

ENANTA PHARMACEUTICALS INC

Form S-1/A

December 18, 2012

Table of Contents

As filed with the Securities and Exchange Commission on December 18, 2012

Registration No. 333-184779

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**Amendment No. 2**

to

**FORM S-1**

**REGISTRATION STATEMENT**

**UNDER**

**THE SECURITIES ACT OF 1933**

**ENANTA PHARMACEUTICALS, INC.**

*(Exact name of registrant as specified in its charter)*

Edgar Filing: ENANTA PHARMACEUTICALS INC - Form S-1/A

**DELAWARE**  
*(State or other jurisdiction of  
incorporation or organization)*

**2834**  
*(Primary Standard Industrial  
Classification Code Number)*  
**500 Arsenal Street**

**04-3205099**  
*(I.R.S. Employer  
Identification Number)*

**Watertown, Massachusetts 02472**

**(617) 607-0800**

*(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)*

**Jay R. Luly, Ph.D.**

**President and Chief Executive Officer**

**Enanta Pharmaceuticals, Inc.**

**500 Arsenal Street**

**Watertown, Massachusetts 02472**

**(617) 607-0800**

*(Name, address, including zip code, and telephone number, including area code, of agent for service)*

***Copies to:***

**Nathaniel S. Gardiner, Esq.**

**Stacie S. Aarestad, Esq.**

**Edwards Wildman Palmer LLP**

**111 Huntington Avenue**

**Boston, Massachusetts 02199**

**(617) 239-0100**

**Richard D. Truesdell, Jr., Esq.**

**Davis Polk & Wardwell LLP**

**450 Lexington Avenue**

**New York, New York 10017**

**(212) 450-4000**

**Approximate date of commencement of proposed sale to public:** As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. "

## Edgar Filing: ENANTA PHARMACEUTICALS INC - Form S-1/A

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer "      Accelerated filer "      Non-accelerated filer       Smaller reporting company "

(Do not check if a smaller reporting company)

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.**

**Table of Contents**

**The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.**

**Subject to completion, dated December 18, 2012**

**Prospectus**

**Shares**

**COMMON STOCK**

This is the initial public offering of common stock of Enanta Pharmaceuticals, Inc. We are selling \_\_\_\_\_ shares of common stock. Prior to this offering, there has been no public market for our common stock. The initial public offering price of our common stock is expected to be between \$ \_\_\_\_\_ and \$ \_\_\_\_\_ per share.

We have applied to list our common stock on The NASDAQ Global Market under the symbol ENTA.

We are an emerging growth company as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, may elect to comply with certain reduced public company reporting requirements for future filings.

	<b>Per share</b>	<b>Total</b>
Initial public offering price	\$	\$
Underwriting discounts and commissions	\$	\$
Proceeds to Enanta, before expenses	\$	\$

We have granted the underwriters an option to purchase up to \_\_\_\_\_ additional shares of common stock to cover over-allotments, if any.

***Investing in our common stock involves risk. See Risk Factors beginning on page 10.***

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares on or about \_\_\_\_\_, 2012.

**J.P. Morgan**

**Credit Suisse**

**Leerink Swann**  
, 2012

**JMP Securities**

**Table of Contents**

We and the underwriters have not authorized anyone to provide any information other than that contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where such offers and sales are permitted. The information in this prospectus or any free writing prospectus is accurate only as of its date, regardless of its time of delivery or of any sale of shares of our common stock offered hereby. Our business, financial condition, results of operations and prospects may have changed since that date. We will update this prospectus as required by law.

**TABLE OF CONTENTS**

	<b>Page</b>
<u>Prospectus Summary</u>	1
<u>Risk Factors</u>	10
<u>Special Note Regarding Forward-Looking Statements</u>	38
<u>Market, Industry and Other Data</u>	39
<u>Use of Proceeds</u>	40
<u>Dividend Policy</u>	40
<u>Capitalization</u>	41
<u>Dilution</u>	43
<u>Selected Financial Data</u>	45
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	47
<u>Business</u>	67
	<b>Page</b>
<u>Management</u>	98
<u>Executive Compensation</u>	104
<u>Related Party Transactions</u>	109
<u>Principal Stockholders</u>	112
<u>Description of Capital Stock</u>	116
<u>Shares Eligible for Future Sale</u>	121
<u>Material U.S. Federal Tax Considerations For Non-U.S. Holders of Common Stock</u>	124
<u>Underwriting</u>	128
<u>Legal Matters</u>	132
<u>Experts</u>	132
<u>Where You Can Find More Information</u>	132
<u>Index to Financial Statements</u>	F-1

Until \_\_\_\_\_, 2012 (the 25<sup>th</sup> day after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third party research, surveys and studies are reliable, we have not independently verified such data.

The Enanta name and logo are our trademarks. This prospectus also includes trademarks, trade names and service marks of other persons. All other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners.

**Table of Contents**

**PROSPECTUS SUMMARY**

*This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, including the more detailed information set forth under Risk Factors and our financial statements and the related notes appearing at the end of this prospectus, before making an investment decision. Some of the statements in this prospectus are forward-looking statements. See Special Note Regarding Forward-Looking Statements. In this prospectus, unless the context otherwise requires, references to we, us, our, or Enanta refer to Enanta Pharmaceuticals, Inc.*

**Overview**

We are a research and development-focused biotechnology company that uses its robust chemistry-driven approach and drug discovery capabilities to create small molecule drugs in the infectious disease field. We are discovering and developing inhibitors designed for use against the hepatitis C virus, referred to as HCV. We believe that a successful approach to a complete cure for HCV in most patients will likely require treatment with a combination of drugs that attack different mechanisms necessary for replication and survival of HCV. Further, as there are many variants of HCV, we are developing inhibitors that may be used in multiple combination therapies, each designed and tested for effectiveness against one or more of those variants. Our development of inhibitors for validated HCV target mechanisms, as well as our collaborations with Abbott Laboratories and Novartis, should allow us to participate in multiple unique drug combinations as we seek the best combination therapies for HCV in its various forms. Total worldwide sales of HCV therapies were over \$3.5 billion in 2011. We believe that annual worldwide sales of these therapies and future approved therapies could increase sales in this market to \$10 to \$20 billion within the next ten years. In addition to our HCV programs, we have used our internal research capabilities to discover a new class of antibiotics which we are developing for the treatment of multi-drug resistant bacteria, including methicillin-resistant *Staphylococcus aureus* bacteria, also referred to as MRSA. We have utilized our internal chemistry and drug discovery capabilities and our collaborations to generate all of our development-stage programs, and we have active research efforts to broaden our infectious disease drug pipeline.

We are pursuing four fundamental, validated targets within the HCV field that represent a broad approach to the disease and specifically address the urgent unmet medical needs for the treatment of HCV. The following table summarizes our product development pipeline in HCV antivirals as well as MRSA antibiotics:

Note: /r refers to ritonavir; NS5A refers to Abbott's NS5A inhibitor ABT-267; NNuc refers to Abbott's non-nucleoside polymerase inhibitor ABT-333; RBV refers to ribavirin.

---

## **Table of Contents**

As detailed above, our only product candidate that has advanced beyond Phase 2 clinical trials is ABT-450. Phase 3 trials of ABT-450 in combination therapy started in October 2012. Phase 3 clinical trials are often lengthy and usually involve from many hundred to thousands of patients. We estimate that it will likely be at least two years before a New Drug Application, or NDA, for one of our collaborators' combination therapies could be approved by the FDA.

From our inception through September 30, 2012, we have generated \$173.9 million from our collaborations (including those with Abbott and Novartis) in the form of upfront, milestone and funded research payments as well as equity investments. The total of these amounts is more than double the amount of our funding from venture capital equity investments, the last of which occurred in 2006. As of September 30, 2012, we had \$45.4 million in cash and investments. In addition, under our collaboration with Novartis, we are entitled to receive an \$11.0 million milestone payment based on Novartis' November 2012 initiation of dosing in a Phase 1 clinical trial that includes EDP-239 and under our collaboration with Abbott, we are entitled to receive a \$15.0 million milestone payment based on Abbott's November 2012 initiation of dosing in a Phase 3 clinical trial that includes ABT-450. We are also eligible to receive over the next several years an aggregate of \$430 million based on potential future pre-commercialization milestones under our Abbott and Novartis collaborations, assuming successful clinical trial results for the respective collaboration programs and our collaborators' continued development of our product candidates through successful regulatory and reimbursement approvals in the United States and other major markets. In addition, we are also eligible to receive tiered royalties ranging on a blended basis from the low double digits up to the high teens on worldwide net sales of any protease inhibitors or NS5A inhibitors under the collaborations, as well as sales milestones under our Novartis collaboration.

### **ABT-450, a Protease Inhibitor for HCV Infection**

ABT-450, discovered through our collaboration with Abbott, is a potent protease inhibitor that has demonstrated *in vitro* potency against known resistant HCV mutants. In Phase 1 studies, ABT-450 co-administered with ritonavir, a commonly used boosting agent to increase the blood concentrations of many protease inhibitors, was shown to be safe and well tolerated. Co-administration of ABT-450 with ritonavir, which we refer to together as ABT-450/r, has enabled once-daily dosing of ABT-450. Phase 2 studies have demonstrated the efficacy of ABT-450/r in patients with chronic HCV, and other interferon-free Phase 2 studies of ABT-450-containing regimens continue. In addition, Abbott has announced Phase 3 studies of ABT-450/r for the treatment of HCV in combination with Abbott's polymerase and NS5A inhibitors, with and without ribavirin. While Abbott and other companies are developing interferon-free and interferon/ribavirin-free HCV therapies in clinical trials, the efficacy of this approach has not yet been proven conclusively, nor has it resulted yet in any product approved by the FDA.

We believe that a treatment regimen containing ABT-450/r may have significant advantages over currently approved HCV treatment regimens containing protease inhibitors because of the following key attributes:

*Improved Antiviral Activity.* Compared to the current market leader, telaprevir (Incivek®, Vertex Pharmaceuticals), ABT-450 has demonstrated superior antiviral activity against HCV in patients.

*No Interferon.* Current HCV therapy still includes injected interferon, which is often associated with flu-like symptoms, fatigue, headaches and nausea during treatment. ABT-450/r, however, is being developed in a number of interferon-free regimens.

*Tolerability.* Serious side effects of current regimens containing protease inhibitors include rash, anemia, itching and gastrointestinal effects. In contrast, most side effects in clinical trials to date of ABT-450/r were mild to moderate.

*Shorter Treatment Regimen.* ABT-450/r is being tested in various treatment combinations that are only 12 weeks in duration, as compared to the 24 to 48 weeks of treatment required with current interferon-containing regimens.

*More Convenient Treatment Regimen.* ABT-450/r is being developed for oral, once-daily dosing. All of the combinations including ABT-450/r that Abbott is testing include only orally administered drugs dosed either once or twice daily. By comparison, current approved treatment regimens require dosing of a protease inhibitor approximately every 8 hours as well as weekly interferon injections.





---

**Table of Contents**

In the first quarter of 2010, we and Abbott announced the advancement of ABT-450/r into Phase 2 clinical trials. The objective of the initial Phase 2 study was to assess the safety, tolerability, pharmacokinetics and antiviral activity of multiple-dose strengths of ABT-450/r in treatment-naïve adults (*i.e.*, those who have not previously received treatment for HCV) infected with HCV genotype 1, the most common genotype globally. This study with ABT-450/r paved the way for additional Phase 2 combination studies that use interferon-free regimens.

The Phase 2 Co-Pilot study, which began in May 2011, consisted of HCV genotype 1, non-cirrhotic patients enrolled in an open-label trial of a 12-week interferon-free regimen consisting of ABT-450/r once daily plus ABT-333 (Abbott's non-nucleoside polymerase inhibitor) 400 mg twice daily plus weight-based ribavirin, a commonly used oral antiviral, twice daily (1000-1200 mg total daily dose). Two different doses of ABT-450/r were evaluated (250/100 mg; 150/100 mg) in treatment-naïve patients, 85% of whom were infected with the harder-to-treat genotype 1a virus (compared to genotype 1b); treatment-experienced patients were also assessed, 94% of whom were infected with genotype 1a. Results demonstrated a sustained virologic response 12 weeks after conclusion of treatment, or SVR<sub>12</sub>, in 93-95% of treatment-naïve HCV genotype 1-infected patients and in 47% of previous non-responders. Co-Pilot is the first 12-week interferon-free regimen to date with high SVR rates and activity that appears not to be affected by HCV genotype 1 subtype. AEs were mild or moderate, and the most common were fatigue, nausea and headache.

The Phase 2b Aviator study, which began in October 2011, consisted of HCV genotype 1, non-cirrhotic patients enrolled in an open-label trial of several 12-week interferon-free regimens consisting of two or three direct acting antivirals, or DAAs, with and without ribavirin. One combination in the study consisted of ABT-450/r 100/100 to 200/100 mg once daily, plus ABT-267 (Abbott's NS5A inhibitor) 25 mg once daily, plus ABT-333 (Abbott's non-nucleoside polymerase inhibitor) twice daily (400 mg total daily dose), plus weight-based ribavirin twice daily (1000-1200 mg total daily dose). As reported in an initial data abstract from the ongoing study, this regimen was evaluated in treatment-naïve patients and treatment-experienced patients who were null responders. Results from this ongoing trial demonstrated SVR<sub>12</sub> in 99% of treatment-naïve HCV genotype 1-infected patients and in 93% of previous null responders (as compared with 47% SVR<sub>12</sub> seen in the Co-Pilot study as detailed above). The most common AEs were fatigue (28% and 27%) and headache (28% and 31%) for treatment-naïve and previous null responders, respectively. Initial results from the Pilot, Co-Pilot and Aviator studies provide compelling support for the potential development of an interferon-free combination therapy containing ABT-450 for treatment of HCV.

Other Phase 2 studies of additional interferon-free ABT-450/r combinations are underway. The Navigator study, which began in September 2011, is evaluating ABT-450/r with Abbott's NS5A inhibitor ABT-267, with and without ribavirin. Abbott also started a Phase 2b Pearl I study of a combination of ABT-450/r with only ABT-267 in August 2012.

In November 2012, Abbott announced the full scope of its initial Phase 3 registrational trials program for an ABT-450-containing regimen for treating genotype 1-infected patients, including six Phase 3 trials designed for a total of 2,200 patients using a combination of three DAAs ABT-450/r (protease inhibitor), ABT-267 (NS5A inhibitor) and ABT-333 (non-nucleoside polymerase inhibitor) with and without ribavirin. Abbott had previously reported the start of three of these Phase 3 clinical trials and announced that it expected regulatory filings in 2014. The first of these reported trials, Turquoise II, which is in patients with compensated cirrhosis, will include two co-formulated tablets of ABT-450/r and ABT-267, or ABT-450/r/ABT-267, once daily, plus ABT-333 in one tablet twice daily, plus ribavirin. The other two trials, Sapphire I and Sapphire II, will be double-blind, placebo-controlled trials of the same three DAAs, co-administered with ribavirin. Sapphire I is in treatment-naïve patients and Sapphire II is in patients who have had prior treatment with interferon plus ribavirin. Three additional Phase 3 trials will study the same three-DAA combination, with and without ribavirin, in treatment-naïve genotype 1a-infected patients, treatment-naïve genotype 1b-infected patients and treatment-experienced genotype 1b-infected patients, respectively. In addition, Abbott has announced that it is conducting additional exploratory clinical studies to determine if a co-formulated tablet of ABT-450/r and ABT-267 dosed once daily can provide high cure rates in specific HCV populations. Abbott has also announced that its development plan would support a target commercial launch of a combination HCV therapy in early 2015, and that there is a potential worldwide market opportunity of

## **Table of Contents**

\$2 billion or more for the combinations being developed. Abbott's projections are subject to risks and uncertainties. One or more Phase 3 trials containing ABT-450/r could take longer than anticipated to complete or could have unexpected results, the FDA could find that the results of these trials are not adequate to support marketing approval and the FDA could require additional clinical trials as a condition for approval.

We believe that we, together with Abbott, will obtain exclusivity in ABT-450 in the United States and other major-market jurisdictions based on pending composition and use patent claims for ABT-450, which we expect will continue at least into 2029, assuming all such patents are issued. Additional HCV protease inhibitors discovered within the Enanta-Abbott collaboration are in preclinical studies.

### **Next-Generation HCV Protease Inhibitor**

Abbott is also developing a next-generation protease inhibitor discovered within the Enanta-Abbott collaboration. Abbott has announced that this protease inhibitor has demonstrated activity in preclinical *in vitro* testing against a broad range of HCV genotypes, including variants that have shown strong resistance to first generation protease inhibitors. Abbott has also announced that this next-generation protease inhibitor was designed to enable once-daily dosing without ritonavir and to be co-formulated with Abbott's next-generation NS5A inhibitor. Abbott initiated a Phase 1 clinical trial of this next-generation protease inhibitor in November 2012.

### **EDP-239, an NS5A Inhibitor for HCV Infection**

EDP-239 is the lead NS5A inhibitor discovered by Enanta. We entered into a collaboration with Novartis in February 2012, granting Novartis exclusive, worldwide rights to develop, manufacture and commercialize EDP-239. The compound has demonstrated potent activity against major genotypes in the replicon assay, which is a common *in vitro* test for determining potency of an active compound in reducing HCV replication. In addition, EDP-239 has additive to synergistic antiviral activity when used in combination with other anti-HCV therapeutics in the replicon assay. Preclinical studies support excellent permeability and absorption potentials in humans, with preferential targeting to the liver, which is the target site of infection. Human pharmacokinetic and pharmacodynamic modeling suggests a low, once-daily dose for future clinical testing. In November 2012, Novartis initiated a Phase 1 trial of EDP-239.

### **EDP-546, a Cyclophilin Inhibitor for HCV Infection**

In anticipation of resistance arising to first-generation HCV therapy that targets viral proteins, we have been developing an alternative host-targeted antiviral, or HTA, approach that targets the human host protein, cyclophilin, which is essential for replication of HCV. We have demonstrated in replicon assays that one of our lead cyclophilin targeting inhibitors, EDP-546, is a potent inhibitor of HCV replication and is more potent than the clinical stage cyclophilin inhibitor alisporivir, under development by Novartis.

EDP-546 is an HTA with a high barrier to resistance which in preclinical studies has demonstrated a number of important attributes. EDP-546 has demonstrated the potential to have additive to synergistic antiviral activity when used in combination with DAAs and has not generated cross-resistance in HCV variants that are resistant to several DAAs. In addition, the superior metabolic stability profile of the drug compared to alisporivir suggests the potential for once-daily dosing of EDP-546.

A number of additional preclinical studies of EDP-546 have been initiated, and we expect to initiate a Phase 1 clinical trial in the first half of 2014. In addition to EDP-546, we are continuing to generate and characterize a number of additional cyclophilin inhibitors in the discovery phase.

### **Nucleotide Polymerase Inhibitor Program for HCV Infection**

We also have a program to develop nucleotide inhibitors to HCV NS5B polymerase, which is another DAA mechanism considered to have a high barrier to resistance. Our researchers have identified a promising nucleotide lead series with significant antiviral potency *in vitro*. One of our lead compounds has demonstrated better *in vitro* potency than a reference clinical stage nucleotide inhibitor, GS-7977, under development by Gilead Sciences.

We have an ongoing discovery effort in this inhibitor class and are considering a number of compounds for further development. We plan to select a candidate in 2013 that is suitable for advancement into preclinical studies.



## **Table of Contents**

### **EDP-788 and Our Bicyclolide Antibiotics**

Through our internal chemistry efforts, we have created a new family of macrolide antibiotics called Bicyclolides that overcomes resistance and possesses a significantly improved target product profile compared to existing macrolides such as Zithromax<sup>®</sup> and Biaxin<sup>®</sup>M. Our lead Bicyclolide antibiotic product candidate is EDP-788, which we are developing for use as an intravenous drug in the hospital setting and for oral dosing in the home setting. EDP-788 is a prodrug, which means that it is inactive until it is converted in the body into an active compound. EDP-788 is a highly water-soluble molecule which, when administered in preclinical models, is cleanly and rapidly converted into the active compound.

The active compound generated from EDP-788 is EDP-322, a Bicyclolide we developed that demonstrates a broad spectrum of activity against many bacterial organisms, including MRSA. Preclinical safety studies performed with EDP-322 presented no significant concerns. EDP-322 was evaluated in normal healthy volunteers in two double-blind, randomized, placebo-controlled Phase 1 trials, evaluating pharmacokinetic and safety parameters. EDP-322 showed good pharmacokinetics and was well tolerated in all dose groups. Adverse events were limited to minor gastrointestinal effects attributed to inadequate water solubility of the drug, which we would not expect when dosing with the water-soluble EDP-788. Neither EDP-322, nor any other compound in the class of Bicyclolides, has yet been shown to be effective in pivotal clinical trials or resulted in any product approved by the FDA.

All current development activities are focused on intravenous and oral formulations of EDP-788, with additional IND-enabling studies in progress and the initiation of clinical trials planned for the first half of 2014. Our preclinical development of EDP-788 is funded under our contract with the National Institute of Allergy and Infectious Diseases, or NIAID, with potential for further NIAID funding of early clinical development.

### **Collaboration with Abbott Laboratories**

In November 2006, we entered into a Collaborative Development and License Agreement with Abbott Laboratories to develop and commercialize HCV NS3 and NS3/4A protease inhibitors worldwide. Abbott has funded all research and development of our protease inhibitors since we entered into the collaboration and is responsible for all costs associated with the development, manufacturing and commercialization of ABT-450 and other compounds under this collaboration agreement. We received \$57.2 million from Abbott upon signing the collaboration agreement and their simultaneous purchase of preferred stock from us in 2006, and we received a \$40.0 million milestone payment in December 2010 following the successful completion of a Phase 2a clinical trial. Based on Abbott's November 2012 initiation of dosing in a Phase 3 clinical trial that includes ABT-450, we are entitled to receive a \$15.0 million milestone payment. Assuming Abbott's successful development of the first protease inhibitor product, we will also be eligible to receive \$195 million of additional pre-commercialization milestone payments, as well as additional milestone payments for any follow-on protease inhibitor products and tiered royalties ranging on a blended basis from the low double digits up to the high teens per product on Abbott's net sales, if any, allocable to our collaboration's protease inhibitors.

### **Collaboration with Novartis**

In February 2012, we entered into a Collaboration and License Agreement with Novartis granting Novartis exclusive, worldwide rights to develop, manufacture and commercialize EDP-239, our lead compound from our NS5A inhibitor program. Novartis is responsible for all costs associated with the development, manufacture and commercialization of EDP-239, EDP-239-containing combinations and any follow-on NS5A inhibitors, as well as funding our efforts to discover follow-on NS5A inhibitors at least through February 2013. We received an upfront payment of \$34.4 million in March 2012, and we are entitled to receive an \$11.0 million milestone payment based on Novartis' November 2012 initiation of dosing in a Phase 1 clinical trial that includes EDP-239. We are eligible to receive up to \$395 million of additional payments if Novartis achieves specified clinical, regulatory, and commercial milestones. We are also eligible to receive tiered royalties ranging on a blended basis from the low double digits up to the high teens on any net sales allocable to our collaboration's NS5A inhibitors.

### **Our Strategy**

Our primary objective is to become a leader in the infectious disease field, with a focus on HCV and multi-drug resistant bacterial infections. Our strategy includes the following key elements:

Develop compounds against four fundamental, validated HCV targets to give us multiple opportunities to participate in one or more of the potentially successful combination therapies for HCV in its various forms;



## **Table of Contents**

Collaborate with large pharmaceutical partners to accelerate the development and commercialization of our lead HCV compounds in combination therapies;

Develop independently our own next generation HCV compounds and combination therapies with lower susceptibility to viral resistance;

Continue to leverage and fortify our intellectual property portfolio; and

Invest in research and early-stage development of product candidates for infectious diseases.

## **Risks Associated with our Business**

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the **Risk Factors** section of this prospectus beginning on page 10. These risks include, among others, our financial prospects being substantially dependent upon the development and marketing efforts of Abbott and Novartis for any drug product candidates incorporating ABT-450 and EDP-239, respectively; substantial competition in the market for HCV and for anti-infectives generally; our lack of clinical development experience; our need to attract and retain senior management and key scientific personnel; risks associated with the lengthy, expensive and uncertain process of clinical development for and regulatory approval of our product candidates; difficulties in commercializing any future product candidates and achieving significant market acceptance of them; the potential for unfavorable pricing regulations, third-party reimbursement practices or related healthcare reform initiatives in the United States and in foreign jurisdictions; and the need to obtain and maintain adequate patent protection for our product candidates and avoid potential infringement of patents or other intellectual property rights of third parties.

We have not generated any revenue to date from product sales and have incurred significant operating losses since our inception in 1995 (other than during the years ended September 30, 2010, 2011 and 2012, when revenue from collaborations generated net income). As of September 30, 2012, we had an accumulated deficit of \$115.4 million and we expect we may incur losses in one or more future years. We are unable to predict the extent of future losses or when we will become profitable based on product sales, if at all. Even if we or our collaborators succeed in developing and commercializing one or more of our product candidates, we may never generate sufficient revenue to sustain profitability.

## **Our Corporate Information**

We were incorporated under the laws of the State of Delaware in 1995. Our principal executive offices are located at 500 Arsenal Street, Watertown, MA 02472 and our telephone number is (617) 607-0800. Our website address is [www.enanta.com](http://www.enanta.com). The information contained on, or that can be accessed through, our website is not a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

We are an **emerging growth company**, as defined in Section 2(a) of the Securities Act of 1933, or the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As such, we are eligible to take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not **emerging growth companies** including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We have not made a decision whether to take advantage of any or all of these exemptions. We could remain an **emerging growth company** for up to five years, or until the earliest of (a) the last day of the first fiscal year in which our annual gross revenue exceeds \$1 billion, (b) the date that we become a **large accelerated filer** as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter, or (c) the date on which we have issued more than \$1 billion in nonconvertible debt during the preceding three-year period.

The Enanta name and logo are our trademarks. This prospectus also includes trademarks, trade names and service marks of other persons. All other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners.





**Table of Contents**

**THE OFFERING**

Issuer	Enanta Pharmaceuticals, Inc.
Common stock offered by us	shares
Common stock to be outstanding after this offering	shares
Over-allotment option	The underwriters have an option for a period of 30 days to purchase up to additional shares of our common stock to cover over-allotments, if any.
Use of proceeds	We estimate that the net proceeds from this offering will be approximately \$ million, or approximately \$ million if the underwriters exercise their over-allotment option in full, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, assuming the shares are offered at \$ per share, the midpoint of the estimated price range set forth on the cover of this prospectus. We intend to use the net proceeds from this offering for clinical development of our internal product candidates, new research and development, working capital and other general corporate purposes.
Risk factors	You should read the Risk Factors section starting on page 10 of this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.

Proposed NASDAQ Global Market Symbol            ENTA

The number of shares of our common stock to be outstanding after this offering is based on 4,889,127 actual shares of our common stock outstanding as of September 30, 2012 and the conversion of all outstanding shares of our redeemable convertible preferred stock and our convertible preferred stock into an aggregate of 50,241,277 shares of our common stock upon the closing of this offering.

The number of shares of our common stock to be outstanding after this offering excludes:

7,635,307 shares of our common stock issuable upon the exercise of stock options outstanding as of September 30, 2012 at a weighted average exercise price of \$0.48 per share;

16,447 shares of our common stock issuable at an exercise price of \$1.91 per share upon the exercise of warrants outstanding at September 30, 2012, which warrants prior to the closing of this offering are exercisable to purchase Series E redeemable convertible preferred stock; and

613,844 additional shares of our common stock available for future issuance as of September 30, 2012 under our Amended and Restated 1995 Equity Incentive Plan.

Unless otherwise indicated, all information in this prospectus assumes or gives effect to:

the conversion of all outstanding shares of our redeemable convertible preferred stock and our convertible preferred stock into an aggregate of 50,241,277 shares of our common stock upon the closing of this offering;

no exercise of the outstanding options and warrants described above;

no exercise by the underwriters of their option to purchase up to                      additional shares of our common stock to cover over-allotments;

the amendment and restatement of our amended and restated certificate of incorporation and the amendment and restatement of our bylaws immediately prior to consummation of this offering; and

the        -for-        reverse stock split of our common stock to be effected prior to the closing of this offering.

**Table of Contents****SUMMARY FINANCIAL INFORMATION**

You should read the following summary financial data together with our financial statements and the related notes appearing at the end of this prospectus and the Management's Discussion and Analysis of Financial Condition and Results of Operations section of this prospectus.

We have derived the statement of operations data for the years ended September 30, 2010, 2011 and 2012 and the balance sheet data as of September 30, 2012 from our audited financial statements included elsewhere in this prospectus. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

	Year Ended September 30,		
	2010	2011	2012
	(in thousands, except per share data)		
<b>Statement of Operations Data:</b>			
Revenue	\$ 22,763	\$ 41,882	\$ 41,706
Operating expenses:			
Research and development	9,716	11,547	15,115
General and administrative	6,105	5,036	5,302
Total operating expenses	15,821	16,583	20,417
Income from operations	6,942	25,299	21,289
Other income (expense):			
Interest income	14	83	118
Interest expense		(3,161)	
Change in fair value of warrant liability	482	(686)	(8)
Therapeutic tax credit		750	
Gain on embedded derivative		670	
Other income (expense), net	309	355	
Total other income (expense), net	805	(1,989)	110
Income before income tax	7,747	23,310	21,399
Income tax benefit	157		
Net income	7,904	23,310	21,399
Accretion of redeemable convertible preferred stock to redemption value	(5,452)	(5,454)	(5,367)
Net income allocable to participating securities	(2,236)	(16,291)	(14,663)
Net income allocable to common stockholders	\$ 216	\$ 1,565	\$ 1,369
Net income per share allocable to common stockholders <sup>(1)</sup> :			
Basic	\$ 0.04	\$ 0.32	\$ 0.29
Diluted	\$ 0.04	\$ 0.31	\$ 0.26
Weighted average common shares outstanding <sup>(1)</sup> :			
Basic	4,873	4,824	4,693
Diluted	6,746	8,005	10,666
Pro forma net income per share allocable to common stockholders (unaudited) <sup>(2)</sup> :			
Basic			\$ 0.39
Diluted			\$ 0.35
Pro forma weighted average common shares outstanding (unaudited) <sup>(2)</sup> :			
Basic			54,934
Diluted			60,910



**Table of Contents**

	As of September 30, 2012	
	Actual	Pro Forma As Adjusted <sup>(3)</sup>
	(in thousands)	
<b>Balance Sheet Data:</b>		
Cash, cash equivalents and marketable securities	\$ 45,418	\$
Working capital <sup>(4)</sup>	41,574	
Total assets	52,162	
Warrant liability	2,001	
Redeemable convertible preferred stock	158,955	
Convertible preferred stock	327	
Total stockholders' equity (deficit)	(115,353)	

- (1) See Note 15 to our financial statements for further details on the calculation of basic and diluted net income per share allocable to common stockholders.
- (2) See Note 15 to our financial statements for further details on the calculation of pro forma net income per share allocable to common stockholders.
- (3) Gives effect to (1) the automatic conversion of all outstanding shares of our redeemable convertible preferred stock and convertible preferred stock into an aggregate of 50,241,277 shares of common stock upon the closing of this offering, (2) the automatic conversion of the warrants for Series E redeemable convertible preferred stock into warrants for 16,447 shares of common stock upon the closing of this offering, and (3) the issuance by us of \_\_\_\_\_ shares of common stock at an initial offering price of \$ \_\_\_\_\_ per share, the midpoint of the estimated price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. A \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the estimated price range set forth on the cover page of this prospectus, would increase (decrease) total stockholders' equity and total capitalization on a pro forma as adjusted basis by approximately \$ \_\_\_\_\_ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted data above is illustrative only and will be adjusted based on the actual initial public offering price and other terms of our initial public offering determined at pricing.
- (4) We define working capital as current assets less current liabilities.

**Table of Contents**

**RISK FACTORS**

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this prospectus, including our financial statements and the related notes appearing at the end of this prospectus and Management's Discussion and Analysis of Financial Condition and Results of Operations, before deciding whether to invest in our common stock. If any of the following risks actually occur, our business, growth prospects, operating results and financial condition could suffer materially, the trading price of our common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations and stock price.*

**Risks Related to Our Business**

*Our financial prospects for the next several years are substantially dependent upon the development and marketing efforts of Abbott for combination therapies incorporating ABT-450 for the treatment of HCV. Abbott may act in its best interest rather than in our best interest, which could adversely affect our business.*

We rely on Abbott to fund and conduct the clinical development and commercialization of ABT-450 and other protease inhibitors, over which Abbott has complete control. Our ability to generate significant revenue in the near term will depend primarily on the successful development, regulatory approval, marketing and commercialization by Abbott of combination therapies incorporating ABT-450. Such success is subject to significant uncertainty, and we have limited control over the resources, time and effort that Abbott may devote to ABT-450. Any of several events or factors could have a material adverse effect on our ability to generate revenue from Abbott's potential commercialization of ABT-450 in combination therapies. For example, Abbott:

may be unable to successfully complete the clinical development of an ABT-450-containing regimen;

may have to comply with additional requests and recommendations from the FDA, including additional clinical trials;

may not make all regulatory filings and obtain all necessary approvals from the FDA and similar foreign regulatory agencies;

may not commit sufficient resources to the development, regulatory approval, marketing and distribution of an ABT-450-containing regimen, whether for strategic reasons or otherwise due to a change in business priorities;

may cease to perform its obligations under the terms of our collaboration agreement;

may unilaterally terminate our collaboration agreement on specified prior notice without any reason and without any further commitment to continue development of any of our product candidates;

may not be able to manufacture our product candidate in compliance with requirements of the FDA and similar foreign regulatory agencies and in commercial quantities sufficient to meet market demand;

may not achieve market acceptance of combination therapies incorporating our product candidate by physicians, patients and third-party payors;

may not compete successfully with any such combination therapies against alternative products and therapies for HCV; and

may independently develop products that compete with our product candidate in the treatment of HCV.

We will not have access to all information regarding the products being developed and potentially commercialized by Abbott, including information about clinical trial design and execution, safety reports from clinical trials, spontaneous safety reports if the product is later approved and marketed, regulatory affairs, process development, manufacturing, marketing and other areas known by Abbott. Thus, our ability to keep our stockholders informed about the status of product candidates under our collaboration will be limited by the degree to which Abbott keeps us informed. If Abbott does not perform in the manner we expect or fulfill its responsibilities in a timely manner, or at all, the clinical development, regulatory approval and commercialization

## **Table of Contents**

efforts related to ABT-450 could be delayed or terminated or be commercially unsuccessful. In addition, Abbott has the right to make decisions regarding the development and commercialization of product candidates without consulting us, and may make decisions with which we do not agree. Conflicts between us and Abbott may arise if there is a dispute about the progress of the clinical development of a product candidate, the achievement and payment of a milestone amount, or the ownership of intellectual property developed during the course of our collaboration agreement. It may be necessary for us to assume responsibility at our own expense for the development of ABT-450 or other protease inhibitors. In that event, we would likely be required to limit the size and scope of one or more of our independent programs or increase our expenditures and seek additional funding which may not be available on acceptable terms or at all, and our business would be materially and adversely affected.

***Our prospects for successful development of EDP-239 or any other NS5A inhibitor are dependent upon the development and marketing efforts of Novartis. Novartis may act in its best interest rather than in our best interest, which could adversely affect our business.***

We rely on Novartis to fund and conduct the clinical development of EDP-239 and any other NS5A inhibitor product candidates under our collaboration, and for the successful regulatory approval, marketing and commercialization of one or more of them. Such success will be subject to significant uncertainty, and we have limited control over the resources, time and effort that Novartis may devote to our NS5A inhibitors. Moreover, Novartis may terminate the collaboration without any reason on 120 days notice to us. As with our Abbott collaboration, any of several events or factors could have a material adverse effect on our ability to generate revenue from Novartis development and commercialization of EDP-239, including ones similar to those described in the preceding risk factor regarding our Abbott collaboration.

If Novartis does not perform in the manner we expect or fulfill its responsibilities in a timely manner, or at all, the clinical development, regulatory approval and commercialization efforts related to EDP-239 could be delayed, terminated or be commercially unsuccessful. Conflicts between us and Novartis may arise if there is a dispute with Novartis similar to potential disputes with Abbott about any of the matters mentioned in the preceding risk factor. It may become necessary for us to assume the responsibility at our own expense for the development of EDP-239 or other NS5A inhibitors. In that event, we would likely be required to limit the size and scope of one or more of our independent programs or increase our expenditures and seek additional funding which may not be available on acceptable terms or at all, and our business would be materially and adversely affected.

***We and our collaborators face substantial competition in the market for HCV drugs and for anti-infectives generally, which may result in others discovering, developing or commercializing products before us or doing so more successfully than we and our collaborators.***

The pharmaceutical and biotechnology industries are intensely competitive and rapidly changing. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations are commercializing or pursuing the development of products that target HCV, MRSA and other infectious diseases that we may target in the future.

We expect our current and future product candidates to face intense and increasing competition as new products enter the HCV and antibacterial markets and advanced technologies become available, particularly in the case of HCV in combinations with existing products and other new products. Two drug products, Incivek (telaprevir) of Vertex and Victrelis (boceprevir) of Merck, were approved in 2011 by the FDA for the treatment of HCV in combination with interferon and ribavirin, which in combination were the previous standard of care. These and other potential new treatment regimens may render our HCV product candidates noncompetitive. In particular, our HCV product candidates may not be able to compete successfully with other products in development in multiple classes of inhibitors of HCV, including protease inhibitors, polymerase inhibitors (nucleoside and non-nucleoside), NS5A inhibitors and cyclophilin inhibitors, under development by companies such as Achillion, Astra-Zeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Gilead, GlaxoSmithKline, Idenix, Johnson & Johnson, Medivir, Merck, Pfizer, Presidio, Roche and Vertex, as well as by our collaborators.



## **Table of Contents**

Our MRSA program faces competition from other therapeutic products that address serious Gram-positive bacterial infections, such as Cubicin<sup>®</sup>, marketed by Cubist; vancomycin, marketed generically by Abbott, Shionogi and others; and Zyvox<sup>®</sup>, marketed by Pfizer, as well as future competition from drug candidates currently in clinical development.

Many of our competitors have substantially greater commercial infrastructure and better financial, technical and personnel resources than we have, as well as drug candidates in late-stage clinical development.

Our competitors may succeed in developing competing products and obtaining regulatory approval before we or our collaborators do with our product candidates, or they may gain acceptance for the same markets that we are targeting. If we are not first to market with one of our product candidates, our competitive position could be compromised because it may be more difficult for us to obtain marketing approval for that product candidate and successfully market that product candidate as a second competitor. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful.

Competitive products in the form of other treatment methods or a vaccine for HCV or MRSA may render our product candidates licensed to others, as well as any future product candidates we may develop ourselves, obsolete or noncompetitive. Even if successfully developed and subsequently approved by the FDA, our product candidates will face competition based on their safety and effectiveness, the timing and scope of the regulatory approvals, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent position and other factors. If the product candidates developed under our collaboration agreements with Abbott and Novartis face competition from generic products, the collaboration agreements provide that the royalty rate applicable to such product candidates is reduced significantly by a specified percentage on a product-by-product, country-by-country basis. If we and our collaborators are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition, operations and stock price will suffer.

***We have no approved products and no clinical development experience, which makes it difficult to assess our ability to develop and commercialize our future product candidates.***

To date, Abbott has been and will continue to be responsible for all of the clinical development of our ABT-450 and other protease inhibitor product candidates, and Novartis is responsible for all future clinical development of our EDP-239 and other NS5A product candidates. We have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties associated with late stage clinical development, regulatory approval and commercialization of therapeutic products such as the ones we plan to develop independently. For example, to execute our business plan for development of our independent programs for cyclophilin inhibitors and nucleotide polymerase inhibitors for HCV and antibiotics for MRSA, we will need to successfully:

execute clinical development of our future product candidates;

obtain required regulatory approvals for the development and commercialization of our future product candidates;

develop and maintain any future collaborations we may enter into for any of these programs;

build and maintain robust sales, distribution and marketing capabilities, either independently or in collaboration with future collaborators;

gain market acceptance for our future product candidates; and

manage our spending as costs and expenses increase due to clinical trials, regulatory approvals and commercialization.

If we are unsuccessful in accomplishing these objectives, we may not be able to successfully develop and commercialize our future product candidates and expand our business or continue our operations.



## Table of Contents

*We may require substantial additional financing to achieve our goals if the development and commercialization of ABT-450 or EDP-239 is delayed or terminated. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development efforts.*

Since our inception, most of our resources have been dedicated to the discovery and preclinical development of our product candidates. In particular, we have expended, and believe that we will continue to expend for the foreseeable future, substantial resources discovering and developing our proprietary preclinical product candidates. These expenditures will include costs associated with research and development, preclinical manufacturing of product candidates, conducting preclinical experiments and clinical trials and obtaining regulatory approvals, as well as commercializing any products later approved for sale. In our fiscal year ending September 30, 2013, we expect to incur approximately \$16 million of costs associated with research and development, which amount is exclusive of costs incurred by our collaborators in developing our licensed product candidates ABT-450 and EDP-239.

Because the outcome of planned and anticipated clinical trials of our product candidates by our collaborators is highly uncertain, we cannot reasonably estimate the timing or amounts, if any, of future milestone payments we will receive from these collaborators. If we do not continue to receive substantial milestone payments from the continued development of our product candidates, we may require substantial additional financing.

Our future capital requirements depend on many factors, including:

whether our existing collaborations continue to generate substantial milestone payments, and ultimately royalties, to us;

the number and characteristics of the future product candidates we pursue;

the scope, progress, results and costs of researching and developing any of our future product candidates on our own, and conducting preclinical research and clinical trials;

the timing of, and the costs involved in, obtaining regulatory approvals for any future product candidates we develop independently;

the cost of commercialization activities, if any, of any future product candidates we develop independently that are approved for sale, including marketing, sales and distribution costs;

the cost of manufacturing our future product candidates and any products we successfully commercialize independently;

our ability to maintain existing collaborations and to establish new collaborations, licensing or other arrangements and the financial terms of such agreements;

the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patents, including litigation costs and the outcome of such litigation; and

the timing, receipt and amount of sales of, or royalties on, ABT-450, EDP-239 and our future product candidates, if any.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. Our ability to raise funds will depend on financial, economic and market conditions and other factors, many of which are beyond our control. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other research and development activities for one or more of our product candidates.

*If we are not successful in discovering further product candidates in addition to ABT-450 and EDP-239, our ability to expand our business and achieve our strategic objectives may be impaired.*

Research programs designed to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying additional potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

the research methodology used may not be successful in identifying additional potential product candidates;

## Table of Contents

competitors may develop alternatives that render our future product candidates obsolete;

a future product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria; and

a future product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all.

If we are unable to identify additional compounds suitable for preclinical and clinical development, we may not be able to obtain sufficient product revenue in future periods, which likely would result in significant harm to our financial position and adversely impact our stock price.

***If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop our product candidates, conduct our clinical trials and commercialize our product candidates.***

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, particularly Jay R. Luly, Ph.D., our Chief Executive Officer and President, and Yat Sun Or, Ph.D., our Senior Vice President, Research and Development and Chief Scientific Officer, as well as other employees and consultants. Although none of these individuals has informed us to date that he intends to retire or resign in the near future, the loss of services of any of these individuals or one or more of our other members of senior management could delay or prevent the successful development of our future product candidates.

Although we have not historically experienced unique difficulties attracting and retaining qualified employees, we could experience such problems in the future. For example, competition for qualified personnel in the biotechnology and pharmaceutical field is intense. In addition, we will need to hire additional personnel as we expand our clinical development and commercial activities. We may not be able to attract and retain quality personnel on acceptable terms.

***We have incurred a substantial cumulative net loss since our inception and anticipate that we may incur substantial operating losses in one or more years in the future. To date, our principal sources of revenue have been our collaboration agreements, including our current agreements with Abbott and Novartis, and future payments under these agreements are uncertain. We have had no products approved for commercial sale. As a result, our ability to achieve sustained profitability is unproven.***

We have incurred cumulative net losses since our inception, and as of September 30, 2012, we had an accumulated deficit of \$115.4 million. Our net income in the fiscal year ended September 30, 2010 resulted primarily from the conclusion of a previous collaboration which accelerated \$16.2 million of deferred revenue into fiscal 2010 that was related to cash received and spent in prior years, and our net income in the fiscal year ended September 30, 2011 resulted primarily from a substantial milestone payment from Abbott. In the fiscal year ended September 30, 2012, our net income resulted primarily from a substantial upfront license payment from Novartis. We are entitled to receive an \$11.0 million milestone payment based on Novartis' November 2012 initiation of dosing in a Phase 1 clinical trial that includes EDP-239 and a \$15.0 million milestone payment based on Abbott's November 2012 initiation of dosing in a Phase 3 clinical trial that includes ABT-450. There is no assurance, however, that we will recognize any additional collaboration revenue during fiscal 2013 or report net income in fiscal 2013 or subsequent years. To date, we have not commercialized any products or generated any revenue from product sales, directly or through any collaborator.

Our principal source of revenue has been our collaboration agreements, including our current agreements with Abbott and Novartis. Future milestone payments are uncertain because our collaborators may choose not to continue research or development activities for one or more potential product candidates. For example, under a prior collaboration for the development of an antibiotic product candidate in Japan, our collaborator decided in 2010 not to pursue further development of the licensed product candidate due to its limited potency against *Haemophilus influenzae* in clinical trials of community-acquired pneumonia, which then resulted in our collaboration being terminated. In addition, we may not achieve the specified milestones, our product candidates may not be approved by the FDA or other regulatory authorities or, if they are approved, may not be accepted in the market. If we are unable to develop and commercialize one or more of our product candidates, either alone or with our collaborators, or if any such product candidate does not achieve market acceptance, we may never

## **Table of Contents**

generate sufficient product royalties or product sales. Even if we do generate product royalties or product sales, we may never achieve or sustain profitability on a quarterly or annual basis. Our failure to sustain profitability would depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. A decline in the market price of our common stock also could cause you to lose all or a part of your investment.

*We may encounter difficulties in managing our growth and expanding our operations successfully.*

As we seek to advance our product candidates through clinical trials, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

*Our government funded contract for our antibiotic program is subject to termination and uncertain future funding and there is no certainty that we will be able to enter into new agreements to provide these funds.*

Under our agreement with the National Institute of Allergy and Infectious Diseases, or NIAID, a division of the National Institutes of Health, an agency of the United States Department of Health and Human Services, to support our antibiotic program, NIAID has the option to make future payments to fund our early clinical development of EDP-788. If NIAID exercises each option under the agreement, the aggregate funding commitment will be \$42.7 million, of which only \$14.3 million has been committed for the first 30 months of our work under the agreement. After the first 30 months, NIAID has several options to decide whether it wants to continue the program in its sole discretion. In addition, the ability of government agencies such as NIAID to perform under these types of agreements is dependent upon adequate continued funding of the agencies and their programs. We have no control over the resources and funding NIAID may devote to our agreement, which may be subject to periodic renewal and which generally may be terminated by NIAID at any time. Any significant reductions in the funding of U.S. government agencies or in the funding areas targeted by our business could materially and adversely affect our antibiotic program and our results of operations and financial condition. If we fail to satisfy our contractual obligations under the agreement, the applicable Federal Acquisition Regulations allow the government to terminate the agreement in whole or in part, and we may be required to perform corrective actions, including but not limited to delivering to the government any incomplete work. If NIAID does not exercise future funding options under the agreement, terminates the agreement or fails to perform its responsibilities under the agreement, it could materially impact our antibiotic program and our financial results.

In addition, our contract related costs and fees, including allocated indirect costs, are subject to audits and adjustments by negotiation between us and the U.S. government. As part of the audit process, the government audit agency verifies that all charges made by a contractor against a contract are legitimate and appropriate. Audits may result in recalculation of contract revenues and non-reimbursement of some contract costs and fees. Any audits of our contract related costs and fees could result in material adjustments to our revenue. In addition, U.S. government contracts are conditioned upon the continuing availability of Congressional appropriations. Congress usually appropriates funds on a fiscal year basis even though contract performance may take several years. Consequently, at the outset of a major program, the contract is usually incrementally funded and additional funds are normally committed to the contract by the procuring agency as appropriations are made by Congress for future fiscal years. Any failure of NIAID to continue to fund our contract could have a material adverse effect on our business, results of operations and financial condition.

## Table of Contents

### **Risks Related to Development, Clinical Testing and Regulatory Approval of Our Product Candidates**

*Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes. If clinical trials are prolonged or delayed, we or our collaborators may be unable to commercialize our product candidates on a timely basis.*

Clinical testing is expensive and, depending on the stage of development, can take a substantial time period to complete. Its outcome is inherently uncertain, and failure can occur at any time during clinical development. Phase 3 trials of ABT-450 in combination therapy started in October 2012 and none of the other product candidates in our pipeline has yet advanced beyond Phase 2 clinical trials. The recently started ABT-450 Phase 3 trials or any future Phase 3 trials may fail to demonstrate sufficient safety and efficacy. Moreover, regulatory and administrative delays may adversely affect our or our collaborators' clinical development plans and jeopardize our or our collaborators' ability to attain product approval, commence product sales and generate revenues.

Clinical trials can be delayed for a variety of reasons, including delays related to:

reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

failure of third-party contractors, such as CROs, or investigators to comply with regulatory requirements;

delay or failure in obtaining the necessary approvals from regulators or institutional review boards, or IRBs, in order to commence a clinical trial at a prospective trial site, or their suspension or termination of a clinical trial once commenced;

difficulty in recruiting suitable patients to participate in a trial;

difficulty in having patients complete a trial or return for post-treatment follow-up;

clinical sites deviating from trial protocol or dropping out of a trial;

problems with drug product or drug substance storage and distribution;

adding new clinical trial sites;

our inability to manufacture, or obtain from third parties, adequate supply of drug product sufficient to complete our preclinical studies and clinical trials;

governmental or regulatory delays and changes in regulatory requirements, policy and guidelines; or

varying interpretations of data by the FDA and similar foreign regulatory agencies.

The results of any Phase 3 clinical trial may not be adequate to support marketing approval. These clinical trials are lengthy and usually involve from many hundreds to thousands of patients. In addition, if the FDA disagrees with our or our collaborator's choice of the key testing criteria, or primary endpoint, or the results for the primary endpoint are not robust or significant relative to the control group of patients not receiving the

## Edgar Filing: ENANTA PHARMACEUTICALS INC - Form S-1/A

experimental therapy or are subject to confounding factors, or are not adequately supported by other study endpoints, the FDA may refuse to approve our or our collaborator's product candidate. The FDA also may require additional clinical trials as a condition for approving any of these product candidates. We estimate that it will likely be more than two years before an NDA for one of our or our collaborator's product candidates could be approved by the FDA.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trial is being conducted, by any Data Safety Monitoring Board, or DSMB, for such trial, or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, delays can occur due



## **Table of Contents**

to safety concerns arising from trials or other clinical data regarding another company's product candidate in the same compound class as one of ours. For example, Novartis' drug candidate that is a cyclophilin inhibitor was recently placed on clinical hold by the FDA based on a small number of cases of pancreatitis in clinical trial patients, one of which resulted in a patient's death. This clinical hold could result in delays for development of other cyclophilin inhibitors such as our EDP-546, including delays due to additional preclinical or clinical testing protocols for all cyclophilin inhibitors. If we or our collaborators experience delays in the completion of, or termination of, any clinical trial of one of our product candidates, the commercial prospects of the product candidate will be harmed, and our or our collaborators' ability to commence product sales and generate product revenues from the product candidate will be delayed. In addition, any delays in completing our clinical trials will increase our costs and slow down our product candidate development and approval process. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

***If we or our collaborators are required to suspend or discontinue clinical trials due to side effects or other safety risks associated with our product candidates, or if we or our collaborators are required to conduct studies on the long-term effects associated with the use of our product candidates, efforts to commercialize our product candidates could be delayed or halted.***

Clinical trials involving our product candidates may be suspended or terminated at any time for a number of safety-related reasons. For example, we or our collaborators may voluntarily suspend or terminate clinical trials if at any time one of our product candidates, or a combination therapy including any of them, presents an unacceptable safety risk to the clinical trial patients. In addition, IRBs or regulatory agencies may order the temporary discontinuation or termination of clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, including if they present an unacceptable safety risk to patients. Administering any product candidate to humans may produce undesirable side effects. The existence of undesirable side effects resulting from any of our product candidates, or a combination therapy including any of them, could cause us, our collaborators or regulatory authorities, such as the FDA, to interrupt, delay or halt clinical trials of our product candidates and could result in the FDA or other regulatory agencies denying further development or approval of our product candidates for any or all targeted indications. This, in turn, could prevent us or our collaborators from commercializing our product candidates.

Our Bicyclolide product candidates are in a novel class of antibiotics. Regulatory authorities may require more extensive studies of the long-term effects for regulatory approval, which could delay development of EDP-788 or our other future antibiotic product candidates. These studies could also be required at any time after regulatory approval of any of our product candidates. Some or all of our product candidates may prove to be unsafe for human use.

***Results of earlier clinical trials may not be predictive of the results of later-stage clinical trials.***

The results of preclinical studies and early clinical trials of our product candidates, whether ABT-450, EDP-239, EDP-546, EDP-788 or any of our future product candidates, may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy results despite having progressed through preclinical studies and initial clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier studies. Similarly, future clinical trial results may not be successful for these or other reasons.

This product candidate development risk is heightened by any changes in the planned clinical trials compared to the completed clinical trials. As product candidates are developed through preclinical to early to late stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could make the results of planned clinical trials or other future clinical trials we or our collaborators may initiate less predictable and could cause our product candidates to perform differently, which

## Table of Contents

could delay completion of clinical trials, delay approval of our product candidates and/or jeopardize our or our collaborators' ability to commence product sales and generate revenues.

***The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we or our collaborators are ultimately unable to obtain timely regulatory approval for our product candidates, our business will be substantially harmed.***

The regulatory approval process is expensive and, while the time required to gain FDA and foreign regulatory approval is uncertain, it may take years. Regulatory approval is unpredictable and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of preclinical and clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We or our collaborators may be required to undertake and complete certain additional preclinical studies to generate toxicity and other data required to support the submission of a New Drug Application, or NDA, to the FDA or other regulatory authority. Neither we nor our collaborators have obtained regulatory approval for any of our product candidates and it is possible that none of our existing product candidates or any of our future product candidates will ever obtain regulatory approval. Furthermore, approval in the United States by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our or our collaborators' clinical trials;

we or our collaborators may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;

the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;

we or our collaborators may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;

the FDA or comparable foreign regulatory authorities may disagree with our or our collaborators' interpretation of data from preclinical studies or clinical trials;

the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;

the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we or our collaborators contract for clinical and commercial supplies; and

the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our or our collaborators' clinical data insufficient for approval.

We and our collaborators cannot be assured that after spending substantial time and resources, we or our collaborators will obtain regulatory approval. Even if we or our collaborators were to obtain approval, regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or

desirable for the successful commercialization of that product candidate. Significant clinical trial delays could allow our competitors to obtain marketing approval before we or our collaborators do or could shorten the patent protection period during which we may have the exclusive right to commercialize our product candidates. In addition, we or our collaborators may not be able to ultimately achieve the prices intended for our products. In many foreign countries, a product candidate must be approved for reimbursement before it can be approved for sale in that country. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

## **Table of Contents**

*Even if we receive regulatory approval for any of our product candidates we develop independently, we will be subject to ongoing FDA obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we or our collaborators fail to comply with regulatory requirements or experience unanticipated problems with our products.*

Any regulatory approvals that we receive for our product candidates we develop independently may be subject to limitations on the approved indicated uses for which the product may be marketed or subject to certain conditions of approval, or may contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate.

In addition, if the FDA approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, as well as continued compliance with current good manufacturing practices, or cGMP, and good clinical practices, or GCP, for any clinical trials that we or our collaborators conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;

finances, warning letters or holds on any post-approval clinical trials;

refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our collaborators, or suspension or revocation of product license approvals;

product seizure or detention, or refusal to permit the import or export of products; and

injunctions or the imposition of civil or criminal penalties.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our product candidate may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

***We or our collaborators may delay or terminate the development of a product candidate at any time if we or our collaborators believe the perceived market or commercial opportunity does not justify further investment, which could materially harm our business.***

Even though the results of preclinical studies and clinical trials that we or our collaborators have conducted or may conduct in the future may support further development of one or more of our product candidates, we, or our collaborator in the case of our partnered product candidates, may delay, suspend or terminate the future development of a product candidate at any time for strategic, business, financial or other reasons, including the determination or belief that the emerging profile of the product candidate is such that it may not receive FDA approval, gain meaningful market acceptance, otherwise provide any competitive advantages in its intended indication or market or generate a significant return to shareholders. Such a delay, suspension or termination could materially harm our business, results of operations or financial condition. In addition, our collaborators may have the right to make decisions regarding the development and commercialization of product candidates without consulting us, and may make decisions with which we do not agree.

## **Table of Contents**

*Our internal computer systems, or those of our collaborators, CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of development programs for our product candidates.*

Despite the implementation of security measures, our internal computer systems and those of our collaborators, CROs, and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our independent drug development programs or those of our collaborators. For example, the loss of clinical trial data from ongoing or future clinical trials for any of our product candidates could result in delays in regulatory approval efforts and significantly increase costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of confidential or proprietary information, we or our collaborators could incur liability and the further development of our product candidates could be delayed.

### **Risks Related to Commercialization of Our Product Candidates**

*If, in the future, we are unable to establish our own sales, marketing and distribution capabilities or enter into licensing or collaboration agreements for these purposes, we may not be successful in commercializing any future product candidates.*

We do not have a sales or marketing infrastructure and have no sales, marketing or distribution experience. We will seek to either build our own commercial infrastructure to commercialize any future products if and when they are approved, or enter into licensing or collaboration agreements where our collaborator is responsible for commercialization, like in the case of our collaborations with Novartis and Abbott, or where we have the right to assist in the future development and commercialization of such products. For example, we have a co-detail option with respect to any product that may be developed under our Novartis collaboration, which would allow us to establish a limited sales force in the United States for a portion of the product's sales.

To develop internal sales, distribution and marketing capabilities, we will have to invest significant amounts of financial and management resources, some of which will be committed prior to any confirmation that any of our proprietary product candidates will be approved. For product candidates for which we decide to perform sales, marketing and distribution functions ourselves, we could face a number of additional risks, including:

our inability to recruit and retain adequate numbers of effective sales and marketing personnel;

the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;

the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and

unforeseen costs and expenses associated with creating an independent sales and marketing organization.

Where and when appropriate, we may elect to utilize contract sales forces or distribution partners to assist in the commercialization of our product candidates. If we enter into arrangements with third parties to perform sales, marketing and distribution services for our products, the resulting revenues or the profitability from these revenues to us are likely to be lower than if we had sold, marketed and distributed our products ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to sell, market and distribute our products effectively.

If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.



**Table of Contents**

*Our commercial success depends upon significant market acceptance among physicians, patients and healthcare payors of our product candidates licensed to Abbott and Novartis, if approved, as well as of any future product candidates we plan to develop independently or in collaboration with others.*

Even if ABT-450 or EDP-239 or any other product candidate that we may develop in the future obtains regulatory approval, whether as part of a combination therapy or as a monotherapy, the product may not gain market acceptance among physicians, healthcare payors, patients and the medical community. For example, the standard of care in HCV is likely to evolve rapidly as many new product candidates are being developed and tested. The degree of market acceptance of any products for which we receive approval for commercial sale depends on a number of factors, including:

the efficacy and safety of our partnered product candidates, as demonstrated in clinical trials, and the degree to which these product candidates represent a clinically meaningful improvement in care as compared with other available therapies;

the clinical indications for which any product candidates become approved;

acceptance among physicians, major operators of clinics and patients of any of our product candidates as safe and effective treatments;

the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

the potential and perceived advantages of our product candidates over alternative treatments;

the cost of treatment in relation to alternative treatments;

the availability of adequate reimbursement and pricing by third parties and government authorities;

the continued projected growth of the HCV drug market;

the relative convenience and ease of administration of any combination therapies including our product candidates;

the prevalence and severity of adverse side effects, whether involving the use of our products candidates or similar, competitive products; and

the effectiveness of our or our collaborators' sales and marketing efforts.

If our product candidates are approved and then fail to achieve market acceptance, we would not be able to generate significant revenue. Further, if new, more favorably received therapies are introduced after our product candidates achieve market acceptance, then we may not be able to maintain that market acceptance over time.

*Even if we or our collaborators are able to commercialize any product candidates, the resulting products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives in the United States, which would harm our business.*

## Edgar Filing: ENANTA PHARMACEUTICALS INC - Form S-1/A

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, collectively referred to as the ACA, may significantly change the way healthcare is financed by both governmental and private insurers. While we cannot predict what impact on federal reimbursement policies this law will have in general or specifically on any product that we or any of our collaborators commercializes, the ACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of new products. In addition, although the United States Supreme Court has upheld the constitutionality of most of the ACA, some states have indicated that they intend not to implement certain sections of the ACA, and some members of the U.S. Congress are still working to repeal the ACA. We cannot predict whether these challenges will continue or other proposals will be made or adopted, or what impact these efforts may have on us or any of our collaborators. Our or any collaborators' ability to commercialize any products successfully also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such



## **Table of Contents**

as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product that we or any collaborator commercialize and, if reimbursement is available, the level of reimbursement. In addition, reimbursement may impact the demand for, or the price of, any product candidate for which we or a collaborator obtains marketing approval. If reimbursement is not available or is available only to limited levels, we or our collaborators may not be able to successfully commercialize any product candidate for which marketing approval is obtained.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also be insufficient to cover our and any collaborator's costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our or any collaborator's inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products that we or our collaborators develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

*Foreign governments tend to impose strict price controls, which may adversely affect our future profitability.*

In most foreign countries, particularly in the European Union, prescription drug pricing and/or reimbursement is subject to governmental control. In those countries that impose price controls, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our collaborators may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies.

Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we or our collaborators might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues that are generated from the sale of the product in that country. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, or if there is competition from lower priced cross-border sales, our profitability will be negatively affected.

### **Risks Related to Our Dependence on Third Parties**

*We may not be successful in establishing new product collaborations, which could adversely affect our ability to develop and commercialize our future product candidates. If we are unsuccessful in maintaining or forming alliances on favorable terms, our business may not succeed.*

We may seek to enter into additional product collaborations in the future, including alliances with other biotechnology or pharmaceutical companies, to enhance and accelerate the development and commercialization of our future product candidates. We face significant competition in seeking appropriate collaborators and the

## Table of Contents

negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish other product collaborations or other alternative arrangements for any future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort and/or third parties may not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy. Even if we are successful in our efforts to establish product collaborations, the terms that we agree upon may not be favorable to us and we may not be able to maintain such product collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing.

If either of our existing collaboration agreements is terminated, or if we determine that entering into other product collaborations is in our best interest but we either fail to enter into, delay in entering into or fail to maintain such collaborations:

the development of certain of our current or future product candidates may be terminated or delayed;

our cash expenditures related to development of certain of our future product candidates would increase significantly and we may need to seek additional financing;

we may be required to hire additional employees or otherwise develop expertise, such as clinical, regulatory, sales and marketing expertise, which we do not currently have;

we will bear all of the risk related to the development of any such product candidates; and

the competitiveness of any product candidate that is commercialized could be reduced.

***We intend to rely on third-party manufacturers to produce our clinical product candidate supplies and any commercial supplies of any approved future product candidates. Any failure by a third-party manufacturer to produce acceptable supplies for us may delay or impair our ability to initiate or complete our clinical trials or sell any resulting product.***

We do not currently own or operate any manufacturing facilities. We plan to work with third-party contract manufacturers to produce sufficient quantities of any future product candidates for preclinical testing, clinical trials and commercialization. If we are unable to arrange for such a third-party manufacturing source, or fail to do so on commercially reasonable terms, we may not be able to successfully produce, develop and market our future product candidates, or we may be delayed in doing so.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including reliance on the third party for regulatory compliance and quality control and assurance, volume production, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to synthesize and manufacture our product candidates in accordance with our product specifications) and the possibility of termination or nonrenewal of the agreement by the third party at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates be manufactured according to cGMP and similar foreign standards. Pharmaceutical manufacturers and their subcontractors are required to register their facilities and/or products manufactured at the time of submission of the marketing application and then annually thereafter with the FDA and certain state and foreign agencies. They are also subject to periodic unannounced inspections by the FDA, state and other foreign authorities. Any subsequent discovery of problems with a product, or a manufacturing or laboratory facility used by us or our collaborators, may result in restrictions on the product or on the manufacturing or laboratory facility, including marketed product recall, suspension of manufacturing, product seizure, or a voluntary withdrawal of the drug from the market. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates.

We plan to rely on third-party manufacturers to purchase from third-party suppliers the materials necessary to produce our future product candidates for our clinical studies. There are a small number of suppliers for certain capital equipment and materials that we plan to use to manufacture our drugs. Such suppliers may not sell these materials to our manufacturers at the times we need them or on commercially reasonable terms. Moreover,



---

**Table of Contents**

we currently do not have any agreements for the production of these materials. Although we do not intend to begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of a product candidate or the material components thereof for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenue from the sale of our product candidates.

Contract manufacturers may not be able to manufacture our product candidates at a cost or in quantities or in a timely manner necessary to develop and commercialize them. If we successfully commercialize any of our product candidates, to meet our projected needs we may need to find third parties that will increase their scale of production, or we may have to establish or access large-scale commercial manufacturing capabilities. We may require additional funds, personnel and other resources to build, lease or operate any manufacturing facility.

***Because a portion of our manufacturing of certain key intermediates used in the manufacture of the active pharmaceutical ingredients for our future product candidates is expected to take place in China through third-party manufacturers, a significant disruption in the operation of those manufacturers or political unrest in China could materially adversely affect our business, financial condition and results of operations.***

Although manufacturing for each of our lead product candidates, namely ABT-450 and EDP-239, is being conducted by our collaborators, we have relied on third parties located in China to manufacture and supply certain key intermediates used in the manufacture of our active pharmaceutical ingredients, or API, for our research product candidates, and we expect to continue to use such third party manufacturers for such intermediates for any future product candidates we develop independently, including EDP-546 and EDP-788. Any disruption in production or inability of our manufacturers in China to produce adequate quantities to meet our needs, whether as a result of a natural disaster or other causes, could impair our ability to operate our business on a day-to-day basis and to continue our research and development of our future product candidates. Furthermore, since these manufacturers are located in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the Chinese government, political unrest or unstable economic conditions in China. Any of these matters could materially and adversely affect our business and results of operations. Any recall of the manufacturing lots or similar action regarding our API used in clinical trials could delay the trials or detract from the integrity of the trial data and its potential use in future regulatory filings. In addition, manufacturing interruptions or failure to comply with regulatory requirements by any of these manufacturers could significantly delay clinical development of potential products and reduce third-party or clinical researcher interest and support of proposed trials. These interruptions or failures could also impede commercialization of our future product candidates and impair our competitive position. Further, we may be exposed to fluctuations in the value of the local currency in China. Future appreciation of the local currency could increase our costs. In addition, our labor costs could continue to rise as wage rates increase due to increased demand for skilled laborers and the availability of skilled labor declines in China.

***We will rely on third parties to monitor, support, conduct and/or oversee clinical trials of our future product candidates that we develop independently and, in some cases, to maintain regulatory files for those product candidates. If we are not able to maintain or secure agreements with such third parties on acceptable terms, if these third parties do not perform their services as required, or if these third parties fail to timely transfer any regulatory information held by them to us, we may not be able to obtain regulatory approval for, or commercialize, our product candidates.***

We will rely on academic institutions, CROs, hospitals, clinics and other third-party collaborators who are outside our control to monitor, support, conduct and/or oversee preclinical and clinical studies of our future product candidates. We will also rely on third parties to perform clinical trials on our future product candidates when they reach that stage. As a result, we have less control over the timing and cost of these studies and the ability to recruit trial subjects than if we conducted these trials wholly by ourselves. If we are unable to maintain or enter into agreements with these third parties on acceptable terms, or if any such engagement is terminated, we

## **Table of Contents**

may be unable to enroll patients on a timely basis or otherwise conduct our trials in the manner we anticipate. In addition, there is no guarantee that these third parties will devote adequate time and resources to our studies or perform as required by a contract or in accordance with regulatory requirements, including maintenance of clinical trial information regarding our future product candidates. If these third parties fail to meet expected deadlines, fail to timely transfer to us any regulatory information, fail to adhere to protocols or fail to act in accordance with regulatory requirements or our agreements with them, or if they otherwise perform in a substandard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, then clinical trials of our future product candidates may be extended, delayed or terminated, or our data may be rejected by the FDA or regulatory agencies.

*To the extent we elect to enter into additional licensing or collaboration agreements to partner our future product candidates, our dependence on such relationships may adversely affect our business.*

Our commercialization strategy for some of our future product candidates may depend on our ability to enter into collaboration agreements with other companies to obtain assistance and funding for the development and potential commercialization of these product candidates, similar to what we have done with Abbott and Novartis. Supporting diligence activities conducted by potential collaborators and negotiating the financial and other terms of a collaboration agreement are long and complex processes with uncertain results. Even if we are successful in entering into one or more additional collaboration agreements, collaborations can involve greater uncertainty for us, as we may have limited or no control over certain aspects of our collaborative programs. We may determine that continuing a collaboration under the terms provided is not in our best interest, and we may terminate the collaboration. Our collaborators could delay or terminate their agreements with us, and our product candidates subject to collaborative arrangements may never be successfully commercialized.

Further, our collaborators may develop alternative products or pursue alternative technologies either on their own or in collaboration with others, including our competitors, and the priorities or focus of our collaborators may shift such that our programs receive less attention or resources than we would like, or they may be terminated altogether. Any such actions by our collaborators may adversely affect our business prospects and ability to earn revenue. In addition, we could have disputes with our collaborators, such as the interpretation of terms in our agreements. Any such disagreements could lead to delays in the development or commercialization of any potential products or could result in time-consuming and expensive litigation or arbitration, which may not be resolved in our favor.

Even with respect to programs that we intend to commercialize ourselves, we may enter into agreements with collaborators to share in the burden of conducting clinical trials, manufacturing and marketing our product candidates or products. In addition, our ability to apply our proprietary technologies to develop proprietary compounds will depend on our ability to establish and maintain licensing arrangements or other collaborative arrangements with the holders of proprietary rights to such compounds. We may not be able to establish such arrangements on favorable terms or at all, and our collaborative arrangements may not be successful.

## **Risks Related to Our Intellectual Property Rights**

*We could be unsuccessful in obtaining or maintaining adequate patent protection for one or more of our product candidates.*

Our commercial success will depend, in large part, on our ability to obtain and maintain patent and other intellectual property protection with respect to our product candidates. We cannot be certain that patents will be issued or granted with respect to our patent applications that are currently pending, or that issued or granted patents will not later be found to be invalid and/or unenforceable, be interpreted in a manner that does not adequately protect our products, or otherwise provide us with any competitive advantage. The patent position of biotechnology and pharmaceutical companies is generally uncertain because it involves complex legal and factual considerations. The standards applied by the United States Patent and Trademark Office and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology and pharmaceutical patents. Consequently, patents may not issue from our pending patent applications. As such,

## **Table of Contents**

we do not know the degree of future protection that we will have on our proprietary products and technology, if any, and a failure to obtain adequate intellectual property protection with respect to our product candidates and proprietary technology could have a material adverse impact on our business.

In addition, certain of our activities have been funded, and may in the future be funded, by the United States federal government. For example, the preclinical and early clinical development of EDP-788, our lead candidate for the treatment of MRSA, is currently funded under a contract with the NIAID, an entity of the United States federal government. When new technologies are developed with United States federal government funding, the government obtains certain rights in any resulting patents, including a nonexclusive license authorizing the government to use the invention for non-commercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our patented technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the United States government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to United States industry. In addition, United States government-funded inventions must be reported to the government and United States government funding must be disclosed in any resulting patent applications. In addition, our rights in such inventions are subject to certain requirements to manufacture products in the United States.

### ***Issued patents covering one or more of our product candidates could be found invalid or unenforceable if challenged in court.***

Despite measures we take to obtain patent and other intellectual property protection with respect to our product candidates and proprietary technology, any of our intellectual property rights could be challenged or invalidated. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States and in some other jurisdictions, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the United States Patent and Trademark Office, or the applicable foreign counterpart, or made a misleading statement, during prosecution. Although we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith, the outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on a product candidate. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. Any loss of patent protection could have a material adverse impact on one or more of our product candidates and our business.

Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend and could require us to pay substantial damages, cease the sale of certain products or enter into a license agreement and pay royalties (which may not be possible on commercially reasonable terms or at all). Any efforts to enforce our intellectual property rights are also likely to be costly and may divert the efforts of our scientific and management personnel.

### ***Claims that our product candidates or the sale or use of our future products infringe the patent or other intellectual property rights of third parties could result in costly litigation or could require substantial time and money to resolve, even if litigation is avoided.***

Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates and use our proprietary technology without infringing the intellectual property rights of others. We cannot guarantee that our product candidates or any uses of our product candidates do not and will not in the future infringe third-party patents or other intellectual property rights. Third parties might allege that we or our

## Table of Contents

collaborators are infringing their patent rights or that we have misappropriated their trade secrets, or that we are otherwise violating their intellectual property rights, whether with respect to the manner in which we have conducted our research or to the composition, use or manufacture of the compounds we have developed or are developing with our collaborators. Such third parties might resort to litigation against us or other parties we have agreed to indemnify, which litigation could be based on either existing intellectual property or intellectual property that arises in the future.

It is also possible that we failed to identify, or may in the future fail to identify, relevant patents or patent applications held by third parties that cover our product candidates. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Other patent applications in the United States and several other jurisdictions are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Furthermore, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we or our collaborators were the first to invent, or the first to file patent applications on, our product candidates or for their uses, or that our product candidates will not infringe patents that are currently issued or that are issued in the future. In the event that a third party has also filed a patent application covering one of our product candidates or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the U.S. Patent and Trademark Office or its foreign counterpart to determine priority of invention. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our products or their use.

In order to avoid or settle potential claims with respect to any patent or other intellectual property rights of third parties, we may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both, which could be substantial. These licenses may not be available on acceptable terms, or at all. Even if we or any future collaborators were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced, by court order or otherwise, to cease some or all aspects of our business operations, if, as a result of actual or threatened patent or other intellectual property claims, we are unable to enter into licenses on acceptable terms. Further, we could be found liable for significant monetary damages as a result of claims of intellectual property infringement. For example, we have received, and may in the future receive, offers to license and demands to license from third parties claiming that we are infringing their intellectual property or owe license fees and, even if such claims are without merit, there can be no assurance that we will successfully avoid or settle such claims.

In addition, we are aware of patents needed to use the replicon assay, which is an *in vitro* test for determining potency of an active compound in reducing HCV replication and is commonly used by us and others engaged in HCV research. We have a license to the relevant patents for one of our HCV programs and expect to seek confirmation of its application to one or more of our other HCV programs. Although the patent owner has granted licenses under the relevant patents to others, if we require such a license, we cannot provide any assurances that we will be able to obtain one on terms that are acceptable to us, or at all. If we do not obtain such a license and if a legal action based on such patents were to be brought against us, we cannot provide any assurances that we would prevail or that we have sufficient resources to defend such claims and the additional risks described above could materialize. If Abbott and Novartis license or otherwise acquire rights to intellectual property controlled by a third party in various circumstances, for example, where a product could not be legally developed or commercialized in a country without the third-party intellectual property right or, in the case of the Novartis agreement, where it is decided that it would be useful to acquire such third-party right to develop or commercialize the product, they are entitled under our collaboration agreements to decrease payments payable to us on a product-by-product basis and, in certain cases, on a country-by-country basis. Any of the foregoing events could harm our business significantly.

Defending against claims of patent infringement, misappropriation of trade secrets or other violation of intellectual property rights could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. Claims that our product

## **Table of Contents**

candidates or the sale or use of our future products infringe, misappropriate or otherwise violate third-party intellectual property rights could therefore have a material adverse impact on our business.

***Unfavorable outcomes in intellectual property litigation could limit our research and development activities and/or our ability to commercialize certain products.***

If third parties successfully assert their intellectual property rights against us, we might be barred from using certain aspects of our technology, or barred from developing and commercializing certain products. Prohibitions against using certain technologies, or prohibitions against commercializing certain products, could be imposed by a court or by a settlement agreement between us and a plaintiff. In addition, if we are unsuccessful in defending against allegations that we have infringed, misappropriated or otherwise violated patent or other intellectual property rights of others, we may be forced to pay substantial damage awards to the plaintiff. There is inevitable uncertainty in any litigation, including intellectual property litigation. There can be no assurance that we would prevail in any intellectual property litigation, even if the case against us is weak or flawed. If litigation leads to an outcome unfavorable to us, we may be required to obtain a license from the intellectual property owner in order to continue our research and development programs or to market any resulting product. It is possible that the necessary license will not be available to us on commercially acceptable terms, or at all. Alternatively, we may be required to modify or redesign our products in order to avoid infringing or otherwise violating third-party intellectual property rights. This may not be technically or commercially feasible, may render our products less competitive, or may delay or prevent the entry of our products to the market. Any of the foregoing could limit our research and development activities, our ability to commercialize one or more product candidates, or both.

Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex intellectual property litigation longer than we could. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to conduct our clinical trials, continue our internal research programs, in-license needed technology, or enter into strategic partnerships that would help us bring our product candidates to market.

In addition, any future intellectual property litigation, interference or other administrative proceedings will result in additional expense and distraction of our personnel. An adverse outcome in such litigation or proceedings may expose us or any future strategic partners to loss of our proprietary position, expose us to significant liabilities, or require us to seek licenses that may not be available on commercially acceptable terms, if at all, each of which could have a material adverse effect on our business.

***Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common stock to decline.***

During the course of any intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our products, programs or intellectual property could be diminished. Accordingly, the market price of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

***Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.***

In addition to patents, we rely on trade secrets, technical know-how and proprietary information concerning our business strategy and product candidates in order to protect our competitive position in the field of HCV and anti-infectives. In the course of our research and development activities and our business activities, we often rely on confidentiality agreements to protect our proprietary information. Such confidentiality agreements are used, for example, when we talk to vendors of laboratory or clinical development services or potential strategic partners. In addition, each of our employees is required to sign a confidentiality agreement and invention assignment agreement upon joining our company. We take steps to protect our proprietary information, and our confidentiality agreements and invention assignment agreements are carefully drafted to protect our proprietary interests. Nevertheless, there can be no guarantee that an employee or an outside party will not make an unauthorized disclosure of our proprietary confidential information. This might happen intentionally or inadvertently. It is possible that a competitor will make use of such information, and that our competitive position will be compromised, in spite of



## **Table of Contents**

any legal action we might take against persons making such unauthorized disclosures. In addition, to the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, business partners or outside scientific collaborators might intentionally or inadvertently disclose our trade secret information to competitors or our trade secrets may otherwise be misappropriated. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States sometimes are less willing than United States courts to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Our collaborators may have rights to publish data and other information to which we have rights. In addition, we sometimes engage individuals or entities to conduct research relevant to our business. The ability of these individuals or entities to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to certain contractual limitations. These contractual provisions may be insufficient or inadequate to protect our confidential information. If we do not apply for patent protection prior to such publication, or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized, which could adversely affect our business.

### ***Intellectual property rights do not necessarily protect us from all potential threats to our competitive advantage.***

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we or our collaborators own or have exclusively licensed;

we or our collaborators or any future collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or may in the future exclusively license, which could result in the patent applications not issuing or being invalidated after issuing;

we or our collaborators or any future collaborators might not have been the first to file patent applications covering certain of our inventions, which could result in the patent applications not issuing or being invalidated after issuing;

the ownership of the intellectual property arising out of our collaborations is subject to complex legal and factual issues, and in certain circumstances our collaborators may own or jointly own important intellectual property relating to our product candidates. Although we have rights to such intellectual property under our collaboration agreements, such rights could potentially be lost or diminished if the applicable collaboration agreement is terminated, which could affect our ability to commercialize our product candidates;

others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;

it is possible that our pending patent applications will not lead to issued patents;

issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;

we may obtain patents for certain compounds many years before we obtain marketing approval for products containing such compounds, and because patents have a limited life, which may begin to run prior to the commercial sale of the related product, the commercial value of our patents may be limited;

## **Table of Contents**

our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

we may fail to develop additional proprietary technologies that are patentable;

the laws of certain foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States, or we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate; and

the patents of others may have an adverse effect on our business, for example by preventing us from marketing one or more of our product candidates for one or more indications.

Any of the aforementioned threats to our competitive advantage could have a material adverse effect on our business.

### ***Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.***

As is the case with many other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining, maintaining and enforcing patents in the biopharmaceutical industry involves both technological complexity and legal complexity. Therefore, obtaining, maintaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. In addition, recent legislative and judicial developments in the United States and elsewhere have in some cases narrowed the protection afforded to patent owners, made patents more difficult to obtain, or increased the uncertainty regarding the ability to obtain, maintain and enforce patents. For example, Congress recently passed patent reform legislation, and may pass patent reform legislation in the future. The United States Supreme Court has ruled on several patent cases in recent years, and in certain circumstances has narrowed the scope of patent protection available or otherwise weakened the rights of patent owners. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions and actions by the United States Congress, the federal courts, the United States Patent and Trademark Office, and their respective foreign counterparts, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to maintain and enforce our existing patents and patents that we might obtain in the future.

## **Risks Related to Industry**

### ***Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.***

As has been widely reported, global credit and financial markets have been experiencing extreme disruptions over the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by the recent economic downturn and volatile business environment and continued unpredictable and unstable market conditions, particularly for securities of biotechnology companies such as our common stock. There is a possibility that our stock price may decline, due in part to the volatility of the stock market and any general economic downturn. If the current equity and credit markets become more volatile, deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to secure, more costly and/or more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon our business and clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

**Table of Contents**

*If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.*

We face an inherent risk of product liability as a result of the clinical testing of our product candidates, and we will face an even greater risk if we commercialize any product candidates. For example, we may be sued if any of our product candidates, including any that are developed in combination therapies, allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. There is also risk that third parties we have agreed to indemnify could incur liability. Regardless of the merits or eventual outcome, liability claims may result in:

decreased demand for our product candidates or any resulting products;

injury to our reputation;

withdrawal of clinical trial participants;

costs to defend the related litigation;

a diversion of management's time and our resources;

substantial monetary awards to trial participants or patients;

product recalls, withdrawals or labeling, marketing or promotional restrictions;

loss of revenue;

the inability to commercialize our product candidates; and

a decline in our stock price.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry product liability insurance covering our clinical studies in the amount of \$5.0 million in the aggregate. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

*Our relationships with customers and third-party payors in the United States and elsewhere will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages,*

*reputational harm and diminished profits and future earnings.*

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal, state and foreign healthcare laws and regulations include the following:

the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;

## Table of Contents

the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or *qui tam* actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

the federal transparency requirements under the Patient Protection and Affordable Care Act of 2010 requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests;

analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures; and

analogous anti-kickback, fraud and abuse and healthcare laws and regulations in foreign countries.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other providers or entities with whom we expect to do business, including our collaborators, are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which could also materially affect our business.

***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.***

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials or our or third parties' disposal of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

We may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.



## **Table of Contents**

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials. This insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of hazardous or radioactive materials.

### **Risks Related to Our Common Stock and this Offering**

*After this offering, our executive officers, directors and principal stockholders will maintain the ability to control all matters submitted to stockholders for approval.*

Upon the closing of this offering, our executive officers and directors and stockholders who owned more than 5% of our outstanding common stock before this offering will, in the aggregate, beneficially own shares representing approximately % of our outstanding capital stock. As a result, if these stockholders were to choose to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. The interests of this group of stockholders may not always coincide with our corporate interests or the interests of other stockholders, and they may act in a way in which you may not agree with or in a way that may not be in the best interests of other stockholders. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

*Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.*

Provisions in our corporate charter and our bylaws that will become effective immediately prior to consummation of this offering may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which they might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

establish a classified or staggered board of directors such that not all members of the board are elected at one time;

allow the authorized number of our directors to be changed only by resolution of our board of directors;

limit the manner in which stockholders can remove directors from the board;

establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;

require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;

limit who may call stockholder meetings;

provide our board of directors with the authority to designate the terms of and issue a new series of preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential



## Edgar Filing: ENANTA PHARMACEUTICALS INC - Form S-1/A

hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and

require the approval of the holders of at least 66 2/3% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibit a person who owns 15% or more of our outstanding

**Table of Contents**

voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Any provision in our corporate charter or our bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

***Our employment agreements with our named executive officers may require us to pay severance benefits to any of those persons who are terminated in connection with a change of control of us, which could harm our financial condition or results.***

Our named executive officers are parties to employment agreements providing for aggregate cash payments of up to approximately \$1.7 million for severance and other benefits and acceleration of vesting of stock options with an intrinsic value of approximately \$0.2 million, each calculated as of September 30, 2012, in the event of a termination of employment in connection with a change of control of our company. The accelerated vesting of options could result in dilution to our stockholders and harm the market price of our common stock. The payment of these severance benefits could harm our financial condition and results. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

***If you purchase shares of common stock in this offering, you will experience immediate and substantial dilution in the net tangible book value of your shares.***

The initial public offering price of our common stock is substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our net tangible book value per share after this offering. To the extent outstanding stock options are exercised, you will incur further dilution. Based on an assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the estimated price range set forth on the cover page of this prospectus, you will experience immediate dilution of \$ \_\_\_\_\_ per share, representing the difference between our pro forma as adjusted net tangible book value per share after giving effect to this offering and the assumed initial public offering price. In addition, purchasers of common stock in this offering will have contributed approximately \_\_\_\_\_ % of the aggregate price paid by all purchasers of our stock, but will own only approximately \_\_\_\_\_ % of our common stock outstanding after this offering. For a further description of the dilution that you will experience immediately after this offering, see Dilution.

***We do not know whether a market will develop for our common stock or what the market price of our common stock will be and as a result it may be difficult for you to sell your shares of our common stock.***

Prior to this offering, there has been no public market for our common stock. Although we are applying to have our common stock listed on The NASDAQ Global Market, an active trading market for our shares may never develop or be sustained following this offering. If an active market for our common stock does not develop, it may be difficult for you to sell shares you purchase in this offering without depressing the market price for the shares or you may not be able to sell your shares at all. The initial public offering price for our common stock will be determined through negotiations with the underwriters and the negotiated price may not be indicative of the market price for our common stock after this offering. The initial public offering price may vary from the market price of our common stock after the offering. As a result of these and other factors, you may not be able to sell your shares of our common stock at or above the initial public offering price or at all. Further, an inactive market may also impair our ability to raise capital by selling additional shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

***We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.***

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to the reporting and other requirements of the Securities Exchange Act of 1934, as amended, known as the Exchange Act, portions of the Sarbanes-Oxley Act of 2002, as well as rules

**Table of Contents**

subsequently adopted by the Securities and Exchange Commission, or SEC, and The NASDAQ Stock Market, or NASDAQ. These rules and regulations will require, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition and establish and maintain effective disclosure and financial controls and corporate governance practices. We expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly, particularly after we are no longer an emerging growth company as defined in the recently enacted Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance. In addition, we estimate that incremental annual compliance costs associated with these reporting obligations will initially approximate \$1.0 million and that the total expenses we expect to incur in connection with this offering will approximate \$ million.

***We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.***

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. As an emerging growth company we are required to report only two years of financial results and selected financial data compared to three and five years, respectively, for comparable data reported by other public companies. We may take advantage of these exemptions until we are no longer an emerging growth company. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds \$700 million as of any March 31 (the end of our second fiscal quarter) before that time, in which case we would no longer be an emerging growth company as of the following September 30 (our fiscal year end). We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption to delay the adoption of new or revised accounting standards and, therefore, will be subject to adopting new or revised accounting standards at the same time as other public companies that are not emerging growth companies.

***If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.***

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act of 2002, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

**Table of Contents**

We will be required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an emerging growth company under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an emerging growth company for up to five years. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

*Our stock price is likely to be volatile, and thus our stockholders could incur substantial losses.*

Our stock price following this offering is likely to be volatile. The stock market in general and the market for biopharmaceutical companies, and for those developing potential therapies for HCV in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the initial public offering price, if at all. The market price for our common stock may be influenced by many factors, including:

actions by any of our collaborators regarding our product candidates they are developing, including announcements regarding clinical or regulatory developments or our collaboration;

results from or delays of clinical trials of our product candidates, as well as results of regulatory reviews relating to the approval of our product candidates;

new products, product candidates or new uses for existing products or technologies introduced or announced by our competitors and the timing of these introductions or announcements;

our or our collaborators' decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;

the results of our efforts to discover or develop additional product candidates;

our dependence on third parties, including our collaborators, CROs, clinical trial sponsors and clinical investigators;

regulatory or legal developments in the United States or other countries;

developments or disputes concerning patent applications, issued patents or other proprietary rights;

the recruitment or departure of key scientific or management personnel;

our ability to commercialize our future product candidates we develop independently, if approved;

the level of expenses related to any of our product candidates or clinical development programs;

## Edgar Filing: ENANTA PHARMACEUTICALS INC - Form S-1/A

actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;

variations in our financial results or those of companies that are perceived to be similar to us;

sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock;

changes in the structure of healthcare payment systems;

market conditions in the pharmaceutical and biotechnology sectors;

general economic, industry and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies; and

the other factors described in this Risk Factors section.

## **Table of Contents**

***We have broad discretion in the use of the net proceeds from this offering and may not use the proceeds effectively.***

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

***We do not anticipate paying any cash dividends on our capital stock in the foreseeable future.***

We do not currently intend to pay any cash dividends on our common stock in the foreseeable future. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

***A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.***

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. After this offering, we will have outstanding \_\_\_\_\_ shares of common stock based on the number of shares outstanding as of September 30, 2012. This includes the shares that we are selling in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates. Of the remaining shares, \_\_\_\_\_ shares are currently restricted as a result of securities laws or lock-up agreements but will be able to be sold after the offering as described in the *Shares Eligible for Future Sale* section of this prospectus. We also intend to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described in the *Underwriting* section of this prospectus.

***If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.***

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no or too few securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

**Table of Contents**

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as aim, anticipate, assume, believe, contemplate, continue, could, due, estimate, expect, goal, objective, plan, predict, potential, positioned, seek, should, target, will, would, and other similar expressions that are predictive of future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

the continued commitment of our collaborators, Abbott and Novartis, with respect to the development of product candidates incorporating ABT-450 and EDP-239, respectively;

the completion, success and timing of preclinical studies and clinical trials conducted by Abbott, Novartis or us;

our and our collaborators' abilities to obtain and maintain regulatory approval of therapies involving our product candidates;

the receipt and timing of any milestone payments or royalties from Abbott, Novartis or any other collaborator;

our ability to obtain and maintain collaborators for our development programs or to obtain additional funding;

the success of competing HCV or MRSA drugs that are now or later become available or other developments or projections relating to our competitors and our industry;

changes in our or our collaborators' plans to develop and commercialize our product candidates;

the rate and degree of market acceptance of any of our product candidates and any combination therapies developed by Abbott, Novartis or us;

the size and growth of the potential markets for our product candidates and our collaborators' and our abilities to serve those markets, including our belief that substantial opportunities exist for improved treatments in HCV and bacterial infections;

our ability to obtain and maintain intellectual property protection for our product candidates and operate our business without infringing on the intellectual property rights of others;

the loss of any of our key scientific or management personnel;

regulatory developments in the United States and foreign countries affecting disease indications for our product candidates or anti-infective drugs generally;

the performance of third-party manufacturers of our product candidates, including our collaborators;

the accuracy of our estimates regarding our expenses, future revenue, capital requirements and needs for additional financing;

our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;

our financial performance; and

our use of the proceeds from this offering.

These forward-looking statements are based on our management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate and our management's beliefs and assumptions. These forward-looking statements are not guarantees of future performance or development and



**Table of Contents**

involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this prospectus may turn out to be inaccurate. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under **Risk Factors** and discussed elsewhere in this prospectus. Potential investors are urged to consider these factors carefully in evaluating the forward-looking statements. These forward-looking statements speak only as of the date of this prospectus. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. You should, however, review the factors and risks we describe in the reports we will file from time to time with the SEC after the date of this prospectus. See **Where You Can Find More Information**.

**MARKET, INDUSTRY AND OTHER DATA**

This prospectus also contains estimates, projections and other information concerning our industry, our business and the HCV and antibiotic markets, including data regarding the estimated size of the HCV and antibiotic markets, patient populations, projected diagnosis rates and the perceptions and preferences of patients and physicians regarding certain therapies, as well as data regarding market research and estimates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources that we believe to be reliable. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires. Abbott has been responsible for all of the clinical development of ABT-450, and Novartis is responsible for all clinical development of EDP-239. All of the clinical trial results included herein relating to ABT-450 and EDP-239, if any, are based solely upon results published by Abbott and Novartis, respectively.

**Table of Contents**

**USE OF PROCEEDS**

We estimate that the net proceeds from our issuance and sale of \_\_\_\_\_ shares of our common stock in this offering will be approximately \$ \_\_\_\_\_, assuming an initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the estimated price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their over-allotment option in full, we estimate that the net proceeds from this offering will be approximately \$ \_\_\_\_\_.

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the estimated price range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds from this offering by approximately \$ \_\_\_\_\_, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds from this offering as follows:

\$ \_\_\_\_\_ million to initiate IND-enabling studies and clinical development through Phase 2a trials of our lead cyclophilin inhibitor, EDP-546;

\$ \_\_\_\_\_ million to initiate preclinical and clinical development through a Phase 1 trial of a nucleotide polymerase inhibitor candidate; and

\_\_\_\_\_ the remaining proceeds to fund new research and development activities, working capital and other general corporate purposes. This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures and the extent of clinical development may vary significantly depending on numerous factors, including the progress of our and our collaborators' development efforts, the status of and results from preclinical studies and any ongoing clinical trials or clinical trials we and they may commence in the future, as well as any collaborations that we may enter into with third parties for our product candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment grade, interest bearing instruments and U.S. government securities.

**DIVIDEND POLICY**

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. We do not intend to pay cash dividends to holders of our common stock in the foreseeable future. Any future determination as to the declaration and payment of dividends, if any, will be at the discretion of our board of directors and will depend upon then existing conditions, including our financial condition, operating results, contractual restrictions, restrictions imposed by applicable law, capital requirements, business prospects and other factors our board of directors may deem relevant.

**Table of Contents****CAPITALIZATION**

The following table sets forth our cash, cash equivalents and marketable securities and our capitalization as of September 30, 2012:

on an actual basis;

on a pro forma basis to give effect to (1) the automatic conversion of all outstanding shares of our redeemable convertible preferred stock and convertible preferred stock into an aggregate of 50,241,277 shares of our common stock upon the closing of this offering, and (2) the automatic conversion of the warrants for Series E redeemable convertible preferred stock into warrants for 16,447 shares of our common stock upon the closing of this offering; and

on a pro forma as adjusted basis to give effect to (1) the automatic conversion of all outstanding shares of our redeemable convertible preferred stock and convertible preferred stock into an aggregate of 50,241,277 shares of our common stock upon the closing of this offering, (2) the automatic conversion of the warrants for Series E redeemable convertible preferred stock into warrants for our common stock upon the closing of this offering, and (3) the issuance by us of                      shares of our common stock at an initial offering price of \$                      per share, the midpoint of the estimated price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma and pro forma as adjusted information below is illustrative only, and our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this information together with our financial statements and related notes appearing elsewhere in this prospectus and the information set forth under the heading "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	As of September 30, 2012		
	Actual (in thousands, except share and per share data)	Pro Forma	Pro Forma As Adjusted
Cash, cash equivalents and marketable securities	\$ 45,418	\$ 45,418	\$
Warrant liability <sup>(1)</sup>	\$ 2,001	\$ 1,981	\$
Redeemable convertible preferred stock (Series C, D, E, F, G-1 and G-2); \$0.01 par value; 45,421,288 shares authorized, 43,115,343 shares issued and outstanding, actual; no shares issued or outstanding, pro forma and pro forma as adjusted	158,955		
Convertible preferred stock (Series A and B); \$0.01 par value; 566,450 shares authorized; 566,450 shares issued and outstanding, actual; no shares issued or outstanding, pro forma and pro forma as adjusted	327		
<b>Stockholders' equity (deficit):</b>			
Common stock; \$0.01 par value; 70,000,000 shares authorized; 5,789,127 shares issued and 4,889,127 shares outstanding, actual; 56,030,404 shares issued and 55,130,404 shares outstanding, pro forma;                      shares issued and                      shares outstanding, pro forma as adjusted	58	560	
Additional paid-in capital		158,800	
Treasury stock, at par value; 900,000 shares, actual; 900,000 shares, pro forma and pro forma as adjusted	(9)	(9)	
Accumulated other comprehensive income	10	10	
Accumulated deficit	(115,412)	(115,412)	
<b>Total stockholders' equity (deficit)</b>	<b>(115,353)</b>	<b>43,949</b>	
Total capitalization	\$ 45,930	\$ 45,930	\$



**Table of Contents**

(1) The warrant liability as of September 30, 2012 consisted of \$20,000 of liability related to warrants to purchase Series E redeemable convertible preferred stock and \$1,981,000 of liability related to warrants to purchase Series 1 nonconvertible preferred stock. As only the warrants for the Series E redeemable convertible preferred stock automatically convert into common stock warrants upon the closing of this offering, the pro forma balance sheet data does not give effect to any change in the warrant liability related to the warrants for the Series 1 nonconvertible preferred stock.

A \$1.00 increase (decrease) in the assumed initial public offering price of \$            per share, the midpoint of the estimated price range set forth on the cover page of this prospectus, would increase (decrease) total stockholders' equity and total capitalization on a pro forma as adjusted basis by approximately \$            million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The number of adjusted shares shown as outstanding in the table above is based on 4,889,127 shares of common stock outstanding as of September 30, 2012 and excludes:

7,635,307 shares of our common stock issuable upon the exercise of stock options outstanding as of September 30, 2012 at a weighted average exercise price of \$0.48 per share;

16,447 shares of our common stock issuable at an exercise price of \$1.91 per share upon the exercise of warrants outstanding at September 30, 2012, which warrants prior to the closing of this offering are exercisable to purchase Series E redeemable convertible preferred stock; and

613,844 additional shares of our common stock available for future issuance as of September 30, 2012 under our Amended and Restated 1995 Equity Incentive Plan.

**Table of Contents**

**DILUTION**

If you invest in our common stock, your interest will be diluted immediately to the extent of the difference between the initial public offering price per share you will pay in this offering and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Our historical net tangible book value as of September 30, 2012 was \$41.8 million, or \$8.55 per share of common stock. The historical net tangible book value per share represents the amount of our total tangible assets less total liabilities, divided by the number of shares of common stock outstanding as of September 30, 2012.

Our pro forma net tangible book value on September 30, 2012 was \$41.8 million, or \$0.76 per share of common stock. Pro forma net tangible book value represents total tangible assets less total liabilities and assumes the automatic conversion of the warrants for Series E redeemable convertible preferred stock into warrants for common stock upon the closing of this offering, which results in a reduction in total liabilities of \$20,000. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding as of September 30, 2012, after giving effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock and convertible preferred stock into an aggregate of 50,241,277 shares of common stock upon the closing of this offering.

After giving effect to adjustments relating to this offering, our pro forma as adjusted net tangible book value as of September 30, 2012 would have been \$            million, or \$            per share. The adjustments made to the pro forma net tangible book value per share to determine pro forma as adjusted net tangible book value per share are the following:

an increase in total assets to reflect our net proceeds of the offering as described under Use of Proceeds (assuming that the initial public offering price will be \$            per share, the midpoint of the estimated price range set forth on the cover page of this prospectus) and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us; and

the addition of the number of shares offered by us pursuant to this prospectus to the number of pro forma shares of common stock outstanding.

The initial public offering price per share will significantly exceed the pro forma as adjusted net tangible book value per share. Accordingly, new investors who purchase shares of common stock in this offering will experience an immediate dilution of their investment of \$            per share. The following table illustrates the increase in pro forma as adjusted net tangible book value of \$            per share and the dilution (the difference between the initial public offering price per share and pro forma as adjusted net tangible book value per share) to new investors:

Assumed initial public offering price per share	\$
Pro forma net tangible book value per share as of September 30, 2012	\$ 0.76
Increase per share attributable to sale of shares of common stock in this offering	
 Pro forma as adjusted net tangible book value per share after this offering	 \$
Dilution per share to new investors in this offering	\$

If the underwriters exercise their over-allotment option in full, the pro forma as adjusted net tangible book value will increase to \$            per share, representing an immediate dilution of \$            per share to new investors, assuming that the initial public offering price will be \$            per share, the midpoint of the estimated price range set forth on the cover page of this prospectus.

A \$1.00 increase (decrease) in the assumed initial public offering price of \$            per share, the midpoint of the estimated price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value by \$            million, the pro forma as adjusted net tangible book value per share by \$            per share, and the dilution in pro forma as adjusted net tangible book value per share to investors in this offering by \$            per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses

payable by us.

**Table of Contents**

If shares are issued in connection with the exercise of all outstanding options for common stock with exercise prices less than \$ \_\_\_\_\_, the midpoint of the estimated price range set forth on the cover page of this prospectus, you will experience further dilution of \$ \_\_\_\_\_ per share. As of September 30, 2012, we had outstanding options to purchase a total of \_\_\_\_\_ shares of our common stock with exercise prices less than \$ \_\_\_\_\_ per share.

The following table summarizes, as of September 30, 2012, on a pro forma as adjusted basis as described above, the differences between the number of shares of common stock purchased from us, the total consideration paid to us, and the average price per share paid by existing stockholders and by investors purchasing shares of common stock in this offering. The calculation below is based on an assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the estimated price range set forth on the cover of this prospectus, before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders			\$		\$
Investors purchasing common stock in this offering					\$
<b>Total</b>		<b>100%</b>	<b>\$</b>	<b>100%</b>	

The total number of shares reflected in the discussion and tables above is based on 4,889,127 shares of common stock outstanding as of September 30, 2012. The tables above assume no exercise of options to purchase shares of common stock outstanding as of September 30, 2012. At September 30, 2012, there were 7,635,307 shares of common stock issuable upon exercise of outstanding options with a weighted average exercise price of \$0.48 per share. The tables above also exclude 613,844 shares of common stock available for future issuance under our Amended and Restated 1995 Equity Incentive Plan at September 30, 2012.

In addition, the tables above assume no exercise of the warrants to purchase 12,500 shares of Series E redeemable convertible preferred stock with an exercise price of \$2.51 per share, which warrants are automatically converted into warrants to purchase 16,447 shares of common stock upon the closing of this offering at an exercise price of \$1.91 per share.

If the underwriters exercise their over-allotment option in full, the number of shares held by new investors will increase to \_\_\_\_\_, or \_\_\_\_\_% of the total number of shares of common stock outstanding after this offering.



**Table of Contents****SELECTED FINANCIAL DATA**

You should read the following selected financial data together with our financial statements and the related notes appearing at the end of this prospectus and the Management's Discussion and Analysis of Financial Condition and Results of Operations section of this prospectus. We have derived the statement of operations data for the years ended September 30, 2010, 2011 and 2012 and the balance sheet data as of September 30, 2011 and 2012 from our audited financial statements included elsewhere in this prospectus. Our historical results for any prior period are not necessarily indicative of any results to be expected for any future period.

	Year Ended September 30,		
	2010	2011	2012
(in thousands, except per share data)			
<b>Statement of Operations Data:</b>			
Revenue	\$ 22,763	\$ 41,882	\$ 41,706
Operating expenses:			
Research and development	9,716	11,547	15,115
General and administrative	6,105	5,036	5,302
Total operating expenses	15,821	16,583	20,417
Income from operations	6,942	25,299	21,289
Other income (expense):			
Interest income	14	83	118
Interest expense		(3,161)	
Change in fair value of warrant liability	482	(686)	(8)
Therapeutic tax credit		750	
Gain on embedded derivative		670	
Other income (expense), net	309	355	
Total other income (expense), net	805	(1,989)	110
Income before income tax	7,747	23,310	21,399
Income tax benefit	157		
Net income	7,904	23,310	21,399
Accretion of redeemable convertible preferred stock to redemption value	(5,452)	(5,454)	(5,367)
Net income allocable to participating securities	(2,236)	(16,291)	(14,663)
Net income allocable to common stockholders	\$ 216	\$ 1,565	\$ 1,369
Net income per share allocable to common stockholders <sup>(1)</sup> :			
Basic	\$ 0.04	\$ 0.32	\$ 0.29
Diluted	\$ 0.04	\$ 0.31	\$ 0.26
Weighted average common shares outstanding <sup>(1)</sup> :			
Basic	4,873	4,824	4,693
Diluted	6,746	8,005	10,666
Pro forma net income per share allocable to common stockholders (unaudited) <sup>(2)</sup> :			
Basic			\$ 0.39
Diluted			\$ 0.35
Pro forma weighted average common shares outstanding (unaudited) <sup>(2)</sup> :			
Basic			54,934
Diluted			60,910

**Table of Contents**

	As of September 30,	
	2011	2012
	(in thousands)	
<b>Balance Sheet Data:</b>		
Cash, cash equivalents and marketable securities	\$ 23,329	\$ 45,418
Working capital <sup>(3)</sup>	22,950	41,574
Total assets	26,096	52,162
Warrant liability	1,993	2,001
Redeemable convertible preferred stock	153,588	158,955
Convertible preferred stock	327	327
Total stockholders' deficit	(131,961)	(115,353)

- (1) See Note 15 to our financial statements for further details on the calculation of basic and diluted net income per share allocable to common stockholders.
- (2) See Note 15 to our financial statements for further details on the calculation of pro forma net income per share allocable to common stockholders.
- (3) We define working capital as current assets less current liabilities.

**Table of Contents**

**MANAGEMENT'S DISCUSSION AND ANALYSIS OF  
FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*You should read the following discussion and analysis of financial condition and results of operations together with the section entitled "Selected Financial Data" and our financial statements and related notes included elsewhere in this prospectus. This discussion and other parts of this prospectus contain forward-looking statements that involve risks and uncertainties, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the "Risk Factors" section of this prospectus.*

**Overview**

We are a research and development-focused biotechnology company that uses its robust chemistry-driven approach and drug discovery capabilities to create small molecule drugs in the infectious disease field. We are discovering and developing inhibitors designed for use against the hepatitis C virus, referred to as HCV. We believe that a successful approach to a complete cure for HCV in most patients will likely require treatment with a combination of drugs that attack different mechanisms necessary for replication and survival of HCV. Further, as there are many variants of HCV, we are developing inhibitors that may be used in multiple combination therapies, each designed and tested for effectiveness against one or more of those variants. Our development of inhibitors for validated HCV target mechanisms, as well as our collaborations with Abbott Laboratories and Novartis, should allow us to participate in multiple unique drug combinations as we seek the best combination therapies for HCV in its various forms. Total worldwide sales of HCV therapies were over \$3.5 billion in 2011. We believe that annual worldwide sales of these therapies and future approved therapies could increase sales in this market to \$10 to \$20 billion within the next ten years. In addition to our HCV programs, we have used our internal research capabilities to discover a new class of antibiotics which we are developing for the treatment of multi-drug resistant bacteria, including methicillin-resistant *Staphylococcus aureus* bacteria, also referred to as MRSA. We have utilized our internal chemistry and drug discovery capabilities and our collaborations to generate all of our development-stage programs, and we have active research efforts to broaden our infectious disease drug pipeline.

Our HCV portfolio includes inhibitors of four fundamental, validated HCV targets:

**NS3 Protease Inhibitor: ABT-450.** Our lead product candidate, ABT-450, is a protease inhibitor being developed in several combination regimens in multiple Phase 2 and Phase 3 trials through our collaboration with Abbott.

**NS5A Inhibitor: EDP-239.** Our lead NS5A product candidate, EDP-239, is being developed through our collaboration with Novartis.

**Cyclophilin Inhibitor: EDP-546.** Our independent research activities are focused on our lead cyclophilin inhibitor compound, EDP-546, which is in preclinical development.

**Nucleotide Polymerase Inhibitor.** We also have a small-molecule drug discovery effort underway for nucleotide polymerase inhibitors.

In our HCV programs, Abbott has funded all research and development of our protease inhibitors since we entered into the collaboration in November 2006, and is responsible for obtaining regulatory approvals and commercializing ABT-450 and any follow-on products worldwide. We received \$57.2 million from Abbott upon signing the collaboration agreement and Abbott's simultaneous purchase of preferred stock from us in 2006, and we received a \$40.0 million milestone payment in December 2010 following completion of a successful Phase 2a clinical trial. Assuming Abbott's successful development of the first protease inhibitor product, we will also be eligible to receive \$195 million of pre-commercialization milestone payments (exclusive of a \$15.0 million milestone payment we became entitled to receive in November 2012 from Abbott), as well as additional milestone payments for any follow-on protease inhibitor products and tiered royalties ranging on a blended basis from the low double digits up to the high teens per product on Abbott's net sales, if any, allocable to our collaboration's protease inhibitors. Novartis is responsible for all further development of our NS5A inhibitors, as well as funding us for further research we conduct to discover additional NS5A compounds at least through February 2013.



## **Table of Contents**

We are currently funding all research and development for our cyclophilin inhibitor and nucleotide polymerase inhibitor programs. We expect to incur substantially greater expenses as we seek to advance these programs into clinical development.

In addition to our HCV programs, we have used our internal research capabilities to discover a new class of antibiotics called Bicyclolides, which we are developing to overcome bacteria with multi-drug resistance, known as superbugs. Up to \$14.3 million of the preclinical development of our lead antibiotic candidate, EDP-788, is funded under a September 2011 contract with the National Institute of Allergy and Infectious Diseases, a division of the National Institutes of Health, an agency of the United States Department of Health and Human Services, or NIAID, and there is potential for further NIAID funding of early clinical development.

Since commencing our operations in 1995, we have devoted substantially all of our resources to the discovery and development of novel inhibitors for the treatment of infectious diseases. We have funded our operations primarily through the sale of convertible preferred stock and payments received under our collaborations and a government contract. As of September 30, 2012, we had \$45.4 million in cash and investments. We are eligible to receive over the next several years an aggregate of \$430 million (exclusive of an \$11.0 million milestone payment we became entitled to receive in November 2012 from Novartis and a \$15.0 million milestone payment we became entitled to receive in November 2012 from Abbott) based on potential future pre-commercialization milestones under our Abbott and Novartis collaborations, assuming successful clinical trial results for the respective collaboration programs and our collaborators' continued development of our product candidates through successful regulatory and reimbursement approvals in the United States and other major markets. In addition, we are also eligible to receive tiered royalties ranging on a blended basis from the low double digits up to the high teens on worldwide net sales of any products containing protease inhibitors or NS5A inhibitors developed pursuant to the collaborations, as well as commercialization sales milestones under our Novartis collaboration.

Our revenue from our collaboration agreements has resulted in our reporting net income in each of the past three fiscal years. However, we have an accumulated deficit of \$115.4 million as of September 30, 2012 and we have generated no royalties or other revenue from product sales. We expect that our revenue in the near term will continue to be substantially dependent on our collaborations with Abbott and Novartis and their continued advancement of the related development programs. Given the schedule of potential milestone payments and the uncertain nature and timing of clinical development, we cannot predict when or whether we will receive further milestone payments under these collaborations or whether we will continue to report either revenue or net income in future years.

## **Financial Operations Overview**

### ***Revenue***

Since our inception, our revenue has been derived from two primary sources: collaboration agreements with pharmaceutical companies and one government research and development contract. We have not generated any revenue from product sales. We have entered into three significant collaboration agreements. In November 2006, we entered into a collaboration agreement with Abbott and in February 2012 we entered into a collaboration agreement with Novartis. Our third collaboration, which we entered into in 2004 for the development of an antibiotic candidate in Japan, concluded in 2010 when our collaborator decided not to pursue further development of the licensed product candidate due to its limited potency against *Haemophilus influenzae* in clinical trials of community-acquired pneumonia. In September 2011, we entered into a contract with NIAID, which will fund us for the preclinical development of our lead product candidate in our new class of Bicyclolide antibiotics.

**Table of Contents**

The following table is a summary of revenue recognized from our collaboration agreements and government contract for the years ended September 30, 2010, 2011 and 2012:

	Year Ended September 30,		
	2010	2011	2012
	(in thousands)		
Abbott agreement:			
Upfront license payment and research funding	\$ 6,518	\$ 1,882	\$
Milestone payments		40,000	
Novartis agreement:			
Upfront license payment and research funding			35,567
Concluded collaboration agreement:			
Upfront license payment and research funding	8,245		
Milestone payments	8,000		
NIAID contract			6,139
<b>Total revenue</b>	<b>\$ 22,763</b>	<b>\$ 41,882</b>	<b>\$ 41,706</b>

Under the terms of the Abbott agreement, as amended, we received an upfront license payment of \$44.7 million and a commitment for research funding through December 15, 2010, and we granted Abbott an option to enter into a six-month evaluation period. We received a total of \$8.1 million of research funding and expense reimbursement from Abbott through June 15, 2011, the conclusion of the evaluation period. In December 2010, we received a \$40.0 million milestone payment from Abbott related to Abbott's successful completion of a Phase 2a clinical study of an ABT-450-containing regimen. We recognized revenue from these payments, as well as from a \$1.6 million premium above fair value paid for Series G-1 redeemable convertible preferred stock that Abbott purchased concurrently with the execution of the original agreement, over the period from the date of the original agreement through the end of the evaluation period using the proportional performance model. Under this revenue recognition model, the revenue we recognized was limited to the amount of nonrefundable payments received or receivable to date. Related to these payments by Abbott, we recognized revenue of \$6.5 million and \$41.9 million during the years ended September 30, 2010 and 2011, respectively. Since all of our research obligations under the agreement were concluded by June 30, 2011, any future milestone payments received will be recognized as revenue when each milestone is achieved by Abbott. In November 2012, we became entitled to receive a \$15.0 million milestone payment when Abbott initiated dosing in a Phase 3 clinical trial that includes ABT-450. Under the terms of the Abbott agreement, we are eligible to receive future milestone payments of \$195 million (exclusive of the \$15.0 million earned milestone payment discussed above) related to the successful development of the first HCV treatment regimen by Abbott incorporating our collaboration's protease inhibitor. We are also eligible to receive royalties on Abbott's net sales, if any, allocable to any one of our collaboration's protease inhibitors.

Under the terms of the Novartis agreement, we received an upfront payment of \$34.4 million and a commitment to fund research at an agreed amount for one year. We recognized the upfront license payment upon receipt as we determined that the license to which the payment related and the research services were separable elements under the agreement that could be accounted for as each was delivered or provided. During the year ended September 30, 2012, revenue recognized under this agreement was \$35.6 million, which consisted of the upfront license payment and research funding earned during that period. Our agreement with Novartis provides that we will receive up to \$1.8 million in research funding during the first year of the agreement, which began in February 2012. Additionally, our collaboration with Novartis provides for future milestone payments of up to \$406 million if certain goals related to drug development and net product sales are achieved by Novartis. In November 2012, we became entitled to receive an \$11.0 million milestone payment when Novartis initiated dosing in a Phase 1 clinical trial that includes EDP-239. An additional milestone payment of \$15 million will be due upon Novartis' initiation of a subsequent Phase 2 trial using a combination containing an NS5A inhibitor. We are also eligible to receive royalties on Novartis' net sales, if any, allocable to our collaboration's NS5A inhibitors.

The conclusion in 2010 of our collaboration for development of an antibiotic in Japan resulted in the full recognition of revenue associated with fees and milestone payments totaling \$16.2 million received in prior years. Due to a technology option within the license agreement for which we had not been able to establish

**Table of Contents**

objective evidence of fair value, we had recorded all payments received from our collaborator as deferred revenue until the option was exercised or the agreement concluded. Upon the conclusion of the collaboration, we recognized the \$16.2 million of previously deferred revenue in fiscal 2010 as we then had no further obligations under this agreement.

Under the terms of the NIAID contract, NIAID will pay us research and development funding payments of up to \$14.3 million over an initial period of 30 months. The award also contains six option periods, which in aggregate could extend the contract at the option of NIAID up to an additional 30 months and provide us additional funding of up to \$28.4 million. We recognize revenue under this contract as the research and development services are performed. We recognized \$6.1 million of revenue under this agreement during the year ended September 30, 2012.

As our internal product candidates are currently in preclinical development, we have not generated any revenue from product sales and do not expect to generate any revenue from product sales for at least the next several years. We expect that our revenue for the next several years will be derived primarily from payments under our current collaboration agreements with Abbott and Novartis, payments under our NIAID contract, and any additional collaborations or government contracts that we may enter into in the future. We cannot provide assurance as to the timing of future milestone or royalty payments or that we will receive any of these payments at all.

***Operating Expenses***

The following table summarizes our operating expenses for the years ended September 30, 2010, 2011 and 2012:

	Year Ended September 30,		
	2010	2011	2012
	(in thousands)		
Research and development	\$ 9,716	\$ 11,547	\$ 15,115
General and administrative	6,105	5,036	5,302
<b>Total operating expenses</b>	<b>\$ 15,821</b>	<b>\$ 16,583</b>	<b>\$ 20,417</b>

***Research and Development Expenses***

Research and development expenses consist of costs incurred to conduct basic research, such as the discovery and development of novel small molecules as therapeutics. We expense all costs of research and development as incurred. These expenses consist primarily of:

personnel costs, including salaries, related benefits and stock-based compensation for employees engaged in scientific research and development functions;

third-party contract costs relating to research, formulation, manufacturing, preclinical study and clinical trial activities;

third-party license fees;

laboratory consumables; and

allocated facility-related costs.

Project-specific expenses reflect costs directly attributable to our clinical development candidates and preclinical candidates nominated and selected for further development. Remaining research and development expenses are reflected in research and drug discovery, which represents early-stage drug discovery programs. At any given time, we typically have several active early stage research and drug discovery projects. Our internal resources, employees and infrastructure are not directly tied to any individual research or drug discovery project and are typically

## Edgar Filing: ENANTA PHARMACEUTICALS INC - Form S-1/A

deployed across multiple projects. As such, we do not maintain information regarding costs incurred for our early-stage research and drug discovery programs on a project-specific basis.

We expect that our research and development expenses will increase in the future as we advance our two independent HCV programs and our antibiotic program for MRSA into clinical development.



## **Table of Contents**

Our research and drug discovery programs are at an early stage; therefore the successful development of our product candidates is highly uncertain and may not result in approved products. Completion dates and completion costs can vary significantly for each product candidate and are difficult to predict. Given the uncertainty associated with clinical trial enrollments and the risks inherent in the development process, we are unable to determine the duration and completion costs of the current or future clinical trials of our product candidates or if, or to what extent, we will generate revenue from the commercialization and sale of any of our product candidates. We anticipate that we will make determinations as to which development programs to pursue and how much funding to direct to each program on an ongoing basis in response to the preclinical and clinical success of each product candidate, as well as ongoing assessments of the commercial potential of each product candidate.

### *General and Administrative Expenses*

General and administrative expenses consist primarily of personnel costs, consisting of salaries, related benefits and stock-based compensation, of our executive, finance, business and corporate development and other administrative functions. General and administrative expenses also include travel expenses, allocated facility-related costs not otherwise included in research and development expenses, and professional fees for auditing, tax and legal services, including legal expenses to pursue patent protection of our intellectual property.

We expect that general and administrative expenses will increase in the future as we expand our operating activities and incur additional costs associated with operating as a public company. These public company related increases will likely include costs of additional personnel; additional legal fees, accounting and audit fees and directors and officers liability insurance premiums; and costs related to investor relations.

### *Other Income (Expense)*

*Interest income.* Interest income consists of interest earned on our cash and investment balances. Our interest income has not been significant due to nominal cash and investment balances and low interest earned on invested balances. We anticipate that our interest income will increase in the future due to our higher cash and investment balances now existing as a result of the \$34.4 million upfront payment that we received from Novartis in March 2012, as well as our receipt of the anticipated cash proceeds from this offering.

*Interest expense.* Interest expense consisted of cash interest paid on our bridge notes and non-cash interest expense related to the accretion of debt issuance costs and debt discounts associated with our issuance of bridge notes in the first quarter of fiscal 2011. We anticipate that we will have little or no interest expense in the future as our outstanding bridge notes were fully repaid in the first quarter of fiscal 2011 and we no longer have any debt outstanding.

*Change in fair value of warrant liability.* We have outstanding warrants for the purchase of our redeemable convertible preferred stock and nonconvertible preferred stock that we believe are financial instruments that may require a transfer of assets because of the redemption features of the underlying stock. Therefore, we have classified these warrants as liabilities that we remeasure to fair value at each reporting period and we record the changes in the fair value of the warrants as a component of other income (expense).

*Therapeutic tax credit.* We recorded other income for the year ended September 30, 2011 related to the Qualifying Therapeutic Discovery Project, or QTDP, reimbursement program of the United States government, which provided for reimbursement in calendar year 2010 of certain costs paid or incurred during calendar years 2009 and 2010 that were directly related to the conduct of a QTDP. We do not anticipate any further income related to the QTDP program.

*Gain on embedded derivative.* In connection with the repayment of our bridge financing that we entered into and fully repaid in the first quarter of fiscal 2011, we settled an embedded derivative at no cost to us and recorded a gain on settlement consisting of the value of the embedded derivative.

*Other income (expense), net.* Other income (expense), net consisted primarily of miscellaneous service income unrelated to our core operations. We do not expect to generate this income in the future as we do not anticipate providing these services in the future.

---

## **Table of Contents**

### ***Income Tax Benefit***

Income tax benefit in fiscal 2010 consisted of a refund we received related to federal Alternative Minimum Tax paid in 2008. In the years ended September 30, 2010, 2011 and 2012, we recorded no income tax provision because, in each of those periods, we used net operating loss carryforwards, which had previously been recorded with a full valuation allowance, to fully offset our income before taxes generated in those periods.

### **Critical Accounting Policies**

Our financial statements are prepared in accordance with generally accepted accounting principles in the United States of America. The preparation of our financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amount of assets, liabilities, revenue, costs and expenses, and related disclosures. We believe that the estimates and assumptions involved in the accounting policies described below may have the greatest potential impact on our financial statements and, therefore, consider these to be our critical accounting policies. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions and conditions. See also Note 2 of our financial statements included elsewhere in this prospectus for information about these critical accounting policies as well as a description of our other significant accounting policies.

### ***JOBS Act***

On April 5, 2012, the JOBS Act was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an emerging growth company. As an emerging growth company, we are electing not to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision not to take advantage of the extended transition period is irrevocable. In addition, we are in the process of evaluating the benefits of relying on the other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, if as an emerging growth company we choose to rely on such exemptions, we may not be required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis), and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the Chief Executive Officer's compensation to median employee compensation. These exemptions will apply for a period of five years following the completion of our initial public offering or until we no longer meet the requirements of being an emerging growth company, whichever is earlier.

### ***Revenue Recognition***

Our revenue is generated primarily through collaborative research and license agreements. The terms of these agreements contain multiple deliverables which may include (i) licenses, (ii) research and development activities, and (iii) participation in joint research and development steering committees. The terms of these agreements may include nonrefundable upfront license fees, payments for research and development activities, payments based upon the achievement of certain milestones, and royalty payments based on product sales derived from the collaboration. In all instances, revenue is recognized only when the price is fixed or determinable, persuasive evidence of an arrangement exists, delivery has occurred or the services have been rendered, collectibility of the resulting receivable is reasonably assured, and we have fulfilled our performance obligations under the contract.

On October 1, 2011, we adopted Accounting Standards Update No. 2009-13, *Multiple-Deliverable Revenue Arrangements*, or ASU 2009-13. This guidance, which applies to multiple element arrangements entered into or

---

**Table of Contents**

materially modified on or after October 1, 2011, amends the criteria for separating and allocating consideration in a multiple element arrangement by modifying the fair value requirements for revenue recognition and eliminating the use of the residual value method. The selling prices of deliverables under the arrangement may be derived using third-party evidence, or TPE, or a best estimate of selling price, or BESP, if vendor-specific objective evidence of fair value, or VSOE, is not available. The objective of BESP is to determine the price at which we would transact a sale if the element within the license agreement was sold on a standalone basis. Establishing BESP involves management's judgment and considers multiple factors, including market conditions and company-specific factors including those factors contemplated in negotiating the agreements as well as internally developed models that include assumptions related to market opportunity, discounted cash flows, estimated development costs, probability of success, and the time needed to commercialize a product candidate pursuant to the license. In validating our BESP, we consider whether changes in key assumptions used to determine the BESP will have a significant effect on the allocation of the arrangement consideration between the multiple deliverables. Deliverables under the arrangement are separate units of accounting if (i) the delivered item has value to the customer on a standalone basis and (ii) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially within our control. The arrangement consideration that is fixed or determinable at the inception of the arrangement is allocated to the separate units of accounting based on their relative selling prices. The appropriate revenue recognition model is applied to each element and revenue is accordingly recognized as each element is delivered. We may exercise significant judgment in determining whether a deliverable is a separate unit of accounting. We elected to adopt ASU 2009-13 prospectively as of October 1, 2011.

In February 2012, we entered into a license and collaboration agreement with Novartis for the development, manufacture, and commercialization of our lead development candidate, EDP-239, from our NS5A inhibitor program for HCV. Under the terms of the Novartis agreement, Novartis agreed to pay us a nonrefundable upfront fee and reimbursement of manufacturing and quality assurance expenses related to EDP-239 totaling \$34.4 million. In addition, Novartis agreed to fund up to \$1.8 million of our NS5A research activities through February 2013. We are eligible to receive milestone payments up to \$406 million if applicable milestones relating to clinical trials, regulatory approvals, and net sales are achieved by Novartis. We are also eligible to receive tiered royalties ranging on a blended basis from the low double digits up to the high teens on net product sales by Novartis, if any, allocable to our collaboration's NS5A inhibitors.

We determined that the deliverables under the Novartis agreement include the exclusive, royalty-bearing, sublicensable license to EDP-239 and the research services. We concluded that the EDP-239 license had standalone value to Novartis and was separable from the research services because the license is sublicensable, there are no restrictions as to Novartis' use of the license, and Novartis has the requisite scientific expertise in the HCV NS5A field. We also concluded that participation on a joint steering committee, as provided for by the agreement, is protective in nature as we have no decision making authority, there are no penalties or recourse if we choose not to participate, and the purpose of the steering committee is to keep us apprised of the status of the development and commercialization efforts. Therefore, no arrangement consideration was allocated to the joint steering committee participation. We were not able to establish VSOE or TPE for either the license or the research services and instead allocated the arrangement consideration between the license and research services based on their relative selling prices using BESP. We developed our estimate of BESP of the license using a discounted cash flow analysis, taking into consideration assumptions including the development and commercialization timeline, discount rate, probability of success, and probable treatment combination and associated peak sales figures which generate royalty amounts. The funding rate for the research services is consistent with the rate received in our prior collaboration arrangement with Abbott and is consistent with its fully burdened cost of service. Therefore, our determination of BESP for the research services is consistent with the reimbursement rate stated in the contract.

In determining our best estimate of selling price, we considered discounted cash flow models. Our key assumptions in these models included the following market conditions and entity-specific factors: (a) the specific rights provided under the license to develop and commercialize EDP-239 worldwide, (b) the stage of development of EDP-239 and estimated remaining development and commercialization timelines, (c) the probability of successfully developing and commercializing EDP-239, (d) the probable treatment combination,

**Table of Contents**

(e) the market size for EDP-239 including the associated sales figures which generate royalty revenue, (f) the expected product life of EDP-239 assuming commercialization, and (g) the competitive environment. We assumed that royalties from sales of EDP-239 would be based on a drug compound that will be part of a triple combination drug therapy. The time to commercialization was based on our estimates, which projected the first sales of EDP-239 in 2018. We utilized a discount rate of 15% in our analysis, representing the weighted average cost of capital derived from returns on equity for comparable companies.

These assumptions involve judgment and inherent uncertainty; however, significant changes in key assumptions used to determine the BESP would not have a significant effect on the revenue recognized.

***Stock-Based Compensation***

The methodology we have used to date in measuring stock-based compensation expense is described below. Following the completion of this offering, stock option pricing and values will be determined based on the quoted market price of our common stock.

We measure stock options granted to employees and directors at fair value on the date of grant and recognize the corresponding compensation expense of those awards, net of estimated forfeitures, over the requisite service period, which is generally the vesting period of the respective award. Generally, we issue stock options with only service-based vesting conditions and record the expense for these options using the straight-line method. We have historically granted stock options with exercise prices equivalent to the fair value of our common stock as of the date of grant.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. We have historically been a private company and lack company-specific historical and implied volatility information. Therefore, we estimate our expected volatility based on the historical volatility of our publicly traded peer companies and expect to continue to do so until such time as we have adequate historical data regarding the volatility of our traded stock price. The expected term of our options has been determined utilizing the simplified method for awards that qualify as plain-vanilla options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that we have never paid cash dividends and do not expect to pay any cash dividends in the foreseeable future. The assumptions we used to determine the fair value of stock options granted are as follows, presented on a weighted average basis:

	<b>Year Ended September 30,</b>		
	<b>2010</b>	<b>2011</b>	<b>2012</b>
Risk-free interest rate	2.57%	2.73%	0.93%
Expected term (in years)	6.25	6.25	6.00
Expected volatility	66%	87%	78%
Expected dividends	0%	0%	0%

These assumptions represent our best estimates, but the estimates involve inherent uncertainties and the application of our judgment. As a result, if factors change and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different. We recognize compensation expense for only the portion of awards that are expected to vest. In developing a forfeiture rate estimate, we have considered our historical experience to estimate pre-vesting forfeitures. If our actual forfeiture rate is materially different from the estimate, our stock-based compensation expense could be different from what we have recorded in the current period.

***Valuations of Common Stock***

The fair value of our common stock is determined by our board of directors, with input from management, and takes into account our most recently available valuation of common stock and our assessment of additional objective and subjective factors we believed were relevant and which may have changed from the date of the

## Table of Contents

most recent valuation through the date of the grant. Because there has been no public market for our common stock and in accordance with the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, our board of directors considered numerous objective and subjective factors to determine its best estimate of the fair value of our common stock as of each grant date, including the following:

the progress of our research and development programs;

achievement of enterprise milestones, including our entering into collaboration and licensing agreements;

contemporaneous third-party valuation of our common stock;

peer group trading multiples;

our historical and forecasted performance and operating results;

our need for future financing to fund operations;

the rights and preferences of our redeemable convertible preferred stock and our convertible preferred stock relative to our common stock;

the likelihood of achieving a discrete liquidity event, such as a sale of our company or an initial public offering, or IPO, given prevailing market conditions; and

external market and economic conditions impacting our industry sector.

We believe our estimates of the fair value of our common stock were reasonable.

Our common stock valuation as of December 31, 2010 was prepared utilizing the option-pricing method, or OPM. The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceed the value of the liquidation preference at the time of a liquidity event, such as a strategic sale, merger or IPO, assuming the enterprise has funds available to make a liquidation preference meaningful and collectible by the holders of preferred stock. The common stock is modeled as a call option on the underlying equity value at a predetermined exercise price. In the model, the exercise price is based on a comparison with the total equity value rather than, as in the case of a regular call option, a comparison with a per share stock price. Thus, common stock is considered to be a call option with a claim on the enterprise at an exercise price equal to the remaining value immediately after the preferred stock is liquidated. The option-pricing method uses the Black-Scholes option-pricing model to price the call options. This model defines the securities' fair values as functions of the current fair value of a company and uses assumptions such as the anticipated timing of a potential liquidity event and the estimated volatility of the equity securities. We allocated the equity value using the OPM assuming 1.05 years to liquidity. The estimated time to liquidity was based on a 60% probability of liquidity in 0.75 years and a 40% probability of liquidity in 1.50 years. The anticipated timing and probability of a liquidity event was based on then-current plans and estimates of our board of directors and management regarding a liquidity event. We assumed volatility of 87% based on historical trading volatility for our peer companies. The aggregate value of the common stock derived from the OPM was then divided by the number of shares of common stock outstanding to arrive at the per share value.

## Edgar Filing: ENANTA PHARMACEUTICALS INC - Form S-1/A

The valuation technique used to estimate enterprise value in order to derive the value of the common stock was the guideline public company method under the market approach. The guideline public company method includes comparisons of our company to publicly traded companies in our industry group based on two categories. The first category consists of publicly-traded companies which are, in certain respects, comparable to our company in terms of stage of clinical trials and indications addressed. The second category consists of life sciences companies which completed IPOs in 2010. The companies used for comparison under the guideline public company method were selected based on a number of factors, including, but not limited to, the similarity of their industry, business model, financial risk and stage of development to those of ours.

## **Table of Contents**

To derive the value of the common stock, the proceeds to the common stockholders were calculated based on the preferences and priorities of the preferred and common stock, including the participation features of certain series of the preferred shares. A discount for lack of marketability of 25% was applied to reflect the increased risk arising from the inability to readily sell the shares.

Our common stock valuations as of May 31, 2012 and September 30, 2012 were prepared utilizing a hybrid of the OPM and the probability-weighted expected return method, or PWERM. Under the PWERM methodology, the fair market value of common stock is estimated based upon an analysis of future values for our company assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available to us as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock. A discount for lack of marketability, to account for the illiquidity of the common stock, is applied to the indicated common stock value to determine the fair value of the common stock.

Three types of future event scenarios were considered: an IPO in the near term, a sale in the near term, and a longer-term liquidity event. The IPO and sale scenarios were valued using the PWERM and the longer-term liquidity event was valued using the OPM. As of May 31, 2012, management and our board of directors determined that the total probability for the IPO scenario was 80%, for the near-term sale scenario 10%, and for the longer-term liquidity event 10%. As of September 30, 2012, management and our board of directors determined that the total probability for the IPO scenario was 90%, for the near-term sale scenario 5%, and for the longer-term liquidity event 5%. Management and our board of directors made these allocations based on an analysis of current market conditions at the time, including current IPO valuations of similarly situated companies, and their expectations as to the timing and likely prospects of these future-event scenarios.

The scenarios referred to above utilized two valuation approaches to estimate enterprise value in order to derive the value of the common stock. We estimated enterprise value using the guideline public company method and guideline transaction method under the market approach and using the discounted future cash flow method under the income approach. Under the guideline public company method, we considered an average of pre-money values for selected IPOs completed by life sciences companies from 2010 through May 2012 for the May 31, 2012 valuation and from 2010 through September 2012 for the September 30, 2012 valuation. In addition, we considered a median multiple of invested capital as indicated by the IPOs. Under the guideline transaction method, we considered the equity values indicated by four acquisitions completed in 2010 and 2011 for the May 31, 2012 valuation and by six acquisitions completed in 2011 and 2012 for the September 30, 2012 valuation. The companies used for comparison were selected based on a number of factors, including, but not limited to, the similarity of their industry, business model, financial risk and stage of development to those of ours. The discounted future cash flow method involves applying appropriate discount rates to estimated cash flows that were based on forecasts of revenue, costs and capital requirements. Our assumptions underlying the estimates were consistent with the plans and estimates that we use to manage the business. The risks associated with achieving our forecasts were assessed in selecting the appropriate discount rates and selecting probability weights for forecasted cash flows.

The longer-term liquidity event scenario referred to above utilized the OPM to allocate equity value to the preferred and common stock. We allocated the equity value using the OPM assuming 2.6 years to liquidity as of May 31, 2012 and 2.3 years to liquidity as of September 30, 2012. The anticipated timing and probability of a liquidity event was based on then-current plans and estimates of our board of directors and management assuming an IPO or sale were not completed in the near term. We assumed volatility of 74% and 75% as of May 31, 2012 and September 30, 2012, respectively, based on historical trading volatility for our peer companies.

To derive the value of the common stock for each scenario, the proceeds to the common stockholders were calculated based on the preferences and priorities of the preferred and common stock. We applied a discount for lack of marketability of 10% to the common stock to account for the lack of access to an active public market and the increased probability that we would achieve a public offering and listing on a national exchange.

**Table of Contents***Option Grants*

The following table summarizes by grant date the number of shares subject to options granted between October 1, 2010 and September 30, 2012, the per share exercise price of the options, the fair value of common stock underlying the options on date of grant, and the per share estimated fair value of the options:

<b>Grant Date</b>	<b>Number of Shares Subject to Options Granted</b>	<b>Per Share Exercise Price of Options<sup>(1)</sup></b>	<b>Fair Value of Common Stock on Date of Option Grant</b>	<b>Per Share Estimated Fair Value of Options<sup>(2)</sup></b>
April 15, 2011	636,000	\$ 0.59	\$ 0.59	\$ 0.46
June 17, 2011	63,313	\$ 0.59	\$ 0.59	\$ 0.44
September 23, 2011	125,000	\$ 0.59	\$ 0.59	\$ 0.43
June 20, 2012	513,500	\$ 2.73	\$ 2.73	\$ 1.81

(1) The Per Share Exercise Price of Options represents the determination by our board of directors of the fair market value of our common stock on the date of grant, as determined taking into account our most recently available valuation of common stock as well as additional factors which may have changed since the date of the most recent contemporaneous valuation through the date of grant.

(2) The Per Share Estimated Fair Value of Options reflects the weighted average fair value of options granted on each grant date as estimated at the date of grant using the Black-Scholes option-pricing model. This model estimates the fair value using as inputs the exercise price of the option and assumptions of the risk-free interest rate, expected term of the option, expected share price volatility of the underlying common stock and expected dividends on the underlying common stock.

We determined that the fair value of our common stock increased from \$0.28 per share on October 1, 2010 to \$3.09 on September 30, 2012. The following discussion describes the reasons for the increases in the fair value of our common stock over this period and as compared to the midpoint of the estimated price range set forth on the cover page of this prospectus of \$ per share.

*Year Ended September 30, 2011.* During the year ended September 30, 2011, or fiscal 2011, we continued to operate our business in the ordinary course. In April 2011, we obtained a third-party valuation of our common stock as of December 31, 2010 as one of the factors considered by our board of directors in its determination of the fair value of our common stock. This valuation reflected our receipt in December 2010 of \$40.0 million as our first milestone payment from our collaboration with Abbott, based on the successful completion of a Phase 2a clinical trial of ABT-450 in combination with interferon treatment. Based on this valuation and other factors considered by our board of directors, we determined that the fair value of our common stock increased to \$0.59 per share as of December 31, 2010. From December 31, 2010 through September 23, 2011, we determined that there had been no further increase in the fair value of our common stock because there had been no material change in our business or in the general market for biotechnology companies, including the market for HCV companies. We still had no completed clinical study to show that our lead compound could be effective without interferon, and we had made little progress in obtaining any other collaboration for our NS5A inhibitor program or any other program. During the year ended September 30, 2011, we had no plans for an initial public offering in the near term because we did not believe that the public markets presented a favorable environment at that time for a biotechnology company such as ours.

*Nine Months Ended June 30, 2012.* During the first eight months of fiscal 2012, which was the period ended May 31, 2012, there were several significant developments in our lead programs, our business development efforts, the prospects for interferon-free treatment regimens for HCV and a substantial increase in the value of companies developing new HCV therapies, as well as improved market interest in initial public offerings of biotechnology companies. In this period, the first successful clinical trials of ABT-450 were completed in orally administered, interferon-free regimens, namely the Pilot and Co-Pilot studies, the results of which were published in early April 2012, showing a very significant sustained virologic response, or SVR, in over 90% of the study patients. A more advanced Phase 2b clinical trial, known as the Aviator study, also began in the first quarter of fiscal 2012 to investigate multiple combination therapies involving ABT-450 without interferon.



**Table of Contents**

In addition, in the first quarter of fiscal 2012, we filed an Investigational New Drug Application, or IND, for our second HCV program, developing NS5A inhibitors, and received no FDA objection to our proceeding with clinical testing. We then completed the successful negotiation and signing in February 2012 of our collaboration with Novartis for the development of these inhibitors. This collaboration resulted in an upfront payment to us of \$34.4 million and a \$1.8 million commitment for future research funding, as well as potential future milestone and royalty payments. Due primarily to the Novartis collaboration, we generated revenue of \$39.8 million during the nine months ended June 30, 2012. On September 30, 2011, we also were awarded our contract from NIAID to fund the preclinical development of our lead antibiotic product candidate.

In addition to the developments in our own business, in November 2011, a publicly held biotechnology company announced the first results of its Phase 2b trial of its orally administered compound in an interferon-free regimen for HCV, which resulted in the November 2011 sale of that company at a price approximately 114% above the company's market value before the first announcement of the results of its successful clinical trial. In January 2012, a second publicly held biotechnology company with a lead HCV program announced its sale at a price representing a premium of approximately 163% above the market capitalization of the company. Following these transactions and other developments in the market for HCV companies, the market value of our most comparable publicly-held peer companies with HCV programs that were still independent increased substantially, in one case increasing 135%, and in a second case 168%, in the four months following September 30, 2011.

In early calendar 2012, we evaluated the public market environment and determined that the market conditions were favorable for HCV-focused biotechnology companies, which caused us to consider an initial public offering. From March 31, 2012 to May 31, 2012, we began to engage investment bankers, lawyers and accountants to start the process of assisting us to prepare for an initial public offering and held our initial IPO organizational meeting in May 2012. In this period, we obtained a third-party valuation of our common stock as one of the factors considered by our board of directors in its determination of the fair value of our common stock as of May 31, 2012. We adjusted our valuation model to account for the increased probability of an IPO scenario, in light of continued favorable market conditions and our progress achieved towards a potential initial public offering of our common stock. Based on the revised model and the changes in our business and in the market values of companies developing novel therapies for HCV, as well as the impact of an increasing enterprise value on the relative value of our common stock as compared to our convertible preferred stock and redeemable convertible preferred stock, we determined that the fair value of our common stock had increased to \$2.73 per share as of May 31, 2012 and remained unchanged through June 30, 2012.

*Three Months Ended September 30, 2012.* During the fourth quarter of fiscal 2012, there was no material change in our business. With respect to our product collaborations, as of September 30, 2012, we believed there was a high probability of Abbott initiating an interferon-free Phase 3 clinical trial of a combination including ABT-450, which would trigger a milestone payment from Abbott in the near term. Accordingly, we factored the probable receipt of the milestone payment into our valuation model as of that date. During the quarter, we obtained a third-party valuation of our common stock as one of the factors considered by our board of directors in its determination of the fair value of our common stock as of September 30, 2012. We also continued to carry out activities related to preparation for the IPO and, on August 30, 2012, submitted a confidential registration statement to the SEC for an initial public offering of our common stock. We adjusted our valuation model to account for the increased probability of an IPO scenario, in light of continued favorable market conditions and our submission of a registration statement to the SEC. Based on the revised model and the changes in the market values of companies developing novel therapies for HCV, as well as the impact of an increasing enterprise value on the relative value of our common stock as compared to our convertible preferred stock and redeemable convertible preferred stock, we determined that the fair value of our common stock had increased to \$3.09 per share as of September 30, 2012.

Based on an assumed initial public offering price of \$            per share, the midpoint of the estimated price range set forth on the cover page of this prospectus, the aggregate intrinsic value of stock options outstanding as of September 30, 2012 was \$            million, of which \$            million related to vested options and \$            million to unvested options.

## Table of Contents

### *Valuation of Warrants to Purchase Series 1 Preferred Stock*

We classify warrants to purchase 1,999,989 shares of our Series 1 nonconvertible preferred stock as liabilities on our balance sheets as these warrants are free-standing financial instruments that may require us to transfer assets upon exercise. The warrants were initially recorded at fair value and are subsequently remeasured to fair value at each balance sheet date. Changes in fair value of the warrants are recognized as a component of other income (expense) in our statement of operations. We will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrants.

These warrants issued in October 2010 in connection with a bridge note financing entitled the note holders to purchase shares of Series 1 nonconvertible preferred at an exercise price of \$0.01 per share. Upon issuance of the warrants, the number of Series 1 nonconvertible preferred shares issuable upon exercise of these warrants was not fixed. The number of Series 1 nonconvertible preferred shares was one share for each dollar of the original principal amount of the term note plus, if the milestone payment from the Abbott agreement was not received on or before March 31, 2011, an additional share for each dollar of the original principal amount of the note. Additionally, if a liquidation event occurred, thereby requiring repayment of the term notes, these warrants would automatically expire and would therefore have no value. Upon our repayment of the term notes in December 2010, the number of shares issuable upon exercise of the Series 1 nonconvertible preferred stock warrants became fixed at one share for each warrant, and the possibility that the term notes could be redeemed and the warrants would have no value was eliminated.

We estimate the fair value of the warrants at the respective balance sheet dates using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model incorporates a number of assumptions and judgments to estimate the fair value of these warrants including the fair value per share of the underlying Series 1 nonconvertible preferred stock, the remaining contractual term of the warrants, risk-free interest rate, expected dividend yield, and expected volatility of the price of the underlying stock. Because the exercise price of the warrants is only \$0.01 per share, the remaining contractual term, risk-free interest rate, expected dividend yield and expected volatility had no material impact on the value of the warrants using the Black-Scholes option-pricing model. The input that most significantly impacted the value of these warrants was the fair value of the underlying Series 1 nonconvertible preferred stock. We determined the fair value of the Series 1 nonconvertible preferred stock to equal its stated liquidation preference of \$1.00 per share. Since the Series 1 nonconvertible preferred stock ranks senior to all other classes of stock and its liquidation preference is small relative to our equity value, the probability of a 100% payout on the Series 1 nonconvertible preferred stock was considered to be high. We believe our estimate of fair value of Series 1 nonconvertible preferred stock was reasonable.

In addition to using the Black-Scholes option-pricing model to value the warrants at each reporting date, we also made a judgment at the date of issuance of the warrants (October 2010) regarding the number of shares of Series 1 nonconvertible preferred stock that would be issued upon exercise of the warrants and whether the warrants would have value at all. We used a decision tree to estimate the probabilities of how many shares the warrants would ultimately be exercised into under each of the two scenarios described above as well as a third scenario under which the note would be redeemed and the warrants would have no value. We valued the warrants using the Black-Scholes option-pricing model under the first two scenarios, and we attributed a value of \$0 to the warrants under the third scenario. We then applied probabilities to the three values to determine the total fair value of the warrants. In December 2010, when the contingency was resolved and the number of shares of Series 1 nonconvertible preferred stock the warrants could be exercised into became fixed at one share per warrant, or 1,999,989 shares in aggregate, we were able to determine the value of the warrants using the Black-Scholes option-pricing model and the fixed number of shares of Series 1 nonconvertible preferred stock the warrants were exercisable into.

The fair value of these outstanding warrants to purchase our Series 1 nonconvertible preferred stock as recorded in our balance sheet was \$2.0 million at September 30, 2011 and 2012.

---

**Table of Contents**

***Income Taxes***

Income taxes are provided for tax effects of transactions reported in the financial statements and consist of income taxes currently due plus deferred income taxes related to timing differences between the basis of certain assets and liabilities for financial statement purposes and for income tax reporting purposes. Deferred taxes are determined based on the difference between the financial statement value and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. A valuation allowance is provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. Based on our analysis of both positive and negative factors, we have determined that it is more likely than not that we will not be able to realize our deferred tax assets, and therefore we have recorded a full valuation allowance against our deferred tax assets. Our analysis included an assessment of our past profitability and our future projections of forecasted revenue and expense levels. More specifically, we considered the following factors in determining that it is more likely than not that we will not be able to realize our deferred tax assets:

We have incurred cumulative net losses since our inception, and as of September 30, 2012 we had an accumulated deficit of \$115.4 million. We expect that we may incur substantial operating losses in the future. Our net income in the fiscal year ended September 30, 2012 resulted primarily from an upfront payment of \$34.4 million from our collaborator Novartis. Our net income in the fiscal year ended September 30, 2011 resulted primarily from a milestone payment from our collaborator Abbott, which was our first significant milestone payment since our operations commenced. Our net income in the year ended September 30, 2010 resulted from the termination of a previous collaboration agreement, which allowed us to recognize \$16.2 million of deferred revenue in fiscal 2010 that related to cash received prior to fiscal 2007;

As of September 30, 2010, we had only \$0.5 million of cash on hand, had a working capital deficit of \$3.4 million, were unable to raise additional proceeds from new investors and were required to enter into a bridge note financing agreement with existing investors in order to continue to fund operations. These circumstances raised substantial doubt about our ability to continue as a going concern;

As of January 18, 2012, based on our net capital deficiency and preferred stock redemption obligations, our independent registered public accounting firm had included an explanatory paragraph in its report on our financial statements as of and for the year ended September 30, 2011, which indicated that those circumstances then raised substantial doubt about our ability to continue as a going concern;

We are a clinical-stage biopharmaceutical company and we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties associated with late stage clinical development, regulatory approval and commercialization of therapeutic products;

To date, we have not commercialized any products or generated any revenue from product sales, directly or through any collaborator;

Our financial prospects and ability to generate revenue for the next several years are substantially dependent upon the development and marketing efforts of Abbott and Novartis for our drug product candidates, and we have limited control over the resources, time and effort that our collaborators may devote to our drug product candidates;

Because the outcome of planned and anticipated clinical trials of our product candidates by our collaborators is highly uncertain, we cannot reasonably estimate the timing or amounts, if any, of future milestone payments we will receive from these collaborators;

Our own independent HCV development programs and antibiotic program are in preclinical development and we will be required to invest significant capital and incur significant additional research and development expenses to develop and commercialize these

compounds;

Since our inception, we have not paid a material amount of U.S. federal income taxes; and

We do not have any taxable income in prior carryback periods or any taxable temporary differences which could represent a source of taxable income upon future reversal.

**Table of Contents**

We account for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement.

**Results of Operations****Comparison of Years Ended September 30, 2010, 2011 and 2012**

	Year Ended September 30,		
	2010	2011	2012
	(in thousands)		
Revenue	\$ 22,763	\$ 41,882	\$ 41,706
Research and development expenses	9,716	11,547	15,115
General and administrative expenses	6,105	5,036	5,302
Other income (expense):			
Interest income	14	83	118
Interest expense		(3,161)	
Change in fair value of warrant liability	482	(686)	(8)
Therapeutic tax credit		750	
Gain on embedded derivative		670	
Other income (expense), net	309	355	

**Revenue.** We recognized revenue of \$41.9 million in the year ended September 30, 2011, as compared to \$41.7 million in the year ended September 30, 2012. In fiscal 2011, we received a milestone payment of \$40.0 million for Abbott's successful completion of a Phase 2a clinical study, which we recognized as revenue during the year based on our completion of our deliverables under the Abbott agreement. We also recorded \$1.9 million of revenue related to research funding received from Abbott during the year ended September 30, 2011. In fiscal 2012, we received an upfront payment of \$34.4 million from Novartis, which we recognized as revenue during the year ended September 30, 2012, and also recognized revenue of \$1.1 million related to research funding from Novartis. Government contract revenue was \$6.1 million in the year ended September 30, 2012 for the EDP-788 program related to the contract with NIAID. We did not have any government contract revenue in fiscal 2011.

We recognized revenue of \$22.8 million for the year ended September 30, 2010, as compared to \$41.9 million for fiscal 2011. Revenue recognized during fiscal 2010 included \$16.2 million from our concluded collaboration in Japan and \$6.5 million from our collaboration with Abbott. We had previously received payments of \$16.2 million under our concluded collaboration, which had been deferred as revenue due to an option within the agreement for which we could not establish fair value. Upon conclusion of the agreement in fiscal 2010, we were able to recognize all previously deferred revenue as we had no further obligations under the agreement. Revenue during fiscal 2011 included a \$40.0 million milestone payment received from Abbott for completion of a Phase 2a clinical trial as well as \$1.9 million of research funding reimbursement from Abbott, which we were able to recognize in full under the proportional performance model because our research obligations under the Abbott agreement were concluded in June 2011.

**Research and development expenses.**

	Year Ended September 30,		
	2010	2011	2012
	(in thousands)		
Development programs:			
Protease inhibitor	\$ 3,543	\$ 1,109	\$
NS5A inhibitor	2,398	6,097	2,993
Antibiotic			4,127
Research and drug discovery	3,775	4,341	7,995

Edgar Filing: ENANTA PHARMACEUTICALS INC - Form S-1/A

Total research and development expenses	\$ 9,716	\$ 11,547	\$ 15,115
---	----------	-----------	-----------

**Table of Contents**

Research and development expenses were \$11.5 million in the year ended September 30, 2011, as compared to \$15.1 million for the same period in 2012. The increase year over year was due primarily to \$4.1 million of preclinical expenses for our antibiotic program, specifically the development of EDP-788, for which we had no costs in 2011, and an increase in our early stage drug discovery programs of \$3.7 million. These increases were partially offset by a decrease of \$3.1 million in expenses for our NS5A inhibitor program and a decrease of \$1.1 million in our expenses for our protease inhibitor program. We incurred preclinical expense for the development of EDP-788 as a result of the contract we entered into in September 2011 with NIAID, which is funding our research program for EDP-788. We incurred increased research expenses in our early stage drug discovery programs due to an increase in both the number of preclinical studies and the related costs as well as a \$0.9 million expense for the cost of a third-party license for intellectual property used in our research activities. Our research costs related to our NS5A inhibitor program decreased as a result of our signing a collaboration agreement with Novartis in February 2012, at which time Novartis became responsible for further clinical trial costs. Prior to entering into the collaboration agreement with Novartis, we had been incurring costs for preclinical and clinical development of EDP-239. We continue to incur research expense for NS5A research to identify additional compounds, for which we are receiving funding from Novartis through at least February 2013. Our research costs related to our protease inhibitor program decreased as a result of the conclusion of our research program with Abbott in June 2011.

Research and development expenses were \$9.7 million in fiscal 2010, as compared to \$11.5 million in fiscal 2011. The increase year over year was primarily due to a \$3.7 million increase in our preclinical and development expenses for our NS5A inhibitor program, specifically our EDP-239 compound, and a \$0.6 million increase in research expense in our early stage drug discovery program, partially offset by a \$2.4 million decrease in preclinical and development expenses in our protease inhibitor program. We incurred increased preclinical expense for the development of our NS5A inhibitor program as a result of increased costs associated with IND-enabling studies. We filed our IND for EDP-239 with the FDA in the first quarter of fiscal 2012. We incurred increased research expenses in our early stage drug discovery programs due to increased preclinical study activity for our compounds. Decreases in costs in our protease inhibitor program resulted from the conclusion of our research program with Abbott.

From inception of each development program through September 30, 2012, we incurred cumulative expenses of \$18.7 million for our protease inhibitor program, \$11.5 million for our NS5A inhibitor program, and \$4.1 million for our EDP-788 antibiotic program.

**General and administrative expenses.** General and administrative expenses increased by \$0.3 million from \$5.0 million in fiscal 2011 to \$5.3 million in fiscal 2012. The increase was primarily due to increased stock-based compensation expense, as a result of additional stock option grants to employees and a higher value of our common stock, as well as higher accounting and audit fees, partially offset by lower facility costs as a result of our move to a new office location on October 1, 2011.

General and administrative expenses decreased by \$1.1 million from \$6.1 million in fiscal 2010 to \$5.0 million in fiscal 2011, primarily due to legal fees incurred in 2010 related to a commercial dispute that was resolved during 2010.

**Other income (expense).** Changes in components of other income (expense) were as follows:

**Interest income.** The increase in interest income for the year ended September 30, 2012, as compared to the year ended September 30, 2011, was due to higher average cash and investment balances primarily due to the receipt of the \$34.4 million upfront payment from Novartis in the second quarter of fiscal 2012.

The increase in interest income for the year ended September 30, 2011, as compared to the year ended September 30, 2010, was due to higher average cash and investment balances following the receipt of the \$40.0 million milestone payment from Abbott in the first quarter of fiscal 2011.

**Interest expense.** Interest expense of \$3.2 million for the year ended September 30, 2011 related entirely to our bridge financing in October and November 2010, under which we borrowed \$2.0 million from existing investors. In connection with the convertible note agreement for this financing, we issued warrants for the purchase of our Series 1 nonconvertible preferred stock, which were initially valued at \$1.3 million and recorded

**Table of Contents**

as a debt discount. The convertible note agreement included call and put options that constituted an embedded derivative valued at \$0.7 million, which was also recorded as a debt discount. We incurred issuance costs of \$0.2 million, which were recorded as deferred financing costs. In December 2010, we repaid the \$2.0 million of principal outstanding plus interest and an applicable premium of \$1.0 million to the note holders upon receipt of a \$40.0 million milestone payment from Abbott. Upon repayment, we accreted the debt discounts and deferred financing costs to interest expense and recorded the premium as interest expense. We had no outstanding debt and therefore no interest expense for either of the years ended September 30, 2010 or 2012.

*Change in fair value of warrant liability.* We account for our outstanding warrants for our Series E redeemable convertible preferred stock and our Series 1 nonconvertible preferred stock warrants as liabilities held at fair value, with changes in fair value recorded as a component of other income (expense).

During the year ended September 30, 2012, we recorded a small amount of expense related to the increase in the fair market value of our warrant liability for the year ended September 30, 2012 primarily as a result of the remeasurement of our Series E warrants at the reporting date utilizing the Black-Scholes option-pricing model.

We recorded expense related to the increase in the fair value of our warrant liability for the year ended September 30, 2011 of \$0.7 million due primarily to the remeasurement of the fair value of warrants for Series 1 nonconvertible preferred stock, which increased in value primarily due to the resolution of certain contingencies of the warrants.

We recorded income of \$0.5 million related to the decrease in the fair value of our warrant liability for the year ended September 30, 2010 as a result of the remeasurement of our Series E warrants at the reporting date utilizing the Black-Scholes option-pricing model.

*Therapeutic tax credit.* We recognized income from a therapeutic tax credit of \$0.8 million for the year ended September 30, 2011 under the QTDP program, which provided for reimbursement in calendar year 2010 of certain costs we paid or incurred during calendar years 2009 and 2010 directly related to the conduct of a QTDP. We did not receive any such reimbursements during fiscal 2010 or 2012.

*Gain on embedded derivative.* We recorded a gain of \$0.7 million on an embedded derivative for the year ended September 30, 2011 related to a derivative liability embedded in our convertible note agreement that was settled upon repayment of the notes in December 2010. We had no comparable item for either of the years ended September 30, 2010 or 2012.

*Other income (expense), net.* Other income in fiscal 2010 and 2011 consisted primarily of miscellaneous service income unrelated to our core operations. Commencing in fiscal 2012, we no longer provided these services.

**Liquidity and Capital Resources**

From our inception through September 30, 2012, we have obtained \$260.5 million to fund our operations, primarily through contract payments under our collaborations, private placements of our equity, and government research and development contracts and grants. As of September 30, 2012, we had \$45.4 million in cash, cash equivalents and marketable securities. In addition, subsequent to that date, we became entitled to receive an \$11.0 million milestone payment from Novartis and a \$15.0 million milestone payment from Abbott under our collaboration agreements with Novartis and Abbott, respectively.

The following table shows a summary of our cash flows for each of the years ended September 30, 2010, 2011 and 2012.

	Year Ended September 30,		
	2010	2011	2012
	(in thousands)		
Cash provided by (used in):			
Operating activities	\$ (10,175)	\$ 24,019	\$ 22,623
Investing activities	\$ 1,663	\$ (17,682)	\$ (18,040)
Financing activities	\$ 8	\$ 34	\$ (909)
<b>Net cash provided by (used in) operating activities</b>			

During the year ended September 30, 2012, operating activities provided \$22.6 million of cash. The cash flow provided by operating activities primarily resulted from our net income of \$21.4 million and net non-cash





**Table of Contents**

charges of \$1.1 million, together partially offset by net uses of cash of \$0.1 million from changes in our operating assets and liabilities. Our net income in the period was primarily due to \$35.6 million of revenue recognized related to the upfront payment and research funding we received under our collaboration arrangement with Novartis as well as \$6.1 million of revenue recognized from the NIAID contract, both offset by our operating expenses. Our net non-cash charges in the period primarily consisted of \$0.6 million of amortization of the premium on our marketable securities and \$0.4 million of stock-based compensation expense. Net uses of cash from changes in our operating assets and liabilities primarily consisted of a \$0.8 million and \$1.9 million increase in our accounts receivable and unbilled receivables, respectively, principally related to our collaboration agreements with NIAID and Novartis as well as an increase of \$0.2 million in our prepaid expenses and other current assets. These amounts were partially offset by a \$2.5 million increase in accounts payable and accrued expenses and a \$0.5 million increase in other long-term liabilities. Our accounts payable, accrued expense and other long-term liabilities balances were affected by the timing of payments made by us to our vendors and additionally reflected a \$1.0 million payable for the cost of a third-party license used in our research activities.

During the year ended September 30, 2011, operating activities provided \$24.0 million of cash. The cash flow provided by operating activities primarily resulted from our net income of \$23.3 million and net non-cash charges of \$3.1 million, together partially offset by net uses of cash of \$2.4 million from changes in our operating assets and liabilities. Our net income was primarily due to \$41.9 million of revenue recognized related to the milestone payment we received under our collaboration agreement with Abbott during fiscal 2011, offset by our operating expenses. Our net non-cash charges in the year primarily consisted of \$2.1 million of non-cash interest expense, a \$0.7 million expense from the increase in the fair value of warrants and \$0.5 million of depreciation and amortization expense, offset by a \$0.7 million non-cash gain from settlement of an embedded derivative. Non-cash interest expense was primarily due to the accretion of debt discounts and deferred financing costs recorded upon repayment of our bridge financing notes in October and November 2010. Net uses of cash from changes in our operating assets and liabilities during the year ended September 30, 2011 consisted primarily of a \$1.1 million decrease in accrued expenses, a \$0.4 million decrease in deferred revenue, a \$0.4 million decrease in accrued rent and a \$0.3 million increase in prepaid expenses and other assets. The aggregate \$1.8 million net use of cash from changes in accrued expenses, accrued rent, and prepaid expenses and other assets was primarily due to the timing of payments made by us to vendors. The decrease \$0.4 million in deferred revenue was the result of revenue we had deferred as of the end of fiscal 2010 that we recognized upon the completion of our obligations under our collaboration agreement with Abbott during fiscal 2011.

During the year ended September 30, 2010, operating activities used \$10.2 million of cash. The cash flow used in operating activities primarily resulted from our net income of \$7.9 million and net non-cash charges of \$0.3 million, together fully offset by net uses of cash of \$18.4 million from changes in our operating assets and liabilities. Our net income was primarily due to \$6.5 million of revenue recognized related to our collaboration agreement with Abbott as well as \$16.2 million of revenue recognized from our concluded collaboration in Japan. Our net non-cash charges in the year primarily consisted of \$0.6 million of depreciation and amortization expense and \$0.3 million of stock-based compensation expense, partially offset by a \$0.5 million gain from a decrease in the fair value of warrants. Net uses of cash from changes in our operating assets and liabilities during the year ended September 30, 2010 consisted primarily of a \$20.0 million decrease in deferred revenue, partially offset by an increase of \$1.8 million in accrued expenses. The \$20.0 million decrease in deferred revenue was the result of \$16.2 million of revenue we recognized upon the termination of our collaboration in Japan in March 2010 as well as \$3.8 million of revenue previously deferred that was recognized in fiscal 2010 related to our collaboration agreement with Abbott. The \$1.8 million increase in accrued expenses was primarily due to the timing of payments made by us to vendors.

***Net cash provided by (used in) investing activities***

During the year ended September 30, 2012, net cash used in investing activities was \$18.0 million. Net cash used in investing activities during this period consisted primarily of purchases of marketable securities, which used cash of \$47.7 million, partially offset by cash received from the sale and maturities of marketable securities of \$28.7 million and an increase in cash of \$1.1 million due to a release of a letter of credit in December 2011 related to the previous lease of our Watertown facility.

## **Table of Contents**

During the year ended September 30, 2011, net cash used in investing activities was \$17.7 million. Net cash used in investing activities in the year consisted primarily of purchases of marketable securities, which used cash of \$33.6 million, and purchases of \$0.4 million of laboratory equipment, partially offset by cash received from the sale of marketable securities of \$16.8 million.

During the year ended September 30, 2010, net cash provided by investing activities was \$1.7 million. Net cash provided by investing activities in the year consisted primarily of cash received from the sale of marketable securities of \$2.3 million, partially offset by cash used for the purchase of marketable securities of \$0.6 million.

### ***Net cash provided by (used in) financing activities***

Net cash used in financing activities for fiscal 2012 consisted of payments of deferred offering costs in anticipation of our initial public offering, partially offset by proceeds received from the exercise of stock options.

Net cash provided by financing activities for fiscal 2010 and 2011 primarily related to the exercise of stock options. In addition, during the first quarter of fiscal 2011, we entered into a bridge note financing arrangement with existing investors, under which we borrowed \$2.0 million. We repaid that amount in full within the same quarter.

As of September 30, 2012, we had \$45.4 million in cash, cash equivalents and investments. We believe that our existing cash, cash equivalents and investments as of September 30, 2012, along with the estimated net proceeds from this offering, will be sufficient to meet our anticipated cash requirements for at least the next 24 months. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially.

Our future capital requirements are difficult to forecast and will depend on many factors, including:

whether our existing collaborations continue to generate substantial milestone payments, and ultimately royalties, to us;

the number and characteristics of the future product candidates we pursue;

the scope, progress, results and costs of researching and developing any of our future product candidates on our own, and conducting preclinical research and clinical trials;

the timing of, and the costs involved in, obtaining regulatory approvals for any future product candidates we develop independently;

the cost of commercialization activities, if any, of any future product candidates we develop independently that are approved for sale, including marketing, sales and distribution costs;

the cost of manufacturing our future product candidates and any products we successfully commercialize independently;

our ability to maintain existing collaborations and to establish new collaborations, licensing or other arrangements and the financial terms of such agreements;

the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patents, including litigation costs and the outcome of such litigation; and

## Edgar Filing: ENANTA PHARMACEUTICALS INC - Form S-1/A

the timing, receipt and amount of sales of, or royalties on, ABT-450, EDP-239 and our future product candidates, if any. We do not believe that inflation had a material effect on our business, financial condition or results of operations in the last two fiscal years. If our costs were to become subject to significant inflationary pressures, we could not offset such higher costs through revenue increases. Our inability to do so could harm our business, financial condition and results of operations.

**Table of Contents****Off-Balance Sheet Arrangements**

We do not engage in any off-balance sheet financing activities. We do not have any interest in entities referred to as variable interest entities, which include special purpose entities and other structured finance entities.

**Recently Issued Accounting Pronouncements**

Accounting standards that have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on our financial statements upon adoption.

**Contractual Obligations and Commitments**

We lease office space in Watertown, Massachusetts under a seven-year lease that commenced on October 1, 2011. In fiscal 2012, we entered into an intellectual property license agreement that will require us to make certain non-cancelable payments over the next three years. The following table summarizes our contractual obligations at September 30, 2012 and the effect such obligations are expected to have on our liquidity and cash flow in future periods:

	Total	Payments Due By Fiscal Year			More Than 5 years
		Less Than 1 Year	1-3 Years (in thousands)	3-5 Years	
Operating lease commitments	\$ 5,762	\$ 897	\$ 1,867	\$ 1,971	\$ 1,027
Intellectual property license	1,050	600	450		
Total <sup>(1)</sup>	\$ 6,812	\$ 1,497	\$ 2,317	\$ 1,971	\$ 1,027

- (1) As of September 30, 2012, we had outstanding warrants for the purchase of 1,999,989 shares of our Series 1 nonconvertible preferred stock that we classified as a long-term liability in our balance sheet, recorded at fair value of \$2.0 million. If those warrants are exercised, the Series 1 nonconvertible preferred stock issued upon exercise would require the payment of \$2.0 million upon a qualifying merger or sale of the company. The table above does not include this liability because we are unable to estimate the timing of this required payment, or if it will be required at all.

**Quantitative and Qualitative Disclosure about Market Risk*****Interest Rate Sensitivity***

We had cash, cash equivalents and marketable securities of \$45.4 million at September 30, 2012, which consisted of cash, government securities, corporate bonds and commercial paper. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, we do not believe that we have any material exposure to changes in the fair value of our investment portfolio as a result of changes in interest rates. We had no debt outstanding as of September 30, 2012.

**Table of Contents****BUSINESS****Overview**

We are a research and development-focused biotechnology company that uses its robust chemistry-driven approach and drug discovery capabilities to create small molecule drugs in the infectious disease field. We are discovering and developing inhibitors designed for use against the hepatitis C virus, referred to as HCV. We believe that a successful approach to a complete cure for HCV in most patients will likely require treatment with a combination of drugs that attack different mechanisms necessary for replication and survival of HCV. Further, as there are many variants of HCV, we are developing inhibitors that may be used in multiple combination therapies, each designed and tested for effectiveness against one or more of those variants. Our development of inhibitors for validated HCV target mechanisms, as well as our collaborations with Abbott Laboratories and Novartis, should allow us to participate in multiple unique drug combinations as we seek the best combination therapies for HCV in its various forms. Total worldwide sales of HCV therapies were over \$3.5 billion in 2011, and we expect that sales will continue to grow with the introduction of new therapies. In addition to our HCV programs, we have used our internal research capabilities to discover a new class of antibiotics which we are developing for the treatment of multi-drug resistant bacteria, including MRSA. We have utilized our internal chemistry and drug discovery capabilities and our collaborations to generate all of our development-stage programs, and we have active research efforts to broaden our infectious disease drug pipeline.

Our HCV portfolio includes inhibitors of four fundamental, validated HCV targets:

**NS3 Protease Inhibitor: ABT-450.** Our lead product candidate, ABT-450, currently in Phase 3 trials, is an inhibitor of NS3 protease, which is a key protein in HCV viral replication. ABT-450 is being developed as part of our collaboration with Abbott, which has yielded ABT-450 and our next-generation protease inhibitor. ABT-450 co-administered with ritonavir, which we refer to together as ABT-450/r, is being tested in several interferon-free Phase 2 studies in multiple combinations with Abbott's non-nucleoside polymerase and NS5A inhibitors for the treatment of HCV. One Phase 2b study, known as the Aviator study, tested several combinations in genotype 1-infected patients receiving a 12-week course of treatment. In testing of a three-DAA combination, which included ABT-450/r, one of Abbott's non-nucleoside polymerase inhibitors, one of Abbott's NS5A inhibitors and ribavirin, 99% of previously untreated patients had no quantifiable virus in their blood 12 weeks after treatment, also known as SVR<sub>12</sub>. In the same study, in patients in whom HCV was still detectable after previous treatment with a standard of care regimen with interferon, who are referred to as null responders, 93% demonstrated SVR<sub>12</sub>. To our knowledge, these SVR percentages are superior to published SVR<sub>4</sub> to SVR<sub>24</sub> results for any currently approved HCV therapies.

In November 2012, Abbott announced the full scope of its initial Phase 3 registrational trials program for an ABT-450-containing regimen for treatment of genotype 1-infected patients, including six Phase 3 trials designed for a total of 2,200 patients. Abbott had previously reported the start of three of these Phase 3 clinical trials of ABT-450/r in combination therapy, using three DAAs, including ABT-450/r, one of Abbott's non-nucleoside polymerase inhibitors and one of Abbott's NS5A inhibitors, plus ribavirin. The other planned Phase 3 trials will use the same 3 DAAs with and without ribavirin. Abbott has publicly projected its development plan would support a target commercial launch of a combination HCV therapy in early 2015. We believe that we, together with Abbott, will obtain exclusivity in ABT-450 in the United States and other major market jurisdictions based on pending composition and use patent claims for ABT-450, which we expect will continue at least into 2029, assuming all such patents issue.

**NS5A Inhibitor: EDP-239.** We have a robust drug discovery effort directed at the NS5A protein, which plays a key role in HCV viral replication. In February 2012, we entered into a collaboration with Novartis for the worldwide development, manufacture and commercialization of NS5A inhibitors, including our lead NS5A product candidate, EDP-239. In November 2012, Novartis initiated a Phase 1 clinical trial for EDP-239. We believe that we, together with Novartis, have exclusivity to EDP-239 in the United States based on issued composition and use claims, which we expect will continue at least into 2030. As of September 30, 2012, our patent estate relating to EDP-239 consisted of one issued

**Table of Contents**

U.S. patent and two pending U.S. patent applications, and our total patent estate in the NS5A inhibitor arena consisted of two issued U.S. patents and 24 pending U.S. patent applications.

**Cyclophilin Inhibitor: EDP-546.** Our research activities have also focused on a more recently validated target against HCV, cyclophilin, which is a protein in the human body that has been shown to be involved in HCV replication. By focusing on a human target rather than a viral target, we have selected a mechanism shown to be less susceptible to the HCV resistance that can occur due to viral mutation in response to therapy. Using our extensive chemistry expertise with small molecules, we have identified a series of active cyclophilin binders designed to disrupt the interactions of HCV with cyclophilin. We have advanced our lead cyclophilin inhibitor compound, EDP-546, into preclinical drug metabolism, pharmacokinetic, and safety studies. We are continuing IND-enabling studies and plan to independently start Phase 1 clinical trials in the first half of 2014. We continue to build our cyclophilin inhibitor intellectual property position, including with respect to EDP-546, with one issued U.S. patent covering a broad scope of cyclophilin inhibitors and six pending U.S. patent applications as of September 30, 2012. Of these patents and patent applications, one pending U.S. patent application relates to EDP-546.

**Nucleotide Polymerase Inhibitor.** We have a small-molecule drug discovery effort underway for inhibitors of nucleotide polymerase in a clinically validated mechanism that is less susceptible to HCV resistance. Our researchers have identified a promising lead series with significant antiviral potency *in vitro*. We expect to select a candidate to advance into preclinical studies on our own in 2013. We continue to build our intellectual property position related to this target, with one allowed U.S. patent covering nucleotide inhibitors and three pending U.S. patent applications as of September 30, 2012.

In addition to our HCV programs, we have used our internal research capabilities to discover a new class of antibiotics, called Bicyclolides, to overcome bacteria with multi-drug resistance, known as superbugs. These new antibiotics include intravenous and oral treatments for hospital and community infections arising from MRSA. EDP-788 is our lead candidate for the treatment of MRSA. Our preclinical development of EDP-788 is funded under a contract with NIAID, with potential for further NIAID funding of early clinical development. We are conducting IND-enabling studies and plan to initiate clinical trials in the first half of 2014.

In connection with our collaboration efforts, Abbott has funded all research and development of our protease inhibitors since we entered into the collaboration in November 2006, and is responsible for obtaining regulatory approvals and commercializing ABT-450 and any next-generation products worldwide. We received \$57.2 million from Abbott upon signing the collaboration agreement and Abbott's simultaneous purchase of preferred stock from us in 2006, and we received a \$40.0 million milestone payment in December 2010 following the successful completion of a Phase 2a clinical trial. In addition, we are entitled to receive a \$15.0 million milestone payment based on Abbott's November 2012 initiation of dosing in a Phase 3 clinical trial that includes ABT-450. Assuming Abbott's successful development of the first protease inhibitor product, we will also be eligible to receive \$195 million of additional pre-commercialization milestone payments, as well as additional milestone payments for any next-generation protease inhibitor products and tiered royalties ranging on a blended basis from the low double digits up to the high teens per product on Abbott's net sales, if any, allocable to our collaboration's protease inhibitors.

Under our collaboration with Novartis, we received a \$34.4 million upfront payment and we are entitled to receive an \$11.0 million milestone payment based on Novartis' November 2012 initiation of dosing in a Phase 1 clinical trial that includes EDP-239. In addition, we are eligible to receive up to \$395 million of additional milestones for EDP-239 and any related NS5A products achieved by Novartis, and tiered royalties ranging on a blended basis from the low double digits up to the high teens on Novartis' net sales allocable to our collaboration's NS5A inhibitors. Novartis will fund all costs associated with further development, regulatory approvals and commercialization of any NS5A product candidates in this collaboration and we retain co-detail rights in the United States.

## **Table of Contents**

From our inception through September 30, 2012, we have generated \$173.9 million from our collaborations (including those with Abbott and Novartis) in the form of upfront, milestone and funded research payments as well as equity investments. The total of these amounts is more than double the amount of our funding from venture capital equity investments, the last of which occurred in 2006. As of September 30, 2012, we had \$45.4 million in cash and investments. We are eligible to receive over the next several years an aggregate of \$430 million (exclusive of the \$26.0 million of earned milestone payments discussed above) based on potential future pre-commercialization milestones under our Abbott and Novartis collaborations, assuming successful clinical trial results for the respective collaboration programs and our collaborators' continued development of our product candidates through successful regulatory and reimbursement approvals in the United States and other major markets. In addition, we are also eligible to receive tiered royalties ranging on a blended basis from the low double digits up to the high teens on worldwide net sales of any protease inhibitors or NS5A inhibitors under the collaborations, as well as sales milestones under our Novartis collaboration.

## **Our Strategy**

Our primary objective is to become a leader in the infectious disease field, with a focus on HCV and multi-drug resistant bacterial infections. Our strategy includes the following key elements:

*Develop compounds against four fundamental, validated HCV targets to give us multiple opportunities to participate in one or more of the potentially successful combination therapies for HCV.* We believe that a successful approach to a complete cure for HCV in most patients will likely require treatment with a combination of drugs that attack different mechanisms necessary for replication and survival of HCV. As there are many variants of HCV, we are developing inhibitors that may be used in multiple combination therapies, each to be designed and tested for effectiveness against one or more of those variants. Our HCV portfolio includes inhibitors of four fundamental, validated HCV targets that we believe will provide the necessary therapeutic compounds for combination therapy, with the goal of placing one or more of our compounds into the combination or combinations that will ultimately be approved and accepted as preferred treatments for one or more genotypes of HCV.

*Collaborate with large pharmaceutical partners to accelerate the development and commercialization of our lead HCV compounds.* Our strategic partnerships allow us to join forces with collaborators with substantially greater resources and late-stage development and commercialization expertise as we seek the right combination for a cure for one or more genotypes of HCV. In the various combinations in which Abbott is testing ABT-450 in clinical trials, Abbott is combining ABT-450 with its own non-nucleoside inhibitors and its NS5A inhibitor. At the same time, our own lead NS5A product candidate, EDP-239, can become part of combination therapies developed by Novartis. The result is that our product candidates will be part of multiple regimens using different combinations of mechanisms, increasing our chances of participating in more than one commercially successful combination therapy for HCV in its various forms.

*Develop independently our own next generation HCV compounds and combination therapies with lower susceptibility to viral resistance.* We are independently developing a lead cyclophilin inhibitor and will be selecting a nucleotide polymerase inhibitor for development, both of which we are seeking to design with lower susceptibility to the viral resistance that is being generated by first-generation (currently marketed) and second-generation HCV products. We are considering potential development of a combination of these inhibitors.

*Continue to leverage and fortify our intellectual property portfolio.* We believe we have a strong intellectual property position relating to the development and commercialization of HCV-targeted therapeutics and antibiotics for the treatment of resistant pathogens. As of September 30, 2012, we had a total of approximately 60 issued U.S. patents and over 50 pending U.S. patent applications. We have also applied for, and in some cases obtained, patents in various foreign jurisdictions. In addition to fortifying our existing intellectual property position, we intend to file new patent applications and take other steps to strengthen, leverage, and expand our intellectual property position.

*Invest in research and early-stage development of product candidates.* We intend to continue to invest significant resources in research programs and early-stage development of product candidates in





## **Table of Contents**

an effort to identify and advance additional compounds that have the potential to address significant unmet medical needs in the infectious disease field. We will continue to seek further innovations for the treatment of HCV and other viral infections, as well as antibiotics for the treatment of resistant bacteria, such as MRSA.

### **Our Research and Development Pipeline**

The following table summarizes our product development pipeline in HCV antivirals as well as MRSA antibiotics:

Note: /r refers to ritonavir; NS5A refers to Abbott's NS5A inhibitor ABT-267; NNuc refers to Abbott's non-nucleoside polymerase inhibitor ABT-333; RBV refers to ribavirin.

As detailed above, our only product candidate that has advanced beyond Phase 2 clinical trials is ABT-450. Phase 3 trials of ABT-450 in combination therapy started in October 2012. Phase 3 clinical trials are often lengthy and usually involve from many hundred to thousands of patients. We estimate that it will likely be at least two years before a New Drug Application, or NDA, for one of our or our collaborators combination therapies could be approved by the FDA.

### **Our HCV Programs**

#### ***Background and Overview of HCV Market***

HCV is a virus that is a common cause of viral hepatitis, an inflammation of the liver. HCV is typically contracted by contact with the blood or other body fluids of another individual infected with HCV. HCV is a leading cause of chronic liver disease, including cirrhosis, organ failure and cancer, and the leading cause of death from liver disease in the United States. HCV disease progression occurs over a period of 20 to 30 years, with the majority of HCV-infected individuals generally exhibiting no symptoms of the disease. Therefore, until a major symptom is diagnosed, many individuals are unaware they are infected and live undiagnosed without seeking treatment. For that reason, new guidelines proposed by the United States Centers for Disease Control and Prevention, or CDC, and currently under review would recommend screening for all Americans born between the years 1945 and 1965 so that HCV-infected individuals would be aware of their condition and could consider treatment options.

## Table of Contents

An estimated 150 million people worldwide are chronically infected with HCV and have an increased risk of eventually developing liver cirrhosis or liver cancer. More than 350,000 people die every year from HCV-related liver diseases. As of July 2008, the CDC estimated that approximately 3.2 million people in the United States are chronically infected with HCV, with an estimated 17,000 new infections each year. We believe that the chronically infected population remains largely untreated, even with the introduction of new regimens containing a protease inhibitor in 2011. Currently approved therapies for HCV, which include interferon, ribavirin and the new protease inhibitors, had aggregate worldwide sales of over \$3.5 billion in 2011. We believe that annual worldwide sales of these therapies and future approved therapies could increase sales in this market to \$10 to \$20 billion within the next ten years.

HCV is a small, single-stranded RNA virus. The specific genetic makeup, or genotype, of the virus can vary and at least six genotypes have been characterized in HCV-infected patients, with over 50 sub-types identified. Genotypes are designated with numbers (genotypes 1-6) and subtypes with letters (e.g. genotype 1a). HCV genotypes 1, 2, 3, and 4 are found worldwide, but their prevalence varies among geographic regions. Genotype 1, including its subtypes 1a and 1b, is the most common genotype globally, accounting for approximately 74% of all HCV infections. It is estimated that patients with genotype 2 or 3 represent approximately 12% of the worldwide chronically infected HCV population, with approximately 6% comprised of genotypes 4 through 6 and the remaining 8% of patients in other undesignated categories. The specific genotype and subtype of HCV in a patient appears to play a significant role in the degree of efficacy of standard of care therapy. Genotype 1 is the most difficult genotype to treat and the most common in North America and Europe. In addition, variations in the human interleukin 28B, or IL28B, gene have also been shown to impact the effectiveness of the current HCV standard of care treatment in any given patient.

Since the discovery of the virus in the late 1980s, considerable progress has been made in the treatment of HCV-infected individuals. However, a protective vaccine is not yet available and current treatments remain ineffective in a large percentage of the HCV-treated population. The standard of care for HCV traditionally has consisted of weekly injections of interferon, a protein that interferes with viral replication, with twice-daily dosing of ribavirin for 24 to 48 weeks. Ribavirin is a broad-spectrum drug that prevents the replication of a number of DNA and RNA-based viruses. This regimen has been moderately effective in many patients, resulting in a cure in only about 50% of genotype 1-infected patients. Medical practice defines a cure as the point at which there is no quantifiable virus in a patient's blood for a sustained period of time after cessation of therapy, which is often referred to as a sustained virologic response, or SVR.

Recently introduced treatment regimens with direct acting antivirals, or DAAs, protease inhibitors, namely telaprevir (Incivek, Vertex Pharmaceuticals) and boceprevir (Victrelis, Merck), have shown increased cure rates of approximately 70% in genotype 1-infected patients. Telaprevir and boceprevir have been approved for use in combination with interferon and ribavirin in patients infected with genotype 1 virus, and this combination therapy is emerging as a new standard of care for HCV patients. However, this new treatment regimen has several limitations that highlight the need for improved HCV therapies, including:

*Sub-Optimal Cure Rates.* Current approved regimens containing a protease inhibitor lead to a cure rate of approximately 70% in previously untreated genotype 1 patients. The cure rate is on average even lower among patients who did not fully respond to prior treatments with interferon and ribavirin therapy. There is a need for a cure for the patients who have failed therapy, many of whom may have developed HCV variants that are resistant to the specific protease inhibitors used in these therapies.

*Dependence on Interferon.* Current HCV therapy still includes injected interferon as part of the treatment regimens, which produces adverse events in over 50% of patients. Interferon often causes flu-like symptoms, fatigue, headaches and nausea during treatment, which affects patients' quality of life and can lead to abandonment of therapy over the standard 24 to 48 weeks of therapy. We believe this has led to many patients waiting for the availability of new, interferon-free therapies before undergoing treatment.

*Side Effects Associated With Currently Approved Protease Inhibitors.* Other serious side effects of the new regimens containing a protease inhibitor include rash, anemia, itching (known as pruritus), and gastrointestinal effects. Rash is observed in approximately half of patients treated with telaprevir and

## **Table of Contents**

telaprevir-containing therapy and requires strict adherence to a rash management plan in close collaboration with an experienced dermatologist. Boceprevir administration can worsen the anemia that is observed with interferon and ribavirin therapy alone.

*Lengthy Treatment Regimen.* The new regimens containing a protease inhibitor that include telaprevir and boceprevir require a total of 24 to 48 weeks of treatment with interferon and ribavirin. We believe that patients and physicians would favor a regimen with a significantly shorter period of treatment.

*Inconvenient Treatment Regimen.* The pharmaceutical properties of telaprevir and boceprevir require that they be dosed approximately every 8 hours, thus resulting in a complex treatment regimen that also includes weekly injections of interferon. We believe this demanding dosing requirement can often lead to poor compliance with the treatment regimen and can accelerate the development of HCV resistance.

*Treatments Limited to Genotype 1 Patients.* The new regimens containing a protease inhibitor are approved only for the treatment of HCV genotype 1 patients. There is need for treatment for the other genotypes, which represent an estimated 26% of HCV incidence worldwide.

In summary, while providing a step forward, this new treatment regimen has sub-optimal cure rates, requires lengthy treatment with interferon, carries other undesirable side effect profiles, requires inconvenient dosing regimens, is ineffective in many patient populations and often results in HCV resistance. Accordingly, we believe there remains a significant unmet medical need in the HCV field, with an urgent need for improved HCV treatments.

## ***Scientific Background***

Many of the new approaches under development targeting HCV focus directly on the viral life cycle and proteins that are critical to HCV replication. Replication of the HCV genome occurs on intracellular membranes and requires the participation of multiple viral proteins, some of which have enzymatic activities. Agents, often referred to as inhibitors, that target viral proteins directly are generally referred to as direct acting antivirals, or DAAs. Current DAA development efforts typically focus on the NS3 protease, the NS5A protein, and the NS5B polymerase. In addition to targets in HCV itself, there are human host proteins that are critical to viral replication. Inhibitors that interfere with host targets resulting in antiviral activity are referred to as host-targeted antivirals, or HTAs. One of the most promising HTA approaches to HCV treatment focuses on the human host protein known as cyclophilin A, or cyclophilin.

### ***Key Proteins in the HCV Replication Complex***

## **Table of Contents**

**NS3 Protease.** As HCV replicates, it generates long strands of protein that must be processed into many individual active functional proteins that are referred to as non-structural proteins with the designated abbreviation NS, including NS3 and NS5A. The NS3 protease is responsible for most of this protein processing of the newly translated HCV protein, and plays an essential role in the viral life cycle. Inhibition of the protease prevents these new critical proteins from forming and therefore prevents replication and survival of the virus. NS3 protease inhibition is the mechanism of action for the two most recently approved HCV drugs, telaprevir and boceprevir, both of which are DAAs.

**NS5A.** The NS5A protein has key roles in both the RNA replication of HCV and modulation of the physiology of its host cell in the body. Research has shown that targeting NS5A gives rise to profound antiviral activity, and as a result, this protein has emerged as an additional important DAA target for anti-HCV drug development.

**NS5B Polymerase.** HCV is a single-stranded RNA virus, and NS5B is an HCV RNA polymerase responsible for synthesis of new HCV RNA, allowing the HCV genome to be copied and the virus to survive and replicate. Two separate classes of DAA inhibitors of NS5B polymerase are in development as treatments for HCV. Nucleoside/nucleotide inhibitors of NS5B directly inhibit the active site of that enzyme and prevent further elongation of the RNA, and thus are equally active against all HCV genotypes. A second class, known as non-nucleoside inhibitors, affects replication of the RNA by altering the shape of the enzyme at remote sites on the enzyme surface so that any given inhibitor is usually only active against certain HCV genotypes.

**Cyclophilin.** Viral function requires an interaction of the viral protein NS5A with the human host protein known as cyclophilin. Inhibitors that interfere with this NS5A-cyclophilin interaction would essentially provide a treatment that protects the human host cells from infection by the virus. Several studies using the immunosuppressive drug cyclosporine A, a known cyclophilin inhibitor, support the clinical validation of cyclophilin as an HTA for treatment of HCV infection. However, the immunosuppressive activity of cyclosporine A and associated side effects limit its clinical use and thus efforts are now focused on new agents devoid of immunosuppressive activity. Alisporivir, a nonimmunosuppressive cyclosporine A derivative under development by Novartis, has demonstrated effectiveness against many HCV genotypes, a high barrier to HCV resistance and no cross-resistance with several DAAs.

The ultimate goal in HCV treatment is complete cure with total eradication of the virus, measured by SVR. We believe that combination therapy will improve overall cure rates and will reduce the probability of resistance arising to any single antiviral agent. In particular, a combination of target mechanisms that includes those with a high barrier to resistance (cyclophilin, polymerase) may prove to be the most effective combination against multiple genotypes of HCV. Unlike treatment for certain viruses, such as HIV, complete clearance of the HCV virus is possible with effective therapy. This exciting prospect suggests that the ultimate goal of a complete cure with total eradication of the virus is within reach.

### ***Our Approach to the Treatment of HCV***

We are pursuing four fundamental, validated targets within the HCV field that represent a broad approach to the disease and specifically address the urgent unmet medical needs in current HCV therapies. Our approach incorporates the main targets for future HCV therapy. Our DAA approach directly targets three critical proteins of HCV, incorporating inhibitors of NS3 protease, NS5A protein, and NS5B polymerase. Inhibitors in our HTA approach protect the human host protein cyclophilin from being co-opted into the viral replication machinery of HCV. We believe a combination of inhibitors from our programs may provide a truly effective all-oral interferon-free or interferon/ribavirin-free therapeutic approach to HCV, with complete eradication of virus, low resistance rates, convenient dosing and acceptable side effect profiles.

### ***ABT-450, a Protease Inhibitor for HCV Infection***

Our protease inhibitor, ABT-450, discovered through our collaboration with Abbott, is a potent DAA that has demonstrated *in vitro* potency against known resistant HCV mutants. In Phase 1 studies, ABT-450 co-administered with ritonavir, a commonly used boosting agent to increase the blood concentrations of many protease inhibitors, was shown to be safe and well tolerated. Co-administration of ABT-450 with ritonavir, which we refer to together as ABT-450/r, has enabled once-daily dosing of ABT-450. Phase 2 studies have demonstrated the efficacy of ABT-450/r in patients with chronic HCV, and other interferon-free Phase 2 studies

## Table of Contents

of ABT-450-containing regimens continue. In addition, Abbott has announced Phase 3 trials of ABT-450/r in combination with Abbott's non-nucleoside polymerase and NS5A inhibitors, with and without ribavirin. While Abbott and other companies are developing interferon-free and interferon/ribavirin-free HCV therapies in clinical trials, the efficacy of this approach has not yet been proven conclusively, nor has it resulted yet in any product approved by the FDA.

We believe that a treatment regimen containing ABT-450/r may have significant advantages over currently approved HCV treatment regimens containing protease inhibitors because of the following key attributes:

*Improved Antiviral Activity.* Compared to the current market leader, telaprevir, ABT-450 has demonstrated superior antiviral activity against HCV in patients.

*No Interferon.* Current HCV therapy still includes injected interferon. Interferon is often associated with flu-like symptoms, fatigue, headaches and nausea during treatment. ABT-450/r is being developed in a number of interferon-free regimens.

*Tolerability.* As noted above, serious side effects of current regimens containing protease inhibitors include rash, anemia, pruritus, or itchy skin, and gastrointestinal effects. In contrast, most side effects in clinical trials including ABT-450/r to date were mild to moderate.

*Shorter Treatment Regimen.* ABT-450/r is being tested in various treatment combinations that are only 12 weeks in duration, as compared to the 24 to 48 weeks of treatment required with current interferon-containing regimens.

*More Convenient Treatment Regimen.* ABT-450/r is being developed for oral, once-daily dosing. All of the combinations including ABT-450/r that Abbott is testing include only orally administered drugs dosed either once or twice daily. By comparison, current treatment regimens require dosing of a protease inhibitor approximately every 8 hours as well as weekly interferon injections.

Under the Abbott collaboration, we have granted Abbott an exclusive worldwide royalty-bearing license, including a right to grant sublicenses, to our intellectual property position for NS3 protease inhibitors. We also granted Abbott access to our drug discovery capabilities in the NS3 protease inhibitor field. Abbott is responsible for and funds all costs associated with the development, manufacturing and commercialization of ABT-450 and other compounds under this collaboration agreement. We will be eligible to receive milestone payments and royalties with respect to these compounds if such products are successfully commercialized by Abbott.

In November 2012, Abbott announced the full scope of its initial Phase 3 registrational trials program for an HCV treatment regimen (including ABT-450) for genotype 1-infected patients, including six Phase 3 trials designed for a total of 2,200 patients using a combination of three DAAs: ABT-450/r (protease inhibitor), ABT-267 (NS5A inhibitor) and ABT-333 (non-nucleoside polymerase inhibitor) with and without ribavirin. Abbott had previously reported the start of three of these Phase 3 clinical trials in genotype 1-infected adults and announced that it expected regulatory filings in 2014. The other planned Phase 3 trials will use the same 3 DAAs with and without ribavirin. In addition, Abbott has announced that it is conducting additional exploratory clinical studies to determine if a co-formulated tablet of ABT-450/r and ABT-267 dosed once daily can provide high cure rates in specific HCV populations. Abbott has also announced that its development plan would support a target commercial launch of a combination HCV therapy in early 2015, and that there is a potential worldwide market opportunity of \$2 billion or more for the combinations being developed. Abbott's projections are subject to risks and uncertainties. One or more Phase 3 trials containing ABT-450/r could take longer than anticipated to complete or could have unexpected results, the FDA could find that the results of these trials are not adequate to support marketing approval and the FDA could require additional clinical trials as a condition for approval.

### *Clinical Development*

*Phase 1.* An Investigational New Drug Application, or IND, was filed for ABT-450 in December 2008 and clinical testing began in early 2009. ABT-450 was evaluated in a Phase 1a single ascending dose trial in doses ranging from 25 mg to 900 mg, with and without ritonavir. Data from this trial showed that ritonavir co-administration significantly boosted the ABT-450 plasma concentrations. ABT-450 is being developed with



**Table of Contents**

low dose ritonavir to enhance exposure and allow once-daily dosing of ABT-450. A 14-day multiple dose study showed that ABT-450/r was well tolerated and demonstrated pharmacokinetics consistent with once-daily dosing.

*Phase 2.* In the first quarter of 2010, we and Abbott announced the advancement of ABT-450/r into Phase 2 clinical trials. The objective of the initial Phase 2 study was to assess the safety, tolerability, pharmacokinetics and antiviral activity of multiple dose strengths of ABT-450/r in treatment-naïve adults (*i.e.*, those who have not previously received treatment for HCV) infected with HCV genotype 1. Initial antiviral activity was evaluated via a 3-day, ABT-450/r monotherapy period, followed by ABT-450/r with interferon and ribavirin for 12 weeks, and then treatment with interferon and ribavirin alone for up to an additional 36 weeks. After the initial three days of monotherapy with ABT-450/r, profound decreases in HCV RNA were noted in all dose groups, with a mean RNA reduction of about 4.0 logs, which is a 10,000-fold reduction, compared to placebo with a 0.36 log reduction, which is a 2.3-fold reduction. In this combination, ABT-450/r was safe and well tolerated during 12 weeks of treatment.

These initial studies with ABT-450/r paved the way for additional Phase 2a and 2b combination studies that use interferon-free regimens. The Pilot and Co-Pilot trials, which were initiated in late 2010 and early 2011, respectively, include combination trials of ABT-450/r with one or the other of two of Abbott's non-nucleoside polymerase inhibitors. The Aviator study, which was initiated in 2011, is a trial of ABT-450/r and various combinations of two or three of the following: one of Abbott's non-nucleoside polymerase inhibitors, one of its NS5A inhibitors and ribavirin. The Navigator study, also initiated in 2011, is a trial with ABT-450/r and Abbott's NS5A inhibitor, with and without ribavirin. In addition, Abbott started a Phase 2b Pearl I study of a combination of ABT-450/r with only ABT-267 in August 2012.



**Table of Contents**

All of the Phase 2 combination regimens being tested by Abbott are interferon-free, with a significantly shorter duration (12 weeks) and a simpler treatment paradigm compared to the currently approved protease inhibitor regimens, which include weekly injections of interferon and daily oral doses of ribavirin for 24 to 48 weeks. The status of these studies is summarized below:

*Summary of Partial Results of Ongoing Interferon-free Phase 2 Combination Trials Using ABT-450/r*

Study Name	Combination Composition <sup>(1)</sup>				Subject Population & Regimen <sup>(2)</sup>	Key Efficacy Data <sup>(3)</sup>	Adverse Events
	Protease: ABT-450/r	Non-Nuc: ABT-333	Non-Nuc: ABT-072	NS5A: ABT-267			
Pilot <sup>(4)</sup>	+		+	+	11 Naïve patients	RVR = 100%	Most were mild in severity; the most common were headache, fatigue, nausea and dry skin.
					GT1a (72.7%); GT1b (27.3%)	eRVR = 100%	
					IL28B non-CC (0%)	SVR <sub>12</sub> = 91%	
					ABT-450/r 150/100mg QD + ABT-072 400mg QD + RBV	SVR <sub>24</sub> = 91% SVR <sub>36</sub> = 82%	
Co-Pilot <sup>(4)</sup>	+	+		+	12-week treatment		Most AEs were mild or moderate. Most common AEs were fatigue (42%), nausea (22%) and headache (20%). One AE lead to premature discontinuation: isolated ALT and AST elevation at week 2, asymptomatic with no associated bilirubin increase; ALT and AST levels improved promptly after study drug discontinuation. Four patients experienced severe AEs (fatigue, hyperbilirubinemia, pain, and vomiting); none of these four resulted in study drug interruption or discontinuation.
					Arm 1: 19 Naïve patients	Arm 1:	
					GT1a (89.5%); GT1b (10.5%)	RVR = 100%	
					IL28B non-CC (47.2%)	eRVR = 100%	
					ABT-450/r 250/100 mg QD + ABT-333 400mg BID + RBV	SVR <sub>4</sub> = 95% SVR <sub>12</sub> = 95%	
					12-week treatment		
					Arm 2: 14 Naïve patients	Arm 2:	
					GT1a (78.6%); GT1b (21.4%)	RVR = 93%	
					IL28B non-CC (64.3%)	eRVR = 93%	
					ABT-450/r 150/100mg QD + ABT-333 400mg BID + RBV	SVR <sub>4</sub> = 93% SVR <sub>12</sub> = 93%	
12-week treatment							
		Arms 1 & 2:					
		100% (18 of 18) of IL28B non-CC patients achieved SVR <sub>24</sub>					
		Arm 3:					
		Arm 3: 17 Non-responders					
		GT1a (94.1%); GT1b (5.9%)	RVR = 88%				
		IL28B non-CC (100%)	eRVR = 65% SVR <sub>4</sub> = 47%				

Edgar Filing: ENANTA PHARMACEUTICALS INC - Form S-1/A

ABT-450/r 150/100mg QD + SVR<sub>12</sub> = 47%  
 ABT-333 400mg BID + RBV

12-week treatment  
 Naïve patients and null  
 responders; 14 arms; n = 571,  
 GT1

In Progress

3 DAAs are ABT-450/r  
 100/100mg to 200/100 QD +  
 ABT-267 25mg QD +  
 ABT-333 400mg BID; RBV  
 1000-1200mg BID  
 Naïve patient arm taking 3 SVR<sub>12</sub>= 92.0% (OD<sup>7</sup>)  
 DAAs for 12 weeks (n=79)

SVR<sub>12</sub>= 87.3% (ITT<sup>8</sup>)

GT1a (67.5%); IL28B non-CC  
 (70.9%)

Overall Initial Adverse Events  
 and Premature  
 Discontinuations (8- and  
 12-week arms, n=448):

ABT-450/r dose= 150/100mg  
 QD

Aviator<sup>(5)(6)</sup> + ± ± ±

Naïve patient arms taking 3 SVR<sub>12</sub>= 98.7% (OD)  
 DAAs + RBV for 12 weeks  
 (n=79)

SVR<sub>12</sub>= 97.5% (ITT)

All DAA combinations  
 studied were well tolerated  
 through 8-12 weeks of  
 treatment

GT1a (68.4%); IL28B non-CC  
 (72.2%)

Fatigue, headache, insomnia,  
 and nausea were the most  
 common adverse events  
 observed

ABT-450/r dose= 100/100 or  
 150/100mg QD

Null responder patient arms SVR<sub>12</sub>= 93.3% (OD)  
 taking 3 DAAs + RBV for 12  
 weeks (n=45)

SVR<sub>12</sub>= 93.3% (ITT)

Transient asymptomatic  
 elevation of indirect bilirubin  
 was seen, consistent with the  
 known effect of ABT-450 on  
 the bilirubin transporter  
 OATP1B1

GT1a (62.2%); IL28B non-CC  
 (95.6%)

<1% of patients discontinued  
 due to adverse events

ABT-450/r dose= 100/100 or  
 150/100mg QD

## Table of Contents

### Abbreviations:

QD refers to daily dosing; BID refers to twice daily dosing

ALT and AST are liver enzymes used to signal possible toxicity to the liver

### Notes:

(1) ABT-450/r is a protease inhibitor from the Enanta/Abbott collaboration that is dosed with the boosting agent, ritonavir (r). ABT-333 and ABT-072 are non-nucleoside polymerase inhibitors from Abbott, and ABT-267 is an NS5A inhibitor from Abbott.

(2) Patients who were treatment Naïve had not previously been treated with HCV therapies. Patients who were treatment Non-Responders were non-responders to previous interferon and ribavirin treatment. Null responders were patients who did not achieve a 2-log, or 100 fold, drop at treatment week 12. Patients were further categorized by which genotype of HCV virus was present (either GT1a or 1b) and by their interleukin-28B (IL28B) genotype. Patients infected with GT1a virus are generally more difficult to treat than GT1b patients. Genetic variation in the IL28B gene has been associated with the response to interferon and ribavirin therapy in hepatitis C virus (HCV) genotype 1-infected patients. Patients with the IL28B non-CC subgenotypes (either CT or TT) are generally more difficult to treat than those with the IL28B CC genotype.

(3) RVR (Rapid Virological Response): HCV virus RNA below Lower Limit of Quantitation (LLOQ) at treatment week 4

eRVR (Extended Rapid Virological Response): HCV virus RNA below LLOQ from week 4 through week 12 of treatment

SVR<sub>4</sub> (Sustained Virological Response 4): Continued HCV virus RNA below LLOQ 4 weeks after end of treatment (EOT)

SVR<sub>12</sub> (Sustained Virological Response 12): Continued HCV virus RNA below LLOQ 12 weeks after EOT

SVR<sub>24</sub> (Sustained Virological Response 24): Continued HCV virus RNA below LLOQ 24 weeks after EOT

SVR<sub>36</sub> (Sustained Virological Response 36): Continued HCV virus RNA below LLOQ 36 weeks after EOT

(4) Pilot and Co-Pilot data were reported at the European Association for the Study of the Liver (EASL) meeting, April 18-22, 2012 in Barcelona, Spain.

(5) ABT-450/r dosed with two or three of the following: Abbott's NS5A inhibitor ABT-267, Abbott's non-nucleoside polymerase inhibitor ABT-333, or ribavirin.

(6) Aviator data are observed data reported at the American Association for the Study of Liver Diseases (AASLD) meeting, November 9-13, 2012 in Boston, Massachusetts, USA.

(7) OD: Observed Data excludes patients with values missing for reasons other than virologic failure or discontinuation due to AEs.

(8) ITT: Intent-to-treat population includes all patients who received at least one dose of study drug, whether or not they completed the study's treatment regimen.

*Pilot Study.* The Pilot study, which began in October 2010, consisted of genotype 1 patients enrolled in an open-label trial of a 12-week interferon-free regimen consisting of ABT-450/r 150/100 mg once daily plus ABT-072 (Abbott's non-nucleoside polymerase inhibitor) 400 mg once daily plus weight-based ribavirin 1000-1200 mg/day twice daily. All patients in the study completed 12 weeks of treatment and were followed for 24 weeks post-treatment, and 73% of the patients were infected with the genotype 1a virus, which is harder to treat than genotype 1b. A rapid decrease in HCV RNA level was observed with treatment, and all patients had HCV RNA levels below the lower limit of quantitation, or LLOQ, by week 3. The treatment regimen was well tolerated and achieved an SVR 24 weeks after conclusion of treatment, or SVR<sub>24</sub> in 91% of treatment-naïve, non-cirrhotic HCV genotype 1-infected patients. In the Pilot study, most adverse events, referred to as AEs, were mild in severity and did not result in any study interruptions or discontinuations. Two patients experienced elevated bilirubin levels, a signal of potential toxicity to the liver, which returned to normal with continued dosing.

*Co-Pilot Study.* The Co-Pilot study, which began in May 2011, consisted of HCV genotype 1, non-cirrhotic patients enrolled in an open-label trial of a 12-week interferon-free regimen consisting of ABT-450/r once daily plus ABT-333 (Abbott's non-nucleoside polymerase inhibitor) 400 mg twice daily plus weight-based ribavirin twice daily (1000-1200 mg total daily dose). Two different doses of ABT-450/r were evaluated (250/100 mg; 150/100 mg) in treatment-naïve patients, 85% of whom were infected with the harder-to-treat genotype 1a virus (compared to genotype 1b); treatment-experienced patients were also assessed, 94% of whom were genotype 1a.

## Edgar Filing: ENANTA PHARMACEUTICALS INC - Form S-1/A

The Co-Pilot study demonstrated a sustained virologic response 12 weeks after conclusion of treatment, or SVR<sub>12</sub>, in 93-95% of treatment-naïve HCV genotype 1-infected patients and in 47% of previous non-responders. Virologic responses appeared to be independent of ABT-450/r dose and IL28B genotype in treatment-naïve patients. In the Co-Pilot study, most AEs were mild or moderate, and the most common were fatigue (42%), nausea (22%), and headache (20%). One patient with an AE discontinued the study in the second week of treatment due to asymptomatic, reversible ALT and AST liver enzyme elevation, with no associated bilirubin increase, and ALT and AST levels improved promptly after study drug discontinuation. Four patients experienced AEs assessed as severe (fatigue, pain, hyperbilirubinemia, and vomiting), though none of the severe AEs resulted in study drug interruption or discontinuation.

*Aviator Study.* The Aviator study, which began in October 2011, consisted of HCV genotype 1 non-cirrhotic patients enrolled in an open-label trial of a 12-week interferon-free regimen consisting of three DAAs, with and without ribavirin. One combination in the study consisted of ABT-450/r 100/100 to 200/100 mg once

**Table of Contents**

daily, plus ABT-267 (Abbott's NS5A inhibitor) 25 mg once daily, plus ABT-333 (Abbott's non-nucleoside polymerase inhibitor) twice daily (400 mg total daily dose), plus weight-based ribavirin twice daily (1000-1200 mg total daily dose). As reported in an initial data abstract from the ongoing study, ABT-450/r was evaluated in treatment-naïve patients and treatment-experienced patients who were null responders. Results from this ongoing trial demonstrated SVR<sub>12</sub> in 99% of treatment-naïve HCV genotype 1-infected patients and in 93% of previous null responders (as compared with 47% SVR<sub>12</sub> seen in the Co-Pilot study as detailed above). The most common AEs were fatigue (28% and 27%) and headache (28% and 31%) for treatment-naïve and previous null responders, respectively.

*Other Studies.* Phase 2 studies of additional interferon-free ABT-450/r combinations are underway. The Navigator study, which began in September 2011, combines ABT-450/r with Abbott's NS5A inhibitor ABT-267, with and without ribavirin. Abbott also started a Phase 2b Pearl I study of a combination of ABT-450/r with only ABT-267 in August 2012.

Initial results from the Pilot, Co-Pilot and Aviator Phase 2 studies provide compelling support for the potential development of an interferon-free combination containing ABT-450 for treatment of HCV.

*Phase 3.* In November 2012, Abbott announced the full scope of its initial Phase 3 registrational trials program for an ABT-450-containing regimen for treating genotype 1-infected patients, including six Phase 3 trials designed for 2,200 patients, and initiated dosing in one of those trials. Abbott had previously reported the start of three of these Phase 3 clinical trials using a co-formulated tablet of ABT-450/r/ABT-267, plus ABT-333, co-administered with ribavirin. The other planned Phase 3 trials will use the same 3 DAAs with and without ribavirin. In addition, Abbott has announced that it is conducting additional exploratory clinical studies to determine if a co-formulated tablet of ABT-450 and ABT-267 dosed once daily can provide high cure rates in specific HCV populations.

The study criteria for these six Phase 3 trials are summarized below:

*Summary of Phase 3 Trials of ABT-450/r-Containing Combinations in Genotype 1-infected Patients*

Study Name	Combination Regimen <sup>(1)</sup>	Subject Population <sup>(2)</sup>	Treatment Duration (Control)
SAPPHIRE I	450/r + 267 + 333 + RBV	Naïve genotype 1a and 1b patients (n=600)	12 weeks (placebo-controlled)
SAPPHIRE II	450/r + 267 + 333 + RBV	Experienced genotype 1a and 1b patients (n=400)	12 weeks (placebo-controlled)
SAPPHIRE III	450/r + 267 + 333 with/without RBV	Naïve genotype 1b patients (n=400)	12 weeks
SAPPHIRE IV	450/r + 267 + 333 with/without RBV	Naïve genotype 1a patients (n=300)	12 weeks
PEARL II	450/r + 267 + 333 with/without RBV	Experienced genotype 1b patients (n=200)	12 weeks
TURQUOISE II	450/r + 267 + 333 + RBV	Compensated cirrhotic naïve and experienced genotype 1a and 1b patients (n=300)	Ranging 12 and 24 weeks

Notes:

(1) 450/r is ABT-450, a protease inhibitor from the Enanta/Abbott collaboration that is dosed with the boosting agent, ritonavir (r). 267 is ABT-267, an NS5A inhibitor from Abbott. 333 is ABT-333, a non-nucleoside polymerase inhibitor from Abbott. RBV refers to ribavirin.

## Edgar Filing: ENANTA PHARMACEUTICALS INC - Form S-1/A

(2) Patients who are treatment naïve have not previously been treated with HCV therapies. Patients who are treatment experienced have been treated previously with interferon and ribavirin. Patients infected with genotype 1a virus are generally more difficult to treat than genotype 1b patients.

**Table of Contents**

Abbott has also announced an additional Phase 3 trial, known as the Turquoise I study, using the same 3 DAAs with ribavirin in patients co-infected with HIV and genotype 1 HCV, which will not be part of the initial registrational program.

***Next-Generation HCV Protease Inhibitor***

Abbott is also developing a next-generation protease inhibitor discovered within the Enanta-Abbott collaboration. Abbott has announced that this protease inhibitor has demonstrated activity in preclinical *in vitro* testing against a broad range of HCV genotypes, including variants that have shown strong resistance to first generation protease inhibitors. Abbott has also announced that this next-generation protease inhibitor was designed to enable once-daily dosing without ritonavir and to be co-formulated with Abbott's next-generation NS5A inhibitor. Abbott initiated a Phase 1 clinical trial of this next-generation protease inhibitor in November 2012.

***EDP-239, an NS5A Inhibitor for HCV Infection***

EDP-239, another DAA, is the lead NS5A inhibitor discovered by Enanta. The EDP-239 compound has demonstrated potent activity against major genotypes in the replicon assay, which is a common *in vitro* test for determining potency of an active compound in reducing HCV replication.

***Replicon Activity of NS5A Inhibitors***

Company	Product Candidate	GT-1a EC50* (pM)	GT-1b EC50* (pM)	Notes
Enanta	EDP-239	31	7	1
Achillion	ACH-3102	26	5	2
Bristol-Myers Squibb	BMS-790052	50	9	3
Gilead	GS-5885	41	5	4
GlaxoSmithKline	GSK2336805	44	8	5
Idenix	IDX-719	6.2	2.4	6
Presidio	PPI-461	210	10	7

\*GT refers to genotype of HCV. EC50 refers to the concentration of drug that inhibits viral replication by 50%. A lower EC50 number corresponds to a more potent drug against the tested virus. The EC50 number varies, however, based on the assay used. Each of the product candidates listed above was tested using a different assay. While the EC50 numbers are not directly comparable, they do provide general guidance as to the high potencies seen in the NS5A inhibitor class.

**Notes:**

Published values: <sup>1</sup>EASL 2011 poster 1213; <sup>2</sup>EASL 2012; <sup>3</sup>Nature 2010, 465, 96-100; <sup>4</sup>J. Hepatol 2011, 54 (1), S481-S482; <sup>5</sup>AASLD 2011; <sup>6</sup>18th International Symposium on Hepatitis C Virus and Related Viruses 2011; <sup>7</sup>AASLD 2010.

In addition, EDP-239 has additive to synergistic antiviral activity when used in combination with other anti-HCV therapeutics (DAA and HTA) in reducing HCV replication. Preclinical studies support excellent permeability and absorption potentials in humans. The compound has preferential penetration to the liver, which is the target site of infection, across all preclinical models tested. Human pharmacokinetic and pharmacodynamic modeling suggests a low, once-daily clinical dose for future testing. In addition, EDP-239 has very little drug-drug interaction potential and thus may be ideally suited for use in HCV combination therapies. EDP-239 has a robust preclinical safety profile, including excellent safety in preclinical cardiovascular studies. The IND for EDP-239 has been filed and we have received a study may proceed notification from the FDA. Novartis is responsible for initiating Phase 1 trials.

We discovered EDP-239 internally at Enanta and entered into a collaboration with Novartis in February 2012, granting Novartis exclusive, worldwide rights to develop, manufacture and commercialize EDP-239. Novartis will fund all costs associated with the development, manufacture and commercialization of EDP-239 and related NS5A products, as well as fund our drug discovery efforts on additional selected compounds targeting NS5A at least until February 2013. Under the agreement, we received an upfront payment of \$34.4

## **Table of Contents**

million and we are entitled to receive an \$11.0 million milestone payment based on Novartis' November 2012 initiation of dosing in a Phase 1 clinical trial that includes EDP-239. We are eligible to receive up to \$395 million of additional payments if Novartis achieves specified clinical, regulatory, and commercial milestones. We are also eligible to receive tiered royalties ranging on a blended basis from the low double digits up to the high teens on worldwide net sales of products, and retain co-detail rights, which would allow us to staff up to a specified percentage of the sales force for a designated product in the United States.

In addition to EDP-239, we have a number of additional NS5A inhibitors in the discovery stage that we believe have strong intellectual property protection and represent a diversity of chemical structures. Enanta and Novartis are now in a research collaboration to discover follow-on NS5A inhibitors with structural diversity and enhanced activity against HCV mutants that have developed resistance to other NS5A inhibitors.

### ***EDP-546, a Cyclophilin Inhibitor for HCV Infection***

In anticipation of resistance arising to DAA HCV therapy that targets viral proteins, we have been developing an alternative HTA approach that targets the human host protein, cyclophilin, which is essential for replication of HCV.

#### *Interruption of Viral Replication of HCV RNA by Cyclophilin Inhibitor*

**Abbreviations:** Cyp refers to cyclophilin  
CypA refers to cyclophilin A

We have demonstrated in replicon assays that one of our lead cyclophilin targeting inhibitors, EDP-546, is a potent inhibitor of HCV replication and is more potent than the clinical stage cyclophilin inhibitor alisporivir. Typically, cyclophilin inhibitors are based on the structures of cyclosporine A, which is known to be immunosuppressant with associated side effects that limit its clinical use. Based on our understanding of the structural elements of cyclosporine A that contribute to immunosuppressive activity, we have designed those elements out of our cyclophilin inhibitors and have confirmed a lack of *in vitro* immunosuppressive activity for EDP-546 and other inhibitors we are developing.

EDP-546 is an HTA with a high barrier to resistance which in preclinical studies has demonstrated a number of important attributes. EDP-546 has demonstrated the potential to have additive to synergistic antiviral activity when used in combination with DAAs and has not shown cross-resistance to HCV variants that are resistant to several DAAs. In addition, the superior metabolic stability profile of the drug compared to alisporivir suggests the potential for once-daily dosing of EDP-546.



---

## **Table of Contents**

A number of additional preclinical studies of EDP-546 have been initiated, and we expect to initiate a Phase 1 clinical trial in the first half of 2014. In addition to EDP-546, we are continuing to generate and characterize a number of additional cyclophilin inhibitors in the discovery phase.

### ***Nucleotide Polymerase Inhibitor Program for HCV Infection***

We also have a program to develop inhibitors to HCV polymerase, which is another DAA mechanism considered to have a high barrier to resistance. Our researchers have identified a promising nucleotide lead series with significant antiviral potency *in vitro*. One of our lead compounds has demonstrated better *in vitro* potency than a reference clinical stage nucleotide inhibitor, GS-7977, under development by Gilead Sciences. We have an ongoing discovery effort in this inhibitor class and are considering a number of compounds for further development. We plan to select a candidate in 2013 that is suitable for advancement into preclinical studies.

### **Our MRSA Antibacterial Program**

#### ***Background of MRSA Antibiotics***

The past three decades have witnessed a dramatic change in the epidemiology of resistant Gram-positive bacterial infections all over the world. Families of common Gram-positive organisms include *Streptococcus*, or *Strep*, *Staphylococcus*, or *Staph*, and *Enterococcus*. Among the conditions associated with these pathogens are skin infections, bacteremia and endocarditis. One of these pathogens, known as methicillin-resistant *Staph aureus*, or MRSA, was principally identified when resistance was observed to methicillin, an early antibiotic used for *Staph aureus* and other bacterial infections. Increasingly, strains of MRSA have been identified that are also resistant to many other antibiotics.

The recognition and spread of MRSA, as well as *Enterococci* resistant to the antibiotic vancomycin, referred to as VRE, in the community and in healthcare facilities represents a major healthcare challenge. Widespread reports of emerging bacterial resistance to existing antibiotics emphasize the need for continued research and development of novel antimicrobials to address possible life-threatening infections caused by Gram-positive resistant pathogens. MRSA was responsible for approximately 94,000 reported infections that resulted in over 19,000 deaths in the United States in 2005, compared to approximately 16,000 deaths from AIDS.

In addition to the high potential for large hospital outbreaks, MRSA and Gram-positive resistance are moving out from hospitals into the community. During the past decade, rates of MRSA in the community have increased rapidly. Thus, an urgent need exists for the development of new antibiotics that will be effective against Gram-positive organisms that are resistant to current antibiotics in the macrolide class, such as clarithromycin (Biaxin<sup>TM</sup>), azithromycin (Zithromax<sup>TM</sup>) and telithromycin (Ketek<sup>TM</sup>), as well as VRE and *Enterococci* that are resistant to the oxazolidinone class of antibiotics, such as linezolid (Zyvox). In addition, there exists a significant need for agents that would allow step-down dosing, wherein MRSA patients being treated in a hospital setting with intravenous treatment could be sent home on the same drug to be taken orally.

#### ***EDP-788 and Our Bicyclolide Antibiotics***

Through our internal chemistry efforts, we have created a new family of macrolide antibiotics called Bicyclolides that overcomes resistance and possesses a significantly improved product profile compared to existing macrolides such as Zithromax and Biaxin<sup>TM</sup>. The main focus of our antibiotic work is on new mechanisms targeting resistant Gram-positive pathogens, including MRSA and other *Staph aureus* bacteria resistant to currently marketed macrolides. Our initial therapeutic focus is on skin infections, namely Acute Bacterial Skin and Skin Structure Infections, or ABSSSI. Examples of ABSSSI are cellulitis/erysipelas, wound infection, major cutaneous abscess and burn infections. Major pathogens involved in skin infections are *Strep pyogenes* and *Staph aureus*.

Our lead Bicyclolide antibiotic product candidate is EDP-788, which we are developing for use as an intravenous drug in the hospital setting and for oral dosing in a home setting. EDP-788 is a prodrug, which means that it is inactive until it is converted in the body into an active compound. EDP-788 is a highly water-soluble molecule which, when administered, is cleanly and rapidly converted into the active compound.

## **Table of Contents**

The active compound generated from EDP-788 is EDP-322, a Bicyclolide we developed that demonstrates a broad spectrum of activity against many bacterial organisms, including MRSA. *In vitro*, EDP-322 had either comparable or superior activity to vancomycin (Vancocin™) or linezolid (Zyvox™) in MRSA clinical isolates. A prominent advantage of EDP-322 is activity against isolates with resistance, in comparison to vancomycin, linezolid and daptomycin (Cubicin™), the three therapies most often utilized as a last stand against resistant bacteria. EDP-322 has also shown good activity against linezolid-resistant *Enterococci*. Finally, EDP-322 demonstrates excellent efficacy in a number of preclinical *in vivo* infection models.

Preclinical safety studies performed with EDP-322 presented no significant concerns. EDP-322 was evaluated in normal healthy volunteers in two double-blind, randomized, placebo-controlled Phase 1 trials, evaluating pharmacokinetic and safety parameters. EDP-322 showed good pharmacokinetics and was well tolerated in all dose groups, with no findings of clinical significance in vital signs, physical exams, electrocardiograms or clinical chemistry. Adverse events were limited to minor gastrointestinal effects attributed to inadequate water solubility of the drug, which we would not expect when dosing with the water-soluble EDP-788.

Owing to its high water solubility, EDP-788 has the significant benefit of allowing for an intravenous, or IV, formulation that has met the initial safety requirements for IV dosing. Preclinical testing has also demonstrated that oral dosing of the prodrug EDP-788 results in higher blood levels of the active compound EDP-322 than when EDP-322 is dosed orally itself. This makes EDP-788 ideally suited for stepdown dosing from IV administration in the hospital to oral administration in the home setting. Neither EDP-322, nor any other compound in the class of Bicyclolides, has yet been shown to be effective in pivotal clinical trials or resulted in any product approved by the FDA.

All current Bicyclolide development activities are focused on EDP-788 with additional IND-enabling studies in progress and the initiation of clinical trials planned for the first half of 2014. Our preclinical development of EDP-788 is funded under our contract with NIAID with potential for further NIAID funding of early clinical development.

## **Drug Discovery and Chemical Development**

We have internally developed all of the initial compounds in our research programs, and have participated in the early development of these programs with our collaborators using our own internal research capabilities. Our scientists have expertise in the areas of medicinal chemistry, molecular virology and pharmacology, with highly developed sets of skills in compound generation, target selection, screening and pharmacology, preclinical development and lead optimization. We are utilizing these skills and capabilities in our discovery and development of antiviral and antibacterial product candidates.

We focus on infectious diseases representing large and growing market opportunities with significant unmet medical needs. Our selection of a particular therapeutic target within those infectious diseases takes into consideration the experience and expertise of our scientific team. The final selection is based on the possibility of being able to generate robust medicinal chemistry structure-activity relationships to assist lead optimization and secure relevant intellectual property rights. Once we have identified lead compounds, they are tested using *in vitro* and *in vivo* pharmacology studies and *in vivo* research models of antiviral or antibacterial efficacy.

## **Collaboration and License Agreements**

### ***Abbott Laboratories***

We entered into a Collaborative Development and License Agreement with Abbott in November 2006 to develop and commercialize HCV NS3 and NS3/4A protease inhibitors. Under the agreement, which was amended in January and December 2009, we have granted Abbott an exclusive, worldwide, royalty-bearing license, including a right to grant sublicenses, to specified intellectual property, including several issued U.S. patents, relating to protease inhibitors. We also granted Abbott access to our drug discovery capabilities in the HCV NS3 and NS3/4A protease inhibitor field. Abbott granted us a co-exclusive (together with Abbott), royalty-free, fully paid license, without the right to grant sublicenses, to certain of Abbott's intellectual property,

---

**Table of Contents**

Abbott's interest in joint intellectual property and improvements discovered by Abbott, for the purpose of allowing us to conduct certain development and commercialization activities in the United States relating to protease inhibitors. Abbott is responsible for and funds all costs associated with the development, manufacturing and commercialization of ABT-450 and other compounds under this agreement. We are eligible to receive milestone payments and royalties with respect to these compounds. So long as a product candidate is being developed or commercialized under the agreement, we undertake not to conduct any activity, or grant licenses to a third party, relating to protease inhibitors.

A joint steering committee was established under the agreement with review and oversight responsibilities for all research, development and commercialization activities. The joint steering committee is comprised of three of our senior personnel and three senior personnel from Abbott; however, Abbott has final authority to make all decisions regarding development and commercialization activities.

The research program and the evaluation period, which was performed by both parties, ended in June 2011. The lead compound is ABT-450, and additional compounds are under development. The first clinical milestone for ABT-450 was achieved in 2010. To date, we have received upfront license payments, research funding, and milestone payments totaling \$92.5 million from Abbott, and additionally we have received an equity investment of \$12.5 million from Abbott. We are also entitled to receive a \$15.0 million milestone payment based on Abbott's November 2012 initiation of dosing in a Phase 3 clinical trial.

We are eligible to receive future milestone payments totaling up to \$40 million (exclusive of the \$15.0 million earned milestone payment discussed above) upon Abbott's achievement of regulatory filing milestones for the first protease inhibitor product resulting from our collaboration and additional milestone payments totaling up to \$155 million upon Abbott's achievement of commercial regulatory approval milestones in several major markets. We are also eligible to receive additional milestone payments totaling up to \$80 million upon Abbott's achievement of similar commercial regulatory approval milestones for each additional product containing a protease inhibitor.

We are eligible to receive tiered royalties ranging on a blended basis from the low double digits up to the high teens based on the annual net sales of each product developed under the agreement. However, if a product is determined to be a combination product under our agreement, the royalties will be adjusted on a country-by-country and product-by-product basis to reflect a good faith determination of the relative value of each pharmaceutically active ingredient, based on a fair market value calculation.

Royalties owed to us under the agreement can be reduced by Abbott in certain circumstances, including (i) if Abbott exercises its right to license or otherwise acquire rights to intellectual property controlled by a third party where a product could not be legally developed or commercialized in a country without the third-party intellectual property right, (ii) where a product developed under the collaboration agreement is sold in a country and not covered by a valid patent claim in such country, and (iii) where sales of a generic product are equal to at least a specified percentage of Abbott's market share of a product in a country.

Abbott's obligation to pay royalties on a product developed under the agreement expires on a country-by-country basis upon the later of (i) the last date upon which the manufacture, use or sale of a product would infringe one of the licensed patents, and (ii) ten years after the first commercial sale of the product in the applicable country.

Under the agreement, we hold an option to fund 40% of U.S. development costs and U.S. commercialization efforts (sales and promotion costs) in exchange for 40% of any U.S. profits of any product candidate that ultimately achieves regulatory approval and commercialization. We did not exercise our option right with respect to ABT-450, but we retain our option right for any next-generation products developed under the agreement, which must be exercised within a specified period after the successful completion of a Phase 2a trial of the next-generation product.

Our intellectual property existing as of the effective date of the agreement remains our property. Any intellectual property jointly developed will be jointly owned. We will have unilateral right to enforce Enanta patent rights on any covered product following the first commercial sale of such product, as will Abbott. In the event of infringement related to any Enanta patents, we will have the first right and option to initiate legal proceedings or take other actions. In the event of infringement related to any Abbott patents, Abbott will have the first right and option to initiate legal proceedings or take other actions. In the event of infringement of a joint

## **Table of Contents**

patent right, we will discuss with Abbott whether to initiate legal proceedings or take other actions. Abbott will have the obligation to defend at its sole expense any actions brought against either party alleging infringement of third-party rights by reason of the activities conducted under the agreement and we will have the right to obtain separate counsel at our own expense. Additionally, Abbott, at its sole expense, will be responsible for all trademark prosecution.

Subject to the exceptions described above, a party's rights and obligations under the agreement continue until: (i) such time as Abbott is no longer developing a product candidate or (ii) if, as of the time Abbott is no longer developing any product candidates, Abbott is commercializing any other protease inhibitor product, such time as all royalty terms for all covered products and all co-development terms for all co-developed products have ended. Accordingly, the final expiration date of the agreement is currently indeterminable.

Either party may terminate the agreement for cause in the event of a material breach, subject to prior notice and the opportunity to cure, or in the event of the other party's bankruptcy. Additionally, Abbott may terminate the agreement for any reason upon specified prior notice.

If we terminate the agreement for cause or Abbott terminates without cause, any licenses and other rights granted to Abbott will terminate and Abbott will be deemed to have granted us (i) a non-exclusive, perpetual, fully paid, worldwide, royalty-free license, with the right to sublicense, under Abbott's intellectual property used in any product candidate and (ii) an exclusive (even as to Abbott), perpetual, fully paid, worldwide, royalty-free license, with the right to sublicense, under Abbott's interest in joint intellectual property rights to develop product candidates resulting from covered compounds and to commercialize any products derived from such compounds. Upon our request, Abbott will also transfer to us all right, title and interest in any related product trademarks, regulatory filings and clinical trials.

If Abbott terminates the agreement for our uncured breach, the milestone and royalty payments payable by Abbott may be reduced, the licenses granted to Abbott will remain in place, we will be deemed to have granted Abbott an exclusive license under our interest in joint intellectual property, Abbott will continue to have the right to commercialize any covered products, and all rights and licenses granted to us by Abbott will terminate.

### ***Novartis Institutes for BioMedical Research, Inc.***

In February 2012, we entered into a Collaboration and License Agreement with Novartis granting Novartis exclusive, worldwide rights to develop, manufacture and commercialize EDP-239, our lead compound from our NS5A inhibitor program, and other NS5A compounds. Under the agreement, we received an upfront payment of \$34.4 million and we are entitled to receive an \$11.0 million milestone payment based on Novartis' November 2012 initiation of dosing in a Phase 1 clinical trial that includes EDP-239. We are eligible to receive up to \$395 million of additional payments if Novartis achieves specified clinical, regulatory, and commercial milestones. An additional milestone payment of \$15 million will be due upon Novartis' initiation of a subsequent Phase 2 trial using a combination containing an NS5A inhibitor.

We are also eligible to receive tiered royalties ranging on a blended basis from the low double digits up to the high teens on net sales allocable to our collaboration's NS5A inhibitors, subject to reduction in certain circumstances, and we retain an option for co-detail rights in the United States, which would allow us to staff up to a specified percentage of the sales force for a designated product. Under our agreement we must exercise these co-detail rights for a collaboration product before its expected commercial launch and then negotiate and finalize a co-detailing agreement with Novartis on reasonable and customary terms. During the term of the collaboration agreement we agree not to research, develop, manufacture or commercialize competing products, either alone or with other parties.

Novartis will fund all costs associated with the development, manufacture and commercialization of EDP-239, EDP-239-containing combinations and any follow-on NS5A inhibitors, as well as fund our efforts to discover follow-on NS5A inhibitors until at least February 2013, which period we refer to as the research term. The research term can be extended by mutual agreement.

A joint steering committee was established under the agreement with review and oversight responsibilities for all research, development and commercialization activities. The joint steering committee is comprised of

---

## **Table of Contents**

three of our senior personnel and three senior personnel from Novartis. However, Novartis has ultimate decision making authority with respect to the research, development and commercialization of collaboration products.

Our patents and know-how existing as of the effective date of the agreement remain our property. Any know-how or inventions jointly developed will be jointly owned, subject to the exclusive rights we grant to Novartis, and subject to such exclusive right may be licensed to any third party. Neither party will assign to any third party its interest in any jointly owned patent rights without the other party's prior written consent. Novartis will be responsible for filing, prosecuting and maintaining patents, at Novartis' expense, relating to our intellectual property which is subject to the license, and all joint intellectual property. Novartis will also have the first right to prosecute any third-party infringement.

Subject to certain exceptions, on a country-by-country and product-by-product basis, a party's rights and obligations under the agreement continue until the later of: (i) the expiration of the last to expire patent rights of a covered product in the applicable country or (ii) ten years from the first commercial sale of a covered product in the applicable country. As a result, the final expiration date of the Novartis license is indeterminable at this time. Upon expiration of the agreement with respect to a particular product and country, the licenses granted to Novartis in the agreement with respect to such product and country will remain in effect and convert to a non-exclusive, perpetual, unrestricted, fully-paid, royalty-free, worldwide license.

We may terminate the agreement (i) in the event of a material breach by Novartis, subject to prior notice and the opportunity to cure, (ii) in the event Novartis fails to use commercially reasonable efforts to develop and commercialize covered products in its territory or (iii) in the event Novartis is subject to an insolvency event. Novartis may terminate the agreement (i) in the event of a material breach by us, subject to prior notice and the opportunity to cure, (ii) in the event we are subject to an insolvency event or (iii) for any reason upon 120 days prior written notice. In the case of a termination for cause by us or a termination without cause by Novartis, any licenses and other rights granted by either party to the other will terminate and revert back to the granting party and we will regain control of the prosecution of the patents relating to our intellectual property. If such termination occurs prior to the second anniversary of the end of the research term, we retain exclusive worldwide rights, with the right to sublicense under all collaboration intellectual property owned in whole or in part by Novartis, to research, develop and commercialize compounds and products contemplated by the collaboration. If such termination occurs after the second anniversary of the end of the research term, then Novartis agrees to negotiate with us to grant us a worldwide, exclusive, field-limited, royalty-bearing license, with right to sublicense, under all collaboration intellectual property owned in whole or in part by Novartis.

Royalties and milestones owed to us under the agreement can be reduced by Novartis in certain circumstances, including (i) where a product could not be legally developed or commercialized in a country without obtaining third-party intellectual property rights, (ii) where it is decided that it would be useful to license or otherwise acquire a third-party intellectual property right to develop or commercialize the product, (iii) where the net sales of a product in a country in one year decrease by a specified percentage when compared to the preceding year because of generic product competition, and (iv) where a product is not covered by a valid patent claim in the country of sale.

### ***NIAID Contract***

In September 2011, we were awarded a contract from NIAID to fund preclinical and early clinical development of a new class of bridged bicyclic antibiotics known as Bicyclolides. The Bicyclolides are to be used as medical countermeasures against multiple biodefense bacteria found in anthrax, plague and tularemia.

The contract has an initial term of 30 months ending on March 30, 2014. NIAID has the option to extend the contract up to 6 times. If each option period is exercised, the contract would be extended until September 29, 2016. The initial award under the initial term was \$14.3 million, with the possibility of up to a total of \$42.7 million if each option period is exercised by NIAID.

Under the contract, all intellectual property rights held by us and any inventions, know-how or other intellectual property rights derived as a result of this contract will be our property, subject to certain rights of the United States federal government. See Risk Factors We could be unsuccessful in obtaining or maintaining

## **Table of Contents**

adequate patent and other intellectual property protection for one or more of our product candidates. We also retain the right to use any data developed under the contract to enter into commercial transactions that are unrelated to the biodefense field.

### **Competition**

We are engaged in segments of the pharmaceutical industry that are highly competitive and rapidly changing. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations are commercializing or pursuing the development of products that target viral diseases, including the same diseases we are targeting.

We expect our licensed product candidates and our future product candidates to face intense and increasing competition as new products enter the HCV and antibacterial markets and advanced technologies become available, particularly in the case of HCV therapies in combinations with existing products and other new products. Two drug products, Incivek (telaprevir) of Vertex and Victrelis (boceprevir) of Merck, were approved in 2011 by the FDA for the treatment of HCV in combination with the previous standard of care consisting of interferon in combination with ribavirin. The evolving standard of care treatment regimens and the cure rates of patients using either one of these approved drugs and future approved combinations of DAAs other than ones we have developed and are developing may be such that our development and discovery efforts in the area of HCV may be rendered noncompetitive.

We believe that a significant number of product candidates that are currently under development may become commercially available in the future for the treatment of HCV. We are aware that many competitors other than our collaborators have product candidates in Phase 2 or later stage clinical trials, including Achillion, Boehringer Ingelheim, Bristol-Myers Squibb, Gilead, Hoffman-La Roche, Idenix, Johnson & Johnson, Medivir, Merck and Vertex. Our competitors' products may be more effective, have fewer side effects, have lower costs or be better marketed and sold than any product candidate that includes ABT-450, EDP-239 or any of our future compounds or than any of our future product candidates. Additionally, products that our competitors successfully develop for the treatment of HCV may be marketed prior to any HCV product that our collaborators or we may successfully develop.

Abbott has the right to market and sell products that compete with the product candidates that we have licensed to it and any competition by Abbott could also have a material adverse effect on our future business.

Our lead antibiotic product candidate, EDP-788, is being developed as a broad-spectrum antibiotic with MRSA coverage for first line use in the hospital setting. In this treatment setting, if approved, EDP-788 would compete with a number of currently-marketed antibiotics, including Tygacil and Teflaro, and antibiotics currently in Phase 3 development, including omadocycline/PTK-0796, a tetracycline under development by Paratek Pharmaceuticals, as well as delafloxacin being developed by Rib-X Pharmaceuticals. We expect that EDP-788 would also compete with currently marketed antibiotics used for serious, Gram-positive infections, including vancomycin, a generic drug that is manufactured by a variety of companies, Zyvox, Cubicin and telavancin (Vibativ). In addition, a number of Gram-positive anti-infective product candidates currently in Phase 3 development could also compete with EDP-788 if they are approved, including dalbavancin (under development by Durata Therapeutics, Inc.), oritavancin (under development by The Medicines Company), tedizolid (under development by Trius Therapeutics, Inc.) and Taksta (under development by Cempre, Inc.).

Competitive products may render our product candidates licensed to others, as well as any future product candidates we may develop ourselves for HCV or MRSA treatment, obsolete or noncompetitive. All of these product candidates will face competition based on their safety and effectiveness, the timing and scope of regulatory approvals, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent position and other factors. Our competitors may succeed in developing competing products before we do, obtaining regulatory approval for products or gaining acceptance for the same markets that we are targeting. If we or our collaborators are not first to market with one of our product candidates for a given disease indication or a given product profile, our competitive position could be compromised because it may be more difficult for us to obtain marketing approval for that product candidate and/or successfully market that product candidate as a second competitor.

**Table of Contents**

Many of our competitors have substantially greater commercial infrastructures and financial, technical and personnel resources than we have. We will not be able to compete successfully unless we are able to:

design and develop products that are superior to other products in the market;

attract qualified scientific, medical, sales and marketing and commercial personnel;

obtain patent and/or other proprietary protection for our processes and product candidates;

obtain required regulatory approvals; and

collaborate with others in the development and commercialization of new products.

Established competitors may invest heavily to quickly discover and develop novel compounds that could make our product candidates obsolete. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. If we and our collaborators are not able to compete effectively against current and future competitors for our product candidates, our business will not grow and our financial condition will be adversely affected.

**Intellectual Property**

As part of our business strategy, we actively seek patent protection for our product candidates in the United States and certain major foreign jurisdictions and file additional patent applications, when appropriate, to cover improvements to our compounds. We also rely on trade secrets, internal know-how, technological innovations and agreements with third parties to develop, maintain and protect our competitive position. Our ability to be competitive will depend on the success of this strategy.

The tables below provide summary information about our patents in each of our major programs. While several of the issued patents and pending patent claims in the program areas contain claims to compounds, methods of use and processes for synthesis, in each program only a few of the issued patents and/or pending patent applications cover the lead product candidate in the program. See Business Overview for additional details regarding the patents and patent applications relating to our lead product candidates.

*HCV NS3 Protease Inhibitor Program.* The patent portfolio directed to the HCV protease inhibitor program with Abbott included the following as of September 30, 2012:

	Issued Patents	Pending Provisional Applications	Pending Non-Provisional Applications	Pending PCT-Applications
U.S.	27		25	
Foreign	39		163	3

The issued United States patents and the applications, if granted, will expire between 2023 and 2031 before taking into account any extension that may be obtained through patent term extension or adjustment, or term reduction due to filing of terminal disclaimers. Abbott is a joint owner of a number of patent applications. Abbott also has rights to some or all of these patents and patent applications pursuant to its collaboration agreement with us.

*HCV NS5A Inhibitor Program.* Our patent portfolio directed to our HCV NS5A inhibitor program with Novartis included the following, as of September 30, 2012:

	<b>Issued Patents</b>	<b>Pending Provisional Applications</b>	<b>Pending Non-Provisional Applications</b>	<b>Pending PCT-Applications</b>
U.S.	4	2	20	
Foreign			72	6

The issued United States patents and the applications, if granted, will expire between 2030 and 2032 before taking into account any extension that may be obtained through patent term extension or adjustment, or term reduction due to filing of terminal disclaimers. Novartis has rights to some or all of these patents and patent applications pursuant to its collaboration agreement with us.



**Table of Contents**

*Cyclophilin Inhibitor Program.* Our ongoing research activities include identifying compounds that inhibit cyclophilin, a protein in the human body that has been shown to be involved in HCV replication. Our current portfolio directed to cyclophilin binders for the treatment of HCV includes the following, as of September 30, 2012:

	<b>Issued Patents</b>	<b>Pending Provisional Applications</b>	<b>Pending Non-Provisional Applications</b>	<b>Pending PCT-Applications</b>
U.S.	1		6	
Foreign			17	

The issued United States patent and patent applications, if granted, will expire between 2030 and 2031 before taking into account any extension that may be obtained through patent term extension or adjustment, or term reduction due to filing of terminal disclaimers.

*HCV Nucleotide Polymerase Inhibitor Program.* Our patent portfolio directed to HCV nucleotide polymerase inhibitor program included the following, as of September 30, 2012:

	<b>Issued Patents</b>	<b>Pending Provisional Applications</b>	<b>Pending Non-Provisional Applications</b>	<b>Pending PCT-Applications</b>
U.S.	1	1	2	
Foreign				1

The issued patents and pending applications, if granted, will expire between 2030 and 2032 before taking into account any extension that may be obtained through patent term extension or adjustment, or term reduction due to filing of terminal disclaimers.

*Antibacterial Program.* Our patent portfolio directed to antibacterials included the following as of September 30, 2012:

	<b>Issued Patents</b>	<b>Pending Provisional Applications</b>	<b>Pending Non-Provisional Applications</b>	<b>Pending PCT-Applications</b>
U.S.	20	1	4	
Foreign	45		20	

These patents and patent applications, if granted, will expire between 2020 and 2032 before taking into account any extension that may be obtained through patent term extension or adjustment, or term reduction due to filing of terminal disclaimers.

We may obtain patents for certain compounds many years before we obtain marketing approval for products containing such compounds. Because patents have a limited life, which may begin to run prior to the commercial sale of the related product, the commercial value of the patent may be limited. However, we may be able to apply for patent term extensions in the United States and in a number of European countries, compensating in part for delays in obtaining marketing approval, but we cannot be certain we will obtain such extensions.

It is also very important that we do not infringe patents or other proprietary rights of others. If we do infringe such patents or other proprietary rights, we could be prevented from developing or selling products or from using the processes covered by those patents, could be required to pay substantial damages, or could be required to obtain a license from the third party to allow us to use their technology, which may not be available on commercially reasonable terms or at all. If we were not able to obtain a required license or develop alternative technologies, we may be unable to develop or commercialize some or all of our products, and our business could be adversely affected.

In addition, we jointly own patent applications, together with Abbott, that claim ABT-450 as a chemical entity. We also own one issued patent that claims EDP-239 as a chemical entity. However, there is no guaranty that such applications will issue. Further, the existence of issued patents does not guarantee our right to practice the patented technology or commercialize the patented product. Third parties may have or obtain rights to patents that could be used to prevent or attempt to prevent us from commercializing our product candidates. If these other parties are successful in obtaining valid and enforceable patents, and establishing our infringement of those patents, we could be prevented from commercializing our product candidates unless we were able to obtain a license under such patents, which may not be available on commercially

reasonable terms or at all.

## **Table of Contents**

Much of our scientific capabilities depend upon the knowledge, experience and skills of key scientific and technical personnel. To protect our rights to our proprietary know-how and technology, we endeavor to require all employees, as well as our consultants and advisors when feasible, to enter into confidentiality agreements that require disclosure and assignment to us of ideas, developments, discoveries and inventions made by these employees, consultants and advisors in the course of their service to us.

We may be unable to obtain, maintain and protect the intellectual property rights necessary to conduct our business, and we may be subject to claims that we infringe or otherwise violate the intellectual property rights of others, which could materially harm our business. For more information, see Risk Factors- Risks Related to Our Intellectual Property Rights.

## **Government Regulation**

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are developing. Any pharmaceutical candidate that we develop must be approved by the FDA before it may be legally marketed in the United States and by the appropriate foreign regulatory agency before it may be legally marketed in foreign countries.

### ***United States Drug Development Process***

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act, or FDCA, and implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

Completion of preclinical laboratory tests, animal studies and formulation studies according to GLPs or other applicable regulations;

Submission to the FDA of an IND, which must become effective before human clinical trials may begin;

Performance of adequate and well-controlled human clinical trials according to the FDA's current Good Clinical Practices, or GCPs, to establish the safety and efficacy of the proposed drug for its intended use;

Submission to the FDA of a New Drug Application, or an NDA, for a new drug product;

Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the drug is to be produced to assess compliance with the FDA's current Good Manufacturing Practice standards, or cGMP, to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;

Potential FDA audit of the nonclinical and clinical trial sites that generated the data in support of the NDA; and

FDA review and approval of the NDA.



---

## **Table of Contents**

The lengthy process of seeking required approvals, which can often take anywhere from eight months from the time the NDA is filed if there is a priority review to twelve months for a standard review, and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources. There can be no certainty that approvals will be granted.

Before testing any compounds with potential therapeutic value in humans, the product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with GLP and other federal regulations and requirements. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a drug at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot assure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trial.

Clinical trials involve the administration of the product candidate to healthy volunteers or patients having the disease being studied under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety. Each protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted in accordance with the FDA's GCP requirements. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until it is completed.

Human clinical trials prior to approval are typically conducted in three sequential phases that may overlap or be combined:

*Phase 1.* The drug is initially introduced into healthy humans and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted only in patients having the specific disease.

*Phase 2.* The drug is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule for patients having the specific disease.

*Phase 3.* Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials, which usually involve more patients than earlier trials, are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. Generally, at least two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA.

Post-approval studies, or Phase 4 clinical trials, may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and may be required by the FDA as part of the approval process.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA by the investigators for serious and unexpected AEs or

## **Table of Contents**

any finding from tests in laboratory animals that suggests a significant risk for human patients. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA, or the sponsor or its data safety monitoring board, may suspend a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional animal studies and develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must include methods for testing the identity, strength, quality and purity of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

### ***U.S. Review and Approval Processes***

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees by the applicant; a waiver of such fees may be obtained under certain limited circumstances.

In addition, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has twelve months in which to complete its initial review of a standard NDA and respond to the applicant, and eight months for a priority NDA. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. In addition to its own review, the FDA may refer applications for novel drug products or drug products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the drug. If the FDA concludes that a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without a REMS, if required.

Before approving an NDA, the FDA will inspect the facilities at which the product is to be manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with cGMP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable it will outline the deficiencies in the submission and often will request additional testing or information.

---

**Table of Contents**

The NDA review and approval process is lengthy and difficult, and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA will issue a complete response letter if the agency decides not to approve the NDA. The complete response letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require Phase 4 testing, which involves clinical trials designed to further assess a product's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

***Expedited Development and Review Programs***

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, new drug products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. Unique to a Fast Track product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor meets certain requirements and the FDA agrees to accept sections on a rolling basis.

Any product submitted to the FDA for marketing approval, including those submitted to a Fast Track program, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or there is a significant improvement in the treatment, diagnosis or prevention of a disease compared with marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Drug products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical studies establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA generally requires that a sponsor of a drug product receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies to establish safety and efficacy for the approved indication. Failure to conduct such studies, or conducting such studies that do not establish the required safety and efficacy may result in revocation of the original approval. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch or subsequent marketing of the product. Fast Track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

***Post-Approval Requirements***

Any drug products for which we receive FDA approvals are subject to continuing regulation by the FDA. Certain requirements include, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information on an annual basis or more

**Table of Contents**

frequently for specific events, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements. These promotion and advertising requirements include, among others, standards for direct-to-consumer advertising, prohibitions against promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as off-label use), rules for conducting industry-sponsored scientific and educational activities and promotional activities involving the internet. Failure to comply with FDA requirements can have negative consequences, including the immediate discontinuation of noncomplying materials, adverse publicity, enforcement letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our product candidates. Manufacturers of our product candidates are required to comply with applicable FDA manufacturing requirements contained in the FDA's cGMP regulations. These regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of comprehensive records and documentation. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are also required to register their establishments and list any products they make with the FDA and to comply with related requirements in certain states. These entities are further subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in serious and extensive restrictions on a product, manufacturer or holder of an approved NDA. These restrictions may include suspension of a product until the FDA is assured that quality standards can be met, continuing oversight of manufacturing by the FDA under a consent decree, which frequently includes the imposition of costs and continuing inspections over a period of many years, as well as possible withdrawal of the product from the market. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

The FDA also may require post-marketing testing, known as Phase 4 testing, as well as risk minimization action plans and surveillance to monitor the effects of an approved product or place conditions on an approval that could otherwise restrict the distribution or use of the product.

***U.S. Patent Term Restoration and Marketing Exclusivity******Drug Price Competition and Patent Term Restoration Act of 1984***

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during federal regulatory review preceding the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted within 60 days of approval, prior to the expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA. However, there is no guarantee that any such application will be approved.

***Federal Food, Drug and Cosmetic Act ( FDCA )***

Market exclusivity provisions under the FDCA, which are independent of patent status and any patent related extensions, can also delay the submission or the approval of certain applications of other companies



**Table of Contents**

seeking to reference another company's NDA. If the new drug is a new chemical entity subject to an NDA, the FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or functional group of a molecule responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a so-called Section 505(b)(2) NDA, submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, such an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The FDCA also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

***Other U.S. Healthcare Laws and Compliance Requirements***

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), other divisions of the United States Department of Health and Human Services (*e.g.*, the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, state attorney generals and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, the privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992, each as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Under the Veterans Health Care Act, or VHCA, drug companies are required to offer certain pharmaceutical products at a reduced price to a number of federal agencies including the United States Department of Veterans Affairs and United States Department of Defense, the Public Health Service and certain private Public Health Service - designated entities in order to participate in other federal funding programs including Medicare and Medicaid. Recent legislative changes purport to require that discounted prices be offered for certain United States Department of Defense purchases for its TRICARE program via a rebate system. Participation under the VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

## **Table of Contents**

### ***Europe/Rest Of World Government Regulation***

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the European Union, for example, a clinical trial application, or CTA, must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trials may proceed.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with International Conference on Harmonisation (ICH) / WHO Good Clinical Practice standards and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug under European Union regulatory systems, we must submit a marketing authorization application to the European Medicines Agency, or the EMA. The application used to file an NDA in the United States is similar to that required in the European Union, with the exception of, among other things, country-specific document requirements.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCPs and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

### ***Pharmaceutical Coverage, Pricing and Reimbursement***

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drug products for a particular indication. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

In 2003, the United States government enacted legislation providing a partial prescription drug benefit for Medicare recipients, which became effective at the beginning of 2006. Government payment for some of the costs of prescription drugs may increase demand for any products for which we receive marketing approval. However, to obtain payments under this program, we would be required to sell products to Medicare recipients

---

**Table of Contents**

through prescription drug plans operating pursuant to this legislation. These plans will likely negotiate discounted prices for our products. Federal, state and local governments in the United States continue to consider legislation to limit the growth of healthcare costs, including the cost of prescription drugs. Future legislation could limit payments for pharmaceuticals such as the product candidates that we are developing.

In March 2010, the President signed one of the most significant healthcare reform measures in decades. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively known as the Affordable Care Act, substantially changes the way healthcare will be financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The comprehensive \$940 billion dollar overhaul is expected to extend coverage to approximately 32 million previously uninsured Americans. The Affordable Care Act contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse, which will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program. Additionally, the Affordable Care Act, as limited by the United States Supreme Court's decision in June 2012:

increases the minimum level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1%;

requires collection of rebates for drugs paid by Medicaid managed care organizations;

requires manufacturers to participate in a coverage gap discount program, under which they must agree to offer 50 percent point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D, beginning January 2011; and

imposes a non-deductible annual fee on pharmaceutical manufacturers or importers who sell branded prescription drugs to specified federal government programs.

There have been proposed in Congress a number of legislative initiatives regarding healthcare, including possible repeal of the Affordable Care Act. At this time, it remains unclear whether there will be any changes made to the Affordable Care Act, whether to certain provisions or its entirety. The full impact that the Affordable Care Act and other new laws will have on our business is uncertain. Nor is it clear whether other legislative changes will be adopted, if any, or how such changes would affect the demand for our product candidates once commercialized.

Different pricing and reimbursement schemes exist in other countries. In the European Community, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any drug candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

## **Table of Contents**

### **Manufacturing**

We do not have our own manufacturing capabilities, except with respect to limited amounts of active pharmaceutical ingredients needed for preclinical development. In the past we have relied on third-party manufacturers for supply of active pharmaceutical ingredients, and we expect that in the future we will rely on such manufacturers for supply of ingredients that will be used in clinical trials of our product candidates that we are developing ourselves. Manufacturing for each of our two lead product candidates, namely ABT-450 and EDP-239, is being conducted by our collaborator for the respective product candidate. We do not expect to establish our own manufacturing facilities and we will continue to rely on third-party manufacturers to produce commercial quantities of any product candidates that we commercialize ourselves. We believe that all of the materials required for the manufacture of those product candidates could be obtained from more than one source.

### **Sales and Marketing**

We currently do not have any commercialization or sales and marketing capabilities, and currently have no fixed plans to invest in or build such capabilities internally. We have already partnered our two lead candidates with Abbott and Novartis, respectively. We may also partner or collaborate with, or license commercial rights to, other larger pharmaceutical or biopharmaceutical companies to support the development of our cyclophilin and nucleotide polymerase inhibitor product candidates through late-stage clinical development and, if successful, commercialization. However, we still retain all commercial rights to our independent programs and we will continue to evaluate our alternatives for commercializing them once they are more advanced in their clinical development.

### **Facilities**

We lease approximately 25,000 square feet of office space in Watertown, Massachusetts. This facility serves as our corporate headquarters and laboratory facility. We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

### **Employees**

As of September 30, 2012, we had 40 full-time employees, 19 of whom hold Ph.D. degrees. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relations with our employees to be good.

### **Legal Proceedings**

We are not currently a party to any material legal proceedings.

**Table of Contents****MANAGEMENT**

The following table sets forth certain information about our executive officers and directors.

<b>Name</b>	<b>Age</b>	<b>Position</b>
Jay R. Luly, Ph.D.	56	President, Chief Executive Officer and Director
Yat Sun Or, Ph.D.	60	Senior Vice President, Research & Development and Chief Scientific Officer
Paul J. Mellett	57	Senior Vice President, Finance & Administration and Chief Financial Officer
Ernst-Günter Afting, M.D., Ph.D.	70	Director
Stephen Buckley, Jr.	63	Director
Marc E. Goldberg	55	Director
David Poorvin, Ph.D.	66	Director
Helmut M. Schühlsler, Ph.D.	53	Director
Terry Vance	56	Director
Gregory L. Verdine, Ph.D.	53	Director

**Jay R. Luly, Ph.D.**, has served as our President and Chief Executive Officer and as a member of our board of directors since July 2003. Prior to joining Enanta, Dr. Luly was an Entrepreneur in Residence at Oxford Bioscience Partners. Before joining Oxford in March 2002, Dr. Luly held the positions of Senior Vice President, Research and Development Operations and Senior Vice President, Discovery Strategy and Operations at Millennium Pharmaceuticals following Millennium's merger with LeukoSite, Inc., where he had served as Senior Vice President, Drug Discovery and Preclinical Development. Prior to joining LeukoSite, he held a number of senior drug discovery positions at Abbott Laboratories from 1983 to 1997. Dr. Luly received a B.S. from the University of Illinois, Urbana/Champaign and a Ph.D. in synthetic organic chemistry from the University of California, Berkeley. Dr. Luly currently serves as a member of the Board of Trustees for the Boston Biomedical Research Institute.

We believe that Dr. Luly is qualified to serve on our board of directors due to his service as our President and Chief Executive Officer and his extensive knowledge of our company and industry.

**Yat Sun Or, Ph.D.**, has been our Senior Vice President, Research and Development and Chief Scientific Officer since November 1999. Prior to joining Enanta, Dr. Or held key leadership positions at Abbott Laboratories from 1985 to 1999, where he received two Chairman's Awards for his outstanding research, which led to the discovery and development of numerous immunosuppressant and antibacterial drugs. Prior to Abbott, Dr. Or was a member of the cardiovascular drug discovery team at Schering-Plough. Dr. Or received his Ph.D. in Organic Chemistry from the University of Chicago and completed Postdoctoral Fellowships at Ohio State University and Indiana University.

**Paul J. Mellett** has served as our Senior Vice President, Finance & Administration and Chief Financial Officer since September 2003. From April 2001 through August 2003, he held the position of Senior Vice President and Chief Financial Officer of Essential Therapeutics, Inc., a publicly-held biotechnology company that filed for reorganization under Chapter 11 of the U.S. bankruptcy code and was reorganized and taken private in October 2003. Previously, Mr. Mellett was the Chief Financial Officer and Vice President of Administration at GelTex Pharmaceuticals, Inc., a publicly held biotechnology company that was acquired by Genzyme Corporation in December 2000. From 1994 to 1997, Mr. Mellett served as Chief Financial Officer of Marshall Contractors, a construction management firm specializing in the pharmaceutical, biotechnology and semiconductor industries, which was acquired by Fluor Corporation in 1996. From 1977 to 1994, Mr. Mellett was employed with Deloitte & Touche LLP, a public accounting firm, and was promoted to Audit Partner in 1989. Mr. Mellett received a BS in Business Administration from Boston College in 1977.

**Ernst-Günter Afting, M.D., Ph.D.**, has served as a member of our board of directors since 1995. Dr. Afting has been a member of the medical faculty at the University of Goettingen, Germany, since 1985. Dr. Afting was President and Chief Executive Officer of the GSF-National Research Center for Environment and Health GmbH,

---

**Table of Contents**

a government research center in Munich, Germany, from 1995 until he retired in 2006. Prior to joining GSF-National, he had served as President and Chief Executive Officer of Roussel UCLAF, a Paris-based pharmaceutical company, since 1993. From 1984 through 1993, Dr. Afting served as an executive in the Pharmaceutical Division of Hoechst Group, most recently as Chairman and Chief Executive Officer of the Divisional Pharmaceutical Board. Dr. Afting also served on the German National Advisory Committee on Health Research to the State Secretaries of Science, Technology and Health from 1996 to 2005 and on the Advisory Committee on Science and Technology for German Chancellor Helmut Kohl from 1996 to 1997. Since 2005, he is a member of the committee New Technologies to the secretary of economy of the state of Bavaria. Dr. Afting currently serves on the boards of Intercell AG, Olympus Europa GmbH and Sequenom, Inc. He received his Ph.D. in Chemistry and M.D. from the University of Freiburg/Breisgau, Germany.

We believe that Dr. Afting is qualified to serve on our board of directors due to his business and research experience, his service on governmental advisory committees and public company boards and his knowledge of our industry.

**Stephen Buckley, Jr.**, was elected to our board of directors in 2012. Mr. Buckley was for 25 years a partner of Ernst & Young, where he led assurance and advisory teams serving public and private companies in life sciences and other technologies. Mr. Buckley led Ernst & Young's Life Sciences Industry Practice of New England from 1991 to 2006, and was Director of its New England Entrepreneurial Services Group from 1991 to 2001. He was previously a partner in the Boston, Massachusetts office of Arthur Young until its merger into Ernst & Young in 1989. Mr. Buckley is a member of the American Institute of CPAs. Mr. Buckley received an A.B. from Bowdoin College and a Masters of Science Accounting from Northeastern University.

We believe that Mr. Buckley is qualified to serve on our board of directors due to his experience working with public and private companies in our industry on corporate finance and accounting matters.

**Marc E. Goldberg** has served as a member of our board of directors since 2002. Mr. Goldberg is a Managing Director at BioVentures Investors, which he co-founded in 1997. Prior to founding BioVentures, Mr. Goldberg served as President and Chief Executive Officer of the Massachusetts Biotechnology Research Institute from 1991 to 1997. From 1987 to 1991, Mr. Goldberg was Vice President, Finance and Corporate Development, CFO, and Treasurer at Safer, Inc., a developer and manufacturer of biopesticides and related products. Prior to joining Safer, he served as Manager, Business Development, at Genetics Institute. Mr. Goldberg was also Founding President of the Massachusetts Biotechnology Council and served four terms as its President and as a Director from 1985 to 1997. He is currently a member of the Harvard Medical School Neuroscience Advisory Committee and he previously served as a member of the Beth Israel Deaconess Medical Center Research Advisory Committee of the board of directors. Mr. Goldberg received an A.B. from Harvard College, a J.D. from Harvard Law School and an M.B.A. from Harvard Business School.

We believe that Mr. Goldberg is qualified to serve on our board of directors due to his business and financial experience as an executive and a venture investor in our industry.

**David Poorvin, Ph.D.**, has served as a member of our board of directors since 2004. Dr. Poorvin is currently a member of the Board of Directors of Avaxia Biologics, Inc. and is President of his own consulting firm. He recently served as the Chief Business Officer at Avaxia Biologics and as an Executive-in-Residence at Oxford Bioscience Partners. At the end of 2003, Dr. Poorvin retired from Schering-Plough Corporation as Vice President of Business Development operations. Prior to spending 14 years in business development, Dr. Poorvin held the position of Director of Clinical Research at Schering-Plough from 1981 to 1989 and at Pfizer Pharmaceuticals from 1977 to 1981. Dr. Poorvin started his career at Lederle Laboratories from 1973 to 1977, where he directed preclinical research in the cardiovascular area. He served as a member of the board of directors of Repros Therapeutics Inc. from 2004 to 2009 and of Nucrust Pharmaceuticals from 2006 to 2009. He received a B.A. from Hunter College of the City University of New York and a Ph.D. from Rutgers University.

We believe that Dr. Poorvin is qualified to serve on our board of directors due to his business development and research experience in our industry.

**Helmut M. Schühlsler, Ph.D.**, has served as a member of our board of directors since September 2011 and from December 1998 until April 2000. Dr. Schühlsler is a Managing Partner of TVM Capital. He has been with TVM since 1990, overseeing more than 80 investments in the life sciences sector during his tenure. Prior to

**Table of Contents**

joining TVM Capital, Dr. Schühsler worked in venture capital for Horizonte Venture Management. Previously he was an assistant professor for corporate finance at the Institute for Advanced Studies in Vienna. Dr. Schühsler currently serves as a member of the board of Max-Planck Innovation GmbH and is a member of the Selection Committee for the Technology Pioneers program and the Steering Committee of the Entrepreneurship and Successful Growth Research Program of the World Economic Forum and the advisory board of Evolve India Life Science Fund, Hyderabad, India. From 2007 to 2008, Dr. Schühsler served as Chairman of the European Private Equity and Venture Capital Association. He also served as Chairman of the board of directors of Sequenom, Inc. from 1996 to 2003. Dr. Schühsler received a Ph.D. in the Social and Economic Sciences from the University of Economics in Vienna.

We believe that Dr. Schühsler is qualified to serve on our board of directors due to his business and financial experience as an investor in and a director of several companies in our industry.

**Terry Vance** has served as a member of our board of directors since June 2011. Mr. Vance is currently a Venture Partner with Saints Capital, a direct secondary investment fund and the Managing Member of EGS Healthcare, a late-stage venture capital fund that he co-founded in 2000. Before starting EGS Healthcare, Mr. Vance was a founding partner in Eagle Advisors, which provided strategic advice to emerging biotechnology companies. Prior to Eagle, Mr. Vance was an investment banker, first with Salomon Brothers and then with Goldman Sachs, where he was a vice president in the Capital Markets Division. Mr. Vance received an AB from Princeton University and an MBA from Stanford University.

We believe that Mr. Vance is qualified to serve on our board of directors due to his business and financial experience as an investor and as an investment banker in our industry.

**Gregory L. Verdine, Ph.D.**, is a co-founder of Enanta and has served as a member of our board of directors since 1996. Dr. Verdine has been a Professor of Chemistry and Chemical Biology at Harvard University since 1998. Dr. Verdine received a B.S. in Chemistry from St. Joseph's University and a Ph.D. in Chemistry from Columbia University. He was a National Institutes of Health Postdoctoral Fellow in Molecular Biology at the Massachusetts Institute of Technology and Harvard Medical School from 1986 to 1988.

We believe that Dr. Verdine is qualified to serve on our board of directors due to his research qualifications and experience and his knowledge of our company's technology and our industry.

**Board Composition and Election of Directors**

Our board of directors is currently authorized to have \_\_\_\_\_ members. We expect that upon the closing of this offering, our board of directors will consist of \_\_\_\_\_ directors. In accordance with the terms of our certificate of incorporation and bylaws that will become effective upon the closing of this offering, our board of directors will be divided into three classes, class I, class II and class III, with members of each class serving staggered three-year terms. Upon the closing of this offering, the members of the classes will be divided as follows:

the class I directors will be \_\_\_\_\_, and their term will expire at the annual meeting of stockholders to be held in 2013;

the class II directors will be \_\_\_\_\_, and their term will expire at the annual meeting of stockholders to be held in 2014; and

the class III directors will be \_\_\_\_\_, and their term will expire at the annual meeting of stockholders to be held in 2015.

Upon the expiration of the term of a class of directors, directors in that class will be eligible to be elected for a new three-year term at the annual meeting of stockholders in the year in which their term expires. Our directors may be removed only for cause by the affirmative vote of the holders of 66 2/3% or more of our outstanding common stock.

Our board of directors has determined that all of our directors, other than Dr. Luly, are independent directors, as defined by the applicable NASDAQ Marketplace Rules. In making such determination, the board of

## **Table of Contents**

directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances that the board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director.

There are no family relationships among any of our directors or executive officers.

## **Board Committees and Independence**

Our board of directors has established an audit committee, a nominating and corporate governance committee and a compensation committee, each of which will operate, upon the closing of this offering, under a charter that has been approved by our board. The composition of each committee will be effective upon the closing of this offering.

Our board of directors has determined that all of the members of the audit committee, the compensation committee and the nominating and corporate governance committee, other than \_\_\_\_\_, are independent as defined under the NASDAQ Marketplace Rules, including, in the case of all the members of our audit committee, the independence requirements contemplated by Rule 10A-3 under the Securities Exchange Act of 1934.

### ***Audit Committee***

The members of our audit committee are \_\_\_\_\_ . \_\_\_\_\_ chairs the audit committee. Upon the closing of this offering, our audit committee's responsibilities will include:

appointing, approving the compensation of and assessing the independence of our registered public accounting firm;

overseeing the work of our registered public accounting firm, including through the receipt and consideration of reports from such firm;

reviewing and discussing with management and the registered public accounting firm our annual and quarterly financial statements and related disclosures;

monitoring our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;

overseeing our internal audit function;

overseeing our risk assessment and risk management policies;

establishing policies regarding hiring employees from the registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;

meeting independently with our internal auditing staff, registered public accounting firm and management;

reviewing and approving or ratifying any related person transactions; and



## Edgar Filing: ENANTA PHARMACEUTICALS INC - Form S-1/A

preparing the audit committee report required by Securities and Exchange Commission, or SEC, rules.

All audit and non-audit services, other than *de minimis* non-audit services, to be provided to us by our independent registered public accounting firm must be approved in advance by our audit committee.

Our board of directors has determined that \_\_\_\_\_ is an audit committee financial expert as defined in applicable SEC rules.

### ***Nominating and Corporate Governance Committee***

The members of our nominating and corporate governance committee are \_\_\_\_\_. \_\_\_\_\_ chairs the nominating and corporate governance committee. Upon the closing of this offering, our nominating and corporate governance committee's responsibilities will include:

identifying individuals qualified to become members of our board of directors;

recommending to our board of directors the persons to be nominated for election as directors and to each of our board's committees;

## **Table of Contents**

reviewing and making recommendations to our board of directors with respect to our board leadership structure;

reviewing and making recommendations to our board of directors with respect to management succession planning;

developing and recommending to our board corporate governance principles; and

overseeing an annual self-evaluation by our board of directors.

### ***Compensation Committee***

The members of our compensation committee are . chairs the compensation committee. Upon the closing of this offering, our compensation committee s responsibilities will include:

annually reviewing and approving corporate goals and objectives relevant to the compensation of our chief executive officer;

reviewing and approving, or making recommendations to our board of directors with respect to, the compensation of our chief executive officer and our other executive officers;

overseeing an evaluation of our senior executives;

overseeing and administering our cash and equity incentive plans;

reviewing and making recommendations to our board of directors with respect to director compensation; and

reviewing and discussing annually with management our executive compensation disclosure, and the compensation committee report, required by SEC rules.

### **Compensation Committee Interlocks and Insider Participation**

None of our executive officers serves as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or our compensation committee.

### **Code of Business Conduct and Ethics**

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Following this offering, a current copy of the code will be posted on the Corporate Governance section of our website, [www.enanta.com](http://www.enanta.com).

### **Limitation on Liability and Indemnification of Directors and Officers**

Our amended and restated certificate of incorporation and bylaws, which will be effective immediately prior to consummation of this offering, limits our directors and officers liability to the fullest extent permitted under Delaware corporate law. Specifically, our directors and officers will not be liable to us or our stockholders for monetary damages for any breach of fiduciary duty by a director or officer, except for liability:

for any breach of the director's or officer's duty of loyalty to us or our stockholders;

for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;

under Section 174 of the Delaware General Corporation Law (unlawful dividends or stock repurchases); or

for any transaction from which a director or officer derives an improper personal benefit.

If the Delaware General Corporation Law is amended to authorize corporate action further eliminating or limiting the personal liability of directors or officers, then the liability of our directors or officers shall be eliminated or limited to the fullest extent permitted by the Delaware General Corporation Law, as so amended.

**Table of Contents**

The provision regarding indemnification of our directors and officers in our amended and restated certificate of incorporation will generally not limit liability under state or federal securities laws.

Delaware law and our amended and restated certificate of incorporation provide that we will, in certain situations, indemnify any person made or threatened to be made a party to a proceeding by reason of that person's former or present official capacity with us against judgments, penalties, fines, settlements and reasonable expenses. Any person is also entitled, subject to certain limitations, to payment or reimbursement of reasonable expenses (including attorneys' fees and disbursements) in advance of the final disposition of the proceeding.

We maintain a directors' and officers' insurance policy pursuant to which our directors and officers are insured against liability for actions taken in their capacities as directors and officers. We believe that these indemnification provisions and insurance are useful to attract and retain qualified directors and officers.

In addition, we have entered into indemnification agreements with each of our directors and named executive officers, which also provide, subject to certain exceptions, for indemnification for related expenses, including, among others, reasonable attorney's fees, judgments, fines and settlements incurred in any action or proceeding.

**Table of Contents****EXECUTIVE COMPENSATION**

The following table summarizes the compensation paid to our Chief Executive Officer, Chief Financial Officer and Chief Scientific Officer (our only executive officers) during or with respect to the fiscal years ended September 30, 2012, 2011 and 2010.

**Summary Compensation Table**

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Option Awards (\$) <sup>(1)</sup>	All Other Compensation (\$) <sup>(2)</sup>	Total (\$)
Jay R. Luly., Ph.D. Chief Executive Officer	2012	407,482	(3)	145,736	4,439	557,657
	2011	397,110	173,491	35,208	4,421	610,230
	2010	394,223	162,278	6,972	4,421	567,893
Yat Sun Or, Ph.D. Chief Scientific Officer	2012	321,415	(3)	143,704	4,439	469,559
	2011	313,208	105,519	80,679	4,421	503,826
	2010	310,932	96,906	43,619	4,421	455,877
Paul J. Mellett Chief Financial Officer	2012	284,168	(3)	54,651	4,439	343,258
	2011	276,914	79,452	13,203	4,421	373,990
	2010	274,902	71,940	2,615	4,421	353,877

(1) The amounts in the Option Awards column reflect the aggregate grant date fair value of stock options granted during the fiscal year computed in accordance with the provisions of ASC 718. The assumptions that we used to calculate these amounts are discussed in Note 14 to our financial statements appearing at the end of this prospectus.

(2) Includes employer contributions under the company's 401(k) plan of \$4,000 for each of our executive officers in fiscal 2012, 2011 and 2010. Also includes company-paid premiums for group term life insurance and accidental death and dismemberment insurance in the aggregate amount of \$282, \$264 and \$264 for each of our executive officers in fiscal 2012, 2011 and 2010.

(3) The amount of the bonus for fiscal 2012 is not available as of the date hereof. It is expected to be determined no later than January 2013.

**Narrative Disclosure to Summary Compensation Table****Employment and Severance Agreements**

We have entered into employment agreements with Dr. Luly and Mr. Mellett and a severance agreement with Dr. Or that provide for severance benefits if their employment is terminated under specified circumstances. For details regarding our obligations under such circumstances, please see Potential Payments Upon Termination or Change in Control below.

**Table of Contents****Outstanding Equity Awards at Fiscal Year-End for Fiscal 2012**

The following table sets forth certain information concerning outstanding equity awards at fiscal year-end (September 30, 2012).

Name	Grant Date	Number of Securities Underlying Unexercised Options Exercisable (#)	Option Awards Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price (\$)	Option Expiration Date
Jay R. Luly, Ph.D. Chief Executive Officer	3/19/2004	1,421,524		0.17	3/19/2014
	7/1/2004	1,050,236		0.17	7/1/2014
	12/23/2004	62,500		0.17	12/23/2014
	6/23/2006	96,106		0.30	6/23/2016
	7/12/2007	287,240		0.69	7/12/2017
	7/11/2008	80,000		0.46	7/11/2018
	3/5/2009	80,000		0.35	3/5/2019
	5/25/2010	40,000		0.28	5/25/2020
	4/15/2011	80,000		0.59	12/31/2020
	6/20/2012		80,000 <sup>(1)</sup>	2.73	6/20/2022
Yat Sun Or, Ph.D. Chief Scientific Officer	7/1/2004	525,118		0.17	7/1/2014
	12/23/2004	31,250		0.17	12/23/2014
	6/23/2006	48,053		0.30	6/23/2016
	7/12/2007	218,620		0.69	7/12/2017
	7/11/2008	60,000		0.46	7/11/2018
	3/5/2009	60,000		0.35	3/5/2019
	5/25/2010	30,000		0.28	5/25/2020
	6/18/2010	192,500	27,500 <sup>(2)</sup>	0.28	6/18/2020
	4/15/2011	60,000		0.59	12/31/2020
	6/17/2011	17,708	7,292 <sup>(2)</sup>	0.59	6/17/2021
	9/23/2011	66,666	33,334 <sup>(2)</sup>	0.59	9/23/2021
6/20/2012	13,125	7,875 <sup>(2)</sup>	2.73	6/20/2022	
6/20/2012		60,000 <sup>(1)</sup>	2.73	6/20/2022	
Paul J. Mellett Chief Financial Officer	9/3/2003	363,183		0.17	9/3/2013
	3/19/2004	63,274		0.17	3/19/2014
	7/1/2004	315,071		0.17	7/1/2014
	12/23/2004	18,750		0.17	12/23/2014
	6/23/2006	28,831		0.30	6/23/2016
	7/12/2007	126,172		0.69	7/12/2017
	7/11/2008	30,000		0.46	7/11/2018
	3/5/2009	30,000		0.35	3/5/2019
	5/25/2010	15,000		0.28	5/25/2020
	4/15/2011	30,000		0.59	12/31/2020
6/20/2012		30,000 <sup>(1)</sup>	2.73	6/20/2022	

(1) The options vest on December 31, 2012.

(2) One half of the options vested on the grant date. The remaining options vest in equal monthly increments over thirty-six months beginning one month after the grant date.

**Potential Payments Upon Termination or Change in Control**

Edgar Filing: ENANTA PHARMACEUTICALS INC - Form S-1/A

We have entered into employment agreements with Dr. Luly and Mr. Mellett and a severance agreement with Dr. Or that provide for severance benefits if their employment is terminated under specified circumstances.

**Table of Contents**

If Dr. Luly is terminated involuntarily without cause or constructively terminated within twelve months of a change in control transaction, such terms as defined in the agreements, he is entitled to the following: (i) a lump sum payment in an amount equal to the higher of (x) eighteen (18) months of his then current base salary or (y) eighteen (18) months of his base salary immediately prior to the effective date of the change in control, (ii) a lump sum payment equal to the higher of (x) one hundred fifty percent (150%) of the last bonus earned prior to his termination or (y) one hundred and fifty percent (150%) of the last bonus earned prior to the effective date of the change in control, in each case annualized if he was employed for less than all of the year for which the applicable bonus is paid, and (iii) a continuation of benefit coverage for up to eighteen (18) months.

If either Mr. Mellett or Dr. Or are terminated involuntarily without cause or constructively terminated within twelve months of a change in control transaction, such terms as defined in the agreements, each are entitled to the following: (i) a lump sum payment in an amount equal to the higher of (x) twelve (12) months of his then current base salary or (y) twelve (12) months of his base salary immediately prior to the effective date of the change in control, (ii) a lump sum payment equal to the higher of (x) his last bonus earned prior to his termination or (y) his last bonus earned prior to the effective date of the change in control, in each case pro-rated for the percentage of the fiscal year for which the applicable bonus is paid, and (iii) a continuation of benefit coverage for up to twelve (12) months.

If Dr. Luly is terminated involuntarily without cause other than in connection with a change in control transaction or if he voluntarily terminates his employment for good reason, such terms as defined in the agreements, he is entitled to the following: (i) a lump sum payment in an amount equal to twelve (12) months of his then current base salary and (ii) a lump sum payment in an amount equal to (x) fifty percent (50%) of his last annual bonus earned if termination occurs before the first of July or (y) one hundred percent (100%) of his last annual bonus earned if termination occurs on or after the first of July and (iii) continuation of benefit coverage for up to twelve (12) months.

If Mr. Mellett or Dr. Or are terminated involuntarily without cause other than in connection with a change in control transaction, such terms as defined in the agreements, each are entitled to the following: (i) a lump sum payment in an amount equal to six (6) months of his then current base salary and (ii) continuation of benefit coverage for up to six (6) months.

In addition, upon a change in control transaction, all shares underlying outstanding stock options held by Dr. Luly, Dr. Or and Mr. Mellett shall become immediately exercisable.

**Director Compensation**

The following table summarizes compensation paid to our non-employee directors during or with respect to the fiscal year ended September 30, 2012.

<b>Name</b>	<b>Fees Earned or Paid in Cash (\$)</b>	<b>All Other Compensation (\$)</b>	<b>Total (\$)</b>
Ernst-Günter Afting, M.D., Ph.D.	20,000		20,000
Stephen Buckley, Jr. <sup>(1)</sup>			
Marc E. Goldberg			
David Poorvin, Ph.D.	20,000		20,000
Helmut M. Schühslers, Ph.D.			
Terry Vance			
Gregory L. Verdine, Ph.D.	20,000	15,000 <sup>(2)</sup>	35,000

(1) Mr. Buckley was appointed to our board of directors on September 28, 2012.

(2) We paid Dr. Verdine \$15,000 in consulting fees in 2012 pursuant to a consulting agreement for advisory services in the field of chemistry, biology and drug discovery and development related to macrolides and antibiotics.



**Table of Contents**

No options were granted to our non-employee directors during the fiscal year ended September 30, 2012. The following table sets forth the shares of common stock underlying outstanding options as of September 30, 2012 for each of our non-employee directors:

Name	Option Awards(#)
Ernst-Günter Afting, M.D., Ph.D.	85,000 <sup>(1)</sup>
Stephen Buckley, Jr.	
Marc E. Goldberg	
David Poorvin, Ph.D.	190,000 <sup>(2)</sup>
Helmut M. Schühlsler, Ph.D.	
Terry Vance	
Gregory L. Verdine, Ph.D.	110,000 <sup>(3)</sup>

(1) Of these, 78,750 were vested.

(2) Of these, 165,000 were vested.

(3) Of these, 97,500 were vested.

**Director Compensation Policy**

During 2012, we paid our non-employee directors who are not designated by any of the company's venture investors as their representatives on the board of directors, Drs. Afting, Poorvin and Verdine, a retainer of \$20,000 each as compensation for their service on the board of directors. We also reimburse Drs. Afting, Poorvin and Verdine for travel expenses incurred to attend board and committee meetings. In November 2012, we awarded a stock option to Mr. Buckley with respect to 60,000 shares in recognition of his joining our board of directors. This option is vesting monthly over three years. Each of our non-employee directors other than Mr. Buckley will be eligible to receive a stock option award with respect to 25,000 shares, which will be granted effective as of the pricing of this offering, with an exercise price equal to the offering price and with monthly vesting over three years. Mr. Goldberg has indicated that he will decline his option award in accordance with the practice of his fund. We currently have no other formal arrangements under which our directors receive compensation for service to our board of directors or its committees. After the closing of this offering, going forward our compensation committee has determined that our non-employee directors will be entitled to receive the following annual retainer fees for their service as directors:

for service as a director, an annual retainer of \$35,000;

for service as the chair of a committee, \$15,000 for audit committee chair, \$10,000 for compensation committee chair, and \$5,000 for nominating and governance committee chair; and

for service as a member of a committee other than as its chair, \$7,500 for audit committee, \$5,000 for compensation committee, and \$2,500 for nominating and governance committee.

In addition, for each year of service after fiscal 2013, each non-employee director will be entitled to an option award with respect to 20,000 shares, vesting monthly over the year of service until the next annual meeting. Any new director will also be entitled to an option award with respect to 40,000 shares upon joining our board of directors, which will vest monthly over three years.

**Amended and Restated 1995 Equity Incentive Plan**

We maintain the Amended and Restated 1995 Equity Incentive Plan (the 1995 Plan), pursuant to which \_\_\_\_\_ shares of our common stock are reserved for grant to our employees, consultants and directors. Pursuant to the 1995 Plan, we may make grants of incentive stock options,

## Edgar Filing: ENANTA PHARMACEUTICALS INC - Form S-1/A

nonstatutory stock options, stock appreciation rights, performance shares, restricted stock, restricted stock units and other stock-based awards to our employees, consultants, and directors.

Our employees, consultants and directors are eligible to receive awards under the 1995 Plan. However, incentive stock options may only be granted to our employees. The maximum number of shares of our common stock with respect to awards which may be granted to any participant under the 1995 Plan is \_\_\_\_\_ per calendar year.

**Table of Contents**

Pursuant to the terms of the 1995 Plan, our compensation committee administers the plan and, subject to any limitations in the plan, selects the recipients of awards and determines:

the number of shares of our common stock covered by options and the dates upon which the options become exercisable;

the type of options to be granted;

the duration of options;

the exercise price of options; and

the number of shares of our common stock subject to and the terms of any stock appreciation rights, performance shares, restricted stock awards, restricted stock units or other stock-based awards and the terms and conditions of such awards, including conditions for repurchase, issue price and repurchase price.

Our compensation committee has delegated authority to our Chief Executive Officer to grant awards under our 1995 Plan. The Chief Executive Officer has the power to make awards to all of our non-executive employees, subject to parameters established by our board of directors from time to time.

Upon the occurrence of a change in control of the company, the compensation committee in its discretion may, at the time an award is made or at any time thereafter, take one or more of the following actions: (i) provide for the acceleration of any time period relating to the exercise or realization of the award, (ii) provide for the purchase of the award upon the participant's request for an amount of cash or other property that could have been received upon the exercise or realization of the award had the award been currently exercisable or payable, (iii) adjust the terms of the award in a manner determined by the compensation committee to reflect the change in control, (iv) cause the award to be assumed, or new rights substituted therefor, by another entity, or (v) make such other provision as the compensation committee may consider equitable and in the best interests of the company.

The board of directors may amend, suspend, alter, or terminate the 1995 Plan subject to any stockholder approval the board determines necessary or advisable. The compensation committee may amend, modify or terminate any awards granted under the 1995 Plan at any time, provided that a participant's rights with respect to outstanding awards may not be impaired without their express written consent.

**Table of Contents****RELATED PARTY TRANSACTIONS**

In addition to the executive officer and director compensation arrangements discussed in [Executive Compensation](#) above, we describe transactions since January 1, 2009, to which we have been a participant, in which the amount involved in the transaction exceeds or will exceed \$120,000 and in which any of our directors, executive officers or holders of more than 5% of our capital stock, or any immediate family member of, or person sharing the household with, any of these individuals, had or will have a direct or indirect material interest. We believe that all of these transactions were made on terms no less favorable to us than could have been obtained from unrelated third parties.

**Participation Right**

Pursuant to the terms of the Series G Preferred Stock Purchase Agreement by and between us, Abbott and the holders of our outstanding Series G-2 Convertible Preferred Stock, we are required to use our commercially reasonable efforts to cause the underwriters to allocate to Abbott or its permitted assignee for purchase common stock in this offering in an amount up to the lesser of (a) the result obtained by dividing \$20 million by the initial per share offering price in this offering and (b) 19.9% of the issued and outstanding shares of our common stock immediately following the closing of this offering.

**Term Note Financing**

In October 2010, we entered into a note and warrant purchase agreement with existing investors, including TVM V Life Science Ventures GmbH & Co. KG and affiliated entities ( [TVM](#) ), certain funds managed by Advent International Corporation ( [Advent](#) ), OBP III-Holding LLC and affiliated entities ( [OBP](#) ), Private Equity Holding (Cayman) Ltd. and affiliated entities ( [PEH](#) ) and HBM Biomedicine (Cayman) Ltd. ( [HBM](#) ), to sell in one or more closings, term notes in the aggregate principal amount of up to \$6,500,000. At closings in October and November 2010, we issued approximately \$2,000,000 in aggregate principal amount of term notes, of which \$544,888.81 in principal amount was held by TVM, \$231,639.81 in principal amount was held by Advent, \$486,247.62 in principal amount was held by OBP, \$149,590.97 in principal amount was held by PEH and \$225,408.31 in principal amount was held by HBM. The term notes bore interest at a rate of 5%, with principal and interest payable at the earlier of the stated maturity date of October 4, 2011 or, if elected by the note holders, upon receipt by the company of the next milestone payment under our agreement with Abbott (the [Abbott Milestone](#) ). In conjunction with the note issuances, TVM, Advent, OBP, PEH and HBM also received warrants to purchase 544,888; 231,637; 486,245; 149,590; and 225,408 shares of Series 1 Nonconvertible Preferred Stock, respectively. These warrants, none of which have been exercised as of the date hereof, have an exercise price of \$0.01 per share and may be exercised at any time on or before October 4, 2017.

Following the receipt by the company of the Abbott Milestone in December 2010, we repaid the \$2,000,000 in aggregate principal amount plus accrued interest of \$19,642 and the applicable premium of \$1,036,360, of which \$288,620.43 in accrued interest and premium was paid to TVM, \$121,744.62 in accrued interest and premium was paid to Advent, \$257,558.96 in accrued interest and premium was paid to OBP, \$78,621.61 in accrued interest and premium was paid to PEH and \$118,469.48 in accrued interest and premium was paid to HBM. The note and warrant purchase agreement was terminated in conjunction with this repayment and we have no ongoing obligations under the note and warrant purchase agreement other than to honor the terms of the outstanding warrants.

**Registration Rights Agreement**

We and the holders of our Series C, Series D, Series E, Series F and Series G Convertible Preferred Stock have entered into a registration rights agreement pursuant to which these stockholders will have, among other things, registration rights under the Securities Act with respect to common stock that they will hold following this offering. Upon the closing of this offering, all outstanding shares of our redeemable convertible preferred stock and convertible preferred stock will be converted into common stock. See [Description of Capital Stock-Registration Rights](#) for a further description of the terms of these agreements.

## **Table of Contents**

### **Voting Agreement**

We have entered into a voting agreement with holders of our Series C, Series D and Series E Convertible Preferred Stock and certain other stockholders that contain agreements with respect to the election of our board of directors and its composition. All of our current directors were elected in accordance with the terms of this voting agreement. The voting agreement will terminate upon the closing of this offering.

### **Investor Rights Agreement**

We have entered into an investor rights agreement with holders of our Series C, Series D and Series E Convertible Preferred Stock that contain covenants requiring us to, among other things, furnish them certain information (including financial information and notice of litigation or certain defaults with respect to outstanding indebtedness); maintain adequate insurance; comply with applicable laws, obtain appropriate licenses and permits; and limit transactions with our affiliates. Pursuant to the investor rights agreement, we also granted the holders of our Series C, Series D and Series E Convertible Preferred Stock a right of first refusal to purchase, pro rata, all (or any part) of any new securities, as defined therein, that we may, from time to time, propose to sell. The shares of common stock that we are offering pursuant to this prospectus are not new securities under the investor rights agreement. The investor rights agreement will terminate upon the closing of this offering.

### **Stock Restriction Agreement**

We have entered into a stock restriction agreement with certain of our founders, each of whom hold shares of our common stock and/or convertible preferred stock, and holders of our Series C, Series D and Series E Convertible Preferred Stock that prohibits those founders from transferring any shares of our capital stock without first making an offer to us to purchase the shares on the same terms and conditions of the proposed transfer. If we do not elect to purchase all of the offered shares, the holders of our Series D and Series E Convertible Preferred Stock have the right to purchase their pro rata portion of any such shares. Holders of our Series C, Series D and Series E Convertible Preferred Stock also have a right to participate in the sale of shares by a founder to a proposed transferee pursuant to the terms of the stock restriction agreement. The stock restriction agreement will terminate upon the closing of this offering.

### **Consulting Agreements**

We have entered into a consulting agreement for advisory services in the field of chemistry, biology and drug discovery and development related to macrolides and antibiotics with Dr. Verdine, who currently serves as a member of our board of directors. Upon execution of the agreement in 2004, Dr. Verdine received a payment of \$17,500. In addition, he receives a consulting retainer of \$15,000 per year and reimbursement for travel and related expenses. During each of 2010, 2011 and 2012, Dr. Verdine received consulting fees of \$15,000.

### **Executive Compensation and Employment Agreements**

For a description of the compensation arrangements we have with our executive officers, see Executive Compensation-Employment and Severance Agreements.

### **Indemnification Agreements**

We have entered into indemnification agreements with each of our directors, executive officers. The indemnification agreements and our certificate of incorporation in effect upon the closing of this offering will require us to indemnify our directors to the fullest extent permitted by Delaware law. For more information regarding these indemnification agreements, see Management-Limitations on Liability and Indemnification of Directors and Officers.

### **Review, Approval or Ratification of Transactions with Related Parties**

Prior to the closing of this offering, our board of directors will adopt written policies and procedures for the review of any transaction, arrangement or relationship in which we are a participant, the amount involved

**Table of Contents**

exceeds \$120,000 and one of our executive officers, directors, director nominees or 5% stockholders, or their immediate family members, each of whom we refer to as a related person, has a direct or indirect material interest.

If a related person proposes to enter into such a transaction, arrangement or relationship, which we refer to as a related person transaction, the related person must report the proposed related person transaction to our Chief Executive Officer and to the chair or any disinterested member of our audit committee who reviews related party transactions. The policy calls for the proposed related person transaction to be reviewed and, if deemed appropriate, approved by our audit committee. Whenever practicable, the reporting, review and approval will occur prior to entry into the transaction. If advance review and approval is not practicable, the committee will review, and in its discretion may ratify, the related person transaction. The policy also permits the chairman of the committee to review and, if deemed appropriate, approve or ratify related person transactions that arise between committee meetings if the aggregate amount involved is expected to be less than \$250,000. A summary of each new related party transaction approved by the chair will be provided to the committee at their meeting. Any related person transactions that are ongoing in nature will be reviewed annually.

A related person transaction reviewed under the policy will be considered approved or ratified if it is authorized by the committee after full disclosure of the related person's interest in the transaction. As appropriate for the circumstances, the committee will review and consider:

the related person's interest in the related person transaction;

whether the terms of the transaction are no less favorable to us than terms that could have been reached with an unrelated third party; and

other factors it deems appropriate.

The committee may approve or ratify the transaction only if the committee determines that, under all of the circumstances, the transaction is in our best interests. The committee may impose any conditions on the related person transaction that it deems appropriate.

In addition to the transactions that are excluded by the instructions to the SEC's related person transaction disclosure rule, our board of directors has determined that the following transactions do not create a material direct or indirect interest on behalf of related persons and, therefore, are pre-approved, although they must still be reported to the chair of the committee (unless otherwise noted by the policy):

any transaction with another entity where (i) the related person's only relationship to the entity is as an employee (other than an executive officer) or director or beneficial owner of less than 10% of that company's shares, (ii) the related person and his or her immediate family members are not involved in the negotiation of the terms of the transaction and (iii) the amount involved in the transaction is less than the greater of \$200,000 or 5% of the annual gross revenues of the other entity;

any transaction involving (i) rates or charges that are determined by competitive bids, (ii) the rendering of services as a common or contract carrier, or public utility, at rates or charges fixed in conformity with law or governmental authority and (iii) services as a bank depository of funds, transfer agent, registrar, trustee under a trust indenture or similar services; and

any transaction where the related person's interest arises solely from the ownership of the company's securities and all holders of the same class or classes of the company's securities received the same benefit on a pro rata basis.

We did not have a written policy regarding the review and approval of related person transactions prior to this offering. Nevertheless, with respect to such transactions, it was our policy for our board of directors to consider the nature of and business reason for such transactions, how the terms of such transactions compared to those which might be obtained from unaffiliated third parties and whether such transactions were otherwise fair to and in the best interests of, or not contrary to, our best interests. In addition, all related person transactions required prior approval, or later ratification, by our board of directors.



**Table of Contents****PRINCIPAL STOCKHOLDERS**

The following table sets forth information with respect to the beneficial ownership of our common stock as of September 30, 2012 by:

each of our directors;

each of our named executive officers;

all of our directors and executive officers as a group; and

each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock.

The percentage of shares beneficially owned before the offering is computed on the basis of 55,130,404 shares of our common stock outstanding as of September 30, 2012, which reflects the assumed conversion of all of our outstanding shares of preferred stock into an aggregate of 50,241,277 shares of common stock.

The percentage of shares beneficially owned after the offering is based on \_\_\_\_\_ shares of our common stock to be outstanding after the offering, which reflects the assumed conversion of all of our outstanding shares of preferred stock into an aggregate of 50,241,277 shares of common stock.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to our common stock. Shares of our common stock that a person has the right to acquire within 60 days of September 30, 2012 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers as a group. Except as otherwise indicated in the footnotes below, we believe the persons and entities in this table have sole voting and investing power with respect to all of the shares of our common stock beneficially owned by them, subject to community property laws, where applicable. Except as otherwise indicated in the footnotes below, the address of the beneficial owner is c/o Enanta Pharmaceuticals, Inc., 500 Arsenal Street, Watertown, MA 02472.

Name and Address of Beneficial Owner	Shares Beneficially Owned Before Offering		Shares Beneficially Owned After Offering	
	Shares	Percentage	Shares	Percentage
<b>5% Stockholders:</b>				
TVM V Life Science Ventures GmbH & Co. KG and affiliated entities <sup>(1)</sup>	10,340,433	18.76%	10,340,433	
OBP III Holdings LLC and affiliated entities <sup>(2)</sup>	8,643,740	15.68%	8,643,740	
Shionogi & Co., Ltd. <sup>(3)</sup>	6,894,966	12.51%	6,894,966	
Abbott Laboratories <sup>(4)</sup>	4,620,764	8.38%	4,620,764	
Industry Ventures Fund VI, L.P. <sup>(5)</sup>	3,937,328	7.14%	3,937,328	
HBM Healthcare Investments (Cayman) Ltd.	3,918,793	7.11%	3,918,793	
Private Equity Holding Cayman and affiliated entity <sup>(7)</sup>	3,280,724	5.95%	3,280,724	
<b>Directors and Named Executive Officers:</b>				
Jay R. Luly, Ph.D. <sup>(8)</sup>	3,197,606	5.48%	3,197,606	
Yat Sun Or, Ph.D. <sup>(9)</sup>	1,677,968	2.97%	1,677,968	
Paul J. Mellett <sup>(10)</sup>	1,020,281	1.82%	1,020,281	
Ernst-Günter Afting, M.D., Ph.D. <sup>(11)</sup>	221,039	*	221,039	
Stephen Buckley, Jr.				
Marc E. Goldberg <sup>(12)</sup>	2,605,259	4.73%	2,605,259	
David Poorvin, Ph.D. <sup>(13)</sup>	177,500	*	177,500	



Edgar Filing: ENANTA PHARMACEUTICALS INC - Form S-1/A

Helmut M. Schühlsler, Ph.D. <sup>(14)</sup>	10,340,433	18.76%	10,340,433
Terry Vance <sup>(15)</sup>			
Gregory L. Verdine, Ph.D. <sup>(16)</sup>	103,750	*	103,750
All directors and executive officers as a group (10 persons) <sup>(17)</sup>	19,343,836	31.69%	19,343,836

**Table of Contents**

\* Represents beneficial ownership of less than one percent of our outstanding common stock.

- (1) Consists of (i) 2,254,323 shares beneficially owned by TVM IV GmbH & Co. KG ( TVM IV ) for which Friedrich Bornikoel, Hans Schreck, Alexandra Goll, and Helmut Schühlsler, members of the investment committee of TVM IV, share voting and investment authority, and each of whom disclaim beneficial ownership of such shares except to the extent of any pecuniary interest therein. The address of each of these individuals is c/o TVM IV GmbH & Co. KG, Maximilianstrasse 35C, 80539 Munich, Germany; (ii) 1,686,854 shares beneficially owned by TVM Medical Ventures GmbH & Co. KG ( TVM Medical ) for which Alexandra Goll and Helmut Schühlsler, members of the investment committee of TVM Medical, share voting and investment authority, and each of whom disclaim beneficial ownership of such shares except to the extent of any pecuniary interest therein. The address of each of these individuals is c/o TVM Medical Ventures GmbH & Co. KG, Maximilianstrasse 35C, 80539 Munich, Germany; and (iii) 6,399,256 shares beneficially owned by TVM V Life Science Ventures GmbH & Co. KG ( TVM V ) for which Hubert Birner, Mark Cipriano, Stefan Fischer, Alexandra Goll, Axel Polack and Helmut Schühlsler, members of the investment committee of TVM V, share voting and investment authority over the shares held by TVM V, and each of whom disclaim beneficial ownership of such shares except to the extent of any pecuniary interest therein. The address of each of these individuals is c/o TVM V Life Science Ventures GmbH & Co. KG, Maximilianstrasse 35C, 80539 Munich, Germany.
- (2) Consists of (i) 81,586 shares ( mRNA shares ) beneficially owned by mRNA Holdings LLC ( mRNA ) for which mRNA Fund L.P. ( mRNA LP ) and Saints Capital Granite, L.P. ( Saints LP ), as members of mRNA, mRNA Partners, L.P. ( mRNA Partners ), as the general partner of mRNA LP, Saints Capital Granite, LLC ( Saints LLC ), as the general partner of Saints LP, each of Jonathan Fleming ( Fleming ) and Alan Walton ( Walton ), as the individual general partners of mRNA Partners, and each of Scott Halsted ( Halsted ), David P. Quinlivan ( Quinlivan ), and Kenneth B. Sawyer ( Sawyer ), managing managers of Saints LLC, share voting and investment control of the mRNA shares and may be deemed to beneficially own the mRNA shares. Each of Fleming, Walton, Sawyer, Quinlivan, and Halsted disclaims beneficial ownership of the shares referred herein except to the extent of their pecuniary interest therein, if any; (ii) 701,045 shares ( OBP (A) III Shares ) beneficially owned by OBP (Adjunct) III Holdings LLC ( OBP (A) III ) for which Oxford Bioscience Partners (Adjunct) III L.P. ( OBP LP ) and Saints LP, as members of OBP (A) III, OBP Management III L.P. ( OBP Management III ), as the general partner of OBP LP, Saints LLC, as the general partner of Saints LP, each of Fleming and Walton, as the individual general partners of OBP Management III, and each of Halsted, Quinlivan, and Sawyer, as managing managers of Saints LLC, share voting and investment control of the OBP (A) III shares and may be deemed to beneficially own the OBP (A) III shares. Each of Fleming, Walton, Sawyer, Quinlivan, and Halsted disclaims beneficial ownership of the shares referred herein except to the extent of their pecuniary interest therein, if any; (iii) 980,290 shares ( OBP (B) III Shares ) beneficially owned by OBP (Bermuda) III Holdings LLC ( OBP (B) III ) for which Oxford Bioscience Partners (Bermuda) III L.P. ( OBP (B) LP ) and Saints LP, as members of OBP (B) III, OBP Management (Bermuda) III L.P. ( OBP Management (B) III ), as the general partner of OBP (B) LP, Saints LLC, as the general partner of Saints LP, each of Fleming and Walton, as the individual general partners of OBP Management (B) III, and each of Halsted, Quinlivan, and Sawyer, as managing managers of Saints LLC, share voting and investment control of the OBP (B) III shares and may be deemed to beneficially own the OBP (B) III shares. Each of Fleming, Walton, Sawyer, Quinlivan, and Halsted disclaims beneficial ownership of the shares referred herein except to the extent of their pecuniary interest therein, if any; and (iv) 6,880,819 shares ( OBP III Shares ) beneficially owned by OBP III Holdings LLC ( OBP III ) for which Oxford Bioscience Partners III L.P. ( OBP LP ) and Saints LLC, as members of OBP III, OBP Management III, as the general partner of OBP LP, Saints LLC, as the general partner of Saints LP, each of Fleming and Walton, as the individual general partners of OBP Management III, and each of Halsted, Quinlivan, and Sawyer, as managing managers of Saints LLC, share voting and investment control of the OBP III Shares and may be deemed to beneficially own the OBP III Shares. Each of Fleming, Walton, Sawyer, Quinlivan, and Halsted disclaims beneficial ownership of the shares referred herein except to the extent of their pecuniary interest therein, if any. The address of each of the individuals listed above is c/o Saints Capital Services, LLC, 475 Sansome Street Suite 1850, San Francisco, California 94111.

**Table of Contents**

- (3) Voting and investment power over the shares held by Shionogi & Co., Ltd. is exercised by its Representative Directors (i.e., Motozo Shiono and Isao Teshirogi) or General Manager of Finance & Accounting Department (i.e., Yuji Hosogai) . The address of Shionogi & Co., Ltd. and the individuals listed above is c/o Shionogi & Co., Ltd. 1-8, Doshomachi 3-chome, Chuo-ku, Osaka 541-0045, Japan.
- (4) Voting and investment power over the shares held by Abbott Laboratories is exercised by its board of directors, which includes Robert J. Alpern, Roxanne S. Austin, Sally Blount, W. James Farrell, Edward M. Liddy, Nancy McKinstry, Phebe N. Novakovic, William A. Osborn, Samuel C. Scott III, Glenn F. Tilton and Miles D. White. The address of Abbott Laboratories and the individuals listed above is c/o Abbott Laboratories, Dept 364, Bldg. AP6D, 100 Abbott Park Road, Abbott Park, Illinois 60064-6400.
- (5) Consists of 3,937,328 shares of common stock held by Industry Ventures Fund VI, L.P. Industry Ventures Management VI, L.L.C. serves as the General Partner of Industry Ventures Fund VI, L.P., has sole voting and investment control over the shares held by such entity, and may be deemed to own beneficially the shares held by such entity. Hans Swildens, Mike Gridley, Justin Burden and Victor Hwang are Managing Directors at Industry Ventures and share voting and dispositive power over the shares held by Industry Ventures Fund VI, L.P. The principal business address of these entities is 750 Battery Street, Floor 7, San Francisco, CA 94111.
- (6) Voting and investment power over the shares held by HBM Healthcare Investments (Cayman) Ltd. is exercised by the board of directors of HBM Healthcare Investments (Cayman) Ltd. The board of directors of HBM Healthcare Investments (Cayman) Ltd. consists of John Arnold, Sophia Harris, Richard Coles, Dr. Andreas Wicki and John Urquhart, none of whom has individual voting or investment power with respect to the shares. The address for HBM Healthcare Investments (Cayman) Ltd. and each of the individuals listed above is Centennial Towers, Suite 305, 2454 West Bay Road, Grand Cayman, Cayman Islands, B.V.I.
- (7) Consists of (i) 552,117 shares beneficially owned by Private Equity Co-Finance; and (ii) 2,728,607 shares beneficially owned by Private Equity Holding Cayman. Voting and investment power over the shares held by Private Equity Co-Finance and Private Equity Holding Cayman is exercised by its directors, which includes Gwendolyn McLaughlin, Nicholas Swartz, Andrew Tyson and Riekele Gorter. The address of Private Equity Co-Finance and Private Equity Holding Cayman and the individuals listed above is c/o Private Equity Co-Finance/Private Equity Holding Cayman. P.O. Box 847, George Town, KY1-1103, Grand Cayman.
- (8) Consists of 3,197,606 shares of common stock underlying options that are exercisable as of September 30, 2012 or will become exercisable within 60 days after such date.
- (9) Consists of (i) 344,762 shares of common stock and (ii) 1,333,206 shares of common stock underlying options that are exercisable as of September 30, 2012 or will become exercisable within 60 days after such date.
- (10) Consists of 1,020,281 shares of common stock underlying options that are exercisable as of September 30, 2012 or will become exercisable within 60 days after such date.
- (11) Consists of (i) 139,164 shares of common stock and (ii) 81,875 shares of common stock underlying options that are exercisable as of September 30, 2012 or will become exercisable within 60 days after such date.
- (12) Consists of 2,605,259 shares beneficially owned by BioVentures Investors Limited Partnership II, for which Mr. Goldberg may be deemed to share voting and investment control. Mr. Goldberg disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein, if any.
- (13)

## Edgar Filing: ENANTA PHARMACEUTICALS INC - Form S-1/A

Consists of 177,500 shares of common stock underlying options that are exercisable as of September 30, 2012 or will become exercisable within 60 days after such date.

- (14) Reflects securities beneficially owned by TVM IV GmbH & Co. KG; TVM Medical Ventures GmbH & Co. KG; and TVM V Life Science as set forth in footnote 1, for which Dr. Schühler may be deemed to share voting and investment control. Dr. Schühler disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein, if any.

**Table of Contents**

- (15) Excludes 8,643,740 shares held by OBP III Holdings LLC and affiliated entities. Mr. Vance is a Venture Partner of Saints Capital an affiliated entity of OBP III Holdings LLC and does not have voting or investment control over these shares.
  
- (16) Consists of 103,750 shares of common stock underlying options that are exercisable as of September 30, 2012 or will become exercisable within 60 days after such date.
  
- (17) Consists of (i) 13,429,618 shares of common stock and (ii) 5,914,218 shares of common stock underlying options that are exercisable as of September 30, 2012 or will become exercisable within 60 days after such date. As to disclaimers of beneficial ownership, see footnotes 12, 14 and 15 above.

---

**Table of Contents**

**DESCRIPTION OF CAPITAL STOCK**

*In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements for at least 90 days, a person who is not deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and who has beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates, is entitled to sell those shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then that person is entitled to sell those shares without complying with any of the requirements of Rule 144.*

*The following is a summary of our capital stock and the material provisions of our amended and restated certificate of incorporation and our amended and restated bylaws, which will become effective upon the closing of this offering, the registration rights agreement to which we and certain of our stockholders are parties and of the Delaware General Corporation Law. For a complete description, you should refer to our amended and restated certificate of incorporation, amended and restated bylaws and the registration rights agreement, copies of which have been filed as exhibits to the registration statement of which this prospectus is part.*

**General**

Our certificate of incorporation that will be in effect upon the closing of this offering, after giving effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock and convertible preferred stock, authorizes us to issue up to \_\_\_\_\_ shares of common stock, par value \$0.01 per share, and \_\_\_\_\_ shares of preferred stock, par value \$0.01 per share, of which 1,999,989 shares will be designated Series 1 Nonconvertible Preferred Stock and \_\_\_\_\_ shares of preferred stock will be undesignated. No shares of preferred stock will be issued or outstanding immediately after this offering.

**Common Stock**

Holders of common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, and do not have cumulative voting rights. Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive dividends, if any, as and when declared by our board of directors. All outstanding shares of common stock are fully paid and nonassessable, and the shares of common stock to be issued upon the closing of this offering will be fully paid and nonassessable. Holders of common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock, including the Series 1 Nonconvertible Preferred Stock and any preferred stock which we may designate in the future. In the event of any liquidation, dissolution or winding-up of our affairs, holders of common stock will be entitled to share ratably in our assets that are remaining after payment or provision for payment of all of our debts and obligations and after liquidation payments to holders of outstanding shares of preferred stock, if any.

As of September 30, 2012, based on 4,889,127 shares of common stock then outstanding and assuming the conversion of all of our redeemable convertible preferred stock and convertible preferred stock into an aggregate of 50,241,277 shares of common stock upon the closing of this offering, the issuance of \_\_\_\_\_ shares of common stock in this offering at a price per share equal to the initial public offering price (which assumes an initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the estimated price range set forth on the cover page of this prospectus), and assuming no exercise of options or warrants, there would have been \_\_\_\_\_ shares of common stock outstanding upon the closing of this offering.

As of September 30, 2012, we had approximately 130 record holders of our common stock, assuming the conversion of all of our outstanding shares of our redeemable convertible preferred stock and convertible preferred stock into an aggregate of 50,241,277 shares of common stock upon the closing of this offering.

## **Table of Contents**

### **Preferred Stock**

*Series 1 Nonconvertible Preferred Stock.* Holders of Series 1 Nonconvertible Preferred Stock are not entitled to receive notice of, to attend, or to vote at any meeting of the stockholders. In any case in which the General Corporation Law of the State of Delaware requires that holders of Series 1 Nonconvertible Preferred Stock be entitled to vote at any meeting of stockholders, such holders will be entitled to vote as a class, separately from any other class or series of capital stock and will be entitled to one vote per share. All outstanding shares of Series 1 Nonconvertible Preferred Stock are fully paid and nonassessable. In the event of any liquidation, dissolution or winding up of the affairs of the company, the Series 1 Nonconvertible Preferred Stock will have priority over the holders of common stock and any other series of stock that we may designate in the future, and shall be entitled to \$1.00 per share to be paid first out of any assets of the company available for distribution. With the approval of a majority of the outstanding shares of the Series 1 Nonconvertible Preferred Stock, we may call for redemption shares of Series 1 Nonconvertible Preferred Stock at a cash redemption price equal to \$1.00 per share. Holders of Series 1 Nonconvertible Preferred Stock have no preemptive, conversion or subscription rights, and there are no sinking fund provisions applicable to the Series 1 Nonconvertible Preferred Stock.

As of September 30, 2012, we had outstanding warrants to purchase 1,999,989 shares of Series 1 Nonconvertible Preferred Stock at an exercise price of \$0.01 per share that expire on October 4, 2017. No shares of Series 1 Nonconvertible Preferred Stock were outstanding as of September 30, 2012.

*Undesignated Preferred.* Upon the closing of this offering, our board of directors will have the authority, without further action by the stockholders, to issue up to \_\_\_\_\_ shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock that are currently undesignated.

### **Stock Options**

As of September 30, 2012, options to purchase 7,635,307 shares of our common stock at a weighted average exercise price of \$0.48 per share were outstanding under our Amended and Restated 1995 Equity Incentive Plan.

### **Warrants**

As of September 30, 2012, we had outstanding warrants to purchase a total of (i) 12,500 shares of our Series E Convertible Preferred Stock at an exercise price of \$2.51 per share and (ii) 1,999,989 shares of Series 1 Nonconvertible Preferred Stock at an exercise price of \$0.01 per share. Of these warrants, warrants to purchase 12,500 shares of Series E Preferred Stock expire on December 31, 2012, and warrants to purchase 1,999,989 shares of Series 1 Preferred Stock expire on October 4, 2017. Upon the closing of this offering, the Series E Preferred Stock warrants will become exercisable for an aggregate of 16,447 shares of our common stock at an exercise price of \$1.91 per share. The Series 1 Nonconvertible Preferred Stock warrants will remain exercisable for an aggregate of 1,999,989 shares of Series 1 Nonconvertible Preferred Stock following this offering. The expiration date of any of these warrants may not be extended without our consent.

### **Registration Rights**

As of September 30, 2012, the holders of 51,788,715 shares of common stock, assuming the conversion of our redeemable convertible preferred stock, are entitled to certain registration rights with respect to these securities pursuant to our registration rights agreement, as amended to date.

## **Table of Contents**

*Demand Rights.* Beginning upon the expiration of the lock-up agreements entered into by the holders of these registrable securities in connection with this offering, as described below in the section entitled "Shares Eligible for Future Sale-Lock-up Agreements," subject to specified limitations, the holders of at least fifty percent (50%) of 51,788,715 shares of common stock deemed registrable securities, including 49,691,274 shares issuable upon conversion of our Series C Preferred Stock, Series D Preferred Stock, Series E Preferred Stock (including shares issuable upon exercise of warrants to purchase Series E Preferred Stock), Series F Preferred Stock and Series G Preferred Stock, may require that we register all or a portion of these securities for sale under the Securities Act. Any such request may be made six months or more after the closing of this offering if at least 20% of the then registrable securities are sought to be registered or if the expected price to the public of the securities requested to be registered equals or exceeds \$10.0 million in the aggregate. We may be required to effect three such registrations. Stockholders with these registration rights who are not part of an initial registration demand are entitled to notice of the registration and are entitled to include their shares of common stock in the registration. Under certain circumstances, the underwriters, if any, may limit the number of shares included in any such registration.

*Incidental Rights.* If at any time after the expiration of the lock-up agreements entered into by the holders of these registrable securities in connection with this offering, we propose to register any of our securities under the Securities Act for sale to the public, either for our own account or for the account of other security holders, or both, other than in connection with:

a registration relating solely to our stock option plans or other employee benefit plans; or

a registration relating solely to a business combination or merger involving us; the holders of these registrable securities are entitled to notice of such registration and are entitled to include their common stock in the registration. Under certain circumstances, the underwriters, if any, may limit the number of shares included in any such registration.

*Form S-3 Rights.* In addition, the holders of these registrable securities will have the right to cause us to register all or a portion of these shares on a Form S-3, provided that we are eligible to use this form. We will not be required to effect such a registration unless the aggregate offering price of the shares to be registered is expected to exceed \$2.0 million. Stockholders with these registration rights who are not part of an initial registration demand are entitled to notice and are entitled to include their shares of common stock in the registration.

### **Anti-Takeover Effects of Provisions of our Certificate of Incorporation, our Bylaws and Delaware Law**

Some provisions of Delaware law, our certificate of incorporation and our bylaws contain provisions that could make the following transactions more difficult: acquisition of us by means of a tender offer; acquisition of us by means of a proxy contest or otherwise; or removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions that might result in a premium over the market price for our shares.

These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.



## **Table of Contents**

### **Undesignated Preferred Stock**

The ability to authorize undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of us. These and other provisions may have the effect of deterring hostile takeovers or delaying changes in control or management of our company.

### **Stockholder Meetings**

Our charter documents provide that a special meeting of stockholders may be called only by the chairman of our board of directors, our Chief Executive Officer, or our board of directors.

### **Requirements for Advance Notification of Stockholder Nominations and Proposals**

Our bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

### **Elimination of Stockholder Action by Written Consent**

Our certificate of incorporation eliminates the right of stockholders to act by written consent without a meeting.

### **Anti-Takeover Provisions**

We are subject to Section 203 of the Delaware General Corporation Law. Subject to certain exceptions, Section 203 prevents a publicly held Delaware corporation from engaging in a business combination with any interested stockholder for three years following the date that the person became an interested stockholder, unless the interested stockholder attained such status with the approval of our board of directors or unless the business combination is approved in a prescribed manner. A business combination includes, among other things, a merger or consolidation involving us and the interested stockholder and the sale of more than 10% of our assets. In general, an interested stockholder is any entity or person beneficially owning 15% or more of our outstanding voting stock and any entity or person affiliated with or controlling or controlled by such entity or person.

### **Staggered Board; Removal of Directors**

Our certificate of incorporation and our bylaws divide our board of directors into three classes with staggered three-year terms. In addition, a director may be removed only for cause and only by the affirmative vote of the holders of at least 66 2/3% of the votes that all our stockholders would be entitled to cast in an annual election of directors. Any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

The classification of our board of directors and the limitations on the removal of directors and filling of vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of our Company.

### **Super-Majority Voting**

The Delaware General Corporation Law provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or by-laws, unless a corporation's certificate of incorporation or by-laws, as the case may be, requires a greater percentage. Our by-laws may be amended or repealed by a majority vote of our board of directors or the affirmative vote of the holders of at least 66 2/3% of the votes that all our stockholders would be entitled to cast in an annual election of directors. In addition, the affirmative vote of the holders of at least 66 2/3% of the votes which all our

## **Table of Contents**

stockholders would be entitled to cast in an election of directors is required to amend or repeal or to adopt any provisions inconsistent with any of the provisions of our certificate of incorporation described in this paragraph and under the heading Staggered Board; Removal of Directors above.

### **Authorized But Unissued Shares**

The authorized but unissued shares of common stock and preferred stock are available for future issuance without stockholder approval, subject to any limitations imposed by the listing standards of The NASDAQ Global Market. These additional shares may be used for a variety of corporate finance transactions, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock could make more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock will be Computershare Trust Company, N.A.

### **NASDAQ Global Market**

We are applying to list our common stock on The NASDAQ Global Market under the symbol ENTA.

**Table of Contents****SHARES ELIGIBLE FOR FUTURE SALE**

Prior to this offering, there has not been a public market for shares of our common stock, and a liquid public market for our common stock may not develop or be sustained after this offering. If a public market does develop, future sales of substantial amounts of shares of our common stock, including shares issued upon exercise of outstanding options, in the public market after our initial public offering, or the possibility of these sales occurring, could cause the prevailing market price for our common stock to fall or could impair our ability to raise capital through the sale of equity securities in the future.

As described below, only a limited number of shares of our common stock will be available for sale in the public market for a period of several months after completion of this offering due to contractual and legal restrictions on resale described below. Nevertheless, sales of a substantial number of shares of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could materially and adversely affect the prevailing market price of our common stock. Although we have applied to list our common stock on The NASDAQ Global Market, we cannot assure you that there will be an active market for our common stock.

Upon the closing of this offering, we will have outstanding \_\_\_\_\_ shares of our common stock based on the number of shares outstanding as of September 30, 2012. This includes \_\_\_\_\_ shares that we are selling in this offering, which shares may be resold in the public market immediately following this offering, and assumes no exercise by the underwriters of their over-allotment option and no exercise of outstanding options.

The \_\_\_\_\_ shares of common stock that were not offered and sold in this offering are, or will be upon issuance, restricted securities, as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or Rule 701 under the Securities Act, which are summarized below.

As a result of the lock-up agreements and market standoff provisions described below and subject to the provisions of Rules 144 and 701 under the Securities Act, these restricted securities will be available for sale in the public market as follows:

<b>Date Available for Sale</b>	<b>Shares Eligible for Sale</b>	<b>Comment</b>
Date of prospectus		Excludes _____ shares of our common stock sold in this offering which may be resold immediately following this offering
91 days after date of prospectus		Shares that are not subject to a lock-up and can be sold under Rule 144
181 days after date of prospectus		Lock-up released*; shares can be sold under Rule 144

\* See Lock-Up Agreements and Market Standoff Provisions below. J.P. Morgan Securities LLC and Credit Suisse Securities (USA) LLC, in their sole discretion may, at any time and without prior notice, release all or any portion of the shares from the restrictions in any of these agreements.

**Rule 144*****Non-Affiliate Resales of Restricted Securities***

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements for at least 90 days, a person who is not deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and who has beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our

## **Table of Contents**

affiliates, is entitled to sell those shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then that person is entitled to sell those shares without complying with any of the requirements of Rule 144.

### ***Affiliate Resales of Restricted Securities***

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell upon the expiration of the lock-up agreements described below, within any three-month period beginning 90 days after the date of this prospectus, a number of shares that does not exceed the greater of:

1% of the number of shares of common stock then outstanding, which will equal approximately \_\_\_\_\_ shares immediately after our initial public offering, or

the average weekly trading volume of the common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

### **Rule 701**

In general, under Rule 701 as currently in effect, any of our employees, consultants or advisors who purchase shares from us in connection with a compensatory stock or option plan or other written agreement in a transaction before the effective date of our initial public offering that was completed in reliance on Rule 701 and complied with the requirements of Rule 701 will, subject to the lock-up restrictions described below, be eligible to resell such shares 90 days after the date of this prospectus in reliance on Rule 144, but without compliance with certain restrictions, including the holding period, contained in Rule 144.

### **Lock-Up Agreements and Market Standoff Provisions**

We and each of our directors and executive officers and certain holders of our outstanding common stock and preferred stock, who collectively own approximately \_\_\_\_\_ shares of our common stock on an as-converted basis, based on shares outstanding as of September 30, 2012, have agreed that, without the prior written consent of J.P. Morgan Securities LLC and Credit Suisse Securities (USA) LLC on behalf of the underwriters, they will not, subject to limited exceptions, during the period ending 180 days after the date of this prospectus:

offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for common stock, or publicly disclose the intention to make any offer, sale, pledge or disposition;

enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our common stock; or

make any demand for or exercise any right with respect to the registration of any shares of our common stock or any security convertible into or exercisable or exchangeable for shares of our common stock.

In addition, we have agreed with our underwriters not to sell any shares of our common stock or securities convertible into or exchangeable for shares of our common stock for a period of 180 days after the date of this prospectus, subject to certain customary exceptions. J.P. Morgan Securities LLC and Credit Suisse Securities (USA) LLC may, in their sole discretion, at any time, release all or any portion of the shares from

these restrictions.

## **Table of Contents**

The lock-up restrictions and specified exceptions are described in more detail under Underwriting.

### **Registration Rights**

Upon the closing of this offering, certain holders of shares of our common stock will be entitled to rights with respect to the registration of the sale of these shares under the Securities Act. Registration of the sale of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. See Description of Capital Stock-Registration Rights for additional information.

### **Registration Statement**

We intend to file a registration statement on Form S-8 under the Securities Act covering all of the shares of common stock subject to options outstanding, as well as reserved for future issuance, under our stock plans. We expect to file this registration statement as soon as practicable after our initial public offering. However, none of the shares registered on Form S-8 will be eligible for resale until the expiration of the lock-up agreements to which they are subject.

**Table of Contents**

**MATERIAL U.S. FEDERAL TAX CONSIDERATIONS FOR  
NON-U.S. HOLDERS OF COMMON STOCK**

The following is a general discussion of the material U.S. federal income and estate tax consequences of the acquisition, ownership and disposition of our common stock, but is not a complete analysis of all the potential U.S. federal income and estate tax consequences relating thereto. Except where noted, this discussion deals only with common stock that is purchased by a non-U.S. holder pursuant to this offering and is held as a capital asset by the non-U.S. holder. A non-U.S. holder means a person (other than a partnership) that is for U.S. federal income tax purposes any of the following:

a nonresident alien individual;

a corporation (or any other entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of a jurisdiction other than the United States, any state thereof or the District of Columbia;

an estate other than one the income of which is subject to U.S. federal income taxation regardless of its source; or

a trust other than a trust that (i) is subject to the primary supervision of a court within the United States and the control of one or more U.S. persons having the authority to control all substantial decisions of the trust, or (ii) has a valid election in effect to be treated as a U.S. person.

If an entity treated as a partnership for U.S. federal income tax purposes holds common stock, the tax treatment of a partner will generally depend on the status of the partner and upon the activities of the partnership. Accordingly, partnerships that hold common stock and partners in such partnerships should consult their respective tax advisors with respect to the U.S. federal income and estate tax consequences of the ownership and disposition of common stock. If you are an individual, you may, in many cases, be deemed to be a resident alien by virtue of being present in the United States for at least 31 days in the current calendar year and for an aggregate of at least 183 days during a three-year period ending in the current calendar year. For these purposes, all the days you are present in the U.S. during the current calendar year, one-third of the days you were present in the U.S. in the immediately preceding year, and one-sixth of the days you were present in the U.S. in the second immediately preceding year are counted. Resident aliens are subject to U.S. federal income tax as if they were U.S. citizens. Such an individual is urged to consult his or her own tax advisor regarding the U.S. federal income and estate tax consequences of the ownership and disposition of common stock.

This discussion does not address all aspects of U.S. federal income and estate taxation that may be relevant in light of a non-U.S. holder's special tax status or special circumstances. U.S. expatriates and certain former citizens or long-term residents of the United States, controlled foreign corporations, passive foreign investment companies, corporations that accumulate earnings to avoid U.S. federal income tax and investors that hold common stock as part of a hedge, straddle or conversion transaction are among those categories of potential investors that may be subject to special rules not covered in this discussion. This discussion does not address any U.S. federal tax consequences other than income and estate tax consequences or any tax consequences arising under the laws of any state, local or non-U.S. taxing jurisdiction. Furthermore, the following discussion is based on current provisions of the Internal Revenue Code of 1986, as amended (the Code), United States Treasury Regulations promulgated thereunder, and administrative and judicial interpretations thereof, all as in effect on the date hereof, and all of which are subject to change, possibly with retroactive effect. Accordingly, each non-U.S. holder should consult its tax advisor regarding the U.S. federal, state, local and non-U.S. income, estate and other tax consequences of acquiring, holding and disposing of shares of our common stock.

**INVESTORS CONSIDERING THE PURCHASE OF SECURITIES PURSUANT TO THIS OFFERING ARE ENCOURAGED TO CONSULT THEIR OWN TAX ADVISORS REGARDING THE APPLICATION OF THE U.S. FEDERAL INCOME AND ESTATE TAX LAWS TO THEIR PARTICULAR SITUATIONS AND THE APPLICATION OF OTHER FEDERAL TAX LAWS, FOREIGN, STATE AND LOCAL TAX LAWS, AND TAX TREATIES.**

---

**Table of Contents**

**Distributions on Our Common Stock**

Distributions in cash or other property on our common stock will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and will first be applied against and reduce a holder's adjusted basis in the common stock, but not below zero, and then the excess, if any, will be treated as gain from the sale of common stock, as described below.

We do not intend to pay cash dividends on our common stock for the foreseeable future. In the event that we do make distributions on our common stock, amounts paid to a non-U.S. holder of common stock that are treated as dividends for U.S. federal income tax purposes generally will be subject to U.S. withholding tax at a rate of 30% of the gross amount of the dividends or such lower rate as may be specified by an applicable tax treaty. In order to receive a reduced treaty rate, a non-U.S. holder generally must provide a valid Internal Revenue Service ( IRS ) Form W-8BEN or other successor form certifying qualification for the reduced rate. If the non-U.S. holder holds the stock through a financial institution or other agent acting on the holder's behalf, the holder will be required to provide appropriate documentation to the agent. The holder's agent will then be required to provide certification to us or our paying agent, either directly or through intermediaries. For payments made to a partnership or other pass-through entity, the certification requirements generally apply to the partners or other owners rather than to the partnership or other entity, and the partnership or other entity must provide the partners' or other owners' documentation to us or our paying agent.

Dividends received by a non-U.S. holder that are effectively connected with a U.S. trade or business conducted by the non-U.S. holder (and, if required by an applicable income tax treaty, are attributable to a U.S. permanent establishment) are exempt from such withholding tax. In order to obtain this exemption, a non-U.S. holder must provide a valid IRS Form W-8ECI or other applicable form properly certifying such exemption. Such effectively connected dividends, although not subject to withholding tax, will generally be subject to regular U.S. federal income tax as if the non-U.S. holder were a U.S. resident, unless an applicable income tax treaty provides otherwise. A non-U.S. corporation receiving effectively connected dividends may also be subject to an additional branch profits tax imposed at a rate of 30% (or a lower treaty rate) on the earnings and profits attributable to its effectively connected income.

**Gain on Disposition of Common Stock**

A non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized upon the sale or other disposition of common stock unless:

the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States (and, if required by an applicable income tax treaty, is attributable to a U.S. permanent establishment);

the non-U.S. holder is an individual who is present in the United States for 183 days or more in the taxable year of the sale, exchange or other disposition of our common stock, and certain other requirements are met; or

we are or have been a U.S. real property holding corporation, as defined below, at any time within the five-year period preceding the disposition or the non-U.S. holder's holding period, whichever period is shorter (the relevant period ).

Unless an applicable treaty provides otherwise, gain described in the first bullet point above generally will be subject to regular U.S. federal income tax as if the non-U.S. holder were a U.S. resident and, in the case of non-U.S. holders taxed as corporations, the branch profits tax described above.

Unless an applicable treaty provides otherwise, gain described in the second bullet point above generally will be subject to U.S. federal income tax at a flat 30% rate, but may be offset by United States source capital losses (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses.



## **Table of Contents**

Generally, a corporation is a U.S. real property holding corporation, or USRPHC, if the fair market value of its U.S. real property interests, as defined in the Code and applicable Treasury regulations, equals or exceeds 50% of the aggregate fair market value of its worldwide real property interests and its other assets used or held for use in a trade or business.

We believe that we are not, and currently do not anticipate becoming, a USRPHC. However, there can be no assurance that our current analysis is correct or that we will not become a USRPHC in the future. Even if we are or become a USRPHC, as long as our common stock is regularly traded on an established securities market, within the meaning of applicable Treasury regulations, such common stock will be treated as U.S. real property interests only if the non-U.S. holder actually or constructively held more than 5% of such regularly traded common stock at some time during the relevant period.

## **Backup Withholding and Information Reporting**

The Code and the Treasury Regulations require payors who make specified payments to report the payments to the IRS. Among the specified payments are dividends and proceeds paid by brokers to their customers. The required information returns enable the IRS to determine whether the recipient properly included the payments in income. This reporting regime is reinforced by backup withholding rules. These rules require payors to withhold tax from payments subject to information reporting if the recipient fails to cooperate with the reporting regime by failing to provide his/her/its taxpayer identification number to the payor, furnishing an incorrect identification number, or failing to report interest or dividends on his/her/its returns. The backup withholding tax rate is currently 28%. The backup withholding rules do not apply to payments to corporations, whether domestic or foreign.

Payments to non-U.S. holders of dividends on our common stock generally will not be subject to backup withholding provided the non-U.S. holder certifies its nonresident status (and we or our paying agent do not have actual knowledge or reason to know the holder is a U.S. person or that the conditions of any other exemption are not, in fact, satisfied) or otherwise establishes an exemption. The certification procedures to claim treaty benefits will satisfy the certification requirements necessary to avoid the backup withholding tax as well. We must report annually to the IRS any dividends paid to each non-U.S. holder and the tax withheld, if any, with respect to such dividends. Copies of these reports may be made available to tax authorities in the country where the non-U.S. holder resides.

Backup withholding is not an additional tax. Any amounts withheld from a payment to a holder of our common stock under the backup withholding rules can be credited against any U.S. federal income tax liability of the holder and may entitle the holder to a refund, provided that the required information is furnished to the IRS in a timely manner.

## **U.S. Federal Estate Tax**

Shares of common stock held (or deemed held) by an individual who is a non-U.S. holder at the time of his or her death will be included in such non-U.S. holder's gross estate for U.S. federal estate tax purposes, unless an applicable estate tax treaty provides otherwise.

## **Legislation Relating to Foreign Accounts**

Legislation enacted in 2010 will generally impose a U.S. federal withholding tax of 30% on dividends and the gross proceeds of a disposition of our common stock paid after December 31, 2012 to a foreign financial institution unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners). The legislation will also generally impose a U.S. federal withholding tax of 30% on dividends and the gross proceeds of a disposition of our common stock paid after December 31, 2012 to a foreign entity (other than a financial institution) unless such entity provides the withholding agent with a certification identifying the direct and indirect U.S. owners of the entity. Under certain circumstances, a holder might be eligible for refunds or credits of such taxes.

**Table of Contents**

Although these rules currently apply to applicable payments made after December 31, 2012, recently proposed U.S. Treasury Regulations, as supplemented by guidance from the U.S. Treasury Department and the IRS, provide that such withholding would generally apply only to dividends paid on or after January 1, 2014 and to other withholdable payments (including payments of gross proceeds from a sale or other disposition of our common stock) made on or after January 1, 2017. These proposed regulations and related guidance will not be effective unless and until final regulations are issued. Investors are encouraged to consult with their own tax advisors regarding the possible impact of these rules on their investment in our common stock.

**Table of Contents**

**UNDERWRITING**

We are offering the shares of common stock described in this prospectus through a number of underwriters. J.P. Morgan Securities LLC and Credit Suisse Securities (USA) LLC are acting as joint book-running managers of the offering and as representatives of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

Name	Number of Shares
J.P. Morgan Securities LLC	
Credit Suisse Securities (USA) LLC	
Leerink Swann LLC	
JMP Securities LLC	
<b>Total</b>	

The underwriters are committed to purchase all the common shares offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the common shares directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of \$ \_\_\_\_\_ per share. After the initial public offering of the shares, the offering price and other selling terms may be changed by the underwriters. Sales of shares made outside of the United States may be made by affiliates of the underwriters. The representatives have advised us that the underwriters do not intend to confirm discretionary sales in excess of 5% of the common shares offered in this offering. The offering of the shares by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part.

The underwriters have an option to buy up to \_\_\_\_\_ additional shares of common stock from us to cover sales of shares by the underwriters which exceed the number of shares specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this over-allotment option. If any shares are purchased with this over-allotment option, the underwriters will purchase shares in approximately the same proportion as shown in the table above. If any additional shares of common stock are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriting fee is equal to the public offering price per share of common stock less the amount paid by the underwriters to us per share of common stock. The underwriting fee is \$ \_\_\_\_\_ per share. The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	Without over-allotment exercise	With full over-allotment exercise
Per Share	\$ _____	\$ _____
Total	\$ _____	\$ _____

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately \$ \_\_\_\_\_.

A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account



**Table of Contents**

holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

We have agreed that we will not (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, or file with the Securities and Exchange Commission a registration statement under the Securities Act relating to, any shares of our common stock or securities convertible into or exchangeable or exercisable for any shares of our common stock, or publicly disclose the intention to make any offer, sale, pledge, disposition or filing, or (ii) enter into any swap or other arrangement that transfers all or a portion of the economic consequences associated with the ownership of any shares of common stock or any such other securities (regardless of whether any such transaction described in (i) or (ii) is to be settled by the delivery of shares of common stock or such other securities, in cash or otherwise), in each case without the prior written consent of J.P. Morgan Securities LLC and Credit Suisse Securities (USA) LLC for a period of 180 days after the date of this prospectus, other than the shares of our common stock to be sold hereunder; any options exercisable for common stock granted under company stock plans in the ordinary course of business consistent with past practice; and any shares of our common stock issued upon the exercise of options granted under company stock plans or outstanding warrants.

Our directors and executive officers, and substantially all of our shareholders have entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each of these persons or entities, for a period of 180 days after the date of this prospectus, may not, without the prior written consent of J.P. Morgan Securities LLC and Credit Suisse Securities (USA) LLC, (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock (including, without limitation, common stock or such other securities which may be deemed to be beneficially owned by such directors, executive officers, shareholders, managers and members in accordance with the rules and regulations of the SEC and securities which may be issued upon exercise of a stock option or warrant), or publicly disclose the intention to make any offer, sale, pledge or disposition, (2) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the common stock or such other securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of common stock or such other securities, in cash or otherwise, or (3) make any demand for or exercise any right with respect to the registration of any shares of our common stock or any security convertible into or exercisable or exchangeable for our common stock, in each case other than transfers of shares of common stock as a bona fide gift, to affiliates of certain of our shareholders, to any trust for the benefit of our directors, executive officers, shareholders or their immediate family members, or by will, other testamentary document or intestate succession, subject to certain requirements and limitations.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

We will apply to have our common stock approved for listing on The NASDAQ Global Market under the symbol ENTA.

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling shares of common stock in the open market for the purpose of preventing or retarding a decline in the market price of the common stock while this offering is in progress. These stabilizing transactions may include making short sales of the common stock, which involves the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering, and purchasing shares of common stock on the open market to cover positions created by short sales. Short sales may be covered shorts, which are short positions in an amount not greater than the underwriters over-allotment option referred to above, or may be naked shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their over-allotment option, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among

## **Table of Contents**

other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the over-allotment option. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act of 1933, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the common stock, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase common stock in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the common stock or preventing or retarding a decline in the market price of the common stock, and, as a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on The NASDAQ Global Market, in the over-the-counter market or otherwise.

Prior to this offering, there has been no public market for our common stock. The initial public offering price will be determined by negotiations among us and the representatives of the underwriters. In determining the initial public offering price, we and the representatives of the underwriters expect to consider a number of factors including:

the information set forth in this prospectus and otherwise available to the representatives;

our prospects and the history and prospects for the industry in which we compete;

an assessment of our management;

our prospects for future earnings;

the general condition of the securities markets at the time of this offering;

the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and

other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for our common shares, or that the shares will trade in the public market at or above the initial public offering price.

The underwriters and their respective affiliates are full-service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

## **Selling Restrictions**

***General***

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in

## **Table of Contents**

compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

### ***United Kingdom***

Each underwriter has represented and agreed that:

(1) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the FSMA) received by it in connection with the issue or sale of our common shares in circumstances in which Section 21(1) of the FSMA does not apply to us; and

(2) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to our common shares in, from or otherwise involving the United Kingdom.

### ***European Economic Area***

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a Relevant Member State ) an offer to the public of any shares which are the subject of the offering contemplated by this prospectus (the Shares ) may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any Shares may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

(1) to any legal entity which is a qualified investor as defined in the Prospectus Directive;

(2) to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives for any such offer; or

(3) in any other circumstances falling within Article 3(2) of the Prospectus Directive;

provided that no such offer of Shares shall result in a requirement for the publication by us or any underwriter of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an offer to the public in relation to any Shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any Shares to be offered so as to enable an investor to decide to purchase any Shares, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression Prospectus Directive means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State, and the expression 2010 PD Amending Directive means Directive 2010/73/EU.



**Table of Contents**

**LEGAL MATTERS**

The validity of the shares of common stock offered hereby will be passed upon for us by Edwards Wildman Palmer LLP. Nathaniel S. Gardiner, Esq., a partner of Edwards Wildman Palmer LLP, is our corporate secretary. Certain legal matters in connection with this offering will be passed upon for the underwriters by Davis Polk & Wardwell LLP.

**EXPERTS**

The financial statements as of September 30, 2011 and 2012 and for each of the three years in the period ended September 30, 2012 included in this prospectus have been so included in reliance on the report (which contains an explanatory paragraph relating to payments the Company may be required to make to redeem a portion of its redeemable convertible preferred stock, as described in Note 1 to the financial statements) of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

**WHERE YOU CAN FIND MORE INFORMATION**

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock we are offering to sell. This prospectus, which constitutes part of the registration statement, does not include all of the information contained in the registration statement and the exhibits, schedules and amendments to the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and to the exhibits and schedules to the registration statement. Statements contained in this prospectus about the contents of any contract, agreement or other document are not necessarily complete, and, in each instance, we refer you to the copy of the contract, agreement or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You may read and copy the registration statement of which this prospectus is a part at the SEC's public reference room, which is located at 100 F Street, N.E., Room 1580, Washington, DC 20549. You can request copies of the registration statement by writing to the Securities and Exchange Commission and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the SEC's public reference room. In addition, the SEC maintains a website, which is located at [www.sec.gov](http://www.sec.gov), that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. You may access the registration statement of which this prospectus is a part at the SEC's website.

Upon completion of this offering, we will be subject to the information reporting requirements of the Securities Exchange Act of 1934, and we will file reports, proxy statements and other information with the SEC. All documents filed with the SEC are available for inspection and copying at the public reference room and website of the SEC referred to above. We maintain a website at [www.enanta.com](http://www.enanta.com). You may access our reports, proxy statements and other information free of charge at this website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information on such website is not incorporated by reference and is not a part of this prospectus.

**Table of Contents**

**INDEX TO FINANCIAL STATEMENTS**

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Balance Sheets</u>	F-3
<u>Statements of Operations</u>	F-4
<u>Statements of Comprehensive Income</u>	F-5
<u>Statements of Changes in Redeemable and Convertible Preferred Stock and Stockholders' Deficit</u>	F-6
<u>Statements of Cash Flows</u>	F-7
<u>Notes to Financial Statements</u>	F-8

F-1

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of

Enanta Pharmaceuticals, Inc.

In our opinion, the accompanying balance sheets and the related statements of operations, comprehensive income, changes in redeemable and convertible preferred stock and stockholders' deficit and cash flows present fairly, in all material respects, the financial position of Enanta Pharmaceuticals, Inc. at September 30, 2011 and 2012 and the results of its operations and its cash flows for each of the three years in the period ended September 30, 2012 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

As discussed in Note 1 to the financial statements, the Company may be required to make payments totaling up to \$39.7 million on December 31, 2013 in order to redeem a portion of its redeemable convertible preferred stock.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts

November 16, 2012

F-2

**Table of Contents****ENANTA PHARMACEUTICALS, INC.****BALANCE SHEETS****(In thousands, except share and per share amounts)**

	September 30,		Pro Forma
	2011	2012	September 30, 2012 (unaudited)
<b>Assets</b>			
<b>Current assets:</b>			
Cash and cash equivalents	\$ 6,837	\$ 10,511	\$ 10,511
Short-term marketable securities	16,492	33,251	33,251
Accounts receivable	261	1,049	1,049
Unbilled receivables		1,893	1,893
Restricted cash	1,140		
Prepaid expenses and other current assets	369	604	604
<b>Total current assets</b>	<b>25,099</b>	<b>47,308</b>	<b>47,308</b>
Property and equipment, net	534	611	611
Long-term marketable securities		1,656	1,656
Restricted cash	436	436	436
Other assets	27	2,151	2,151
<b>Total assets</b>	<b>\$ 26,096</b>	<b>\$ 52,162</b>	<b>\$ 52,162</b>
<b>Liabilities, Redeemable and Convertible Preferred Stock and Stockholders Deficit</b>			
<b>Current liabilities:</b>			
Accounts payable	\$ 566	\$ 1,851	\$ 1,851
Accrued expenses	1,583	3,866	3,866
Deferred revenue		17	17
<b>Total current liabilities</b>	<b>2,149</b>	<b>5,734</b>	<b>5,734</b>
Warrant liability	1,993	2,001	1,981
Other long-term liabilities		498	498
<b>Total liabilities</b>	<b>4,142</b>	<b>8,233</b>	<b>8,213</b>
<b>Commitments and contingencies (Note 16)</b>			
Redeemable convertible preferred stock (Series C, D, E, F, G-1 and G-2); \$0.01 par value; 45,421,288 shares authorized, 43,115,343 shares issued and outstanding at September 30, 2011 and 2012; aggregate liquidation preference of \$159,079 at September 30, 2012; no shares issued or outstanding pro forma (unaudited)	153,588	158,955	
Convertible preferred stock (Series A and B); \$0.01 par value; 566,450 shares authorized, issued and outstanding at September 30, 2011 and 2012; aggregate liquidation preference of \$327 at September 30, 2012; no shares issued or outstanding pro forma (unaudited)	327	327	
<b>Stockholders' equity (deficit):</b>			
Common stock; \$0.01 par value; 70,000,000 shares authorized; 5,283,748 and 5,789,127 shares issued and 4,383,748 and 4,889,127 shares outstanding at September 30, 2011 and 2012, respectively; 56,030,404 shares issued and 55,130,404 shares outstanding pro forma (unaudited)	53	58	560
Additional paid-in capital			158,800

Edgar Filing: ENANTA PHARMACEUTICALS INC - Form S-1/A

Treasury stock, at par value; 900,000 shares at September 30, 2011 and 2012; 900,000 shares pro forma (unaudited)	(9)	(9)	(9)
Accumulated other comprehensive income (loss)	(1)	10	10
Accumulated deficit	(132,004)	(115,412)	(115,412)
Total stockholders' equity (deficit)	(131,961)	(115,353)	43,949
Total liabilities, redeemable and convertible preferred stock and stockholders' equity (deficit)	\$ 26,096	\$ 52,162	\$ 52,162

The accompanying notes are an integral part of these financial statements.

F-3

**Table of Contents****ENANTA PHARMACEUTICALS, INC.****STATEMENTS OF OPERATIONS**

(In thousands, except share and per share amounts)

	Year Ended September 30,		
	2010	2011	2012
Revenue	\$ 22,763	\$ 41,882	\$ 41,706
Operating expenses:			
Research and development	9,716	11,547	15,115
General and administrative	6,105	5,036	5,302
Total operating expenses	15,821	16,583	20,417
Income from operations	6,942	25,299	21,289
Other income (expense):			
Interest income	14	83	118
Interest expense		(3,161)	
Change in fair value of warrant liability	482	(686)	(8)
Therapeutic tax credit		750	
Gain on embedded derivative		670	
Other income (expense), net	309	355	
Total other income (expense), net	805	(1,989)	110
Income before income tax	7,747	23,310	21,399
Income tax benefit	157		
Net income	7,904	23,310	21,399
Accretion of redeemable convertible preferred stock to redemption value	(5,452)	(5,454)	(5,367)
Net income allocable to participating securities	(2,236)	(16,291)	(14,663)
Net income allocable to common stockholders	\$ 216	\$ 1,565	\$ 1,369
Net income per share allocable to common stockholders:			
Basic	\$ 0.04	\$ 0.32	\$ 0.29
Diluted	\$ 0.04	\$ 0.31	\$ 0.26
Weighted average common shares outstanding:			
Basic	4,873,295	4,823,966	4,692,657
Diluted	6,746,450	8,004,846	10,666,488
Pro forma net income per share allocable to common stockholders (unaudited):			
Basic			\$ 0.39
Diluted			\$ 0.35
Pro forma weighted average common shares outstanding (unaudited):			
Basic			54,933,934
Diluted			60,910,089

The accompanying notes are an integral part of these financial statements.

**Table of Contents****ENANTA PHARMACEUTICALS, INC.****STATEMENTS OF COMPREHENSIVE INCOME****(In thousands)**

	<b>Year Ended September 30,</b>		
	<b>2010</b>	<b>2011</b>	<b>2012</b>
Net income	\$ 7,904	\$ 23,310	\$ 21,399
Other comprehensive income (loss):			
Net unrealized gains (losses) on marketable securities, net of tax of \$0		(1)	11
Total other comprehensive income (loss)		(1)	11
Comprehensive income	\$ 7,904	\$ 23,309	\$ 21,410

The accompanying notes are an integral part of these financial statements.

**Table of Contents****ENANTA PHARMACEUTICALS, INC.****STATEMENTS OF CHANGES IN REDEEMABLE AND CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT**

(In thousands, except share amounts)

	Series C, D, E, F and G Redeemable Convertible Preferred Stock		Series A and B Convertible Preferred Stock		Common Stock			Treasury Stock Shares	Accumulated Other Compre- hensive Accumulated		Total Stockholders' Deficit	
	Shares	Amount	Shares	Amount	Shares	Par Value	Additional Paid-in Capital		Amount	(Loss) Deficit		
<b>Balance at September 30, 2009</b>	43,115,343	\$ 142,682	566,450	\$ 327	5,168,970	\$ 52	\$	(310,000)	\$ (3)	\$	\$(152,850)	\$(152,850)
Exercise of stock options					43,905		15					15
Compensation expense related to stock options							259					259
Amortization of redeemable convertible preferred stock to redemption value		5,452					(274)				(5,178)	(5,452)
Net income											7,904	7,904
<b>Balance at September 30, 2010</b>	43,115,343	148,134	566,450	327	5,212,875	52		(310,000)	(3)		(150,124)	(150,075)
Exercise of stock options					70,873	1	33					33
Restricted common stock forfeited by former employees							6	(590,000)	(6)			
Compensation expense related to stock options							225					225
Amortization of redeemable convertible preferred stock to redemption value		5,454					(264)				(5,190)	(5,454)
Other comprehensive loss										(1)		(1)
Net income											23,310	23,310
<b>Balance at September 30, 2011</b>	43,115,343	153,588	566,450	327	5,283,748	53		(900,000)	(9)	(1)	(132,004)	(131,961)
Exercise of stock options					505,379	5	136					141
Compensation expense related to stock options							424					424
Amortization of redeemable convertible preferred stock to redemption value		5,367					(560)				(4,807)	(5,367)
Other comprehensive income										11		11
Net income											21,399	21,399
<b>Balance at September 30, 2012</b>	43,115,343	\$ 158,955	566,450	\$ 327	5,789,127	\$ 58	\$	(900,000)	\$ (9)	\$ 10	\$(115,412)	\$(115,354)

The accompanying notes are an integral part of these financial statements.



**Table of Contents****ENANTA PHARMACEUTICALS, INC.****STATEMENTS OF CASH FLOWS**

(In thousands)

	2010	Year Ended September 30, 2011	2012
<b>Cash flows from operating activities</b>			
Net income	\$ 7,904	\$ 23,310	\$ 21,399
Adjustments to reconcile net income to net cash provided by (used in) operating activities:			
Depreciation and amortization expense	553	499	172
Non-cash interest expense		2,059	
Change in fair value of warrant liability	(482)	686	8
Gain on embedded derivative		(670)	
Stock-based compensation expense	259	225	424
(Gain) loss on disposal of property and equipment	2	(7)	(63)
Amortization of premium on marketable securities		317	590
Change in operating assets and liabilities:			
Accounts receivable	(6)	(251)	(788)
Unbilled receivables			(1,893)
Prepaid expenses and other current assets	65	(273)	(235)
Accounts payable	181	58	763
Accrued expenses	1,765	(1,120)	1,726
Other long-term liabilities	(275)	(356)	498
Deferred revenue	(20,036)	(432)	17
Other assets	(105)	(26)	5
Net cash provided by (used in) operating activities	(10,175)	24,019	22,623
<b>Cash flows from investing activities</b>			
Purchases of property and equipment	(37)	(445)	(252)
Proceeds from sales of property and equipment		9	66
Purchases of marketable securities	(603)	(33,574)	(47,694)
Sales of marketable securities	2,303	16,764	15,750
Maturities of marketable securities			12,950
Change in restricted cash		(436)	1,140
Net cash provided by (used in) investing activities	1,663	(17,682)	(18,040)
<b>Cash flows from financing activities</b>			
Proceeds from issuance of convertible notes		2,000	
Repayment of convertible notes		(2,000)	
Payments of capital lease obligations	(7)		
Proceeds from exercise of stock options	15	34	141
Payments of initial public offering costs			(1,050)
Net cash provided by (used in) financing activities	8	34	(909)
<b>Net increase (decrease) in cash and cash equivalents</b>	(8,504)	6,371	3,674
Cash and cash equivalents at beginning of period	8,970	466	6,837
Cash and cash equivalents at end of period	\$ 466	\$ 6,837	\$ 10,511

**Supplemental disclosure of cash flow information:**

Cash paid for interest	\$	\$	1,056	\$
Cash paid for (received from) income taxes	\$	(157)	\$	\$

**Supplemental disclosure of noncash financing activities:**

Accretion of redeemable convertible preferred stock to redemption value	\$	5,452	\$	5,454	\$	5,367
Deferred initial public offering costs included in accounts payable or accrued expenses	\$		\$		\$	1,079

The accompanying notes are an integral part of these financial statements.

**Table of Contents**

**ENANTA PHARMACEUTICALS, INC**

**NOTES TO FINANCIAL STATEMENTS**

**(Amounts in thousands, except share and per share data)**

**1. Nature of the Business and Basis of Presentation**

Enanta Pharmaceuticals, Inc. (the Company), incorporated in Delaware in 1995, is a research and development-focused biotechnology company that uses its chemistry-driven approach and drug discovery capabilities to create small molecule drugs in the infectious disease field. The Company is developing novel protease, NS5A, cyclophilin and nucleotide polymerase inhibitors targeted against the hepatitis C virus (HCV). Additionally, the Company has created a new class of macrolide antibiotics known as Bicyclolides that overcomes bacterial resistance. Antibacterial focus areas include superbugs, respiratory tract infections, and intravenous and oral treatments for hospital and community Methicillin-resistant *Staphylococcus aureus* (MRSA).

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, dependence on collaborative arrangements, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure, and extensive compliance reporting capabilities.

The accompanying financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The Company had an accumulated deficit of \$115,412 as of September 30, 2012. The Company believes that its cash, cash equivalents and marketable securities will be sufficient to meet its working capital and capital expenditure requirements for at least twelve months from the most recent balance sheet date. As of September 30, 2012, the Company has redeemable convertible preferred stock outstanding that is redeemable at the election of the holders at various dates commencing on December 31, 2013, which could require the Company to make payments totaling up to \$39,696 on December 31, 2013 (see Note 9).

The Company is seeking to complete an initial public offering of its common stock. Upon a successful qualified public offering with gross proceeds of not less than \$25,000, subject to certain terms, the Company's outstanding redeemable convertible preferred stock and convertible preferred stock will automatically convert into shares of common stock. In the event the Company does not complete an initial public offering, the Company may be required to seek amendments to the terms of its redeemable convertible preferred stock to delay or eliminate its redemption payment requirements or seek additional private financing to fund the redemption and its operations. There is no assurance that the Company would be successful in obtaining such amendments or private financing on acceptable terms, or at all. Alternatively, the Company may be required to seek additional funding through existing or new collaboration agreements. The Company may not be able to enter into additional collaborative arrangements. Arrangements with collaborators or others may require the Company to relinquish rights to certain of its technologies or product candidates. If the Company is unable to obtain funding, the Company could be forced to delay, reduce or eliminate its research and development programs or commercialization efforts, which could adversely affect its business prospects, and may not have sufficient funds to redeem its outstanding preferred stock when it becomes due.

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (GAAP).

**2. Summary of Significant Accounting Policies**

**Use of Estimates**

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and



---

**Table of Contents****ENANTA PHARMACEUTICALS, INC****NOTES TO FINANCIAL STATEMENTS (Continued)****(Amounts in thousands, except share and per share data)****2. Summary of Significant Accounting Policies (Continued)**

liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, management's judgments of separate units of accounting and best estimate of selling price of those units of accounting within its revenue arrangements; the valuation of common stock, warrants, embedded derivatives and stock-based awards; the useful lives of property and equipment; and the accounting for income taxes, including uncertain tax positions and the valuation of net deferred tax assets. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company's estimates.

**Unaudited Pro Forma Information**

Upon the closing of a qualified initial public offering, (i) all of the redeemable convertible preferred stock and convertible preferred stock outstanding (see Notes 9 and 10) will automatically convert into common stock and (ii) all warrants to purchase Series E redeemable convertible preferred stock will automatically convert into warrants to purchase common stock. The accompanying unaudited pro forma balance sheet as of September 30, 2012 has been prepared to give effect to (i) the automatic conversion of all outstanding shares of redeemable convertible preferred stock and convertible preferred stock into 50,241,277 shares of common stock and (ii) the automatic conversion of outstanding warrants to purchase Series E redeemable convertible preferred stock into warrants to purchase 16,447 shares of common stock as though the proposed initial public offering had occurred on September 30, 2012. Unaudited pro forma basic and diluted net income per share allocable to common stockholders for the year ended September 30, 2012 has been prepared to give effect to (i) the automatic conversion of all outstanding shares of redeemable convertible preferred stock and convertible preferred stock into 50,241,277 shares of common stock and (ii) the automatic conversion of outstanding warrants to purchase Series E redeemable convertible preferred stock into warrants to purchase 16,447 shares of common stock as though the proposed initial public offering had occurred on October 1, 2011.

**Cash Equivalents and Marketable Securities**

The Company considers all short-term, highly liquid investments with original maturities of ninety days or less at acquisition date to be cash equivalents. Marketable securities with original maturities of greater than three months and remaining maturities of less than one year from the balance sheet date are classified as short-term marketable securities. Marketable securities with remaining maturities of greater than one year from the balance sheet date are classified as long-term marketable securities.

The Company classifies all of its marketable securities as available-for-sale. All marketable securities are held with one investment manager. The Company continually evaluates the credit ratings of its investment portfolio and underlying securities. The Company invests in accordance with its investment policy and invests in securities with a rating of A2 or higher and A or higher according to Moody's and S&P, respectively. The Company reports available-for-sale investments at fair value as of each balance sheet date and records any unrealized gains and losses as a component of stockholders' equity (deficit). The cost of securities sold is determined on a specific identification basis, and realized gains and losses are included in other income (expense) within the statement of operations. If any adjustment to fair value reflects a decline in the value of the investment, the Company considers available evidence to evaluate the extent to which the decline is other than temporary and reduces the investment to fair value through a charge to the statement of operations. There were no such adjustments necessary during the years ended September 30, 2010, 2011 or 2012.

---

**Table of Contents**

**ENANTA PHARMACEUTICALS, INC**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(Amounts in thousands, except share and per share data)**

**2. Summary of Significant Accounting Policies (Continued)**

**Restricted Cash**

As of September 30, 2011, the Company had outstanding a letter of credit collateralized by a certificate of deposit of \$1,140 to the benefit of the landlord of the Company's former office lease. This amount was classified as short-term restricted cash as of September 30, 2011. On December 2, 2011, the landlord released the letter of credit to the Company. As of September 30, 2011 and 2012, the Company had outstanding a letter of credit collateralized by a money market account of \$436 to the benefit of the landlord of the Company's current office lease. This amount was classified as long-term restricted cash as of September 30, 2011 and 2012.

**Concentration of Credit Risk and of Significant Customers and Suppliers**

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents, marketable securities, accounts receivable and unbilled receivables. The Company has all cash and investment balances at one accredited financial institution, in amounts that exceed federally insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company has historically generated all of its revenue from its collaborative research and license agreements and one government contract (see Note 8). As of September 30, 2011, accounts receivable consisted of amounts due under a therapeutic tax credit grant from the U.S. government (see Note 20). As of September 30, 2012, accounts receivable and unbilled receivables consisted of amounts due from the Company's collaborators and under a U.S. government contract (see Note 8).

The Company is completely dependent on third-party manufacturers for product supply for preclinical research activities in its non-partnered programs. In particular, the Company relies and expects to continue to rely exclusively on one manufacturer to supply it with its requirements for the active pharmaceutical ingredients related to these programs. These research programs would be adversely affected by a significant interruption in the supply of active pharmaceutical ingredients.

**Fair Value Measurements**

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. A fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last is considered unobservable, is used to measure fair value:

Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Observable inputs (other than Level 1 quoted prices) such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

## Edgar Filing: ENANTA PHARMACEUTICALS INC - Form S-1/A

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques. The Company's cash equivalents and marketable securities assets and its warrant liabilities are carried at fair value determined according to the fair value hierarchy described above (see Note 3). The carrying values of accounts receivable and unbilled receivables, accounts payable, and accrued expenses approximate their fair value due to the short-term nature of these assets and liabilities. The carrying value of accrued third-party license fees included in other long-term liabilities has been recorded at its present value, which approximates fair value.

F-10

**Table of Contents****ENANTA PHARMACEUTICALS, INC****NOTES TO FINANCIAL STATEMENTS (Continued)****(Amounts in thousands, except share and per share data)****2. Summary of Significant Accounting Policies (Continued)****Property and Equipment**

Property and equipment are stated at cost less accumulated depreciation or amortization. Depreciation and amortization expense is recognized using the straight-line method over the following estimated useful lives:

Laboratory and office equipment	3 5 years
Leasehold improvements	Shorter of life of lease or estimated useful life
Purchased software	3 5 years
Computer equipment	3 5 years
Furniture	7 years

Expenditures for repairs and maintenance of assets are charged to expense as incurred. Costs of major additions and betterments are capitalized and depreciated on a straight-line basis over their useful lives. Upon retirement or sale, the cost and related accumulated depreciation or amortization of assets disposed of are removed from the accounts and any resulting gain or loss is included in income (loss) from operations.

**Impairment of Long-Lived Assets**

The Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows. To date, the Company has not recorded any impairment losses on long-lived assets.

**Revenue Recognition**

The Company's revenue is generated primarily through collaborative research and license agreements. The terms of these agreements contain multiple deliverables, which may include (i) licenses, (ii) research and development activities, and (iii) participation in joint research and development steering committees. The terms of these agreements may include nonrefundable upfront license fees, payments for research and development activities, payments based upon the achievement of certain milestones, and royalty payments based on product sales derived from the collaboration. In all instances, revenue is recognized only when the price is fixed or determinable, persuasive evidence of an arrangement exists, delivery has occurred or the services have been rendered, collectibility of the resulting receivable is reasonably assured, and the Company has fulfilled its performance obligations under the contract.

For agreements entered into prior to October 1, 2011, the Company evaluated license agreements with multiple deliverables to determine if the deliverable elements could be recognized separately by considering (i) if the delivered elements (typically the license) had standalone value to the customer, (ii) if the fair value of any undelivered elements (typically the research and development services and the steering committee activities) could be determined based on vendor-specific objective evidence ( VSOE ) or vendor objective evidence ( VOE ), and (iii) if the arrangement included a general right of return relative to the delivered item, the delivery or performance





---

**Table of Contents****ENANTA PHARMACEUTICALS, INC****NOTES TO FINANCIAL STATEMENTS (Continued)****(Amounts in thousands, except share and per share data)****2. Summary of Significant Accounting Policies (Continued)**

of the undelivered item was considered probable and substantially within the control of the Company. VSOE of fair value was based on the consistent price of a deliverable when the Company regularly sold it on a standalone basis. Alternatively, VOE was based upon third-party objective evidence of fair value. If the delivered elements had value on a standalone basis and the fair value of the undelivered elements could be determined based on VSOE or VOE, revenues of such elements were then accounted for separately as delivered with arrangement consideration allocated to the delivered elements based on the residual value method. If either (i) the delivered elements were considered to not have standalone value or (ii) VSOE or VOE of fair value for any of the undelivered elements could not be determined, the arrangement was accounted for as a single unit of accounting and all payments received were recognized as revenue over the estimated period of performance of the entire arrangement.

On October 1, 2011, the Company adopted Accounting Standards Update ( ASU ) No. 2009-13, *Multiple-Deliverable Revenue Arrangements* ( ASU 2009-13 ). This guidance, which applies to multiple-element arrangements entered into or materially modified on or after October 1, 2011, amends the criteria for separating and allocating consideration in a multiple-element arrangement by modifying the fair value requirements for revenue recognition and eliminating the use of the residual value method. The selling prices of deliverables under the arrangement may be derived using third-party evidence ( TPE ) or a best estimate of selling price ( BESP ), if VSOE is not available. The objective of BESP is to determine the price at which the Company would transact a sale if the element within the license agreement was sold on a standalone basis. Establishing BESP involves management's judgment and considers multiple factors, including market conditions and company-specific factors including those factors contemplated in negotiating the agreements as well as internally developed models that include assumptions related to market opportunity, discounted cash flows, estimated development costs, probability of success, and the time needed to commercialize a product candidate pursuant to the license. In validating the Company's BESP, the Company considers whether changes in key assumptions used to determine the BESP will have a significant effect on the allocation of the arrangement consideration between the multiple deliverables. Deliverables under the arrangement are separate units of accounting if (i) the delivered item has value to the customer on a standalone basis, and (ii) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially within the control of the Company. The arrangement consideration that is fixed or determinable at the inception of the arrangement is allocated to the separate units of accounting based on their relative selling prices. The appropriate revenue recognition model is applied to each element, and revenue is accordingly recognized as each element is delivered. The Company may exercise significant judgment in determining whether a deliverable is a separate unit of accounting. The Company elected to adopt ASU 2009-13 prospectively as of October 1, 2011.

In determining the separate units of accounting, the Company evaluates whether the license has standalone value to the collaborator based on consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research and development capabilities of the collaborator and the availability of relevant research expertise in the marketplace. In addition, the Company considers whether or not (i) the collaborator can use the license for its intended purpose without the receipt of the remaining deliverables, (ii) the value of the license is dependent on the undelivered items, and (iii) the collaborator or other vendors can provide the undelivered items.

Under a collaborative research and license agreement, a steering committee is typically responsible for overseeing the general working relationships, determining the protocols to be followed in the research and development performed, and evaluating the results from the continued development of the product in order to determine the clinical studies to be performed. The Company evaluates whether its participation in joint research and development steering committees is a substantive obligation or whether the services are considered inconsequential or perfunctory. The Company's participation on a steering committee is considered

**Table of Contents****ENANTA PHARMACEUTICALS, INC****NOTES TO FINANCIAL STATEMENTS (Continued)****(Amounts in thousands, except share and per share data)****2. Summary of Significant Accounting Policies (Continued)**

participatory and therefore accounted for as a separate element when the collaborator requires the participation of the Company to ensure all elements of an arrangement are maximized. Steering committee services that are considered participatory are combined with other research services or performance obligations required under an arrangement, if any, in determining the level of effort required in an arrangement and the period over which the Company expects to complete its aggregate performance obligations. Alternatively, the Company's participation on a steering committee is considered protective and therefore not accounted for as a separate element in a case where the Company can exercise or control when to be involved at its own discretion. Factors the Company considers in determining if its participation in a joint steering committee is participating or protective include: (i) which party negotiated or requested the steering committee, (ii) how frequently the steering committee meets, (iii) whether or not there are any penalties or other recourse if the Company does not attend the steering committee meetings, (iv) which party has decision making authority on the steering committee, and (v) whether or not the collaborator has the requisite experience and expertise associated with the research and development of the licensed intellectual property.

For all periods presented, whenever the Company determines that an element is delivered over a period of time, revenue is recognized using either a proportional performance model or a straight-line model over the period of performance, which is typically the research and development term. Full-time equivalents ( FTEs ) are typically used as the measure of performance. At each reporting period, the Company reassesses its cumulative measure of performance and makes appropriate adjustments, if necessary. The Company recognizes revenue using the proportional performance model whenever the Company can make reasonably reliable estimates of the level of effort required to complete its performance obligations under an arrangement. Revenue recognized under the proportional performance model at each reporting period is determined by multiplying the total expected payments under the contract (excluding royalties and payments contingent upon achievement of milestones) by the ratio of the level of effort incurred to date to the estimated total level of effort required to complete the performance obligations under the arrangement. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the proportional performance model as of each reporting period. Alternatively, if the Company cannot make reasonably reliable estimates the level of effort required to complete its performance obligations under an arrangement, then revenue under the arrangement is recognized on a straight-line basis over the period expected to complete the Company's performance obligations. If and when a contingent milestone payment is earned, the additional consideration to be received is allocated to the separate units of accounting in the arrangement based on their relative selling prices at the inception of the arrangement. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined on a straight-line basis as of the period end date. If the Company cannot reasonably estimate when its performance obligation period ends, then revenue is deferred until the Company can reasonably estimate when the performance obligation period ends.

The Company recognized revenue of \$35,567 during the year ended September 30, 2012 as a result of the collaborative arrangement with Novartis, the Company's only arrangement that is being accounted for under ASU 2009-13 (see Note 8). If the Company had recognized revenue from this Novartis arrangement under the guidance in effect prior to October 1, 2011, the Company would have recognized revenue of \$22,651 related to the Novartis agreement during the year ended September 30, 2012. Under the previously issued guidance, fees related to the nonrefundable license fee and the funding for research would have been accounted for as a single unit of accounting and recognized over the one-year period of the research obligation based on the proportional performance model, due to the fact that the Company would have been unable to establish VSOE or VOE of fair value for the undelivered research obligation.

**Table of Contents**

**ENANTA PHARMACEUTICALS, INC**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(Amounts in thousands, except share and per share data)**

**2. Summary of Significant Accounting Policies (Continued)**

Royalty revenue, if any, is recognized based on contractual terms when reported sales are reliably measurable and collectibility is reasonably assured, provided that there are no performance obligations then remaining. To date, none of the Company's products have been approved, and therefore the Company has not earned any royalty revenue from product sales.

During the year ended September 30, 2012, the Company also generated revenue from a government contract that reimburses the Company for certain allowable costs for the funded project. Revenue from the government contract is recognized when the related service is performed. The related costs incurred by the Company under the government contract are included in research and development expense in the Company's statements of operations.

The Company's adoption of ASU 2010-17, *Revenue Recognition - Milestone Method*, as of October 1, 2010, had no impact on its financial position, results of operations or cash flows as the Company made a policy election under this standard not to apply the milestone method. All milestone payments that the Company has received or is eligible to receive under its existing collaboration agreements result solely from the efforts of its collaborators and not from the efforts of the Company and, therefore, are not deemed to be substantive milestones.

Amounts received prior to satisfying all revenue recognition criteria are recorded as deferred revenue in the accompanying balance sheets. Amounts not expected to be recognized as revenue within the next twelve months of the balance sheet date are classified as long-term deferred revenue.

In the event that a collaborative research and license agreement is terminated and the Company then has no further performance obligations, the Company recognizes as revenue any portion of the upfront payment that had not previously been recorded as revenue but was classified as deferred revenue at the date of such termination.

**Research and Development Costs**

Research and development costs are expensed as incurred. Included in research and development costs are wages, stock-based compensation and benefits of employees, third-party license fees and other operational costs related to the Company's research and development activities, including facility-related expenses and external costs of outside contractors engaged to conduct both preclinical and clinical studies. The Company also includes in research and development expense the costs to complete the Company's obligations under research collaborations.

**Patent Costs**

All patent-related costs incurred in connection with filing and prosecuting patent applications are recorded as general and administrative expenses as incurred, as recoverability of such expenditures is uncertain.

**Deferred Offering Costs**

The Company capitalizes certain legal, accounting and other third-party fees that are directly associated with in-process equity financings as other assets until such financings are consummated. After consummation of the equity financing, these costs are recorded in shareholders' equity as a reduction of additional paid-in capital generated as a result of the offering. As of September 30, 2012, the Company recorded deferred financing costs of \$2,129 in other assets in the accompanying balance sheet in contemplation of a probable calendar-year 2012 equity financing. Should the equity financing no longer be considered probable of being consummated, the deferred financing costs would be expensed immediately as a charge to operating expenses in the statement of operations.



**Table of Contents**

**ENANTA PHARMACEUTICALS, INC**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(Amounts in thousands, except share and per share data)**

**2. Summary of Significant Accounting Policies (Continued)**

**Accounting for Stock-Based Compensation**

The Company measures all stock options and other stock-based awards granted to employees at the fair value on the date of the grant using the Black-Scholes option-pricing model. The fair value of the awards is recognized as expense, net of estimated forfeitures, over the requisite service period, which is generally the vesting period of the respective award. The straight-line method of expense recognition is applied to all awards with service-only conditions. The Company classifies stock-based compensation expense in the statements of operations in the same manner in which the award recipient's payroll costs are classified.

**Income Taxes**

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the financial statements or in the Company's tax returns. Deferred taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

**Net Income Per Share**

The Company follows the two-class method when computing net income per share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net income per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

The Company's redeemable convertible preferred shares and convertible preferred shares contractually entitle the holders of such shares to participate in dividends, but do not contractually require the holders of such shares to participate in losses of the Company. Accordingly, the two-class method does not apply for periods in which the Company reports a net loss or a net loss attributable to common stockholders resulting from dividends, accretion or modifications to its redeemable convertible preferred stock or convertible preferred stock.

---

**Table of Contents****ENANTA PHARMACEUTICALS, INC****NOTES TO FINANCIAL STATEMENTS (Continued)****(Amounts in thousands, except share and per share data)****2. Summary of Significant Accounting Policies (Continued)**

Basic net income per share allocable to common stockholders is computed by dividing the net income allocable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net income allocable to common stockholders is computed by adjusting net income allocable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities, including outstanding stock options and outstanding warrants. Diluted net income per share allocable to common stockholders is computed by dividing the diluted net income allocable to common stockholders by the weighted average number of common shares outstanding for the period, including potential dilutive common shares assuming the dilutive effect of outstanding stock options and outstanding warrants.

**Segment Data**

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company is a biotechnology company focused on discovering and developing small molecule drugs in the infectious disease field. Revenue is generated exclusively from transactions occurring in the United States, and all assets are held in the United States.

**Comprehensive Income (Loss)**

Comprehensive income (loss) includes net income (loss) as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. The Company's only element of other comprehensive income (loss) is unrealized gains and losses on available-for-sale marketable securities.

**Recently Issued and Adopted Accounting Pronouncements**

In May 2011, the Financial Accounting Standards Board (the FASB) issued ASU No. 2011-04, *Fair Value Measurement: Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*. This accounting standard clarifies the application of certain existing fair value measurement guidance and expands the disclosures for fair value measurements that are estimated using significant unobservable (Level 3) inputs. This ASU is effective on a prospective basis for annual and interim reporting periods beginning on or after December 15, 2011. The Company's adoption of this standard on January 1, 2012 did not have a material effect on its financial position, results of operations or cash flows.

In June 2011, the FASB issued ASU 2011-05, *Presentation of Comprehensive Income*, which provides companies with two options for presenting comprehensive income. Companies can present the total of comprehensive income, the components of net income and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. This guidance eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. In December 2011, the FASB indefinitely deferred the requirement of the guidance to present reclassification adjustments of other comprehensive income by line item on the face of the applicable statement. However, all other requirements of the guidance are effective for the Company on October 1, 2012. The Company early adopted this guidance effective October 1, 2011 and applied it retrospectively for all periods presented. As the guidance relates only to how comprehensive income is disclosed and does not change the items that must be reported as comprehensive income, adoption did not have an effect on the Company's financial position, results of operations or cash flows.

Other accounting standards that have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on the Company's financial statements upon adoption.





**Table of Contents****ENANTA PHARMACEUTICALS, INC****NOTES TO FINANCIAL STATEMENTS (Continued)**

(Amounts in thousands, except share and per share data)

**3. Fair Value of Financial Assets and Liabilities**

The following tables present information about the Company's financial assets and liabilities that were subject to fair value measurement on a recurring basis as of September 30, 2011 and 2012 and indicate the fair value hierarchy of the valuation inputs utilized to determine such fair value:

<b>Fair Value Measurements as of September 30, 2011 Using:</b>				
	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Assets:</b>				
Cash equivalents	\$ 4,027	\$ 1,399	\$	\$ 5,426
Marketable securities	1,002	15,490		16,492
	\$ 5,029	\$ 16,889	\$	\$ 21,918
<b>Liabilities:</b>				
Warrant liability	\$	\$	\$ 1,993	\$ 1,993
	\$	\$	\$ 1,993	\$ 1,993

<b>Fair Value Measurements as of September 30, 2012 Using:</b>				
	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Assets:</b>				
Cash equivalents	\$ 6,471	\$	\$	\$ 6,471
Marketable securities	1,015	33,892		34,907
	\$ 7,486	\$ 33,892	\$	\$ 41,378
<b>Liabilities:</b>				
Warrant liability	\$	\$	\$ 2,001	\$ 2,001
	\$	\$	\$ 2,001	\$ 2,001

During the years ended September 30, 2010, 2011 and 2012, there were no transfers between Level 1, Level 2 and Level 3.

The warrant liability in the tables above is comprised of the values of warrants for the purchase of Series E redeemable convertible preferred stock and warrants for the purchase of Series 1 nonconvertible preferred stock, measured at fair value, and is based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The Company's valuation of the warrant liability utilizes the Black-Scholes option-pricing model, which incorporates assumptions and estimates to value the warrants. The Company assesses these assumptions and estimates on a quarterly basis as additional information impacting the assumptions is obtained. Changes in the fair value of the warrant liability are recognized in the statements of operations.

Related to the valuation of warrants for the purchase of Series 1 nonconvertible preferred stock (see Note 13), the quantitative elements associated with the Company's Level 3 inputs impacting fair value measurement include the fair value per share of the underlying Series 1 nonconvertible preferred stock, the remaining contractual term of the warrants, risk-free interest rate, expected dividend yield, and expected volatility of the price of the underlying preferred stock. Because the exercise price of the warrants is only \$0.01 per share, the assumptions used

## Edgar Filing: ENANTA PHARMACEUTICALS INC - Form S-1/A

as inputs in the model for the remaining contractual term, risk-free interest rate, expected dividend yield and expected volatility had no material impact on the fair value of the warrants. The input that most significantly impacted the value of these warrants was the fair value of the underlying Series 1 nonconvertible preferred stock. The Company determined that the fair value of the Series 1 nonconvertible

F-17

**Table of Contents****ENANTA PHARMACEUTICALS, INC****NOTES TO FINANCIAL STATEMENTS (Continued)****(Amounts in thousands, except share and per share data)****3. Fair Value of Financial Assets and Liabilities (Continued)**

preferred stock equals its stated liquidation preference of \$1.00 per share. Since the Series 1 nonconvertible preferred stock ranks senior to all other classes of stock and its liquidation preference is small relative to the Company's equity value, the probability of a 100% payout on the Series 1 nonconvertible preferred stock was considered to be high. The fair value of the warrants for the purchase of the Series 1 nonconvertible preferred stock was \$1,984 and \$1,981 as of September 30, 2011 and 2012, respectively.

The fair value of warrants for the purchase of Series E redeemable convertible preferred stock (see Note 13) was \$27, \$9 and \$20, respectively, as of September 30, 2010, 2011 and 2012.

The following table provides a rollforward of the aggregate fair values of the Company's warrants for the purchase of Series E preferred stock and Series 1 nonconvertible preferred stock for which fair value is determined by Level 3 inputs:

<b>Balance, October 1, 2009</b>	\$ 509
Decrease in fair value	(482)
<b>Balance, September 30, 2010</b>	27
Warrants issued	1,280
Increase in fair value	705
Decrease in fair value	(19)
<b>Balance, September 30, 2011</b>	1,993
Warrants expired	(8)
Increase in fair value	19
Decrease in fair value	(3)
<b>Balance, September 30, 2012</b>	\$ 2,001

**4. Marketable Securities**

As of September 30, 2011 and 2012, the fair value of available-for-sale marketable securities by type of security was as follows:

	Amortized Cost	September 30, 2011		Fair Value
		Gross Unrealized Gains	Gross Unrealized Losses	
Commercial paper	\$ 5,046	\$	\$	\$ 5,046
Corporate bonds	7,888	2	(7)	7,883
U.S. Agency bonds	2,561			2,561
U.S. Treasury notes	998	4		1,002

Edgar Filing: ENANTA PHARMACEUTICALS INC - Form S-1/A

		September 30, 2012		
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	\$ 8,143	\$	\$	\$ 8,143
Corporate bonds	25,741	9	(1)	25,749
U.S. Treasury notes	1,013	2		1,015
	\$ 34,897	\$ 11	\$ (1)	\$ 34,907

F-18

**Table of Contents****ENANTA PHARMACEUTICALS, INC****NOTES TO FINANCIAL STATEMENTS (Continued)****(Amounts in thousands, except share and per share data)****4. Marketable Securities (Continued)**

At September 30, 2012, marketable securities consisted of investments that mature within one year, with the exception of one U.S. Treasury note and one corporate bond, which have maturities within two years and an aggregate fair value of \$1,656.

**5. Property and Equipment**

Property and equipment consisted of the following as of September 30, 2011 and 2012:

	September 30,	
	2011	2012
Laboratory and office equipment	\$ 4,200	\$ 4,142
Leasehold improvements	229	268
Purchased software	403	402
Computer equipment	76	76
Furniture	260	259
	5,168	5,147
Less: Accumulated depreciation and amortization	(4,634)	(4,536)
	\$ 534	\$ 611

Depreciation and amortization expense was \$553, \$499 and \$172 for the years ended September 30, 2010, 2011 and 2012, respectively. During the years ended September 30, 2010, 2011 and 2012, assets with a cost of \$216, \$3,810 and \$273, respectively, were sold or disposed of, resulting in a (gain) loss of \$2, \$(7) and \$(63), respectively.

**6. Accrued Expenses and Other Long-Term Liabilities**

Accrued expenses (current) and other long-term liabilities consisted of the following as of September 30, 2011 and 2012:

	September 30,	
	2011	2012
<b>Accrued expenses:</b>		
Accrued payroll and related expenses	\$ 828	\$ 1,305
Accrued vendor manufacturing	146	1,330
Accrued professional fees	253	718
Accrued third-party license fee		222
Accrued other	356	291

	\$ 1,583	\$ 3,866
<b>Other long-term liabilities:</b>		
Accrued rent expense	\$	\$ 75
Present value of accrued third-party license fee		423
	\$	\$ 498

---

**Table of Contents****ENANTA PHARMACEUTICALS, INC****NOTES TO FINANCIAL STATEMENTS (Continued)****(Amounts in thousands, except share and per share data)****7. Convertible Notes****2011 Bridge Financing**

In October 2010, the Company entered into a convertible note and warrant purchase agreement with existing investors to sell, in one or more closings, term notes in the aggregate principal amount of up to \$6,500. The term notes had an interest rate of 5% per annum, with principal and interest payable at the stated maturity date of October 4, 2011 or earlier if put to the Company by the noteholders or if called by the Company. The noteholders could put the term notes to the Company for early repayment upon receipt by the Company of the next milestone payment under the Company's collaborative development and license agreement with Abbott Laboratories or upon a merger, sale or liquidity event as specified by the note agreement. The Company could call the term notes for early repayment at any time. If called by the Company prior to maturity, repaid at maturity, or put by the noteholders upon receipt by the Company of the milestone payment, the term notes required payment of a prepayment premium equal to 51.8% of the principal amount of the notes in addition to the principal and interest payable. If put by the noteholders due to a liquidity event, the term notes were not subject to the premium of 51.8% but were to be repaid at the following multiples:

two times the principal amount if the liquidity event occurred on or before March 31, 2011, and

three times the principal amount if the liquidity event occurred after March 31, 2011.

During the first closing of the term notes in October and November 2010, the Company borrowed a total of \$2,000. The remaining balance of \$4,500 under the agreement was not drawn down.

The call and put options within the notes agreement constituted an embedded derivative, which was required to be separately recognized and measured at fair value, resulting in the Company recognizing a debt discount and derivative liability of \$670 at the date of issuance of the notes.

In addition, each purchaser of a note received warrants to purchase shares of Series 1 nonconvertible preferred stock (the Nonconvertible Preferred ) at the rate of one warrant for each dollar of the original purchase amount of the note. The warrants have an exercise price of \$0.01 per share. At issuance, the number of shares issuable upon exercise of the warrants was not yet fixed. The number of shares for which the warrants could be exercisable was (i) one share for each dollar of the original principal amount of the Note, plus (ii) if the milestone payment was not received on or before March 31, 2011, an additional share for each dollar of the original principal amount of the notes. Additionally, if a liquidation event occurred, thereby requiring repayment of the term notes, these warrants would automatically expire and would therefore have no value. At the date of issuance, the warrants were valued using the Black-Scholes option-pricing model for each of the two scenarios described above. A decision tree was used to estimate the probability of how many shares the warrants would ultimately be exercised into or if the warrants would have no value under the third scenario. This resulted in a total fair value of \$1,280 at date of issuance. Upon repayment of the notes in December 2010, the number of shares issuable upon exercise of the warrants became fixed at 1,999,989 Nonconvertible Preferred shares. Additionally, the possibility that the notes would not be redeemed and that the warrants would therefore have no value was eliminated. Accordingly, at the time of the note repayment in December 2010, the Company revalued the warrants, which resulted in a total fair value of \$1,983. The change in the fair value of the warrants was recorded within other income (expense) in the statement of operations. Additionally, as these warrants are financial instruments that may require a future transfer of assets, they are classified as liabilities on the balance sheet. Upon issuance of the notes and warrants, the fair value of the warrants was recorded as a warrant liability and a corresponding debt discount was recognized. The warrants are remeasured at each balance sheet date using the Black-Scholes options-pricing model, and the change in fair value is recorded within other income (expense).

Following the receipt by the Company of a \$40,000 milestone payment from Abbott Laboratories in December 2010 (see Note 8), the Company repaid the \$2,000 in principal plus the accrued interest of \$20 and the applicable premium of \$1,036 (51.8% of the principal amount). Upon repayment of the notes, the unamortized debt discount





---

**Table of Contents****ENANTA PHARMACEUTICALS, INC****NOTES TO FINANCIAL STATEMENTS (Continued)****(Amounts in thousands, except share and per share data)****7. Convertible Notes (Continued)**

derived from both the embedded derivatives and the warrants was accreted as a charge to interest expense and the derivative liability (recorded at fair value) was removed, resulting in a gain recorded in the statement of operations. The warrants, however, remained outstanding as of September 30, 2012. The note agreement was canceled upon the December 2010 repayment and no further warrants were issued under the agreement.

In connection with this financing, the Company incurred issuance costs of \$109 and \$41 during the years ended September 30, 2010 and 2011, respectively. These costs were initially recorded as deferred financing costs in other assets on the balance sheet. In December 2010, upon repayment of the notes, the total deferred financing costs of \$150 were charged to interest expense.

**8. Collaboration Agreements****Abbott Collaboration**

On November 27, 2006, the Company entered into a Collaborative Development and License Agreement with Abbott Laboratories (the Abbott Agreement) to identify, develop and commercialize HCV NS3 and NS3/4A protease inhibitor compounds, including ABT-450. Under the terms of the Abbott Agreement, as amended, through September 30, 2009, Abbott Laboratories (Abbott) paid \$48,300 to the Company for upfront license payments and FTE reimbursements to fund research activities. The Company is also eligible to receive milestone payments for the successful development by Abbott of one or more HCV compounds as well as tiered royalties ranging on a blended basis from the low double digits up to the high teens on net sales per product by Abbott allocable to the collaboration's protease inhibitors.

Also on November 27, 2006, the Company entered into a Series G preferred stock purchase agreement with Abbott. In connection with that agreement, the Company sold to Abbott 4,620,764 shares of Series G-1 redeemable convertible preferred stock for a price of \$2.70518 per share, resulting in gross proceeds of \$12,500. Due to the simultaneous issuance of Series G-2 redeemable convertible preferred stock to a third party unrelated to Abbott which had similar terms to Series G-1 but a lower price per share, the Company determined that the Series G-1 redeemable convertible preferred stock sold to Abbott was issued at a premium of \$1,617. The Company aggregated this premium with the upfront payments received and recorded it as deferred revenue to be recognized over the period of performance under the Abbott Agreement.

In January 2009, the Company and Abbott amended the Abbott Agreement to include an option for Abbott to opt into an evaluation period that would commence upon the termination or expiration of the research program term and continue for a period of six months. During the evaluation period, Abbott would have the right to analyze certain compounds for the purpose of identifying any suitable for further development. In December 2009, the Company and Abbott further amended the Abbott Agreement to extend funding of the research activities for another year through December 2010. In December 2010, Abbott opted into the evaluation period and additional research activities for the six-month evaluation period ended June 15, 2011. In connection with these amendments, Abbott paid the Company an additional \$4,150 for the research services performed from December 15, 2009 through June 15, 2011.

On December 17, 2010, the Company received a milestone payment of \$40,000 for the successful completion of Abbott's Phase 2a clinical study. Through September 30, 2012, the Company has received upfront license payments, research funding, and milestone payments totaling \$92,450 under the Abbott Agreement. The Company is eligible to receive future milestone payments totaling up to \$55,000 upon Abbott's achievement of clinical trial initiation and regulatory filing milestones for the first protease inhibitor product resulting from its collaboration and additional milestone payments totaling up to \$155,000 upon Abbott's achievement of



**Table of Contents****ENANTA PHARMACEUTICALS, INC****NOTES TO FINANCIAL STATEMENTS (Continued)****(Amounts in thousands, except share and per share data)****8. Collaboration Agreements (Continued)**

commercial regulatory approval milestones in several major markets. The next anticipated clinical milestone payment of \$15,000 will be due to the Company upon Abbott's initiation of dosing in a Phase 3 clinical trial involving ABT-450 (see Note 21). The Company is also eligible to receive additional milestone payments totaling up to \$80,000 upon Abbott's achievement of similar commercial regulatory approval milestones for each additional product containing a protease inhibitor.

The Company determined that the deliverables under the Abbott agreement included (i) the non-exclusive, royalty-free, worldwide research license and the exclusive, royalty-bearing development and commercialization license, (ii) the research services, and (iii) a commitment to participate on a steering committee, all of which were to be delivered over a three-year period. The Company concluded that the license did not have standalone value as it was dependent, in part, upon the Company's continuing involvement in the HCV protease inhibitor research and its involvement in the joint steering committee. Additionally, the undelivered items, including the Company's participation in the joint steering committee, which was considered participatory due to its decision making responsibilities, and the research services, did not have VSOE or VOE of fair value. Therefore, the license, the research services, and the joint steering committee participation were treated as a single unit of accounting. Accordingly, all amounts received were deferred, and revenue was recognized using the proportional performance model over the period during which the Company performed research services in connection with the Abbott Agreement, as amended. Under this model, the revenue recognized was limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the proportional performance model, as of each reporting period. At each reporting period, the Company updated its estimates of effort remaining to complete its obligations under the Abbott Agreement, the expected term over which the obligations would be performed, and the total expected revenue based on all known information. Based on the obligations and responsibilities of the joint steering committee, the Company determined that the obligation to participate in the joint steering committee was participatory only through the research and evaluation period, which ended June 15, 2011. Subsequent to the research and evaluation period, all decisions related to the development, commercialization and marketing are to be made by Abbott. The Company has the right to continue to attend the joint steering committee meetings to monitor the development and marketing plans; however, the Company has no decision making rights. As such, the joint steering committee commitment became protective in nature as of June 16, 2011.

Through September 30, 2009, the Company recognized \$46,017 in revenue under the Abbott Agreement. During fiscal 2010 and 2011, revenue related to the Abbott Agreement was recognized in the amounts of \$6,518 and \$41,882, respectively. In fiscal 2011, the Company completed all remaining obligations under the agreement. As such, no revenue was recognized related to this agreement during the year ended September 30, 2012. Since all obligations under the Abbott Agreement were concluded by the end of fiscal 2011, any future milestone payments received will be recognized as revenue when each milestone is achieved by Abbott.

The Company has the option, but not the obligation, to co-develop and share in the profit of any product in the United States that is developed as a result of the Abbott Agreement. This option for the first compound (ABT-450) expired in fiscal 2011. The Company has no further obligations in regard to the Abbott Agreement and will evaluate future options as they arise.

Royalties owed to the Company under the agreement can be reduced by Abbott in certain circumstances, including (i) if Abbott exercises its right to license or otherwise acquire rights to intellectual property controlled by a third party where a product could not be legally developed or commercialized in a country without the third-party intellectual property right, (ii) where a product developed under the collaboration agreement is sold in a country and not covered by a valid patent claim in such country, and (iii) where sales of a generic product are equal to at least a specified percentage of Abbott's market share of a product in a country.

---

**Table of Contents**

**ENANTA PHARMACEUTICALS, INC**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(Amounts in thousands, except share and per share data)**

**8. Collaboration Agreements (Continued)**

Abbott's obligation to pay royalties on a product developed under the agreement expires on a country-by-country basis upon the later of (i) the last date upon which the manufacture, use or sale of a product would infringe one of the licensed patents, and (ii) ten years after the first commercial sale of the product in the applicable country.

Subject to certain exceptions, a party's rights and obligations under the agreement continues until (i) such time as Abbott is no longer developing a product candidate or (ii) if, as of the time Abbott is no longer developing any product candidates, Abbott is commercializing any other protease inhibitor product, such time as all royalty terms for all covered products and all co-development terms for all co-developed products have ended. Accordingly, the final expiration date of the agreement is currently indeterminable.

Either party may terminate the agreement for cause in the event of a material breach, subject to prior notice and the opportunity to cure, or in the event of the other party's bankruptcy. Additionally, Abbott may terminate the agreement for any reason upon specified prior notice.

If the Company terminates the agreement for cause or Abbott terminates without cause, any licenses and other rights granted to Abbott will terminate and Abbott will be deemed to have granted the Company (i) a non-exclusive, perpetual, fully paid, worldwide, royalty-free license, with the right to sublicense, under Abbott's intellectual property used in any product candidate, and (ii) an exclusive (even as to Abbott), perpetual, fully paid, worldwide, royalty-free license, with the right to sublicense, under Abbott's interest in any joint intellectual property rights to develop product candidates resulting from covered compounds and to commercialize any products derived from such compounds. Upon the Company's request, Abbott will also transfer to the Company all right, title and interest in any related product trademarks, regulatory filings and clinical trials.

If Abbott terminates the agreement for the Company's uncured breach, the milestone and royalty payments payable by Abbott may be reduced, the licenses granted to Abbott will remain in place, the Company will be deemed to have granted Abbott an exclusive license under the Company's interest in joint intellectual property, Abbott will continue to have the right to commercialize any covered products, and all rights and licenses granted to the Company by Abbott will terminate.

**Novartis Collaboration**

On February 16, 2012, the Company entered into a license and collaboration agreement with Novartis (the "Novartis Agreement") for the development, manufacture and commercialization of its lead development candidate, EDP-239, from its NS5A HCV inhibitor program. Under the terms of the Novartis Agreement, Novartis agreed to pay a nonrefundable upfront fee to the Company and reimbursement of manufacturing and quality assurance expenses related to EDP-239 totaling \$34,442. The Company is eligible to receive milestone payments of up to \$406,000 upon Novartis' initiation of clinical trials, achievement of regulatory approvals, and/or net sales of products containing the Company's NS5A inhibitors. The Company is also eligible to receive tiered royalties ranging on a blended basis from the low double digits up to the high teens on net product sales by Novartis allocable to the collaboration's NS5A inhibitors. The first anticipated clinical milestone payment of \$11,000 will be due to the Company upon Novartis' initiation of dosing in a Phase 1 clinical trial involving EDP-239 or another NS5A inhibitor (see Note 21), and an additional milestone payment of \$15,000 will be due upon Novartis' initiation of a subsequent Phase 2 clinical trial using a combination containing an NS5A inhibitor. In addition, Novartis agreed to fund research activities for one year commencing February 2012, up to a total of \$1,800.

The Company determined that the deliverables under the Novartis agreement include (i) the exclusive, royalty-bearing, sublicensable license to EDP-239 and (ii) the research services. The Company concluded that the EDP-239 license had standalone value to Novartis and was separable from the research services as the license



---

**Table of Contents****ENANTA PHARMACEUTICALS, INC****NOTES TO FINANCIAL STATEMENTS (Continued)****(Amounts in thousands, except share and per share data)****8. Collaboration Agreements (Continued)**

is sublicensable, there are no restrictions as to Novartis' use of the license and Novartis has the requisite scientific expertise in the HCV NS5A field. The Company also concluded that its participation on the joint steering committee, as provided by the agreement, is protective in nature as the Company has no decision making authority, there are no penalties or recourse if the Company chooses not to participate, and the purpose of the steering committee is to keep the Company apprised as to the status of the development and commercialization efforts. Therefore, no arrangement consideration was allocated to the joint steering committee participation. The Company was not able to establish VSOE or TPE for either the license or the research services and instead allocated the arrangement consideration between the license and research services based on their relative selling prices using BESP. The Company developed its estimate of BESP of the license using a discounted cash flow analysis, taking into consideration assumptions including the development and commercialization timeline, discount rate, probability of success, and probable treatment combination and associated peak sales figures that generate royalty amounts. The funding rate for the research services is consistent with the rate received in the Company's prior collaboration arrangement with Abbott and is consistent with its fully burdened cost of service. Therefore, the Company's determination of BESP for the research services is consistent with the reimbursement rate stated in the contract. These assumptions involve judgment and inherent uncertainty; however, significant changes in key assumptions used to determine the BESP would not have a significant effect on the total amount of revenue recognized.

The Company received an upfront cash payment of \$34,442 in March 2012 related to the Novartis Agreement. The Company recognized the entire upfront cash receipt as revenue because the allocated selling price of the license deliverable exceeded the upfront noncontingent cash payments received. During the year ended September 30, 2012, the Company recognized total revenue of \$35,567 related to the delivery of the license and the performance of the research services.

Subject to certain exceptions, on a country-by-country and product-by-product basis, a party's rights and obligations under the agreement continue until the later of (i) the expiration of the last to expire patent rights of a covered product in the applicable country or (ii) ten years from the first commercial sale of a covered product in the applicable country. As a result, the final expiration date of the Novartis license is indeterminable at this time. Upon expiration of the agreement with respect to a particular product and country, the licenses granted to Novartis in the agreement with respect to such product and country will remain in effect and convert to a nonexclusive, perpetual, unrestricted, fully paid, royalty-free, worldwide license.

The Company may terminate the agreement (i) in the event of a material breach by Novartis, subject to prior notice and the opportunity to cure, (ii) in the event Novartis fails to use commercially reasonable efforts to develop and commercialize covered products in its territory, or (iii) in the event Novartis is subject to an insolvency event. Novartis may terminate the agreement (i) in the event of a material breach by the Company, subject to prior notice and the opportunity to cure, (ii) in the event the Company is subject to an insolvency event, or (iii) for any reason upon 120 days prior written notice. In the case of a termination for cause by the Company or a termination without cause by Novartis, any licenses and other rights granted by either party to the other will terminate and revert back to the granting party and the Company will regain control of the prosecution of the patents relating to the Company's intellectual property. If such termination occurs prior to the second anniversary of the end of the research term, the Company retains exclusive worldwide rights, with the right to sublicense under all collaboration intellectual property owned in whole or in part by Novartis, to research, develop and commercialize compounds and products contemplated by the collaboration. If such termination occurs after the second anniversary of the end of the research term, then Novartis agrees to negotiate with the Company to grant it a worldwide, exclusive, field-limited, royalty-bearing license, with right to sublicense, under all collaboration intellectual property owned in whole or in part by Novartis.

---

**Table of Contents**

**ENANTA PHARMACEUTICALS, INC**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(Amounts in thousands, except share and per share data)**

**8. Collaboration Agreements (Continued)**

**NIAID Contract**

On September 30, 2011, the Company entered into a contract with the National Institute of Allergy and Infectious Diseases ( NIAID ), a division of the National Institutes of Health ( NIH ), which could provide up to \$42,700 in development funding to the Company over a five-year period. The award will fund the preclinical and clinical development of a new class of bridged bicyclic antibiotics known as Bicyclolides to be used as medical countermeasures against multiple biodefense Category A and B bacteria.

The contract has an initial term of 30 months ending on March 30, 2014. NIAID has the option to extend the contract up to six times. If each extension option is exercised, the contract would be extended until September 30, 2016. The initial award under the initial term was \$14,300, with the possibility of up to a total of \$42,700 if each option period is exercised by NIAID.

The Company recognizes revenue under this agreement as development services are performed in accordance with the funding agreement. During the year ended September 30, 2012, \$6,139 of revenue was recognized under this agreement, of which \$1,049 was invoiced but unpaid and included in accounts receivable and \$1,668 was unpaid and included in unbilled receivables on the Company's balance sheet as of September 30, 2012.

NIAID may terminate performance of work under this contract if it determines that a termination is in the government's interest or if the Company defaults in performing the contract. After termination, the Company would submit a final termination settlement proposal in order to settle all outstanding liabilities, including those arising from the termination of subcontracts, the cost of which would be reimbursable in whole or in part, under this contract, contingent on approval by NIAID. If the Company and NIAID fail to agree in whole or in part on the amount of costs to be paid because of the termination of work, NIAID shall determine, on the basis of information available, the amount to be repaid.

**Concluded Collaboration**

The Company had a license and option agreement, entered into in 2004, with a collaborator to develop and commercialize EP-013420, the Company's first-in-class Bicyclolide antibiotic for the treatment of community respiratory tract infections, in Japan and certain East Asian countries. The Company also entered into a supply agreement as well as a cost-sharing agreement with the collaborator during that same calendar year. Due to a technology option within the license agreement for which the Company was not able to establish objective evidence of fair value, all payments received from this agreement were recorded as deferred revenue until such time as the option was exercised or the agreement was terminated.

On March 31, 2010, the agreement was terminated. Upon conclusion of the agreement, all previously deferred revenue was recognized as the Company had no further obligations in regard to the collaborative agreement. Accordingly, during the year ended September 30, 2010, the Company recorded revenue totaling \$16,245, comprised of \$13,000 related to upfront and milestone payments received under the license and option agreement, \$1,461 related to the supply agreement, and \$1,784 related to the cost-sharing agreement.

On June 18, 2004, the Company also entered into a Series F preferred stock purchase agreement with this same collaborator (see Note 9).

**9. Redeemable Convertible Preferred Stock**

The Company's Certificate of Incorporation, as amended, authorizes the Company to issue 58,987,738 shares of \$0.01 par value preferred stock, inclusive of redeemable convertible preferred stock and convertible preferred stock.





**Table of Contents****ENANTA PHARMACEUTICALS, INC****NOTES TO FINANCIAL STATEMENTS (Continued)**

(Amounts in thousands, except share and per share data)

**9. Redeemable Convertible Preferred Stock (Continued)**

The Company has issued Series C, Series D, Series E, Series F, Series G-1 and Series G-2 redeemable convertible preferred stock (collectively, the Redeemable Preferred Stock). The Redeemable Preferred Stock is classified outside of stockholders' deficit because the shares contain redemption features that are not solely within the control of the Company.

Redeemable Preferred Stock consisted of the following as of September 30, 2011:

	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Liquidation Preference	Carrying Value	Common Stock Issuable Upon Conversion
Series C redeemable convertible preferred stock	2,543,603	2,543,603	\$ 8,244	\$ 8,244	2,543,603
Series D redeemable convertible preferred stock	5,968,334	5,968,334	36,311	36,311	7,990,551
Series E redeemable convertible preferred stock	16,132,546	14,368,037	62,890	62,890	18,905,304
Series F redeemable convertible preferred stock	6,894,966	6,894,966	15,000	15,000	6,894,966
Series G-1 redeemable convertible preferred stock	4,729,543	4,620,764	12,500	12,173	4,620,764
Series G-2 redeemable convertible preferred stock	9,152,296	8,719,639	18,970	18,970	8,719,639
	45,421,288	43,115,343	\$ 153,915	\$ 153,588	49,674,827

Redeemable Preferred Stock consisted of the following as of September 30, 2012:

	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Liquidation Preference	Carrying Value	Common Stock Issuable Upon Conversion
Series C redeemable convertible preferred stock	2,543,603	2,543,603	\$ 8,551	\$ 8,551	2,543,603
Series D redeemable convertible preferred stock	5,968,334	5,968,334	37,922	37,922	7,990,551
Series E redeemable convertible preferred stock	16,132,546	14,368,037	66,136	66,136	18,905,304
Series F redeemable convertible preferred stock	6,894,966	6,894,966	15,000	15,000	6,894,966
Series G-1 redeemable convertible preferred stock	4,729,543	4,620,764	12,500	12,376	4,620,764
Series G-2 redeemable convertible preferred stock	9,152,296	8,719,639	18,970	18,970	8,719,639
	45,421,288	43,115,343	\$ 159,079	\$ 158,955	49,674,827

The holders of the Redeemable Preferred Stock have the following rights and preferences:

**Voting Rights**

Holders of all Redeemable Preferred Stock have the right to vote the number of shares equal to the number of shares of common stock into which such Redeemable Preferred Stock could be converted into on the date for determination of stockholders entitled to vote at a meeting or on the date of any written consent.

**Dividends**

Holders of the Series C redeemable convertible preferred stock, Series D redeemable convertible preferred stock and Series E redeemable convertible preferred stock are entitled to receive, out of funds legally available, cumulative dividends at an annual rate of 7%, 9% and 9%, respectively, when and if declared by the board of directors. Holders of the Series F redeemable convertible preferred stock and Series G-1 and G-2 redeemable convertible preferred stock are entitled to receive, out of funds legally available, noncumulative dividends at an annual rate of 7%, if declared by the board of directors. No dividends have been declared or paid through September 30, 2012.

---

**Table of Contents**

**ENANTA PHARMACEUTICALS, INC**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(Amounts in thousands, except share and per share data)**

**9. Redeemable Convertible Preferred Stock (Continued)**

The Company recorded cumulative dividends and accretion to redemption value through charges to stockholders' deficit of \$5,452, \$5,454 and \$5,367 in fiscal 2010, 2011 and 2012, respectively, in connection with these dividend and redemption rights.

**Liquidation Preference**

In the event of any liquidation, dissolution or winding up of the Company, inclusive of a sale of the Company, a sale of the capital stock representing a majority of the voting power or a merger or consolidation of the Company into or with another corporation in which the existing Company holds less than 80% of the voting power of the surviving or resulting corporation, the Series E, Series F and Series G-1 and G-2 redeemable convertible preferred stockholders are entitled to receive, in preference to all other stockholders, except for holders of Series 1 Nonconvertible Preferred stock, and to the extent available, an amount equal to the original offering price per share (\$2.51, \$2.1755, \$2.70518 and \$2.1755, respectively, adjusted for any stock dividends, stock splits or reclassifications) plus all dividends declared but unpaid. Holders of Series E redeemable convertible preferred stock receive with their preference all cumulative dividends, whether or not declared. In the event that proceeds are not sufficient to permit payment in full to these holders, the proceeds will be ratably distributed among Series E, F, G-1 and G-2 holders in proportion to the full preferential amount each such holder is otherwise entitled to receive.

After the Series E, Series F and Series G-1 and G-2 redeemable convertible preferred stockholders have been paid, and to the extent available, the Series D redeemable convertible preferred stockholders are entitled to receive, in preference to all other stockholders, an amount equal to the original offering price per share (\$3.00, adjusted for any stock dividends, stock splits or reclassifications) plus all cumulative Series D dividends, whether or not declared.

After the Series D redeemable convertible preferred stockholders have been paid, and to the extent available, the Series C redeemable convertible preferred stockholders are entitled to receive an amount equal to the original offering price per share (\$1.72, adjusted for any stock dividends, stock splits or reclassifications) plus all cumulative Series C dividends, whether or not declared.

After payments have been made in full to the Series 1 Nonconvertible Preferred stockholders, if any, to the holders of the Series G-1, Series G-2, Series F, Series E, Series D and Series C redeemable convertible preferred stock and to the holders of the Series B and Series A convertible preferred stock, to the extent available, holders of the common stock and holders of the Series C, Series D and Series E redeemable convertible preferred stock will receive the remaining amounts available for distribution ratably in proportion to the number of common shares held by them or issuable to them upon conversion of their preferred stock into common stock. The distributions are subject to an overall distribution limit of two times the original purchase price per share of the Series C, Series D and Series E redeemable convertible preferred stock.

**Conversion**

Each share of Redeemable Preferred Stock is convertible into common stock at the option of the stockholder at any time after the date of issuance. Each share of the preferred stock will automatically be converted into shares of common stock at the applicable Series C, Series D, Series E, Series F and Series G-1 and G-2 redeemable convertible preferred stock conversion rates then in effect upon a qualified public offering with gross proceeds of not less than \$25,000, as amended. The conversion rate of the Series C, Series D, Series E, Series F and Series G-1 and G-2 redeemable convertible preferred stock as defined is \$1.72, \$3.00, \$2.51, \$2.1755, \$2.70518 and \$2.1755, respectively, (subject to adjustment for stock dividends, stock splits, recapitalizations, or similar events) divided by the conversion price. The conversion prices of Series C, Series D, Series E, Series F,

**Table of Contents****ENANTA PHARMACEUTICALS, INC****NOTES TO FINANCIAL STATEMENTS (Continued)**

(Amounts in thousands, except share and per share data)

**9. Redeemable Convertible Preferred Stock (Continued)**

Series G-1 and G-2 redeemable convertible preferred stock as of September 30, 2012 were \$1.72, \$2.24077, \$1.9076, \$2.1755, \$2.70518 and \$2.1755, respectively, and are subject to adjustments as set forth in the Company's Certificate of Incorporation, as amended. As a result, as of September 30, 2012, all outstanding shares of Series D redeemable convertible preferred stock were convertible into common stock on a 1.33883-for-1 basis, all outstanding shares of Series E redeemable convertible preferred stock were convertible into common stock on a 1.31579-for-1 basis, and all outstanding shares of Series C, Series F, Series G-1 and G-2 redeemable convertible preferred stock were convertible into common stock on a 1-for-1 basis.

**Redemption Rights**

At the written election of the majority of the holders of the Series C, Series D, Series E, Series F or Series G-1 and G-2 redeemable convertible preferred stock, the shares of Series C, Series D, Series E, Series F and Series G-1 and G-2 redeemable convertible preferred stock outstanding as of September 30, 2012 are redeemable as follows:

	Redemption Dates	Number of shares	Redemption Price Per Share	Accrued Dividends	Redemption Value at Redemption Dates
Series C redeemable convertible preferred stock	December 31, 2013	847,868	\$ 1.72	\$ 1,520	\$ 2,978
Series C redeemable convertible preferred stock	December 31, 2014	847,868	1.72	1,622	3,080
Series C redeemable convertible preferred stock	December 31, 2015	847,867	1.72	1,724	3,182
Series D redeemable convertible preferred stock	December 31, 2013	1,989,445	3.00	7,347	13,315
Series D redeemable convertible preferred stock	December 31, 2014	1,989,445	3.00	7,884	13,852
Series D redeemable convertible preferred stock	December 31, 2015	1,989,444	3.00	8,421	14,389
Series E redeemable convertible preferred stock	December 31, 2013	4,789,346	2.51	11,382	23,403
Series E redeemable convertible preferred stock	September 1, 2014	4,789,346	2.51	12,105	24,126
Series E redeemable convertible preferred stock	September 1, 2015	4,789,345	2.51	13,187	25,208
Series F redeemable convertible preferred stock	September 1, 2015	2,298,322	2.18		5,000
Series F redeemable convertible preferred stock	September 1, 2016	2,298,322	2.18		5,000
Series F redeemable convertible preferred stock	September 1, 2017	2,298,322	2.18		5,000
Series G-1 redeemable convertible preferred stock	January 1, 2018	1,540,255	2.71		4,167
Series G-1 redeemable convertible preferred stock	January 1, 2019	1,540,255	2.71		4,167
Series G-1 redeemable convertible preferred stock	January 1, 2020	1,540,254	2.71		4,167
Series G-2 redeemable convertible preferred stock	January 1, 2018	2,906,546	2.18		6,323
Series G-2 redeemable convertible preferred stock	January 1, 2019	2,906,546	2.18		6,323
Series G-2 redeemable convertible preferred stock	January 1, 2020	2,906,547	2.18		6,323
					\$ 170,003

If any redeemable convertible preferred stockholder does not elect to redeem the redeemable convertible preferred stock on any redemption date, the stockholder may elect to have all shares redeemed on any subsequent redemption date or on December 31 of any year after 2015 for Series C and Series D redeemable convertible preferred stock, September 1 of any year after 2015 for Series E redeemable convertible preferred stock, September 1 of any year after 2017 for Series F redeemable convertible preferred stock, and January 1 of any year after 2020 for Series G-1 and G-2 redeemable convertible preferred stock, provided that no stockholder may request redemption of any shares of Series C, Series D, Series F or Series G redeemable convertible preferred stock if any shares of Series E redeemable convertible preferred stock remain outstanding. The Company must redeem the stock within 60 days of such election made by the preferred stockholder.

Edgar Filing: ENANTA PHARMACEUTICALS INC - Form S-1/A

The carrying values of the Series C, Series D, Series E, Series F and Series G-1 and G-2 redeemable convertible preferred stock are being accreted to their redemption values through the respective redemption dates.

F-28

**Table of Contents****ENANTA PHARMACEUTICALS, INC****NOTES TO FINANCIAL STATEMENTS (Continued)****(Amounts in thousands, except share and per share data)****9. Redeemable Convertible Preferred Stock (Continued)**

The following table summarizes the aggregate amount of the Redeemable Preferred Stock that becomes redeemable in each respective fiscal year:

<b>Year ending September 30,</b>	
2013	\$
2014	63,822
2015	47,140
2016	22,571
2017	5,000
Thereafter	31,470
<b>Total redemption amount</b>	<b>\$ 170,003</b>

**Reissuance**

Shares of any Series C, Series D, Series E, Series F or Series G-1 or G-2 redeemable convertible preferred stock that are redeemed or converted will be retired or canceled and not reissued by the Company.

**10. Convertible Preferred Stock**

The Company has outstanding Series A convertible preferred stock with a par value of \$0.01 and Series B convertible preferred stock with a par value of \$0.01 (collectively, the Convertible Preferred Stock ).

Convertible Preferred Stock consisted of the following as of September 30, 2011 and 2012:

	<b>Preferred Shares Authorized</b>	<b>Preferred Shares Issued and Outstanding</b>	<b>Liquidation Preference</b>	<b>Carrying Value</b>	<b>Common Stock Issuable Upon Conversion</b>
Series A convertible preferred stock	379,450	379,450	\$ 140	\$ 140	379,450
Series B convertible preferred stock	187,000	187,000	187	187	187,000
	566,450	566,450	\$ 327	\$ 327	566,450

The holders of the Convertible Preferred Stock have the following rights and preferences:

**Voting Rights**

Holders of all Convertible Preferred Stock have the right to vote the number of shares equal to the number of shares of common stock into which such preferred shares could be converted into on the date for determination of stockholders entitled to vote at a meeting or on the date of any written consent.

**Dividends**

If dividends are declared and paid on the shares of Series A or Series B convertible preferred stock, the Company must declare at the same time a dividend payable with respect to the Series C, Series D, Series E, Series F, Series G-1 and G-2 redeemable convertible preferred stock equivalent to the dividend amount they would receive if all convertible preferred shares were converted into common stock. The Company may not pay dividends to the holders of the Series A and Series B convertible preferred stock until all cumulative dividends accrued but unpaid on Series C, Series D, Series E, Series F, Series G-1 and G-2 redeemable convertible preferred stock have been paid in full. Holders of the Series A and B convertible preferred stock are not entitled to receive cumulative dividends.

**Table of Contents**

**ENANTA PHARMACEUTICALS, INC**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(Amounts in thousands, except share and per share data)**

**10. Convertible Preferred Stock (Continued)**

**Liquidation Preference**

In the event of any liquidation, dissolution or winding up of the Company, inclusive of a deemed liquidation (defined as a sale of the Company, a sale of the capital stock representing a majority of the voting power, or a merger or consolidation of the Company into or with another corporation of the Company in which the existing Company holds less than 80% of the voting power of the surviving or resulting corporation), after the holders of the Series 1 Nonconvertible Preferred stock, if any, and Redeemable Preferred Stock have been paid, and to the extent available, holders of Series A and Series B convertible preferred stock are entitled to receive an amount equal to the original offering price per share (\$0.37 for Series A convertible preferred stock and \$1.00 for Series B convertible preferred stock, adjusted for any stock dividends, stock splits or reclassifications) plus all dividends declared but unpaid.

**Conversion**

Each share of Convertible Preferred Stock is convertible into common stock at the option of the stockholder at any time after the date of issuance. Each share of the convertible preferred stock will automatically be converted into shares of common stock at the applicable conversion rates then in effect upon a qualified public offering with gross proceeds of not less than \$25,000, as amended. All outstanding shares of Series A and Series B convertible preferred stock are convertible into common stock on a 1-for-1 basis.

**Redemption Rights**

There are no redemption rights afforded the Series A and Series B convertible preferred stockholders. The Series A and Series B convertible preferred stockholders have liquidation rights in the event of a deemed liquidation that, in certain situations, is not solely within the control of the Company. Therefore, the Series A and Series B convertible preferred stock is classified outside of stockholders' deficit.

**Reissuance**

Shares of any Series A or Series B convertible preferred stock that are converted into common stock will be retired or canceled and not reissued by the Company.

**Series 1 Nonconvertible Preferred Stock**

In October 2010, the Company amended its Certificate of Incorporation to authorize 13,000,000 shares of Series 1 Nonconvertible Preferred Stock (the Series 1 Nonconvertible Preferred) at a par value of \$0.01 per share. As of September 30, 2011 and 2012, there were no shares of Series 1 Nonconvertible Preferred issued or outstanding. Holders of Series 1 Nonconvertible Preferred stock are not entitled to receive dividends. In the event of any liquidation, deemed liquidation, dissolution or winding up of the Company, the Series 1 Nonconvertible Preferred stockholders are entitled to receive in preference to all other stockholders, an amount equal to \$1.00 per share, adjusted for any stock dividends, stock splits or reclassifications. Series 1 Nonconvertible Preferred holders will not be entitled to vote unless required by the Company pursuant to the laws of the State of Delaware. The Company may redeem the Series 1 Nonconvertible Preferred stock with the approval of the holders of a majority of the outstanding shares of Series 1 Nonconvertible Preferred at a redemption price of \$1.00 per share. The Company must redeem the stock within 60 days of such election. Shares that are redeemed will be retired or canceled and not reissued by the Company.

If all outstanding warrants to purchase the Series 1 Nonconvertible Preferred stock are exercised, the resulting outstanding shares of Series 1 Nonconvertible Preferred stock will carry an aggregate liquidation preference of \$2,000 that is superior to all other classes of preferred stock.





---

**Table of Contents**

**ENANTA PHARMACEUTICALS, INC**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(Amounts in thousands, except share and per share data)**

**11. Common Stock**

The Company's Certificate of Incorporation, as amended, authorizes the Company to issue 70,000,000 shares of \$0.01 par value common stock.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any, subject to the preferential dividend rights of the Series A and Series B convertible preferred stockholders and of the Series C, Series D, Series E, Series F and Series G-1 and G-2 redeemable convertible preferred stockholders. When dividends are declared on shares of common stock, the Company must declare at the same time a dividend payable to the holders of Convertible Preferred Stock and Redeemable Preferred Stock equivalent to the dividend amount they would receive if each preferred share were converted into common stock. The Company may not pay dividends to common stockholders until all dividends accrued or declared but unpaid on the Convertible Preferred Stock and the Redeemable Preferred Stock have been paid in full. As of September 30, 2011 and 2012, no dividends had been declared.

As of September 30, 2012, the Company had reserved 57,893,031 shares of common stock for the conversion of the Series A, Series B, Series C, Series D, Series E, Series F, Series G-1 and Series G-2 preferred stock (see Notes 9 and 10) and for the exercise of outstanding common stock options (see Note 14) and warrants for the purchase of Series E preferred stock (see Note 13).

During the year ended September 30, 2011, the Company reacquired 590,000 shares of restricted common stock that were forfeited by former employees. The Company recorded these shares as treasury stock at their par value.

**12. Common Stock Warrants**

As of September 30, 2010, warrants to purchase 1,491,055 shares of common stock were outstanding. The value of these warrants was classified as equity as these warrants were exercisable into common stock only and, as such, would not require a transfer of assets. In October 2010, these warrants expired unexercised. As a result, as of September 30, 2011 and 2012, no common stock warrants are outstanding.

**13. Preferred Stock Warrants**

**Warrants to Purchase Series E Preferred Stock**

Warrants for the purchase of Series E redeemable convertible preferred stock (Series E preferred stock) were issued by the Company in fiscal 2002 and fiscal 2004 during various financings. As these warrants are financial instruments that may require a transfer of assets because of the redemption feature at the option of the holders of the Series E preferred stock, these warrants are classified as liabilities on the Company's balance sheet.

As of September 30, 2011, warrants for the purchase of 341,556 shares of Series E preferred stock were outstanding. During the year ended September 30, 2012, warrants for the purchase of 329,056 shares expired. As of September 30, 2012, warrants for the purchase of 12,500 shares of Series E preferred stock remained outstanding and are due to expire in December 2012.

The Company is required to remeasure the fair value of these preferred stock warrants at each reporting date, with any adjustments recorded as other income (expense). The warrants outstanding at each reporting date were remeasured using the Black-Scholes option-pricing model, and the resulting change in fair value was recorded in other income (expense) in the statement of operations. As a result, the Company recorded income of \$482 and \$18 for the years ended September 30, 2010 and 2011, respectively, and expense of \$19 for the year ended September 30, 2012, related to the change in fair value of the warrants. The Company also recorded income of \$8 for the year ended September 30, 2012 related to

the expiration of 329,056 warrants. As of September 30, 2012, the total fair value of the outstanding Series E preferred stock warrants was \$20.

F-31

**Table of Contents****ENANTA PHARMACEUTICALS, INC****NOTES TO FINANCIAL STATEMENTS (Continued)****(Amounts in thousands, except share and per share data)****13. Preferred Stock Warrants (Continued)****Warrants to Purchase Series 1 Preferred Stock**

In October and November 2010, a total of 1,999,989 warrants to purchase Series 1 nonconvertible preferred stock were issued. These warrants expire on October 4, 2017. As these warrants are free-standing financial instruments that may require the Company to transfer assets upon exercise, these warrants are classified as liabilities. These warrants had a fair value upon issuance of \$1,280. The Company is required to remeasure the fair value of these preferred stock warrants at each reporting date, with any adjustments recorded within the change in fair value of warrant liability included in other income (expense) in the statement of operations. The warrants were remeasured at each reporting period, resulting in net expense of \$704 and income of \$3 for the years ended September 30, 2011 and 2012, respectively. As of September 30, 2011 and 2012, the total fair value of the Series 1 nonconvertible preferred stock warrants was \$1,984 and \$1,981, respectively.

The following table summarizes the Company's warrant activity since October 1, 2009:

	Common Stock Exercisable	Weighted Average Exercise Price	Series E Preferred Stock Exercisable	Weighted Average Exercise Price	Series 1 Preferred Stock Exercisable	Weighted Average Exercise Price
<b>Outstanding, as of October 1, 2009</b>	1,491,055	\$ 1.95	341,556	\$ 2.51		N/A
Granted						
Expired						
Exercised						
<b>Outstanding, as of September 30, 2010</b>	1,491,055	\$ 1.95	341,556	\$ 2.51		N/A
Granted					1,999,989	
Expired	(1,491,055)					
Exercised						
<b>Outstanding, as of September 30, 2011</b>		N/A	341,556	\$ 2.51	1,999,989	\$ 0.01
Granted						
Expired			(329,056)			
Exercised						
<b>Outstanding, as of September 30, 2012</b>		N/A	12,500	\$ 2.51	1,999,989	\$ 0.01

**14. Stock-Based Awards  
1995 Equity Incentive Plan**

In fiscal 1995, the Company's board of directors adopted the 1995 Equity Incentive Plan (the "1995 Plan"). The 1995 Plan provides for the Company to sell or issue common stock or restricted common stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, members of the board of directors and consultants of the Company. Sales, issuances or grants of shares entitle the holder to purchase common stock from the Company, for a specified exercise price, during a period specified by the applicable

## Edgar Filing: ENANTA PHARMACEUTICALS INC - Form S-1/A

equity award agreement. The 1995 Plan is administered by the board of directors and exercise prices, vesting and other restrictions are all determined at their discretion.

Options granted under the 1995 Plan to non-executive employees generally vest 25% per year and expire after ten years; options granted to executive employees generally vest over one to four years; and options granted to the board of directors vest over a two-year period. On April 29, 2010, the board of directors voted to transfer

F-32

**Table of Contents****ENANTA PHARMACEUTICALS, INC****NOTES TO FINANCIAL STATEMENTS (Continued)****(Amounts in thousands, except share and per share data)****14. Stock-Based Awards (Continued)**

493,018 issuable shares to the 1995 Plan from a prior plan that was terminated. The total number of shares of common stock that may be issued under the 1995 Plan is 10,950,673 shares as of September 30, 2012, of which 613,844 shares remain available for future grant.

The Company currently grants stock-based awards with employment service conditions only ( service-based awards). The Company applies the fair value recognition provisions for all stock-based awards granted or modified and records compensation costs over the requisite service period of the award based on the grant-date fair value. The straight-line method is applied to all service-based awards granted. The requisite service period for service-based awards is generally four years, with restrictions lapsing evenly over the period.

**Stock Option Valuation**

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company historically has been a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of its publicly traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the simplified method for awards that qualify as plain-vanilla options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future. The relevant data used to determine the value of the stock option grants is as follows, presented on a weighted average basis:

	<b>Year Ended September 30,</b>		
	<b>2010</b>	<b>2011</b>	<b>2012</b>
Risk-free interest rate	2.57%	2.73%	0.93%
Expected term (in years)	6.25	6.25	6.00
Expected volatility	66%	87%	78%
Expected dividend yield	0%	0%	0%

The Company recognizes compensation expense for only the portion of awards that are expected to vest. In developing a forfeiture rate estimate, the Company has considered its historical experience to estimate pre-vesting forfeitures for service-based awards. The impact of a forfeiture rate adjustment will be recognized in full in the period of adjustment, and if the actual forfeiture rate is materially different from the Company's estimate, the Company may be required to record adjustments to stock-based compensation expense in future periods.

As required by the 1995 Plan, the exercise price for awards granted is not to be less than the fair value of common shares as estimated by the Company as of the date of grant. The Company values its common stock by taking into consideration its most recently available valuation of common shares performed by management and the board of directors as well as additional factors which may have changed since the date of the most recent contemporaneous valuation through the date of grant.

**Table of Contents****ENANTA PHARMACEUTICALS, INC****NOTES TO FINANCIAL STATEMENTS (Continued)**

(Amounts in thousands, except share and per share data)

**14. Stock-Based Awards (Continued)**

The following table summarizes stock option activity for the years ended September 30, 2010, 2011 and 2012:

	Shares Issuable Under Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In years)	Aggregate Intrinsic Value
<b>Outstanding as of October 1, 2009</b>	8,313,881	\$ 0.34		
Granted	654,200	0.28		
Exercised	(43,905)	0.34		
Forfeited	(181,851)	0.42		
Expired	(1,074,500)	0.49		
<b>Outstanding as of September 30, 2010</b>	7,667,825	\$ 0.31		
Granted	824,313	0.59		
Exercised	(70,873)	0.47		
Forfeited	(554,181)	0.52		
Expired	(150,313)	0.60		
<b>Outstanding as of September 30, 2011</b>	7,716,771	\$ 0.32	4.6	\$ 2,181
Granted	513,500	2.73		
Exercised	(505,379)	0.28		
Forfeited	(36,585)	0.42		
Expired	(53,000)	0.60		
<b>Outstanding as of September 30, 2012</b>	7,635,307	\$ 0.48	4.1	\$ 19,928
<b>Options vested and expected to vest as of September 30, 2012</b>	7,562,793	\$ 0.47	4.0	\$ 19,833
<b>Options exercisable as of September 30, 2012</b>	6,723,726	\$ 0.32	3.4	\$ 18,625

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the options and the deemed fair value of the Company's common stock for those shares that had exercise prices lower than the deemed fair value of the Company's common stock. The aggregate intrinsic value of stock options exercised was \$2, \$10 and \$606 during the years ended September 30, 2010, 2011 and 2012, respectively.

The Company received cash proceeds from the exercise of stock options of \$15, \$34 and \$141 during the years ended September 30, 2010, 2011 and 2012, respectively. The weighted average grant date fair value of options granted during September 30, 2010, 2011 and 2012 was \$0.17, \$0.45 and \$1.81, respectively.

The Company recorded stock-based compensation expense for the years ended September 30, 2010, 2011 and 2012 in the following expense categories:

	Year Ended September 30,		
	2010	2011	2012
Research and development	\$ 57	\$ 66	\$ 126
General and administrative	202	159	298
	\$ 259	\$ 225	\$ 424

The Company had an aggregate of \$635 of unrecognized stock-based compensation cost as of September 30, 2012, which is expected to be recognized over a weighted average period of 2.9 years.



**Table of Contents****ENANTA PHARMACEUTICALS, INC****NOTES TO FINANCIAL STATEMENTS (Continued)****(Amounts in thousands, except share and per share data)****15. Net Income Per Share and Unaudited Pro Forma Net Income Per Share  
Net Income Per Share**

Basic and diluted net income per share allocable to common stockholders was calculated as follows for the years ended September 30, 2010, 2011 and 2012:

	Year Ended September 30,		
	2010	2011	2012
<b>Basic net income per share allocable to common stockholders:</b>			
<b>Numerator:</b>			
Net income	\$ 7,904	\$ 23,310	\$ 21,399
Accretion of redeemable convertible preferred stock to redemption value	(5,452)	(5,454)	(5,367)
Net income allocable to participating securities	(2,236)	(16,291)	(14,663)
<b>Net income allocable to common stockholders</b>	<b>\$ 216</b>	<b>\$ 1,565</b>	<b>\$ 1,369</b>
<b>Denominator:</b>			
Weighted average common shares outstanding basic	4,873,295	4,823,966	4,692,657
<b>Net income per share allocable to common stockholders basic</b>	<b>\$ 0.04</b>	<b>\$ 0.32</b>	<b>\$ 0.29</b>
<b>Diluted net income per share allocable to common stockholders:</b>			
<b>Numerator:</b>			
Net income	\$ 7,904	\$ 23,310	\$ 21,399
Accretion of redeemable convertible preferred stock to redemption value	(5,452)	(5,454)	(5,367)
Net income allocable to participating securities	(2,163)	(15,401)	(13,225)
<b>Net income allocable to common stockholders diluted</b>	<b>\$ 289</b>	<b>\$ 2,455</b>	<b>\$ 2,807</b>
<b>Denominator:</b>			
Weighted average common shares outstanding basic	4,873,295	4,823,966	4,692,657
Dilutive effect of common stock equivalents	1,873,155	3,180,880	5,973,831
<b>Weighted average common shares outstanding diluted</b>	<b>6,746,450</b>	<b>8,004,846</b>	<b>10,666,488</b>
<b>Net income per share allocable to common stockholders diluted</b>	<b>\$ 0.04</b>	<b>\$ 0.31</b>	<b>\$ 0.26</b>

Stock options for the purchase of 7,227,009, 2,562,096 and 143,780 weighted average shares were excluded from the computation of diluted net income per share allocable to common stockholders for the years ended September 30, 2010, 2011 and 2012, respectively, because those options had an anti-dilutive impact due to the assumed proceeds per share using the treasury stock method being greater than the average fair value of the Company's common shares for those periods.

Warrants outstanding as of September 30, 2010 for the purchase of 1,491,055 shares of common stock were excluded from the calculation of diluted net income per share allocable to common stockholders for the year ended September 30, 2010 because those warrants had an anti-dilutive impact due to the assumed proceeds per share using the treasury stock method being greater than the average fair value of the

## Edgar Filing: ENANTA PHARMACEUTICALS INC - Form S-1/A

Company's common shares for that year. Warrants outstanding as of September 30, 2010 and 2011 for the purchase of 341,556 shares of Series E preferred stock were also excluded from the calculations of diluted net income per share allocable to common stockholders for the years ended September 30, 2010 and 2011 because those warrants had an anti-dilutive impact due to the assumed proceeds per share using the treasury stock method being greater than the average fair value of the Company's common shares for those respective years.

F-35

**Table of Contents****ENANTA PHARMACEUTICALS, INC****NOTES TO FINANCIAL STATEMENTS (Continued)****(Amounts in thousands, except share and per share data)****15. Net Income Per Share and Unaudited Pro Forma Net Income Per Share (Continued)****Unaudited Pro Forma Net Income Per Share**

The unaudited pro forma basic and diluted net income per share allocable to common stockholders for the year ended September 30, 2012 gives effect to adjustments arising upon the closing of a qualified initial public offering. The unaudited pro forma net income allocable to common stockholders used in the calculation of unaudited basic and diluted pro forma net income per share allocable to common stockholders does not include the effects of the accretion to redemption value of the redeemable convertible preferred stock and the allocation of net income to participating securities because it assumes that the conversion of the redeemable convertible preferred stock and the convertible preferred stock into common stock had occurred on October 1, 2011. The unaudited pro forma net income allocable to common stockholders has also been adjusted to remove the remeasurement loss recorded on the warrants for Series E redeemable convertible preferred stock because it assumes that the outstanding warrants for the Series E convertible preferred stock were converted into warrants for common stock and that the common stock warrants are classified as equity, and it assumes the conversion had occurred on October 1, 2011.

The unaudited pro forma basic and diluted weighted average common shares outstanding used in the calculation of unaudited basic and diluted pro forma net income per share allocable to common stockholders has been adjusted to reflect the issuance of common stock upon the automatic conversion of all outstanding shares of redeemable convertible preferred stock and convertible preferred stock upon an initial public offering as well as the conversion of the outstanding warrants for Series E redeemable convertible preferred stock into warrants for the purchase of common stock, assuming each such conversion had occurred on October 1, 2011.

The computation of pro forma net income per share allocable to common stockholders is as follows:

	<b>Year Ended September 30, 2012 (unaudited)</b>
<b>Numerator:</b>	
Net income	\$ 21,399
Change in fair value of warrant liability	11
Pro forma net income allocable to common stockholders	\$ 21,410
<b>Denominator:</b>	
Weighted average number of common shares outstanding	4,692,657
Pro forma adjustment for assumed conversion of redeemable convertible preferred stock and convertible preferred stock to common stock upon the closing of the proposed initial public offering	50,241,277
Pro forma weighted average common shares outstanding basic	54,933,934
Dilutive impact of outstanding common stock equivalents	5,976,155
Pro forma weighted average common shares outstanding diluted	60,910,089
<b>Pro forma net income per share allocable to common stockholders:</b>	
Basic	\$ 0.39

Diluted

\$

0.35

F-36

**Table of Contents****ENANTA PHARMACEUTICALS, INC****NOTES TO FINANCIAL STATEMENTS (Continued)****(Amounts in thousands, except share and per share data)****16. Commitments and Contingencies****Leases**

The Company leased office space in Watertown, Massachusetts under a ten-year lease that expired at the end of September 2011. During the year ended September 30, 2011, the Company signed a seven-year lease for new office space that began on October 1, 2011. Both leases provided for payment escalations during the terms of the leases. Payment escalations as specified in the lease agreements are accrued such that rent expense is recognized on a straight-line basis over the terms of occupancy. The Company incurred rent expense of \$2,030, \$1,995 and \$948, respectively, for the years ended September 30, 2010, 2011 and 2012.

Future minimum lease payments for operating leases as of September 30, 2012 are as follows:

<b>Year ending September 30,</b>	
2013	\$ 897
2014	921
2015	946
2016	972
2017	999
Thereafter	1,027
<b>Total</b>	<b>\$ 5,762</b>

In connection with the prior office lease, the Company issued a \$1,140 letter of credit through November 2011 to the benefit of the landlord, collateralized by a certificate of deposit. On December 2, 2011, the landlord released the letter of credit to the Company. In connection with the new lease, the Company issued a \$436 letter of credit, collateralized by a money market account. As of September 30, 2011 and 2012, the Company classified amounts of \$1,576 and \$436, respectively, as restricted cash relating to these leases.

**Intellectual Property License**

During the year ended September 30, 2012, in response to correspondence the Company received from a third party related to assets the Company used or may have used in prior periods, the Company entered into a non-exclusive intellectual property license agreement with the third party. Under the agreement, the Company is required to pay the third-party licensor an upfront license fee of \$350 and additional license fees of \$250 on the first anniversary, \$250 on the second anniversary and \$200 on the third anniversary of the agreement. In addition, the Company is required to pay (1) annual maintenance fees of \$105 for each year that the agreement remains in effect, commencing on the first anniversary of the agreement, in order to maintain the right to use the license, and (2) a one-time fee of \$50 in each circumstance in which the Company provides the licensed intellectual property to one of its collaborators with the prior consent of the licensor. As a result, during fiscal 2012, the Company recorded in research and development expense a total of \$895 of license expense, which represents the fair value of the payments that the Company believes relate to its use of the assets in fiscal 2012 and prior periods. As of September 30, 2012, the Company had recorded liabilities totaling \$995 related to the agreement. Of that amount, \$350 was included in accounts payable, \$222 was included in accrued expenses and \$423 was included in other long-term liabilities on the balance sheet at September 30, 2012.

**Table of Contents****ENANTA PHARMACEUTICALS, INC****NOTES TO FINANCIAL STATEMENTS (Continued)****(Amounts in thousands, except share and per share data)****16. Commitments and Contingencies (Continued)**

Future non-cancelable minimum payments under the agreement are as follows:

<b>Year ending September 30,</b>	
2013	\$ 600
2014	250
2015	200
<b>Total</b>	<b>\$ 1,050</b>

**Litigation and Contingencies Related to Use of Intellectual Property**

From time to time, the Company may become subject to legal proceedings, claims and litigation arising in the ordinary course of business. The Company currently is not a party to any threatened or pending litigation. However, third parties might allege that the Company or its collaborators are infringing their patent rights or that the Company is otherwise violating their intellectual property rights. Such third parties may resort to litigation against the Company or its collaborators, which the Company has agreed to indemnify. With respect to some of these patents, the Company expects that it will be required to obtain licenses and could be required to pay license fees or royalties, or both. These licenses may not be available on acceptable terms, or at all. A costly license, or inability to obtain a necessary license, could have a material adverse effect on the Company's financial condition, results of operations or cash flows. The Company accrues contingent liabilities when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

As of September 30, 2012, the Company was aware of a potential license it may need to acquire with respect to patents it used, or may have used, in prior years or periods. As of September 30, 2012, the Company believed that license costs were probable, but a range of the loss could not be reasonably estimated; therefore, no accrual for this matter was recorded as of September 30, 2012.

**Indemnification Agreements**

In the ordinary course of business, the Company may provide indemnifications of varying scope and terms to customers, vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements, from services to be provided by the Company, or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its financial statements as of September 30, 2011 or 2012.

**17. Income Taxes**

During the year ended September 30, 2010, the Company recorded a net income tax benefit of \$157 related to income taxes paid in 2008 that were subsequently refunded under the American Recovery Assistance Act and a research and development credit. This net income tax benefit of \$157 was also the result of the Company's use of net operating loss carryforwards to fully offset the income before income taxes of \$7,747

generated in that year. As the deferred tax assets for those utilized net operating loss carryforwards had previously been recorded

F-38

**Table of Contents****ENANTA PHARMACEUTICALS, INC****NOTES TO FINANCIAL STATEMENTS (Continued)****(Amounts in thousands, except share and per share data)****17. Income Taxes (Continued)**

with a full valuation allowance, the use of the net operating loss carryforwards in fiscal 2010 resulted in an income tax benefit being recognized, which substantially offset the tax provision recorded as a result of the income before income taxes generated.

During the years ended September 30, 2011 and 2012, no provision for income taxes was recorded due primarily to the Company's use of net operating loss carryforwards to fully offset the income before income taxes of \$23,310 and \$21,399, respectively, generated in those periods. As the deferred tax assets for those utilized net operating loss carryforwards had previously been recorded with a full valuation allowance, the use of the net operating loss carryforwards in each of those periods resulted in an income tax benefit being recognized, which substantially offset the tax provision recorded as a result of the income before income taxes generated.

In all periods presented, all income before income taxes was sourced from the United States.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	<b>Year Ended September 30,</b>		
	<b>2010</b>	<b>2011</b>	<b>2012</b>
Federal statutory income tax rate	34.0%	34.0%	34.0%
State taxes, net of federal benefit	5.2	5.8	5.4
Federal research and development tax credit	(1.3)	(2.0)	(0.2)
Change in deferred tax asset valuation allowance	(39.3)	(40.5)	(40.1)
Other	1.4	2.7	0.9
Effective income tax rate	0.0%	0.0%	0.0%

Net deferred tax assets as of September 30, 2011 and 2012 consisted of the following:

	<b>September 30,</b>	
	<b>2011</b>	<b>2012</b>
Net operating loss carryforwards	\$ 17,112	\$ 10,961
Tax credit carryforwards	5,669	5,731
Capitalized research and development expenses	12,966	9,750
Other temporary differences	622	1,357
Gross deferred tax assets	36,369	27,799
Valuation allowance	(36,369)	(27,799)
Net deferred tax assets	\$	\$

As of September 30, 2012, the Company had net operating loss carryforwards for federal and state income tax purposes of \$30,882 and \$8,729, respectively, which begin to expire in fiscal 2018 and 2014, respectively. The Company also has available research and development tax credit carryforwards for federal and state income tax purposes of \$4,136 and \$2,415, respectively, which begin to expire in fiscal 2013 and 2015,



## Edgar Filing: ENANTA PHARMACEUTICALS INC - Form S-1/A

respectively. Utilization of the net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income.

F-39

**Table of Contents****ENANTA PHARMACEUTICALS, INC****NOTES TO FINANCIAL STATEMENTS (Continued)****(Amounts in thousands, except share and per share data)****17. Income Taxes (Continued)**

As of September 30, 2011 and 2012, the Company's gross deferred tax asset balances of \$36,369 and \$27,799, respectively, were comprised principally of net operating loss carryforwards and research and development credits. During the years ended September 30, 2010, 2011 and 2012, gross deferred tax assets related to net operating loss carryforwards decreased due to their utilization as a result of income before income taxes generated during those periods. The Company has concluded, based on the weight of available evidence, that its net deferred tax assets are not more likely than not to be realized in the future. Management has considered the Company's history of cumulative net losses incurred since inception, its lack of commercialization of any products or generation of any revenue from product sales since inception and its inability to reasonably estimate the timing or amounts, if any, of future milestone payments it will receive from its collaborators, and concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of September 30, 2011 and 2012. Management reevaluates the positive and negative evidence at each reporting period.

Changes in the valuation allowance for deferred tax assets during the years ended September 30, 2010, 2011 and 2012 were as follows:

	Year Ended September 30,		
	2010	2011	2012
Valuation allowance as of beginning of year	\$ 48,857	\$ 45,812	\$ 36,369
Decreases recorded as benefit to income tax provision	(3,045)	(9,443)	(8,570)
Increases recorded to income tax provision			
Valuation allowance as of end of year	\$ 45,812	\$ 36,369	\$ 27,799

The Company has not recorded any amounts for unrecognized tax benefits as of September 30, 2011 and 2012.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending income tax examinations. The Company's tax years are still open under statute from 2008 to the present. Earlier years may be examined to the extent that tax credit or net operating loss carryforwards are used in future periods. The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision.

**18. 401(k) Plan**

In December 1999, the Company established a 401(k) plan. This plan covers substantially all employees who meet minimum age and service requirements. Under the terms of the plan, the Company contributes on an annual basis up to 2% of an employee's base salary up to a maximum of \$4 per employee.

During the years ended September 30, 2010, 2011 and 2012, the Company recognized \$26, \$95 and \$84, respectively, of expense related to its contributions to this plan.

**19. Related Party Transactions**

The Company has entered into consulting agreements for research and development and business management activities with certain members of the Company's board of directors. Consulting fees paid for each of the years ended September 30, 2010, 2011 and 2012 were \$75.

As further described in Note 7, the Company had entered into a note and warrant purchase agreement with stockholders in fiscal 2011.

F-40

**Table of Contents**

**ENANTA PHARMACEUTICALS, INC**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(Amounts in thousands, except share and per share data)**

**20. Qualifying Therapeutic Discovery Project Program**

In November 2010, the Company received notification from the Internal Revenue Service that it had been awarded grants for four research projects under the Qualifying Therapeutic Discovery Project Credit program, covering 50% of qualifying expenses incurred, up to a maximum of \$244 for each of the four projects.

A payment of \$489 was received in fiscal 2011 for work on two of the projects already carried out during fiscal 2010. For the two projects carried out during fiscal 2011, a total amount receivable of \$261 was recorded as of September 30, 2011, and was received in full in October 2011.

During the year ended September 30, 2011, the Company recorded the proceeds of \$750 in other income (expense) in the statement of operations, upon approval of the qualifying expenses.

**21. Subsequent Events**

For its financial statements as of September 30, 2012 and for the year then ended, the Company evaluated subsequent events through November 16, 2012, the date on which those financial statements were originally issued, and through December 17, 2012, the date on which those financial statements were reissued.

**Novartis Milestone Payment**

In early November 2012, Novartis initiated dosing in a Phase 1 clinical trial involving EDP-239. As of that time, the Company became entitled to receive an \$11,000 milestone payment from Novartis under its collaboration agreement (see Note 8).

**Abbott Milestone Payment (Unaudited)**

In late November 2012, Abbott initiated dosing in a Phase 3 clinical trial involving ABT-450. As of that time, the Company became entitled to receive a \$15,000 milestone payment from Abbott under its collaboration agreement (see Note 8).

Table of Contents

*Shares*

*Common stock*

**Prospectus**

**J.P. Morgan**

**Credit Suisse**

**Leerink Swann**  
, 2012

**JMP Securities**

**Table of Contents****PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other expenses of issuance and distribution.**

The following table sets forth the expenses to be incurred in connection with the offering described in this Registration Statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimates except the Securities and Exchange Commission registration fee and the Financial Industry Regulatory Authority, Inc. filing fee.

Securities and Exchange Commission registration fee	\$ 9,412
Financial Industry Regulatory Authority, Inc. filing fee	10,850
NASDAQ Global Market listing fee	*
Accountants' fees and expenses	*
Legal fees and expenses	*
Blue sky fees and expenses	*
Transfer agents' fees and expenses	*
Printing and engraving expenses	*
Miscellaneous	*
 Total expenses	 \$ *

\*To be filed by amendment.

**Item 14. Indemnification of directors and officers.**

Section 102 of the Delaware General Corporation Law permits a corporation to eliminate the personal liability of its directors or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his or her duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our certificate of incorporation provides that no director shall be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the Delaware General Corporation Law prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the Delaware General Corporation Law provides that a corporation has the power to indemnify a director, officer, employee or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he or she is party or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnification for such expenses which the Court of Chancery or such other court shall deem proper.

Our certificate of incorporation provides that we will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding whether civil, criminal, administrative or investigative (other than an action by or in the right of us) by reason of the fact that he or she is or was, or has agreed to become, our director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an



## **Table of Contents**

Indemnitee ), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful.

Our certificate of incorporation also provides that we will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of us to procure a judgment in our favor by reason of the fact that the Indemnitee is or was, or has agreed to become, our director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee or, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding, and any appeal therefrom, if the Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, he or she will be indemnified by us against all expenses (including attorneys' fees) actually and reasonably incurred by him or her or on his or her behalf in connection therewith. If we don't assume the defense, expenses must be advanced to an Indemnitee under certain circumstances.

We have entered into indemnification agreements with our directors. In general, these agreements provide that we will indemnify the director to the fullest extent permitted by law for claims arising in his or her capacity as a director of our company or in connection with his or her service at our request for another corporation or entity. The indemnification agreements also provide for procedures that will apply in the event that a director makes a claim for indemnification and establish certain presumptions that are favorable to the director.

We maintain a general liability insurance policy which covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers.

The underwriting agreement we will enter into in connection with the offering of common stock being registered hereby provides that the underwriters will indemnify, under certain conditions, our directors and officers (as well as certain other persons) against certain liabilities arising in connection with such offering.

### **Item 15. Recent sales of unregistered securities.**

Set forth below is information regarding shares of common stock and warrants issued, and options granted, by us within the past three years that were not registered under the Securities Act of 1933, as amended, or the Securities Act. Also included is the consideration, if any, received by us for such shares, warrants and options and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.

#### **(a) Issuance of Warrants**

In October and November 2010, we issued \$2,000,000 in aggregate principal amount of term notes and warrants to purchase 1,999,989 shares of our Series 1 Nonconvertible Preferred Stock at an exercise price of \$0.01 per share to existing investors pursuant to a Note and Warrant Purchase Agreement dated October 4, 2010.

No underwriters were involved in the foregoing issuance. The securities described in this section (a) of Item 15 were issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(2) under the Securities Act, relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. All investors described above represented to us in connection with the issuance of the warrants that they were accredited investors and were acquiring the warrants for their own account for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof. The investors received written disclosures that



## **Table of Contents**

the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

### **(b) Stock Option Grants and Exercises**

Since January 1, 2009, we have issued to certain employees, directors and consultants options to purchase an aggregate of 2,986,561 shares of common stock, of which, as of September 30, 2012, 155,113 had been exercised for cash consideration in the aggregate amount of \$54,798, 678,953 had been forfeited, and 2,152,495 remained outstanding at a weighted average exercise price of \$0.99 per share.

The stock options and the common stock issued and issuable upon the exercise of such options as described in this section (b) of Item 15 were issued pursuant to written compensatory plans or arrangements with our employees, directors and consultants, in reliance on the exemption from the registration requirements of the Securities Act provided by Rule 701 promulgated under the Securities Act or the exemption set forth in Section 4(2) under the Securities Act and Regulation D promulgated thereunder relative to transactions by an issuer not involving any public offering. All recipients either received adequate information about us or had access, through employment or other relationships, to such information.

All of the foregoing securities are deemed restricted securities for purposes of the Securities Act. All certificates representing the issued shares of common stock and the warrants described in this Item 15 included appropriate legends setting forth that the securities had not been registered and the applicable restrictions on transfer.

### **Item 16. Exhibits and financial statement schedules.**

The exhibits to the Registration Statement are listed in the Exhibit Index attached hereto and incorporated by reference herein.

### **Item 17. Undertakings.**

- (a) The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.
- (b) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that, in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.
- (c) The undersigned registrant hereby undertakes that:
  - (1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
  - (2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such

securities at that time shall be deemed to be the initial bona fide offering thereof.

II-3

**Table of Contents****SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Amendment No. 2 to the Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Watertown, Commonwealth of Massachusetts, on this 17th day of December, 2012.

**ENANTA PHARMACEUTICALS, INC.**

By: /s/ Jay R. Luly, Ph.D.  
Jay R. Luly, Ph.D.  
President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, this Amendment No. 2 to the Registration Statement has been signed by the following persons in the capacities held on the dates indicated.

Signature	Title	Date
/s/ Jay R. Luly, Ph.D.	President and Chief Executive Officer and Director	December 17, 2012
Jay R. Luly, Ph.D.	<i>(Principal Executive Officer)</i>	
/s/ Paul J. Mellett	Chief Financial Officer	December 17, 2012
Paul J. Mellett	<i>(Principal Financial and Accounting Officer)</i>	
*	Director	December 17, 2012
Ernst-Günter Afting, M.D., Ph.D.		
*	Director	December 17, 2012
Stephen Buckley, Jr.		
*	Director	December 17, 2012
Marc E. Goldberg		
*	Director	December 17, 2012
David Poorvin, Ph.D.		
*	Director	December 17, 2012
Helmut M. Schühlsler, Ph.D.		
*	Director	December 17, 2012
Terry Vance		
*	Director	December 17, 2012
Gregory Verdine, Ph.D.		

\*By: /s/ Jay R. Luly, Ph.D.

Edgar Filing: ENANTA PHARMACEUTICALS INC - Form S-1/A

Jay R. Luly, Ph.D.

Attorney-in-Fact

**Table of Contents****EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
1.1#	Underwriting Agreement.
3.1#	Fifth Amended and Restated Certificate of Incorporation of Enanta Pharmaceuticals, Inc. (the Company ) filed with the Secretary of State of Delaware on August 30, 2012.
3.2#	Bylaws of the Company.
3.3*	Certificate of Incorporation of the Company to be effective upon the closing of this offering.
3.4*	Bylaws of the Company to be effective upon the closing of this offering.
4.1*	Specimen certificate evidencing shares of common stock.
4.2#	Form of Series 1 Nonconvertible Preferred Stock Warrant.
5.1*	Opinion of Edwards Wildman Palmer LLP.
10.1	Collaborative Development and License Agreement between the Company and Abbott Laboratories, dated November 27, 2006; as amended by a First Amendment to Collaborative Development and License Agreement dated January 27, 2009 and a Second Amendment to Collaborative Development and License Agreement dated December 9, 2009.
10.2	Collaboration and License Agreement between the Company and Novartis Institutes for BioMedical Research, Inc., dated February 16, 2012.
10.3 #	Agreement between the Company and the National Institute of Allergy and Infectious Diseases, dated September 30, 2011.
10.4#	Third Amended and Restated Registration Rights Agreement, dated as of August 23, 2012.
10.5*	Form of Executive Employment Agreement.
10.6#	Lease Agreement between Company and ARE-500 Arsenal Street LLC, dated as of April 15, 2011.
10.7*	Form of Indemnification Agreement between the Company and each director.
10.8#	Amended and Restated 1995 Equity Incentive Plan.
10.9*	Form of Incentive Stock Option Certificate under Amended and Restated 1995 Equity Incentive Plan.
10.10*	Form of Non-Statutory Stock Option Certificate under Amended and Restated 1995 Equity Incentive Plan.
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
23.2*	Consent of Edwards Wildman Palmer LLP (to be included in Exhibit 5.1).
24.1#	Power of Attorney (included on signature page).
99.1#	Original Draft Registration Statement on Form S-1, dated August 30, 2012.
99.2#	Amendment No. 1 to Draft Registration Statement on Form S-1, dated October 10, 2012.

\* To be filed by amendment.

# Previously filed.

Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.