with AbbVie, Enanta is entitled to annually tiered, double-digit royalties on specified portions of sales that are allocated to paritaprevir using 30% of 3-DAA sales (VIEKIRA PAK™ or VIEKIRAX® + EXVIERA®) and 45% of 2-DAA sales (TECHNIVIE® or VIEKIRAX®).
- For the full fiscal year ending September 30, 2016, Enanta expects to incur between $40 and $50 million of research and development expenses.

**Upcoming Events and Presentations**

- 34th Annual J.P. Morgan Healthcare Conference, January 11-14, 2016, San Francisco
- Enanta plans to issue its fiscal first quarter financial results press release, and hold a conference call regarding those results, in the week of February 8, 2016.

**Conference Call and Webcast Information**

Enanta will host a conference call and webcast today at 4:30 p.m. ET. To participate in the live conference call, please dial (855) 840-0595 in the U.S. or (518) 444-4814 for international callers. A replay of the conference call will be available starting at approximately 6:30 p.m. Eastern time on November 23, 2015, through 11:59 p.m. Eastern time on November 30, 2015 by dialing (855) 859-2056 from the U.S. or (404) 537-3406 for international callers. The passcode for both the live call and the replay is 58326369. A live audio webcast of the call and replay can be accessed by visiting the "Calendar of Events" section on the "Investors" page of Enanta's website at www.enanta.com.

**About Enanta**

Enanta Pharmaceuticals is a research and development-focused biotechnology company that uses its robust chemistry-driven approach and drug discovery capabilities to create small molecule drugs for viral infections and liver diseases. Enanta has developed novel protease and NS5A inhibitors that are members of the direct-acting-antiviral (DAA) inhibitor classes designed for use against the hepatitis C virus (HCV). Enanta's protease inhibitors partnered with AbbVie include paritaprevir, which is contained in AbbVie's marketed DAA regimens for HCV, and ABT-493, Enanta's next-generation protease inhibitor which recently initiated phase 3 development in combination with ABT-530, AbbVie's next-generation NS5A inhibitor. Enanta also has discovered a host-targeted antiviral (HTA) inhibitor for HCV targeted against cyclophilin, which Enanta plans to study in a phase 1 clinical trial in the first quarter of 2016 as well as another DAA program to develop nucleotide polymerase inhibitors. In addition, Enanta has a preclinical program in non-alcoholic steatohepatitis, or NASH, which is a condition that results in liver inflammation and liver damage caused by a buildup of fat in the liver.

**Forward Looking Statements Disclaimer**

This press release contains forward-looking statements, including statements with respect to the prospects for royalties on sales of AbbVie's HCV treatment regimens containing paritaprevir, the prospects for AbbVie's development of a next-generation regimen containing ABT-493, the prospects for advancement of the NASH development program, expectations for a commercialization regulatory approval in Japan milestone payment from AbbVie, the prospects for Enanta's cyclophilin inhibitor being valuable in treating resistance forms of HCV, the prospects for advancing a cyclophilin inhibitor for the treatment of HCV and an FXR agonist for the treatment of NASH into clinical trials, and the projected sufficiency of Enanta's cash-equivalent resources and marketable securities. Statements that are not historical facts are based on management's current expectations, estimates, forecasts and projections about Enanta's business and the industry in which it operates and management's beliefs and assumptions. The

statements contained in this release are not guarantees of future performance and involve certain risks, uncertainties and assumptions, which are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed in such forward-looking statements. Important factors and risks that may affect actual results include: Enanta's revenues are dependent upon the success of AbbVie's planned regulatory approval and commercialization efforts for its treatment regimens containing paritaprevir; Enanta's longer term revenues will likely be dependent upon the success of AbbVie's planned clinical development and commercialization of next-generation regimens containing ABT-493; regulatory actions affecting any approval of a treatment regimen containing ABT-493; the pricing, market acceptance and reimbursement rates of treatment regimens containing paritaprevir or ABT-493 compared to competitive HCV products on the market and product candidates of other companies under development; the discovery and development risks of early stage discovery efforts in new disease areas; potential competition from the development efforts of others in those new disease areas; Enanta's lack of clinical development experience; Enanta's need to attract and retain senior management and key scientific personnel; Enanta's need to obtain and maintain patent protection for its product candidates and avoid potential infringement of the intellectual property rights of others; and other risk factors described or referred to in "Risk Factors" in Enanta's most recent Form 10-K for the fiscal year ended September 30, 2014 and other periodic reports filed more recently with the Securities and Exchange Commission. Enanta cautions investors not to place undue reliance on the forward-looking statements contained in this release. These statements speak only as of the date of this release, and Enanta undertakes no obligation to update or revise these statements, except as may be required by law.

**ENANTA PHARMACEUTICALS, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**
**(in thousands, except per share amounts)**

| | Three Months Ended September 30, | | Year Ended September 30, | |
|---|---|---|---|---|
| | 2015 | 2014 | 2015 | 2014 |
| Revenue | $ 14,416 | $ 2,637 | $160,880 | $47,741 |
| Operating expenses | | | | |
| Research and development | 7,049 | 5,202 | 23,189 | 18,740 |
| General and administrative | 3,693 | 2,761 | 13,543 | 10,016 |
| Total operating expenses | 10,742 | 7,963 | 36,732 | 28,756 |
| Income (loss) from operations | 3,674 | (5,326) | 124,148 | 18,985 |
| Other income, net | 509 | 236 | 1,307 | 283 |
| Income (loss) before income taxes | 4,183 | (5,090) | 125,455 | 19,268 |
| Income tax (expense) benefit | 1,629 | 48 | (46,463) | 15,170 |
| Net income (loss) | $ 5,812 | $ (5,042) | $ 78,992 | $34,438 |
| | | | | |
| Net income (loss) per share | | | | |
| Basic | $ 0.30 | $ (0.27) | $ 4.23 | $ 1.88 |
| Diluted | $ 0.29 | $ (0.27) | $ 4.09 | $ 1.80 |
| Weighted average common shares outstanding | | | | |
| Basic | 18,714 | 18,589 | 18,673 | 18,355 |
| Diluted | 19,337 | 18,589 | 19,295 | 19,185 |

**ENANTA PHARMACEUTICALS, INC.**
**CONDENSED CONSOLIDATED BALANCE SHEETS**
**(in thousands)**

| | September 30, 2015 | September 30, 2014 |
|---|---|---|
| Assets | | |
| Current assets | | |
| Cash and cash equivalents | $ 21,726 | $ 30,699 |
| Short-term marketable securities | 123,479 | 60,065 |
| Accounts receivable | 15,289 | 1,724 |
| Unbilled receivables | 433 | 2,770 |
| Deferred tax assets | 1,447 | 11,123 |
| Prepaid expenses and other current assets | 8,267 | 1,594 |
| Total current assets | 170,641 | 107,975 |
| Property and equipment, net | 5,886 | 1,803 |
| Long-term marketable securities | 64,238 | 41,003 |
| Deferred tax assets | 4,640 | 4,198 |

| | | |
|---|---|---|
| Restricted cash | 608 | 436 |
| Total assets | $ 246,013 | $ 155,415 |
| Liabilities and Stockholders' Equity | | |
| Current liabilities | | |
| Accounts payable | $ 1,543 | $ 1,874 |
| Accrued expenses and other current liabilities | 3,962 | 2,872 |
| Income taxes payable | 1,199 | - |
| Total current liabilities | 6,704 | 4,746 |
| Warrant liability | 1,276 | 1,584 |
| Series 1 nonconvertible preferred stock | 163 | 202 |
| Other long-term liabilities | 1,713 | 229 |
| Total liabilities | 9,856 | 6,761 |
| Total stockholders' equity | 236,157 | 148,654 |
| Total liabilities and stockholders' equity | $ 246,013 | $ 155,415 |

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