### UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

### Form 10-Q

☑ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended December 31, 2015

OR

□ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

**Commission File Number 001-35839** 

## ENANTA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

**DELAWARE** (State or other jurisdiction of incorporation or organization) 2834 (Primary Standard Industrial Classification Code Number) 04-3205099 (I.R.S. Employer Identification Number)

500 Arsenal Street Watertown, Massachusetts 02472 (617) 607-0800

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes  $\boxtimes$  No  $\square$ 

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files): Yes 🗵 No 🗆

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  $\Box$ 

Non-accelerated filer

 $\Box$  (Do not check if a smaller reporting company)

Accelerated filer ⊠ Smaller reporting company □ Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes  $\Box$  No  $\boxtimes$  The number of shares of the registrant's Common Stock, \$0.01 par value, outstanding as of January 31, 2016, was 18,925,311 shares.

#### ENANTA PHARMACEUTICALS, INC. FORM 10-Q — Quarterly Report For the Quarterly Period Ended December 31, 2015

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#### PART I—FINANCIAL INFORMATION

#### ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS

#### ENANTA PHARMACEUTICALS, INC. CONSOLIDATED BALANCE SHEETS (unaudited) (in thousands, except share and per share amounts)

|  | December 31,<br>2015 | September 30,<br>2015 |
|--|----------------------|-----------------------|
| Assets   |                      |                       |
| Current assets:  |                      |                       |
| Cash and cash equivalents  | \$ 46,233            | \$ 21,726             |
| Short-term marketable securities   | 133,786              | 123,479               |
| Accounts receivable  | 17,869               | 15,289                |
| Unbilled receivables   | 1,009                | 433                   |
| Deferred tax assets  | 1,581                | 1,447                 |
| Prepaid expenses and other current assets  | 8,543                | 8,267                 |
| Total current assets   | 209,021              | 170,641               |
| Property and equipment, net  | 7,872                | 5,886                 |
| Long-term marketable securities  | 56,618               | 64,238                |
| Deferred tax assets  | 4,260                | 4,640                 |
| Restricted cash  | 608                  | 608                   |
| Total assets   | \$ 278,379           | \$ 246,013            |
| Liabilities and Stockholders' Equity   |                      |                       |
| Current liabilities:   |                      |                       |
| Accounts payable   | \$ 2,767             | \$ 1,543              |
| Accrued expenses and other current liabilities   | 3,165                | 3,962                 |
| Income taxes payable   | 4,940                | 1,199                 |
| Total current liabilities  | 10,872               | 6,704                 |
| Warrant liability  | 1,290                | 1,276                 |
| Series 1 nonconvertible preferred stock  | 164                  | 163                   |
| Other long-term liabilities  | 1,774                | 1,713                 |
| Total liabilities  | 14,100               | 9,856                 |
| Commitments and contingencies (Note 11)  |                      |                       |
| Stockholders' equity:  |                      |                       |
| Common stock; \$0.01 par value; 100,000,000 shares authorized; 18,795,114 and 18,716,834 shares issued and |                      |                       |
| outstanding at December 31, 2015 and September 30, 2015, respectively                                      | 188                  | 187                   |
| Additional paid-in capital   | 232,111              | 229,957               |
| Accumulated other comprehensive income (loss)  | (189)                | 33                    |
| Retained earnings  | 32,169               | 5,980                 |
| Total stockholders' equity   | 264,279              | 236,157               |
| Total liabilities and stockholders' equity   | \$ 278,379           | \$ 246,013            |

The accompanying notes are an integral part of these consolidated financial statements.

#### ENANTA PHARMACEUTICALS, INC. CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited) (in thousands, except share and per share amounts)

|  |            | e Months Ended<br>ecember 31, |
|--|------------|-------------------------------|
|  | 2015       | 2014                          |
| Revenue:   |            |                               |
| Milestone payments   | \$ 30,000  | 4 - )                         |
| Royalties  | 17,869     | 1,392                         |
| Other  | 576        | 1,106                         |
| Total revenue  | 48,445     | 77,498                        |
| Operating expenses:  |            |                               |
| Research and development   | 9,033      | 4,519                         |
| General and administrative   | 3,818      | 2,769                         |
| Total operating expenses   | 12,851     | 7,288                         |
| Income from operations   | 35,594     | 70,210                        |
| Other income:  |            |                               |
| Interest income  | 356        | 127                           |
| Interest expense   | (12        | 2) (2)                        |
| Change in fair value of warrant liability and Series 1 nonconvertible preferred stock, net | (15        | 6) 176                        |
| Total other income, net  | 329        | 301                           |
| Income before income taxes   | 35,923     | 70,511                        |
| Income tax expense   | (9,734     | (28,502)                      |
| Net income   | \$ 26,189  | \$ 42,009                     |
| Net income per share:  |            |                               |
| Basic  | \$ 1.39    | \$ 2.26                       |
| Diluted  | \$ 1.36    | \$ 2.18                       |
| Weighted average common shares outstanding:  |            |                               |
| Basic  | 18,775,553 | 18,603,067                    |
| Diluted  | 19,269,357 | 19,283,223                    |

The accompanying notes are an integral part of these consolidated financial statements.

#### ENANTA PHARMACEUTICALS, INC. CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (unaudited) (in thousands)

|   | Three Months Ended<br>December 31, |          |
|---|------------------------------------|----------|
|   | 2015                               | 2014     |
| Net income  | \$26,189                           | \$42,009 |
| Other comprehensive income (loss):  |                                    |          |
| Net unrealized gains (losses) on marketable securities, net of tax of \$135 and \$3 | (222)                              | 5        |
| Total other comprehensive income (loss)   | (222)                              | 5        |
| Comprehensive income  | \$25,967                           | \$42,014 |
| Total other comprehensive income (loss)   | (222)                              | \$42,01  |

The accompanying notes are an integral part of these consolidated financial statements.

#### ENANTA PHARMACEUTICALS, INC. CONSOLIDATED STATEMENTS OF CASH FLOWS (unaudited) (in thousands)

|   | Three M<br>Ended Dec<br>2015 |           |
|---|------------------------------|-----------|
| Cash flows from operating activities  | 2013                         | 2014      |
| Net income  | \$ 26,189                    | \$ 42,009 |
| Adjustments to reconcile net income to net cash used in operating activities:         |                              |           |
| Stock-based compensation expense  | 1,992                        | 1,028     |
| Amortization of premium on marketable securities                                      | 562                          | 471       |
| Deferred income taxes   | 382                          | 11,487    |
| Depreciation and amortization expense   | 339                          | 129       |
| Change in fair value of warrant liability and Series 1 nonconvertible preferred stock | 15                           | (176)     |
| Non-cash interest expense   | —                            | 2         |
| Gain on sale of marketable securities   | _                            | (1)       |
| Income tax benefit from exercise of stock options                                     | —                            | (1,919)   |
| Premium on marketable securities  | (171)                        | (169)     |
| Changes in operating assets and liabilities:  |                              |           |
| Accounts receivable   | (2,580)                      | (74,902)  |
| Unbilled receivables  | (576)                        | 888       |
| Prepaid expenses and other current assets   | (276)                        | 409       |
| Accounts payable  | 149                          | (1,296)   |
| Accrued expenses  | 150                          | (475)     |
| Income taxes payable  | 3,741                        | 16,896    |
| Other long-term liabilities   | 77                           | 9         |
| Net cash provided by (used in) operating activities                                   | 29,993                       | (5,610)   |
| Cash flows from investing activities  |                              |           |
| Purchases of property and equipment   | (2,197)                      | (256)     |
| Purchases of marketable securities  | (34,622)                     | (8,153)   |
| Sales of marketable securities  |                              | 2,210     |
| Maturities of marketable securities   | 31,187                       | 13,226    |
| Net cash provided by (used in) investing activities                                   | (5,632)                      | 7,027     |
| Cash flows from financing activities  |                              |           |
| Proceeds from exercise of stock options   | 162                          | 95        |
| Payments of capital lease obligations   | (16)                         | _         |
| Income tax benefit from exercise of stock options                                     | ()<br>                       | 1,919     |
| Net cash provided by financing activities   | 146                          | 2,014     |
| Net increase in cash and cash equivalents   | 24,507                       | 3,431     |
| Cash and cash equivalents at beginning of period                                      | 24,307                       | 30,699    |
| Cash and cash equivalents at beginning of period                                      | \$ 46,233                    | \$ 34,130 |
|   | \$ 40,233                    | \$ 54,150 |
| Supplemental disclosure of cash flow information:                                     |                              |           |
| Cash paid for income taxes  | \$ 5,707                     | \$ 66     |

The accompanying notes are an integral part of these consolidated financial statements.

#### ENANTA PHARMACEUTICALS, INC. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (unaudited) (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 robust chemistry-driven approach and drug discovery capabilities to create small molecule drugs primarily for the treatment of viral infections and liver diseases. The Company has developed novel protease inhibitors for treatment of hepatitis C virus ("HCV") infection. The Company also has clinical programs to develop cyclophilin and NS5A inhibitors targeted against HCV and a lead FXR agonist candidate for non-alcoholic steatohepatitis ("NASH"). Additionally, the Company has programs to discover new chemical entities, or compounds, for the treatment of hepatitis B virus ("HBV") infection and respiratory syncytial virus ("RSV") infection.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, the uncertainties of research and development, competition from technological innovations of others, 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.

#### **Unaudited Interim Financial Information**

The consolidated balance sheet at September 30, 2015 was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America ("GAAP"). The accompanying unaudited consolidated financial statements as of December 31, 2015 and for the three months ended December 31, 2015 and 2014 have been prepared by the Company, pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. These financial statements should be read in conjunction with the Company's audited financial statements and the notes thereto included in the Company's Annual Report on Form 10-K for the year ended September 30, 2015.

In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company's financial position as of December 31, 2015 and results of operations for the three months ended December 31, 2015 and 2014 and cash flows for the three months ended December 31, 2015 and 2014 have been made. The results of operations for the three months ended December 31, 2015 are not necessarily indicative of the results of operations that may be expected for the year ending September 30, 2016.

The accompanying consolidated financial statements have been prepared in conformity with GAAP. All dollar amounts in the consolidated financial statements and in the notes to the consolidated financial statements, except share and per share amounts, are in thousands unless otherwise indicated.



#### 2. Summary of Significant Accounting Policies

For the Company's Significant Accounting Policies refer to its Annual Report on Form 10-K for the fiscal year ended September 30, 2015.

#### **Use of Estimates**

The preparation of consolidated 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 liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions reflected in these consolidated 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; valuation of warrants, Series 1 nonconvertible preferred stock 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.

#### **Recently Issued Accounting Pronouncements**

In May, 2014, the Financial Accounting Standards Board (the "FASB") issued ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606), which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. The new standard will be effective for the Company on October 1, 2018. The Company is currently evaluating the potential impact that Topic 606 may have on its financial position and results of operations.

In November 2015, the FASB issued ASU No. 2015-17, *Balance Sheet Classification of Deferred Taxes* ("ASU 2015-17"), which simplifies the presentation of deferred income taxes by eliminating the need for entities to separate deferred income tax liabilities and assets into current and noncurrent amounts in a classified statement of financial position. This amendment is effective for the Company in the fiscal year beginning October 1, 2017, but early adoption is permissible. The Company is currently evaluating the potential impact that ASU 2015-17 may have on its financial position.

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.

#### 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 December 31, 2015 and September 30, 2015 and indicate the fair value hierarchy of the valuation inputs utilized to determine such fair value:

|   | Fair Val                                      | Fair Value Measurements as of December 31, 2015 Using: |          |            |  |  |
|---|---|--|----------|------------|--|--|
|   | Level 1                                       | Level 2  | Level 3  | Total      |  |  |
| Assets:                                 |   |  |          |            |  |  |
| Cash equivalents                        | \$ 40,462                                     | \$ —   | \$ —     | \$ 40,462  |  |  |
| U.S. Treasury notes                     | 14,469  |  | —        | 14,469     |  |  |
| Corporate bonds                         | —   | 132,90   | 2 —      | 132,902    |  |  |
| U.S. Agency bonds                       | —   | 31,04  | 9 —      | 31,049     |  |  |
| Commercial paper                        |   | 11,98  | 4        | 11,984     |  |  |
|   | \$ 54,931                                     | \$ 175,93  | 5 \$ —   | \$ 230,866 |  |  |
| Liabilities:                            |   |  |          |            |  |  |
| Warrant liability                       | \$ —  | \$ —   | \$ 1,290 | \$ 1,290   |  |  |
| Series 1 nonconvertible preferred stock | —   |  | 164      | 164        |  |  |
|   | <u>\$                                    </u> | \$ —   | \$ 1,454 | \$ 1,454   |  |  |
|   |   |  |          |            |  |  |



|   | Fair Value | Fair Value Measurements as of September 30, 2015 Using: |          |            |  |  |  |
|---|------------|---|----------|------------|--|--|--|
|   | Level 1    | Level 1 Level 2 Level 3                                 |          |            |  |  |  |
| Assets:                                 |            |   |          |            |  |  |  |
| Cash equivalents                        | \$ 21,327  | \$ —  | \$ —     | \$ 21,327  |  |  |  |
| Corporate bonds                         | _          | 151,020   |          | 151,020    |  |  |  |
| U.S. Agency bonds                       | —          | 36,697  | —        | 36,697     |  |  |  |
|   | \$ 21,327  | \$ 187,717  | \$ —     | \$ 209,044 |  |  |  |
| Liabilities:                            |            |   |          |            |  |  |  |
| Warrant liability                       | \$ —       | \$ —  | \$ 1,276 | \$ 1,276   |  |  |  |
| Series 1 nonconvertible preferred stock | _          |   | 163      | 163        |  |  |  |
|   | \$ —       | \$ —  | \$ 1,439 | \$ 1,439   |  |  |  |

During the three months ended December 31, 2015 and 2014, there were no transfers between Level 1, Level 2 and Level 3.

As of December 31, 2015 and September 30, 2015, respectively, the warrant liability was comprised of the values of warrants for the purchase of Series 1 nonconvertible preferred stock measured at fair value. The outstanding Series 1 nonconvertible preferred stock was also measured at fair value. The fair value of both of these instruments was based on significant inputs not observable in the market, which represented a Level 3 measurement within the fair value hierarchy. The Company utilized a probability-weighted valuation model which takes into consideration various outcomes that may require the Company to transfer assets upon exercise. The fair value of outstanding warrants to purchase the Company's Series 1 nonconvertible preferred stock was \$1,290 and \$1,276, at December 31, 2015 and September 30, 2015, respectively. The fair value of Series 1 nonconvertible preferred stock was \$164 and \$163 as of December 31, 2015 and September 30, 2015, respectively. Changes in the fair value of the warrant liability and Series 1 nonconvertible preferred stock are recognized in the consolidated statements of operations.

As of December 31, 2015 and September 30, 2015, the recurring Level 3 fair value measurements of the Company's warrant liability and Series 1 nonconvertible preferred stock using probability-weighted discounted cash flow include the following significant unobservable inputs:

#### December 31, 2015

|   | Unobservable Input                           | Range<br>(Weighted<br>Average) |
|---|--|--------------------------------|
| Warrant liability and Series 1 nonconvertible | Probabilities of payout                      | 5% - 60%                       |
| preferred stock                               | Periods in which payout is expected to occur | 2016 - 2017                    |
|   | Discount rate                                | 4.37%                          |

#### September 30, 2015

|   | Unobservable Input                           | Range<br>(Weighted<br>Average) |
|---|--|--------------------------------|
| Warrant liability and Series 1 nonconvertible | Probabilities of payout                      | 5% - 60%                       |
| preferred stock                               | Periods in which payout is expected to occur | 2016 - 2017                    |
|   | Discount rate                                | 4.25%                          |

The following table provides a rollforward of the aggregate fair values of the Company's warrants for the purchase of Series 1 nonconvertible preferred stock and the outstanding Series 1 nonconvertible preferred stock for which fair value is determined by Level 3 inputs:

| Balance, September 30, 2015 | \$1,439 |
|-----------------------------|---------|
| Increase in fair value      | 15      |
| Balance, December 31, 2015  | \$1,454 |

#### 4. Marketable Securities

As of December 31, 2015 and September 30, 2015, the fair value of available-for-sale marketable securities by type of security was as follows:

|                     | December 31, 2015 |                    |    |                     |    |                      |            |
|---------------------|-------------------|--------------------|----|---------------------|----|----------------------|------------|
|                     | Am                | ortized Cost       |    | Unrealized<br>Jains |    | Unrealized<br>Losses | Fair Value |
| Corporate bonds     | \$                | 133,112            | \$ | 8                   | \$ | (218)                | \$132,902  |
| U.S. Agency bonds   |                   | 31,115             |    |                     |    | (66)                 | 31,049     |
| U.S. Treasury notes |                   | 14,497             |    | 1                   |    | (29)                 | 14,469     |
| Commercial paper    |                   | 11,984             |    |                     |    |                      | 11,984     |
|                     | \$                | 190,708            | \$ | 9                   | \$ | (313)                | \$190,404  |
|                     |                   | September 30, 2015 |    |                     |    |                      |            |
|                     |                   |                    |    | Unrealized          |    | Unrealized           |            |
|                     | Am                | ortized Cost       |    | ains                | I  | Josses               | Fair Value |
| Corporate bonds     | \$                | 151,012            | \$ | 77                  | \$ | (69)                 | \$151,020  |
| U.S. Agency bonds   |                   | 36,652             |    | 45                  |    |                      | 36,697     |
|                     | \$                | 187,664            | \$ | 122                 | \$ | (69)                 | \$187,717  |

As of December 31, 2015, marketable securities consisted of investments that mature within one year, with the exception of certain corporate bonds, which have maturities within three years and an aggregate fair value of \$56,618.

#### 5. Accrued Expenses and Other Long-Term Liabilities

Accrued expenses (current) and other long-term liabilities consisted of the following as of December 31, 2015 and September 30, 2015:

|   | ember 31,<br>2015 | September 30,<br>2015 |  |
|---|-------------------|-----------------------|--|
| Accrued expenses:                         |                   |                       |  |
| Accrued payroll and related expenses      | \$<br>789         | \$<br>1,622           |  |
| Accrued third-party license fee           | 500               | —                     |  |
| Accrued vendor manufacturing              | 433               | 18                    |  |
| Accrued fixed assets purchases            | 383               | 1,307                 |  |
| Accrued preclinical and clinical expenses | 353               | 237                   |  |
| Accrued professional fees                 | 304               | 338                   |  |
| Capital lease obligation                  | 69                | 69                    |  |
| Accrued other                             | 334               | 371                   |  |
|   | \$<br>3,165       | \$<br>3,962           |  |
| Other long-term liabilities:              |                   | <br>                  |  |
| Accrued rent expense                      | \$<br>646         | \$<br>628             |  |
| Capital lease obligation                  | 513               | 529                   |  |
| Uncertain tax positions                   | 498               | 448                   |  |
| Asset retirement obligation               | 117               | 108                   |  |
|   | \$<br>1,774       | \$<br>1,713           |  |

#### 6. Ongoing Collaboration Agreements

#### **AbbVie Collaboration**

The Company has a Collaborative Development and License Agreement (the "AbbVie Agreement"), as amended, with AbbVie Inc. to identify, develop and commercialize HCV NS3 and NS3/4A protease inhibitor compounds, including paritaprevir, under which it has received license payments, proceeds from a sale of preferred stock, research funding payments and milestone payments totaling \$349,000 through December 31, 2015. As of December 31, 2015, the Company is eligible to receive additional milestone payments totaling up to \$80,000 upon AbbVie's achievement of commercialization regulatory approval milestones in the U.S. and other selected world markets for any additional protease inhibitor commercialized by AbbVie. Since the Company completed all its performance obligations under the AbbVie Agreement by the end of fiscal 2011, any milestone payments received since then have been and will be

recognized as revenue when the milestones are achieved by AbbVie. The Company is also receiving annually tiered royalties per product ranging from the low double digits up to twenty percent, or on a blended basis from the low double digits up to the high teens, on calendar year net sales by AbbVie allocated to the collaboration's protease inhibitors. Beginning with each January 1 the cumulative net sales of a given royalty-bearing product start at zero for purposes of calculating the tiered royalties.

During the three months ended December 31, 2015, the Company earned and recognized as revenue a \$30,000 milestone amount upon AbbVie's achievement of commercialization regulatory approval of a paritaprevir-containing regimen in Japan. During the three months ended December 31, 2014, the Company earned and recognized as revenue a \$75,000 milestone amount due from AbbVie as a result of U.S. FDA regulatory approval of AbbVie's first HCV treatment regimen containing paritaprevir.

#### 7. Warrants to Purchase Series 1 Nonconvertible Preferred Stock and Series 1 Nonconvertible Preferred Stock

In October and November 2010, the Company issued warrants to purchase up to a total of 1,999,989 shares of Series 1 nonconvertible preferred stock, which 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. 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 consolidated statement of operations. On February 5, 2014, 225,408 warrants were exercised resulting in the net issuance of 223,153 shares of Series 1 nonconvertible preferred stock.

#### 8. Stock-Based Awards

The Company may grant stock-based awards under its existing 2012 Equity Incentive Plan (the "2012 Plan") and its Employee Stock Purchase Plan (the "ESPP"). The Company also has outstanding stock-based awards under its 1995 Equity Incentive Plan (the "1995 Plan"), but is no longer granting awards under this plan. As of December 31, 2015, 554,679 shares of common stock are available for issuance under the 2012 Plan based on the target number of units awarded, none of which have yet vested. As of December 31, 2015, a total of 185,614 shares of common stock are available for issuance under the ESPP. As of December 31, 2015, the Company had not commenced any offering under the ESPP and no shares have been issued.

The Company applies the fair value recognition provisions for all stock-based awards granted or modified in accordance with authoritative guidance. Under this guidance the Company 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 grants with service conditions, while the graded vesting method is applied to all grants with both service and performance conditions.

|   | Shares<br>Issuable<br>Under<br>Options | Weighted<br>Average<br>Exercise<br>Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Term<br>(in years) | Aggregate<br>Intrinsic<br>Value |
|---|--|--|---|---------------------------------|
| Outstanding as of September 30, 2015                        | 1,752,010                              | \$ 23.76                                 | 7.2   | \$ 25,093                       |
| Granted   | 401,280                                | 31.42                                    |   |                                 |
| Exercised   | (78,280)                               | 2.07                                     |   |                                 |
| Forfeited   | (5,531)                                | 36.01                                    |   |                                 |
| Outstanding as of December 31, 2015                         | 2,069,479                              | \$ 26.03                                 | 7.7   | \$ 19,496                       |
| Options vested and expected to vest as of December 31, 2015 | 1,887,232                              | \$ 27.03                                 | 7.7   | \$ 16,293                       |
| Options exercisable as of December 31, 2015                 | 843,731                                | \$ 17.13                                 | 5.9   | \$ 14,359                       |

In December 2015, the Company awarded certain executive officers a total of 50,000 share units consisting of 25,000 performance share units, or PSUs, and 25,000 relative total shareholder return units, or rTSRUs. The number of units represents the target number of shares of common stock that may be earned; however, the actual number of shares that may be earned ranges from 0% to 200% of the target number.

The PSUs will vest and result in issuance, or settlement, of common shares, based upon continued employment and achievement of specified research and development milestones on or before December 31, 2017. The aggregate grant date fair value of the 25,000 PSUs ranges between \$0 and \$1,602. During the three months ended December 31, 2015, the Company recorded no compensation expense related to the PSU awards as none of the performance-based targets was probable of being achieved during this period.

The rTSRUs will vest and result in the issuance of common stock based on continuing employment and the relative ranking of the total shareholder return, or TSR, of the Company's common stock in relation to the TSR of the component companies in the NASDAQ Biotech Index over a two-year period based on a comparison of average closing stock prices in November 2015 and December 2017. The number of market-based rTSRUs awarded represents the target number of shares of common stock that may be earned; however, the actual number of shares that may be earned ranges from 0% to 200% of the target number.

The Company used a Monte Carlo simulation model to estimate that the grant-date fair value of the rTSRUs was \$942. The table below sets forth the assumptions used to value the awards and the estimated grant-date fair value:

| Risk-free interest rate                          | 0.97%   |
|--|---------|
| Dividend yield                                   | 0%      |
| Expected volatility                              | 63.95%  |
| Remaining performance period (years)             | 2.03    |
| Estimated fair value per share of rTSRUs granted | \$37.67 |

The fair value related to the rTSRUs will be recorded as compensation expense over the period from date of grant to December 2017 regardless of whether the target relative total shareholder returns are reached.

In addition, in December 2015, the Company awarded an executive officer 5,250 share units consisting of 2,625 PSUs and 2,625 rTSRUs. The number of units represents the target number of shares of common stock that may be earned; however, the actual number of shares that may be earned ranges from 0% to 200% of the target number.

The PSUs will vest and result in issuance, or settlement, of common shares, based upon continued employment and achievement of specified research and development milestones on or before December 31, 2016. The aggregate grant date fair value of the 2,625 PSUs ranges between \$0 and \$168. During the three months ended December 31, 2015, the Company recorded no compensation expense related to the PSU awards as none of the performance-based targets was probable of being achieved during this period.

The rTSRUs will vest and result in the issuance of common stock based on continuing employment and the relative ranking of the total shareholder return, or TSR, of the Company's common stock in relation to the TSR of the component companies in the NASDAQ Biotech Index over a two-year period based on a comparison of average closing stock prices in December 2014 and December 2016. The number of market-based rTSRUs awarded represents the target number of shares of common stock that may be earned; however, the actual number of shares that may be earned ranges from 0% to 200% of the target number.

The Company used a Monte Carlo simulation model to estimate that the grant-date fair value of the rTSRUs was \$44. The table below sets forth the assumptions used to value the awards and the estimated grant-date fair value:

| Risk-free interest rate                          | 0.65%   |
|--|---------|
| Dividend yield                                   | 0%      |
| Expected volatility                              | 72.30%  |
| Remaining performance period (years)             | 1.03    |
| Estimated fair value per share of rTSRUs granted | \$16.90 |

The fair value related to the rTSRUs will be recorded as compensation expense over the period from date of grant to December 2016 regardless of whether the target relative total shareholder returns are reached.

The Company recognized stock-based compensation expense on all awards in the following expense categories:

|                            |          | Three Months Ended<br>December 31, |  |
|----------------------------|----------|------------------------------------|--|
|                            | 2015     | 2014                               |  |
| Research and development   | \$ 714   | \$ 242                             |  |
| General and administrative | 1,278    | 786                                |  |
|                            | \$ 1,992 | \$ 1,028                           |  |

As of December 31, 2015, the Company had an aggregate of \$24,166 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 3.1 years.

#### 9. Net Income Per Share

Basic and diluted net income per share attributable to common stockholders was calculated as follows for the three months ended December 31, 2015 and 2014:

|  | Three Months Ended<br>December 31, |           |      | l,       |
|--|------------------------------------|-----------|------|----------|
|  |                                    | 2015      | 2014 |          |
| Basic net income per share:                        |                                    |           |      |          |
| Numerator:   |                                    |           |      |          |
| Net income   | \$                                 | 26,189    | \$   | 42,009   |
| Denominator:                                       |                                    |           |      |          |
| Weighted average common shares outstanding—basic   | 18                                 | 8,775,553 | 18   | ,603,067 |
| Net income per share—basic                         | \$                                 | 1.39      | \$   | 2.26     |
| Diluted net income per share:                      |                                    |           |      |          |
| Numerator:   |                                    |           |      |          |
| Net income   | \$                                 | 26,189    | \$   | 42,009   |
| Denominator:                                       |                                    |           |      |          |
| Weighted average common shares outstanding—basic   | 18                                 | 3,775,553 | 18   | ,603,067 |
| Dilutive effect of common stock equivalents        |                                    | 493,804   |      | 680,156  |
| Weighted average common shares outstanding—diluted | 19                                 | ,269,357  | 19   | ,283,223 |
| Net income per share—diluted                       | \$                                 | 1.36      | \$   | 2.18     |

Stock options and awards for the purchase of 1,119,345 and 288,490 weighted average shares were excluded from the computation of diluted net income per share attributable to common stockholders for the three months ended December 31, 2015 and 2014, 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.

#### 10. Income Taxes

For the three months ended December 31, 2015 and December 31, 2014, the Company recorded an income tax provision of \$9,734 and \$28,502, respectively, representing an effective tax rate of 27.1% and 40.4%, respectively. The income tax provision for the three months ended December 31, 2015 and 2014 was primarily attributable to the tax provision on the earnings of the Company's domestic operations. For the three months ended December 31, 2015 the Company's effective tax rate differs from the statutory rate of 35% primarily due to reinstatement of the federal research and development tax credits. For the three months ended December 31, 2014 the Company's effective tax rate differs from the statutory rate of 35% primarily due to state income taxes and certain expenditures which are permanently not deductible for tax purposes.

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 had an unrecognized tax benefit of \$498 and \$448 as of December 31, 2015 and September 30, 2015, respectively. Unrecognized tax benefits represent tax positions for which reserves have been established. The Company's policy is to record interest and penalties related to uncertain tax positions as part of its income tax provision.

#### 11. Commitments and Contingencies

#### Leases

The Company has an office and laboratory lease that expires in September 2022. Payment escalation as specified in the lease agreement is accrued such that rent expense is recognized on a straight-line basis over the term of occupancy. The Company recorded rent expense of \$506 and \$237 for the three months ended December 31, 2015 and 2014, respectively.

In connection with the lease, the Company has outstanding a \$608 letter of credit, collateralized by a money market account. As of December 31, 2015 and September 30, 2015, the Company classified \$608 related to the letter of credit as restricted cash. Additionally, the lease, as amended, included a \$598 tenant improvement allowance from the landlord, which allowance is accounted for as a capital lease obligation.

#### **Intellectual Property Licenses**

The Company has a non-exclusive intellectual property license agreement with a third party, under which 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.

The Company also has a non-exclusive license with respect to patents it uses in its HCV research. Under the license, the Company is obligated to pay milestones totaling up to \$5,000, plus low single digit royalties, for the development and regulatory approval of each HCV product outside of the Company's collaboration with AbbVie and any other collaboration it may enter into in the future with a partner that has already licensed these patents. During the three months ended December 31, 2015 the Company became obligated for a \$500 milestone payment under this license agreement upon its filing to commence clinical development of its cyclophilin inhibitor candidate. During the three months ended December 31, 2014, no events triggering such payment occurred.

#### 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, would 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.

#### **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 and its executive officers 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 indemnification. In addition, the Company maintains officers and directors insurance coverage. 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 December 31, 2015.

#### ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the unaudited consolidated financial statements and notes thereto included elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto for our fiscal year ended September 30, 2015 included in our Annual Report on Form 10-K for that fiscal year. This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "should," "estimate," or "continue," and similar expressions or variations. Such forward-looking statements are subject to risks, uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section titled "Risk Factors," set forth in Part II, Item 1A of this Quarterly Report on Form 10-Q. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q.

#### 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 primarily for the treatment of viral infections and liver diseases. Our lead product, paritaprevir, a protease inhibitor designed for use against the hepatitis C virus, referred to as HCV, is a key compound in AbbVie's marketed HCV treatment regimens. We also have a second HCV protease inhibitor in phase 3 development with AbbVie, as well as a wholly-owned HCV program using a different class of molecules known as cyclophilin inhibitors, one of which is now in phase 1 development after we initiated a clinical trial in January 2016. In addition, we have a program in non-alcoholic steatohepatitis, or NASH, with a lead candidate, EDP-305, which we plan to take into clinical trials in calendar 2016, as well as research programs targeting hepatitis B Virus, or HBV, and respiratory syncytial virus, or RSV.

Our HCV protease inhibitors have been discovered and developed through our collaboration with AbbVie (formerly Abbott Laboratories), including:

- <u>Paritaprevir</u>: Paritaprevir is the protease inhibitor contained in VIEKIRA PAK<sup>®</sup> and AbbVie's other all-oral, interferon-free HCV treatment regimens currently marketed in the U.S., EU, Japan and other countries around the world. VIEKIRA PAK was approved and first sold in the U.S. in December 2014 for treatment of genotype 1 HCV, the most prevalent genotype of HCV in the U.S., EU and Japan. A regimen containing paritaprevir and only one other direct-acting antiviral, or DAA, is now approved in Japan (VIEKIRAX<sup>®</sup>, September 2015) for the treatment of genotype 1 HCV and in the U.S. (TECHNIVIE<sup>™</sup>, July 2015), EU (VIEKIRAX, January 2015) and other countries for the treatment of genotype 4 HCV.
- <u>ABT-493:</u> Our next-generation protease inhibitor, ABT-493, is being developed by AbbVie in combination with its next-generation NS5A inhibitor, ABT-530, as a pan-genotypic, once daily, all oral, fixed-dose combination treatment for HCV. AbbVie completed two Phase 2 clinical trials of this investigational 2-DAA treatment and reported results in November 2015:
  - After 12 weeks of treatment with doses at or closest to the Phase 3 clinical dose, SVR<sub>12</sub> rates were 100% in genotype 1 HCV patients, 96% in genotype 2, and 93% in genotype 3.



Data after 8 weeks of treatment in non-cirrhotic genotype 1 chronic HCV patients demonstrated an SVR<sub>12</sub> rate of 97%.

AbbVie has now initiated a series of six phase 3 trials with this next-generation combination treatment, which will investigate 8-week and 12-week courses of this 2-DAA combination against several genotypes of HCV. AbbVie is planning for the first approval of this treatment in the U.S. in 2017.

In our fiscal 2015, we received \$125 million in milestone payments for commercialization regulatory approvals of paritaprevir, and we earned \$34.1 million in royalties on its allocated portion of AbbVie's net sales of paritaprevir-containing HCV regimens. In our first quarter of fiscal 2016, we received a \$30 million milestone payment for the November 2015 reimbursement approval of paritaprevir in Japan, and we earned \$17.9 million in royalties on its allocated portion of AbbVie's net sales of paritaprevir-containing HCV regimens. We had \$236.6 million in cash and marketable securities at December 31, 2015, exclusive of the \$17.9 million in royalty receivables due us from AbbVie at that date. These existing resources will allow us to continue to invest for the foreseeable future in our current research and development programs in virology, namely HCV, HBV and RSV, and in liver disease (non-virology), namely NASH and PBC:

- <u>EDP-494</u>: We have a cyclophilin inhibitor, EDP-494, for which we initiated a clinical trial in HCV in the first quarter of calendar 2016 to demonstrate its potential benefit as a host targeted antiviral, or HTA. Cyclophilin is a protein in the human body that has been shown to be involved in HCV replication. By focusing on this human, or host, 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. We believe that cyclophilin inhibitors will be particularly valuable in the setting of resistance associated variants, or RAVs, of HCV. The presence of pre-treatment, or baseline, RAVs in treatment-naïve patients, and the emergence of treatment emergent RAVs in treatment-experienced patients, can result in reduced ability to eradicate the HCV virus. Since cyclophilin is a human host target, and not a viral target, cyclophilin inhibitors are not affected by changes in the virus and, therefore, use of this class of inhibitor may provide a unique solution for a subset of hard-to-treat HCV patients. We plan to develop EDP-494 for use in combination with one or more DAAs for the treatment of any emerging HCV resistance to currently approved therapies and other therapies under development for HCV that use DAAs. It is also possible that an EDP-494-containing regimen may find utility in other hard-to-treat subpopulations of HCV patients.
- <u>EDP-305</u>: We are also working on multiple compounds that selectively bind to and activate the farnesoid X receptor, referred to as FXR agonists, which we plan to develop for use in the treatment of non-alcoholic steatohepatitis, or NASH, and possibly primary biliary cholangitis, or PBC, both of which are liver diseases with very few therapeutic options. We plan to initiate clinical trials of our lead FXR agonist candidate, EDP-305, in 2016.
- <u>HBV and RSV</u>: We also have other programs to discover and develop new chemical entities for the treatment of HBV and RSV.

We have utilized our internal chemistry and drug discovery capabilities to generate all of our development-stage programs.

We are currently funding all research and development for our internal programs. We have prioritized our cyclophilin program because we believe that highbarrier-to-resistance mechanisms are going to be increasingly important for the treatment of HCV patients, including those that have failed on current DAA therapies. We expect to incur substantially greater expenses as we continue to advance our cyclophilin inhibitor, EDP-494, through Phase 1 clinical development, which began in January 2016. We are also funding our FXR agonist program, including substantial preclinical development work, which we expect will enable us to initiate clinical development of our lead candidate, EDP-305, in 2016. In addition, we expect increases in expenses in 2016 as we advance other compounds into substantial preclinical 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 and liver diseases. For the periods included in this report we have funded our operations primarily through payments received under our collaborations and a NIAID government contract, as well as net proceeds of approximately \$59.9 million that we received from our March 2013 IPO, after deducting underwriting discounts and commissions.

Our revenue from our collaboration agreements has resulted in our reporting net income in each of our past five fiscal years. We expect that our revenue in the near term will continue to be dependent on our collaboration with AbbVie, including royalties from sales of paritaprevir-containing regimens and potential milestone payments and royalties from the development program for AbbVie's next-generation HCV product containing ABT-493. Given the schedule of potential milestone payments and the uncertainties due to the nature and timing of clinical development and regulatory approval and market acceptance of any AbbVie regimen containing ABT-493, as well as uncertainty regarding the extent of royalty payments related to paritaprevir, we cannot be certain as to when or whether we will receive further milestone payments or the extent of our royalty revenues under this collaboration or whether we will continue to report net income in future periods.

#### **ENANTA** PIPELINE **Pharmaceuticals**

| 1 11011 1110 | accontents   |                |                 |         |         |          |   |
|--------------|--|----------------|-----------------|---------|---------|----------|---|
|              | T CANDIDATE<br>PARTNER)  | PRECLIN        | PHASE 1         | PHASE 2 | PHASE 3 | APPROVED | STATUS  |
|              |  |                |                 |         |         |          |   |
| нсу          | Protease inhibitor:<br>paritaprevir-containing                                   | (paritaprevir/ | r + NS5A + NNuc | :)±RBV  |         |          | GT1: Marketed by AbbVie                         |
|              | regimens (AbbVie)  | (paritaprevir/ | r + NS5A) + RB\ | /       |         |          | GT4: Marketed by AbbVie                         |
|              |  | (paritaprevir/ | r + NS5A)       |         |         |          | GT1: Approved in Japan<br>Marketed by AbbVie    |
| нсу          | Next-generation<br>protease inhibitor:<br>ABT-493-containing<br>regimen (AbbVie) | ABT-493 + Ne   | xt-Gen NS5A     |         |         |          | Phase 3 ongoing                                 |
| нсу          | NS5A inhibitor:<br>EDP-239   | EDP-239        |                 |         |         |          | Proof-of-concept study<br>completed in GT1      |
| HCV          | Cyclophilin inhibitor:<br>EDP-494  | EDP-494        |                 |         |         |          | Phase 1 ongoing                                 |
| HBV          | Core inhibitor   |                |                 |         |         |          | Preclinical candidate<br>identification ongoing |
| RSV          | Respiratory<br>Syncytial Virus<br>Non-Fusion inhibitor                           |                |                 |         |         |          | Preclinical candidate<br>identification ongoing |
| NASH<br>PBC  | Non-alcoholic steato-<br>hepatitis (NASH)<br>Primary biliary                     | EDP-305        |                 |         |         |          | Preclinical FXR agonist<br>candidate identified |

NOTE: "/r" refers to ritonavir; "NS5A" refers to AbbVie's NS5A inhibitor ombitasvir; "NNuc" refers to AbbVie's non-nucleoside polymerase inhibitor dasabuvir; "Next-Gen NS5A" refers to AbbVie's next-generation NS5A inhibitor ABT-530; "RBV" refers to ribavirin.

#### **Financial Operations Overview**

cholangitis (PBC)

#### 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 entered into three significant collaboration agreements and contracts since 2006, the most significant of which is our collaboration agreement with AbbVie. Our second collaboration was with Novartis, from February 2012 through September 2014. In addition, from September 2011 through August 2015, we had a contract with NIAID, which funded the preclinical and early clinical development of an antibiotic product candidate for potential use in biodefense.

Beginning in our fiscal year ended September 30, 2015, we generated royalty revenue from AbbVie's net sales allocable to paritaprevir, which is part of AbbVie's treatment regimens for HCV approved in the U.S. in December 2014, in the EU in January 2015 and in dozens of other countries since then. AbbVie received reimbursement approval for paritaprevir in Japan in November 2015.

The following table is a summary of revenue recognized from our collaboration agreement and our government contract for the three months ended December 31, 2015 and 2014:

|                    |          | onths Ended<br>mber 31, |
|--------------------|----------|-------------------------|
|                    | 2015     | 2014                    |
|                    | (in th   | ousands)                |
| AbbVie agreement:  |          |                         |
| Milestone payments | \$30,000 | \$75,000                |
| Royalties          | 17,869   | 1,392                   |
| NIAID contract     | 576      | 1,106                   |
| Total revenue      | \$48,445 | \$77,498                |
| lotal revenue      | \$48,445 | \$77,498                |

#### AbbVie Agreement

Since all of our research obligations under the AbbVie agreement were concluded by June 30, 2011, all milestone payments received since then, have been recognized as revenue upon achievement of each milestone by AbbVie. During the three months ended December 31, 2015, we earned and recognized as revenue a \$30.0 million milestone payment upon AbbVie's achievement of commercialization regulatory approval of a paritaprevir-containing regimen in Japan. During the three months ended December 31, 2014, we earned and recognized as revenue a \$75.0 million milestone amount due from AbbVie as a result of U.S. regulatory approval by the FDA for AbbVie's first treatment regimen containing paritaprevir. Under the terms of the AbbVie agreement, we are eligible to receive additional future milestone payments totaling up to \$80.0 million related to the successful commercialization regulatory approval by AbbVie of the first HCV treatment regimen incorporating another of our collaboration's protease inhibitors.

We also receive annually tiered, double-digit royalties per product on AbbVie's net sales allocable to any one of our collaboration's protease inhibitors. Under the terms of our agreement, as amended in October 2014, 30% of net sales of 3-DAA regimens containing paritaprevir and 45% of net sales of 2-DAA regimens containing paritaprevir are allocated to paritaprevir for purposes of calculating our annually tiered royalties. Beginning with each January 1 the cumulative net sales of a given royalty-bearing product start at zero for purposes of calculating the tiered royalties.

#### **Operating Expenses**

The following table summarizes our operating expenses for the three months ended December 31, 2015 and 2014:

|                            |          | nths Ended<br>ıber 31, |
|----------------------------|----------|------------------------|
|                            | 2015     | 2014                   |
| Research and development   | \$ 9,033 | \$4,519                |
| General and administrative | 3,818    | 2,769                  |
| Total operating expenses   | \$12,851 | \$7,288                |

#### 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 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 cyclophilin inhibitor program for HCV and our research and development efforts in NASH, HBV and RSV.

Our research and drug discovery programs are at early stages; 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, which include 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, director's and officer's liability insurance premiums, and professional fees for auditing, tax and legal services and patent expenses.

#### Other Income (Expense)

Interest income. Interest income consists of interest earned on our cash equivalents and short-term and long-term marketable securities balances

Interest expense. Interest expense consists of interest expense related to our capital lease obligation and to the value of accrued third-party license fees.

*Change in fair value of warrant liability and Series 1 nonconvertible preferred stock.* We have issued warrants for the purchase of our Series 1 nonconvertible preferred stock and we have issued Series 1 nonconvertible preferred stock, both of which we believe are financial instruments that may require a transfer of assets because of the liquidation preference features of the underlying stock. Therefore, we have classified these warrants and Series 1 nonconvertible preferred stock as liabilities that we remeasure to fair value at each reporting period and we record the changes in the fair value of the warrants and Series 1 nonconvertible preferred stock as a component of other income (expense).

#### Income Tax Expense

Income tax expense is based on our best estimate of applicable rates applied to pre-tax profit reported during the period.

#### **Critical Accounting Policies**

Our consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of our consolidated 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 consolidated 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 our Annual Report on Form 10-K for the fiscal year ended September 30, 2015 (referred to as our 2015 Form 10-K) for information about these accounting policies as well as a description of our other significant accounting policies. We believe that of our significant accounting policies, the following accounting policies involve the most judgment and complexity:

- Revenue recognition;
- Income taxes;
- Stock-based compensation; and
- Fair value of warrants and related preferred stock.

Accordingly, we believe the policies set forth above are critical to fully understanding and evaluating our financial condition and results of operations. If actual results or events differ materially from the estimates, judgments and assumptions used by us in applying these policies, our reported financial condition and results of operations could be materially affected.

There have been no material changes in our critical accounting policies since September 30, 2015. For further information, please see the discussion of critical accounting policies included in our 2015 Form 10-K.

#### **Results of Operations**

#### Comparison of Three Months Ended December 31, 2015 and 2014

|   | Three Months Ended<br>December 31, |           |
|---|------------------------------------|-----------|
|   | 2015                               | 2014      |
|   | (in tho                            | usands)   |
| Revenue   | \$48,445                           | \$ 77,498 |
| Research and development expenses   | 9,033                              | 4,519     |
| General and administrative expenses   | 3,818                              | 2,769     |
| Other income (expense):   |                                    |           |
| Interest income   | 356                                | 127       |
| Interest expense  | (12)                               | (2)       |
| Change in fair value of warrant liability and Series 1 nonconvertible preferred |                                    |           |
| stock   | (15)                               | 176       |
| Income tax expense  | (9,734)                            | (28,502)  |

#### Revenue.

|                    |          | lonths Ended<br>ember 31, |
|--------------------|----------|---------------------------|
|                    | 2015     | 2014                      |
|                    | (in th   | nousands)                 |
| AbbVie agreement:  |          |                           |
| Milestone payments | \$30,000 | \$75,000                  |
| Royalties          | 17,869   | 1,392                     |
| NIAID contract     | 576      | 1,106                     |
| Total revenue      | \$48,445 | \$77,498                  |

We recognized revenue of \$48.4 million during the three months ended December 31, 2015, as compared to \$77.5 million during the three months ended December 31, 2015, revenue consisted of a \$30.0 million milestone payment upon AbbVie's achievement of reimbursement approval of a paritaprevir-containing regimen in Japan as well as royalties of \$17.9 million on the portion of AbbVie's net sales of its HCV treatment regimens allocable to paritaprevir and \$0.6 million milestone payment due from AbbVie based on U.S. FDA approval of AbbVie's new treatment for HCV containing paritaprevir, \$1.4 million in royalties payable on the portion of AbbVie's net sales of its HCV treatment regimen allocable to paritaprevir, and \$1.1 million under our contract with NIAID.

#### Research and development expenses.

|   |          | onths Ended<br>nber 31, |
|---|----------|-------------------------|
|   | 2015     | 2014                    |
|   | (in the  | ousands)                |
| R&D programs:                           |          |                         |
| Virology                                | \$ 4,348 | \$ 2,303                |
| Liver disease                           | 4,309    | 760                     |
| Other                                   | 376      | 1,456                   |
| Total research and development expenses | \$ 9,033 | \$ 4,519                |

Research and development expenses were \$9.0 million in the three months ended December 31, 2015, as compared to \$4.5 million for the same period in 2014. We incurred increased research and development expenses in the first quarter of fiscal 2016 as compared to the 2015 quarter due to additional headcount, expansion of our research facilities, additional preclinical activities and preparation for clinical studies of EDP-494.

*General and administrative expenses.* General and administrative expenses increased by \$1.0 million from \$2.8 million in the three months ended December 31, 2014 to \$3.8 million for the same period in 2015. The increase was primarily due to an increase in stock-based compensation expense related to additional stock option grants to employees and a greater Black-Scholes value for these options granted in the later period and additional expense to support our expanding operations.

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

*Interest income*. The increase in interest income for the three months ended December 31, 2015, as compared to the three months ended December 31, 2014, was due to higher average investment balances in the first fiscal quarter of 2016 as compared to 2015 primarily due to the receipt of \$125.0 million of milestone payments and \$34.1 million in royalties from AbbVie during the fiscal 2015.

*Change in fair value of warrant liability and Series 1 nonconvertible preferred stock.* During the three months ended December 31, 2015, we recorded an expense due to an increase in the fair value of our warrant liability and Series 1 nonconvertible preferred stock as a result of the remeasurement of our warrant liability and Series 1 nonconvertible preferred stock.

*Income tax expense.* For the three months ended December 31, 2015 and December 31, 2014, we recorded an income tax provision of \$9.7 million and \$28.5 million, respectively, representing an effective tax rate of 27.1% and 40.4%, respectively. The income tax provision for the three months ended December 31, 2015 and 2014 was primarily attributable to the tax provision on the earnings of our domestic operations. For the three months ended December 31, 2015 our effective tax rate was significantly lower than that in comparable period of 2014 primarily due to reinstatement of the federal research and development tax credits during the recent fiscal quarter.

#### Liquidity and Capital Resources

At December 31, 2015, our principal sources of liquidity were cash, cash equivalents and short-term and long-term marketable securities totaling \$236.6 million.

From our inception through December 31, 2015, we have financed our operations, primarily through contract payments under our collaborations, government research and development contracts and grants, private placements, and our initial public offering of our equity. The following table shows a summary of our cash flows for the three months ended December 31, 2015 and 2014.

|                             | Decemb     | Three Months Ended<br>December 31, |  |
|-----------------------------|------------|------------------------------------|--|
|                             | 2015       | 2014                               |  |
| Cash provided by (used in): |            |                                    |  |
| Operating activities        | \$29,993   | \$(5,610)                          |  |
| Investing activities        | \$ (5,632) | \$ 7,027                           |  |
| Financing activities        | \$ 146     | \$ 2,014                           |  |

#### Net cash used in operating activities

During the three months ended December 31, 2015, operating activities provided \$30.0 million of cash. Cash provided by operating activities primarily resulted from our net income of \$26.2 million, net non-cash charges of \$3.1 million and net change in operating assets and liabilities of \$0.7 million. Our net income in the period was primarily due to normal operating expenses and revenue consisting of a \$30.0 million milestone payment and \$17.9 million in royalties due from AbbVie as well as \$0.6 million in connection with the completion of our contract with NIAID. Our net non-cash charges in the period primarily consisted of \$2.0 million of stock-based compensation expense, change in deferred tax assets of \$0.4 million, depreciation expense of \$0.3 million and \$0.6 million related to amortization of the premium on our marketable securities, which were partially offset by \$0.2 million of premium on marketable securities. The \$3.2 million in royalties earned but not yet received from AbbVie as of December 31, 2015, as well as timing of our billings under the NIAID contract. The \$3.7 million increase in accounts payable is a result of the current tax provision on pretax income during the period offset by the use of deferred tax assets. The \$0.3 million increase in accounts payable and in accrued expenses was primarily due to the timing of payments made by us to vendors.

During the three months ended December 31, 2014, operating activities used \$5.6 million of cash. Cash used in operating activities primarily resulted from our net income of \$42.0 million and net non-cash charges of \$10.9 million, offset by the net change in operating assets and liabilities of \$58.5 million. Our net income in the period was primarily due to normal operating expenses and revenue consisting of a \$75.0 million milestone payable by and \$1.4 million in royalties due from AbbVie and \$1.1 million of reimbursement under our NIAID contract. Our net non-cash charges in the period primarily consisted of change in deferred tax assets of \$11.5 million, \$1.0 million of stock-based compensation expense and \$0.5 million related to amortization of the premium on our marketable securities, which were partially offset by \$1.9 million milestone earned but not yet received from AbbVie as of December 31, 2014, as well as timing of our billings under the NIAID contract. The \$16.9 million increase in accounts payable is a result of the current tax provision on pretax income during the period offset by the use of deferred tax assets. The \$1.8 million decrease in accounts payable and in accrued expenses was primarily due to the timing of payments made by us to vendors.

#### Net cash provided by investing activities

During the three months ended December 31, 2015, net cash used in investing activities was \$5.6 million. Net cash used in investing activities during the period consisted primarily of cash used to purchase \$34.6 million of marketable securities and \$2.2 million to purchase fixed assets partially offset by maturities of marketable securities of \$31.2 million.

During the three months ended December 31, 2014, net cash provided by investing activities was \$7.0 million. Net cash provided by investing activities during the period consisted primarily of cash received from sales and maturities of marketable securities of \$15.4 million offset by \$8.2 million used to purchase marketable securities.

#### Net cash provided by financing activities

Net cash provided by financing activities during the three months ended December 31, 2015 was \$0.1 million and consisted primarily of proceeds from exercise of stock options.

Net cash provided by financing activities during the three months ended December 31, 2014 was \$2.0 million and consisted of income tax benefit from exercise of stock options of \$1.9 million and proceeds from exercise of stock options of \$0.1 million.

#### Funding requirements

As of December 31, 2015, we had \$236.6 million in cash, cash equivalents and short-term and long-term marketable securities. We believe that our existing cash, cash equivalents and marketable securities as of December 31, 2015, will be sufficient to meet our anticipated cash requirements for the foreseeable future. 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 significant royalties, to us;
- whether we exercise any opt-in right under the AbbVie Agreement regarding any protease inhibitor other than paritaprevir or ABT-493;
- 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, paritaprevir, ABT-493 and our future product candidates, if any.

#### **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.

#### **Contractual Obligations and Commitments**

In our Annual Report on Form 10-K for the year ended September 30, 2015, Part II, Item 7, Management's Discussion and Analysis of Financial Conditions and Results of Operations, under the heading "Contractual Obligations and Commitments", we have described our commitments and contingencies. There were no material changes in our commitments and contingencies during the three months ended December 31, 2015.

#### **Recently Issued Accounting Pronouncements**

A description if recently issued accounting pronouncements that may potentially impact our financial position and results of operations is set forth in Note 2 to the consolidated financial statements included in this Quarterly Report on Form 10-Q.

#### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

#### Interest Rate Sensitivity

We had cash, cash equivalents and short-term and long-term marketable securities of \$236.6 million at December 31, 2015, which consisted of cash, money market funds, commercial paper, corporate bonds and government securities. 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 December 31, 2015.

#### ITEM 4. CONTROLS AND PROCEDURES

#### a) Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures.

Our management, with the participation of the principal executive officer and principal financial officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the period covered by this quarterly report. Based on this evaluation, the principal executive officer and principal financial officer concluded that these disclosure controls and procedures are effective and designed to ensure that the information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the requisite time periods.

#### b) Changes in Internal Control Over Financial Reporting.

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) identified in connection with the evaluation of our internal control performed during the last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

#### PART II - OTHER INFORMATION

#### ITEM 1A. RISK FACTORS

#### **RISK FACTORS**

Our business faces significant risks and uncertainties. Certain factors may have a material adverse effect on our business prospects, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in or incorporated by reference into this Annual Report on Form 10-K and our other public filings with the SEC. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

#### **Risks Related to Our Business**

Our financial prospects for the next several years are dependent upon the development and commercialization efforts of AbbVie for combination therapies incorporating the protease inhibitors paritaprevir or ABT-493 for the treatment of HCV. AbbVie may act in its best interest rather than in our best interest, which could adversely affect our business.

We rely on AbbVie to fund and conduct the clinical development and commercialization of paritaprevir and ABT-493 (our next-generation protease inhibitor, in clinical development), over which AbbVie 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 AbbVie of combination therapies incorporating paritaprevir or ABT-493. Such success is subject to significant uncertainty, and we have no control over the resources, time and effort that AbbVie may devote to paritaprevir or ABT-493. Any of several events or factors could have a material adverse effect on our ability to generate revenue from AbbVie's commercialization of paritaprevir or potentially ABT-493 in combination therapies. For example, AbbVie:

- may not achieve satisfactory levels of market acceptance and reimbursement by physicians, patients and third-party payers for combination therapies incorporating one of our protease inhibitor product candidates in the various markets of the world where these therapies are being introduced and sold by AbbVie;
- may not compete successfully with any such combination therapies against alternative products and therapies for HCV;
- may have to comply with additional requests and recommendations from the FDA, including label restrictions for paritaprevir or similar restrictions or additional clinical trials for ABT-493;
- may not make all regulatory filings and obtain all necessary approvals from the FDA and similar foreign regulatory agencies, and all
  commercially necessary reimbursement approvals;
- may be unable to complete successfully the clinical development of an ABT-493-containing regimen;
- may not commit sufficient resources to the development or regulatory approval of regimens containing ABT-493 or to the marketing and distribution of regimens containing paritaprevir or ABT-493, whether for competitive or 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 protease inhibitor candidates;
- may not be able to manufacture paritaprevir or ABT-493 in compliance with requirements of the FDA and similar foreign regulatory agencies and in commercial quantities sufficient to meet market demand; and
- may independently develop products that compete with regimens containing paritaprevir or ABT-493 in the treatment of HCV.

We do not have access to all information regarding the products being developed and potentially commercialized by AbbVie, including information about clinical trial design and execution, safety reports from clinical trials, spontaneous safety reports for any marketed product, regulatory affairs, process development, manufacturing, marketing, sales and other areas known by AbbVie. Thus, our ability to keep our stockholders informed about the status of products and product candidates under our collaboration is limited by the degree to which AbbVie keeps us informed. If AbbVie does not perform in the manner we expect or fulfill its responsibilities in a timely manner, or at all, the further development and global commercialization of paritaprevir and the clinical development, regulatory approval and commercialization efforts related to ABT-493 could be delayed or terminated or be commercially unsuccessful. In addition, AbbVie 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 AbbVie may arise if there is a dispute about the progress of the clinical development of a milestone amount, the

relative values allocated to the pharmaceutically active ingredients, or the ownership of intellectual property developed during the course of our collaboration agreement. If AbbVie acts in a manner that is not in our best interest, then it could adversely affect our business and prospects.

We and AbbVie face substantial competition in the markets for HCV drugs, and there are many companies developing potential therapies for nonalcoholic steatohepatitis ("NASH"), hepatitis B virus ("HBV") and respiratory syncytial virus ("RSV"), as well as other liver and viral diseases, which may result in others discovering, developing or commercializing products before we do or doing so more successfully than we or 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, NASH, HBV, RSV and other infectious diseases or liver diseases that we may target in the future.

Many of our competitors have substantially greater commercial infrastructure and greater 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 any collaborator of ours does 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 in one or more disease indications, our competitive position could be compromised because it may be more difficult for us to obtain marketing approval for that product candidate and market acceptance of that product candidate as a second competitor. In addition, any new product that competes with an approved product typically must demonstrate compelling advantages in efficacy, convenience, tolerability or safety, or some combination of these factors, in order to overcome price competition and be commercially successful.

We expect our current and future product candidates to face intense and increasing competition as new products enter the HCV and antiviral markets and advanced technologies become available, particularly in the case of HCV in combinations with existing products and other new products. First generation protease inhibitors, Incivek<sup>®</sup> (telaprevir) of Vertex and Victrelis<sup>™</sup> (boceprevir) of Merck, were approved in 2011 by the FDA for the treatment of HCV, which combinations with interferon and ribavirin, which in combination were the previous standard of care. However, by January 2015 both Vertex and Merck had announced they would discontinue the sale of these products, noting competing treatments and diminishing market demand. A third protease inhibitor, simeprevir (Olysio®) from Janssen Therapeutics, was approved by the FDA in November 2013 for use in genotype 1 HCV patients only when used in combination with pegylated interferon and ribavirin. The evolving competitive landscape in HCV intensified in December 2013, when the FDA approved sofosbuvir (Sovaldi®), a nucleotide analogue inhibitor of the HCV NS5B polymerase enzyme from Gilead, for patients with genotype 2 or 3 HCV and no requirement for interferon (also approved for patients with genotypes 1 or 4 when combined with pegylated interferon and ribavirin). On July 9, 2014, Bristol-Myers Squibb gained approval in Japan for the NS5A/protease inhibitor combination daclatasvir/asunaprevir. In October 2014 the FDA approved Gilead's interferon-free Harvoni®, a fixed-dose combination of sofosbuvir and ledipasvir (a NS5A inhibitor) for patients with genotype 1 HCV. Also in November 2014 the FDA approved an interferon-free combination therapy of simeprevir and sofosbuvir for genotype 1 HCV patients. In December 2014, AbbVie's VIEKIRA PAK treatment regimen containing our collaboration's paritaprevir was approved by the FDA, and since then approvals of other paritaprevir-containing regimens and Harvoni followed in the EU and Japan. In July 2015, BMS received approval in the US for daclatasvir in combination with sofosbuvir for genotype 3 HCV patients. Also in that month, the FDA approved the paritaprevir-containing regimen Technivie<sup>TM</sup> from our partner AbbVie for genotype 4 HCV patients. On January 28, 2016 Merck received FDA approval for its combination of a protease and an NS5A inhibitor for the treatment of patients with genotypes 1 or 4 HCV infection. Other all-oral, next-generation treatment regimens are under development at Merck, Gilead and Johnson & Johnson and may obtain regulatory approvals in other settings for the treatment of HCV in the next year. These other potential new treatment regimens may render AbbVie's treatment regimens containing any of our HCV product candidates noncompetitive. In particular, regimens containing our HCV product candidates may not be able to compete successfully with other products and regimens, a number of which remain under active development and involve multiple classes of inhibitors of HCV, including protease inhibitors, polymerase inhibitors (nucleoside and non-nucleoside), NS5A inhibitors, and others, under development by companies such as Achillion, Bristol-Myers Squibb, Co-Crystal Pharma, Gilead, Johnson & Johnson, Medivir, Merck, Regulus and Roche, as well as by our collaborator AbbVie.

Competitive products in the form of other treatment methods or a vaccine for HCV 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, reimbursement coverage, price, patent position, the availability and cost of supply, marketing and sales capabilities, and other factors. If the product candidates developed under our collaboration agreement with AbbVie face competition from generic products, the collaboration agreement provides 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 collaborator 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.

Though there is currently no approved treatment for NASH, we expect significant competition from other companies in the development of new treatments for NASH and related conditions. We are aware of several companies with programs that are significantly more advanced than ours, including companies with compounds in Phase 2 or later stage clinical trials for NASH or related conditions. These companies include Alberio, Conatus, Galectin, Galmed, Genfit, Gilead, GlaxoSmithKline, Intercept, Novo Nordisk, and Tobira. A significant number of other companies are conducting earlier clinical trials that may be applicable in NASH and other cholestatic diseases, including AstraZeneca, Boehringer Ingelheim, Cymabay, Durect, Islet, Medicnova, Metabolic Solutions Development Company, NGM, Nimbus, Shire, and Viking, and there are additional companies conducting preclinical studies in these disease areas.

Similarly, HBV and RSV represent competitive therapeutic areas. While there are effective antiviral medications prescribed for HBV, they generally have low true cure rates. Many companies are seeking to develop new HBV drugs that alone or in combination with other mechanisms could lead to a functional cure of HBV. Gilead, Roche, and Arrowhead Research have Phase 2 programs in progress, and a number of companies have Phase 1 or earlier stage HBV programs, including Alnylam, Arbutus, Assembly, Johnson & Johnson, Ionis, Spring Bank and Replicor.

For RSV, there are no safe and effective approved therapies. Several companies are seeking new antiviral treatments for RSV in adult and pediatric settings. Johnson & Johnson and Gilead each have compounds in Phase 2 development, as does Ablynx with a potential therapeutic antibody. Earlier stage programs have also been reported by Ark Biosciences, Biota, and Medivir.

If we are not able to develop new products that can 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 not developed independently any approved products and we have limited clinical development experience, which makes it difficult to assess our ability to develop and commercialize our future product candidates.

AbbVie has been and will continue to be responsible for all of the clinical development of our paritaprevir and ABT-493 protease inhibitor product candidates. We have not yet demonstrated an ability to address successfully 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 our cyclophilin inhibitor and any combinations including it, for HCV, as well as for any of our research programs beyond HCV, we will need to successfully:

- execute clinical development of our future product candidates and demonstrate acceptable safety and efficacy for them alone and, at least in the case of HCV, in combination with other drugs or drug 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;
- obtain and maintain patent protection for our product candidates and freedom from infringement of intellectual property of others;
- establish acceptable commercial manufacturing arrangements with third-party manufacturers;
- 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 among physicians, payers and patients; 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.

### If we are not successful in discovering further product candidates in addition to paritaprevir, ABT-493 and EDP-494, our ability to expand our business and achieve our strategic objectives will be impaired.

Most of our internal research programs are at preclinical stages. 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;
- competitors may develop alternatives that render our future product candidates less commercially viable or obsolete;
- competitors may obtain intellectual property protection that effectively prevents us from developing a potential product candidate;
- a future product candidate may, on further study, be shown not to be an effective treatment in humans or 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.

Additional drug candidates that we may develop will require significant research, preclinical and clinical studies, regulatory approvals and commitments of resources before they can be commercialized. We cannot give assurance that our research will lead to the discovery of any additional drug candidates that will generate additional revenue for us. 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 or she 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 fields 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 may encounter difficulties in managing our growth and expanding our operations successfully.

As we expand our research efforts and 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.

#### Expenses associated with development of our product candidates may cause our earnings to fluctuate from period to period.

Many of the preclinical and clinical development activities required for our product candidates will have to be contracted out to CROs at significant expense. It is difficult to accurately predict the timing of these expenses, and we expect that they will vary from quarter to quarter. In addition, the FDA or other regulatory agencies may require more preclinical or clinical testing than we originally anticipated for any of our drug candidates. We may also be required to purchase expensive competitor drugs for use in our trials, either to demonstrate potential treatment combinations or as comparators to our product candidates. As a result, the expenses of our development programs and our operating results may fluctuate significantly from quarter to quarter, and our stock price may be adversely affected.

To date, our principal sources of revenue have been our collaboration agreements, including our current agreement with AbbVie and our prior agreement with Novartis. Future milestone payments and the level of royalties under the AbbVie agreement are uncertain. We have had no products approved for commercial sale by us. Therefore, it is possible that we may incur operating losses in one or more years in the future, and our ability to achieve sustained profitability is unproven.

In each of our 2013, 2014 and 2015 fiscal years as well as in the first quarter of fiscal 2016, our net income resulted primarily from license payments, including milestone payments we earned from AbbVie and/or Novartis and royalties we earned since December 2014 on AbbVie's net sales allocated to paritaprevir. There is no assurance, however, that we will report net income in subsequent years. To date, we have not commercialized any products ourselves and we have not yet generated sustained revenue from product sales by AbbVie.

Our principal source of revenue has been our collaboration agreements, including our current agreement with AbbVie. The level of future royalties on paritaprevir are uncertain given the competitive nature of the market for HCV therapies, the emergence of new, but not yet approved, therapies for HCV, the changing nature of payer contracts of AbbVie and others, and the varying rates of reimbursement in different countries. In addition, it is not yet clear what will be the long-term impact, if any, of the October 2015 drug safety communication from the FDA regarding the risks of AbbVie's VIEKIRA PAK and TECHNIVIE regimens in patients with decompensated cirrhosis, for which it had never been recommended. Future milestone payments are uncertain because AbbVie may choose not to continue research or development activities for our ABT-493 product candidate. For example, under our previous collaboration with Novartis for the development of our NS5A inhibitor, Novartis decided in September 2014 not to pursue further development of the licensed product candidate in light of its decision that HCV was no longer a strategic focus of Novartis, which resulted in the NS5A inhibitor program being transferred back to us and our collaboration being terminated. In addition, under our AbbVie collaboration we may not achieve the specified milestones for ABT-493, that product candidate may not be approved by the FDA or other regulatory authorities or, if ABT-493 is approved, the combination containing it may not be accepted in the market. If we are unable to develop and commercialize any more of our product candidates, either alone or with our collaborators, or if any such product candidate or paritaprevir does not achieve market acceptance, we may never generate sufficient product royalties or product sales. In addition, for any of our product candidates other than paritaprevir or ABT-493 included in a treatment regimen with more than one active compound, it would be uncertain what portion of net sales of the regimen would be allocated to our product candidate. The existence of multiple active compounds in the regimen or an unfavorable allocation to our product candidate could adversely affect our royalty revenue. Even if we do generate significant product royalties or product sales, we may not be able to sustain profitability on a quarterly or annual basis. Our failure to sustain profitability could depress the market price of our common stock and ultimately 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 require substantial additional financing in the longer term to achieve our goals if the further commercialization of paritaprevir is delayed or curtailed or if the development of ABT-493 is delayed or terminated. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate some or all of 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 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. For the foreseeable future, we expect to incur substantial additional costs associated with research and development for our internally developed programs, exclusive of costs incurred by our collaborator in developing our licensed product candidate ABT-493. In addition, we may seek opportunities to in-license or otherwise acquire new therapeutic candidates and therapies.

Our future capital requirements depend on many factors, including:

- 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, including 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, including manufacturing for clinical development;



- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patents, including litigation costs and the outcome of such litigation; and
- the level of future sales of paritaprevir-containing regimens and the resulting levels of annually tiered royalties on paritaprevir, as well as the level of potential sales, if any, of ABT-493-containing regimens.

Additional funds may not be available if and 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.

## Our government funded contract for our antibiotic program, which was concluded in fiscal 2015, is subject to audit and adjustments that could affect our previously reported revenues.

Our contract 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, was completed in fiscal 2015. 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 reported revenue and require payments by us to the U.S. government.

#### 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, AbbVie or any other future collaborator 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. None of our product candidates in our pipeline other than paritaprevir has yet advanced beyond Phase 2 clinical trials. Any future clinical trials of our other product candidates may fail to demonstrate sufficient safety and efficacy. Moreover, regulatory and administrative delays for any product candidate in our pipeline may adversely affect our or any collaborator's clinical development plans and jeopardize our or any collaborator's ability to attain product approval, commence product sales and compete successfully against other therapies.

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, including guidelines specifically addressing requirements for the development of DAAs for the treatment of HCV;
- program discontinuations or clinical holds for a program of a competitor, which could increase the level of regulatory scrutiny or delay data review or other response times by regulators with respect to one of our programs in the same class as the competitor's program; or
- varying interpretations of data by the FDA, the EMA and similar foreign regulatory agencies.

The results of any Phase 3 clinical trial may not be adequate to support marketing approval for one of AbbVie's regimens containing a protease inhibitor. These clinical trials are lengthy and usually involve from many hundreds to thousands of patients. In addition, if the FDA or the EMA disagrees with AbbVie'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 experimental therapy or are subject to confounding factors, or are not adequately supported by other study endpoints, the FDA or the EMA, or both, may refuse to approve AbbVie's product candidate. The FDA or the EMA also may require additional clinical trials as a condition for approving any of these product candidates. AbbVie estimates that it will likely be 2017 before an NDA for one of AbbVie's HCV treatment regimens containing one of our product candidates other than paritaprevir could be approved by the FDA or the EMA.

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, the EMA 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 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. 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.

### EDP-494 or any product candidate in our current NASH program may have undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require our product candidate to be taken off the market, require us to include safety warnings or otherwise limit sales.

We have designed our EDP-494 to be substantially different from another cyclophilin inhibitor, alisporivir. The combination of interferon with ribavirin and alisporivir has been associated with pancreatitis in patients receiving treatment with the combination during clinical trials. We do not plan to develop EDP-494 in combination with interferon or ribavirin, which have also been associated with pancreatitis in other clinical contexts not including a cyclophilin inhibitor. However, we cannot give any assurance that EDP-494 will not result in any unforeseen side effects.

In our NASH program we are developing agonists of the farnesoid X receptor, or FXR, that are designed to bind to that receptor and then trigger a response from it. With the exception of one drug approved to treat cholesterol gallstone dissolution and a rare lipid storage disease, there are no approved FXR agonists and the adverse effects from long-term exposure to this drug class are unknown. Unforeseen side effects from any of our product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. The range and potential severity of possible side effects from systemic therapies like FXR agonists could be significant.

In addition, our drug candidates for NASH will be developed as a potential treatment for a severe disease that commonly occurs in patients with other serious conditions, including metabolic syndrome and diabetes. Any clinical trials in NASH will necessarily be conducted in patient populations that may be more prone than the general population to exhibit certain disease states or adverse events. It may be difficult to discern whether certain events or symptoms observed during our trials were due to our drug candidates or placebo, resulting in our company and our development programs being negatively affected even if such events or symptoms are ultimately determined to be unlikely related to our drug candidates.

If any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products:

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we may be required to change instructions regarding the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- regulatory authorities may require us to take our approved product off the market;

- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us or any potential future collaborator from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of any product we develop with EDP-494 or any of our FXR agonists for NASH.

## If we, or AbbVie in the case of our protease inhibitor product candidates, 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 AbbVie are required to conduct studies on the long-term effects associated with the use of any of those product candidates, efforts to commercialize any of those 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 AbbVie 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, AbbVie or regulatory authorities, such as the FDA or EMA, to interrupt, delay or halt clinical trials of our product candidates and could result in the FDA or EMA 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 AbbVie from commercializing our product candidates.

#### 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-493, EDP-494, EDP-239 or any of our future product candidates, may not be predictive of the results of later-stage clinical trials, if any. In addition, results of Phase 3 clinical trials in one or more ethnic groups are not necessarily indicative of results in other ethnic groups. 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.

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 early and 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 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, the EMA and other 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 approvals are unpredictable and depend 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 comparable application to other regulatory authorities. AbbVie obtained all regulatory approvals for paritaprevir, our sole approved product. We have not obtained regulatory approval by ourselves for any of our other 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 foreign countries or by the FDA.

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

- the FDA, the EMA or other 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, the EMA or other 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, the EMA or other 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, the EMA or other 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 submissions 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 of any of our product candidate; and
- the approval policies or regulations of the FDA, the EMA or other 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 approvals in any desired jurisdiction. 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 in effect 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, including those in the European Union, 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 and our business.

# 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 in other jurisdictions, 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 manufactures 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;
- fines, 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 candidates 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 only AbbVie in the case of paritaprevir or ABT-493, may delay or terminate the development of a product candidate at any time if we or AbbVie believe the perceived market or commercial opportunity does not justify further investment, which could materially harm our business and adversely affect our stock price.

Even though the results of preclinical studies and clinical trials that we or AbbVie have conducted or may conduct in the future may support further development of one or more of our product candidates, we, or only AbbVie in the case of ABT-493, 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 regulatory approvals in key markets, gain meaningful market acceptance, otherwise provide any competitive advantages in its intended indication or market or generate a significant return to stockholders. Such a delay, suspension or termination could materially harm our business, results of operations or financial condition. In addition, AbbVie has the right to make decisions regarding the development and commercialization of paritaprevir and ABT-493 without consulting us, and may make decisions with which we do not agree.

## 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, as in the case of our collaboration with AbbVie, or where we have the right to assist in the future development and commercialization of such products.

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.

## Our commercial success depends upon significant market acceptance among physicians, patients and healthcare payors of products containing paritaprevir or ABT-493 as well as similar market acceptance of any future product candidates we plan to develop independently or in collaboration with others.

Paritaprevir and ABT-493 as well as EDP-494 or any other product candidate that we may develop in the future that obtains regulatory approval, whether as part of a combination therapy or as a monotherapy, 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 continue to evolve rapidly as many new product candidates are being developed and tested. The degree of market acceptance of any product for which we or any collaborator of ours receives approval for commercial sale depends on a number of factors, including:

- the efficacy and safety of treatment regimens containing one of our product candidates, as demonstrated in clinical trials, and the degree to which
  these regimens represent a clinically meaningful improvement in care as compared with other available therapies;
- the clinical indications for which any treatment regimen containing one of our product candidates become approved;
- acceptance among physicians, major operators of clinics, payors and patients of any treatment regimen containing one of our product candidates;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the potential and perceived advantages of treatment regimens containing one of our product candidates over alternative treatments;
- the cost of treatment of regimens containing one of our product candidates in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities and successful negotiation of favorable agreements with payors by us or our collaborator, as well as the impact of any agreements among any of the foregoing and one or more of our competitors limiting access to our product in favor of one or more competitive products;
- the continued growth and longevity of the HCV drug market or any other market for which we develop a drug;
- the levels of funding provided by government-funded healthcare for HCV treatment or treatment of any other disease for which we develop a drug;
- the relative convenience and ease of administration of any treatment regimen containing one of our product candidates compared to competitive regimens;
- the prevalence and severity of adverse side effects, whether involving the use of treatment regimens containing one of our products candidates or similar, competitive treatment regimens; and
- the effectiveness of our or our collaborators' sales and marketing efforts.

If treatment regimens containing one of our product candidates are approved and then fail to achieve market acceptance, we may not be able to generate significant additional revenue. Further, if new, more favorably received therapies are introduced after any such regimen achieves market acceptance, then we may not be able to maintain that market acceptance over time.

# Even if AbbVie successfully commercializes ABT-493 in new HCV treatment regimens, or even if we are able to commercialize EDP-494 or any other treatment regimen containing one of our product candidates, the resulting products, as well as AbbVie's existing products containing paritaprevir, may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives in the United States, which would harm our business.

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, is significantly changing 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 or regimen 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 AbbVie. AbbVie or any other collaborator's 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 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. In the case of HCV, limitations of coverage have recently been used to limit access to HCV treatments only for those patients with more advanced fibrosis. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and, in many cases involving HCV drugs, seeking discounts in exchange for greater patient access to a particular HCV drug. In addition, there are private and public payors 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 AbbVie 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 or comparable authorities in other jurisdictions. 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 any collaborator or we 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 results of operations 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 one or more of 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 one or more of our future product candidates. We face significant competition in seeking appropriate collaborators and the 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 our existing collaboration agreement with AbbVie 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, 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 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 manufactures 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.

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

Although manufacturing for our lead product candidates paritaprevir and ABT-493 is being conducted by AbbVie, 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. 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. We also use contract researchers in China to conduct a portion of our search for our early stage programs. Any disruption in the team conducting that research could cause delays in one or more of our research programs and could require us to curtail one or more programs, at least until we could contract for that research to be done elsewhere. Furthermore, since these researchers and 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 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 AbbVie. 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 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, 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 our lead antibiotic candidate, which we are no longer developing, was funded under a contract with 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, or 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 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, if AbbVie licenses or otherwise acquires 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, it is entitled under our collaboration agreement 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 violations 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 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, other antivirals and liver disease. 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 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;
- 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 declines in consumer confidence, declines in economic growth, and uncertainty about economic stability. There can be no assurance that deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by the 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 debt or equity financing more difficult to secure, more costly and/or more dilutive if our circumstances change and we seek such financing. 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.

### 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;
- 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.

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**

#### Our stock price has been, and is likely to continue to be, volatile, and thus our stockholders could incur substantial losses.

Our stock price has been volatile and could be subject to wide fluctuations in response to various factors, many of which are beyond our control. Since our initial public offering in March 2013, the price of our common stock on The NASDAQ Global Select Market has ranged from \$16.49 to \$52.58. 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 your purchase price, if at all. The market price for our common stock may be influenced by many factors, including:

- actions by AbbVie regarding HCV treatment regimens containing any of our product candidates it is developing, including announcements regarding clinical or regulatory developments or our collaboration;
- market expectations about and response to the levels of sales or scripts achieved by, or the announced prices or discounts for, AbbVie's
  paritaprevir-containing HCV treatment regimens or competitive HCV drugs;
- failure of AbbVie's paritaprevir-containing HCV treatment regimens to achieve commercial success;
- 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 collaborator's 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;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- period-to-period 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 or other actions that affect the effective reimbursement rates for treatment regimens containing our products or for competitive regimens;
- 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.

### 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 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 that the state courts or, in certain circumstances, the federal courts, in Delaware shall be the sole and exclusive forum for certain actions involving us, our directors, officers, employees and stockholders;
- 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 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 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 that provide for aggregate cash payments of up to approximately \$3.8 million for severance and other non-equity-based benefits in the event of a termination of employment in connection with a change of control of our company. In addition, based on the December 31, 2015 closing price of our common stock at \$33.02 per share, the aggregate intrinsic value of unvested stock options and other equity awards subject to accelerated vesting upon these events

was \$5.5 million as of December 31, 2015. 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 company's financial condition and results. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

### 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 stockholder approval of any golden parachute payments not previously approved. As an "emerging growth company" we are required to report periodic financial results and selected financial data related to two fiscal years compared to three and five years, respectively, for comparable data required to be reported by other public companies in selected SEC reports. We may take advantage of these exemptions until we are no longer an "emerging growth company." We could be an "emerging growth company" until September 30, 2018, 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.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is 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" until September 30, 2018. 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.

### Because we do not anticipate paying cash dividends on our common stock for the foreseeable future, investors in our common stock may never receive a return on their investment.

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any cash dividends to holders of our common stock for the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations.

Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not invest in our common stock.



### A sale of a substantial number of shares of our common stock in the public market 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. As of December 31, 2015, we had outstanding 18,795,114 shares of common stock. In addition, at that date 2,111,289 shares of common stock that are subject to outstanding options or stock unit awards under our equity plan are eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, and Rules 144 and 701 under the Securities Act. If these additional shares of common stock are sold, or it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

### 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. If too few securities or industry analysts cover our company, the trading price for our stock would likely be negatively impacted. In the event that 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.

#### ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

#### **Unregistered Sales of Equity Securities**

None.

#### Use of Proceeds from the Sale of Registered Securities

In March 2013, we completed our IPO of 4,600,000 shares of our common stock at a public offering price of \$14.00 per share. The offer and sale of the shares in the offering were registered pursuant to a registration statement on Form S-1 (File No. 333-184779), which was declared effective by the Securities and Exchange Commission on March 20, 2013.

As of December 31, 2015, we have used approximately \$49.7 million of the net proceeds from the IPO to fund our programs for the development of a cyclophilin inhibitor candidate and the development of a nucleotide polymerase inhibitor candidate and to fund new research and development activities. None of the net proceeds has been paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates. The balance of the net proceeds from the offering has been invested in cash and cash equivalents and in short-term and long-term marketable securities, consisting of investment grade, interest bearing instruments and U.S. government securities, with maturities of no longer than 38 months. These investments are reflected in cash and cash equivalents, short-term marketable securities and long-term marketable securities on our balance sheet at December 31, 2015. There has been no material change in the expected use of the net proceeds from our IPO as described in our registration statement on Form S-1.

#### ITEM 6. EXHIBITS

| Exhibit |   |      | Incorporate | d by Referer<br>Exhibit | ice         | Filed    |
|---------|---|------|-------------|-------------------------|-------------|----------|
| Number  | Exhibit Description   | Form | Date        | Number                  | File Number | Herewith |
| 3.1     | Restated Certificate of Incorporation of Enanta Pharmaceuticals, Inc.   | 8-K  | 08/18/2015  | 3.1                     | 001-35839   |          |
| 3.2     | Amended and Restated Bylaws of Enanta Pharmaceuticals, Inc.   | 8-K  | 08/18/2015  | 3.2                     | 001-35839   |          |
| 10.1†   | Collaborative Development and License Agreement between the Company and Abbott<br>Laboratories, dated November 27, 2006; as amended by a First Amendment to<br>Collaborative Development and License Agreement dated January 27, 2009, a Second<br>Amendment to Collaborative Development and License Agreement dated December 9,<br>2009 and a Third Amendment to Collaborative Development and License Agreement<br>dated October 20, 2014 (assigned to AbbVie Inc. as of January 1, 2013).   |      | _           | _                       | _           | Х        |
| 31.1    | Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.  | —    | —           | —                       | —           | Х        |
| 31.2    | Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.  | —    | —           | _                       | —           | Х        |
| 32.1    | Certification of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.  | —    | _           | —                       | _           | Х        |
| 101     | The following materials from the Quarterly Report of Enanta Pharmaceuticals, Inc. on<br>Form 10-Q for the quarter ended December 31, 2015, formatted in XBRL (eXtensible<br>Business Reporting Language): (i) Consolidated Balance Sheets as of December 31,<br>2015 and September 30, 2015 of Enanta Pharmaceuticals, Inc., (ii) Statements of<br>Operations for the three months ended December 31, 2015 and 2014 of Enanta<br>Pharmaceuticals, Inc., (iii) Statements of Cash Flows for the three months ended<br>December 31, 2015 and 2014 of Enanta Pharmaceuticals, Inc., and (iv) Notes to<br>Consolidated Financial Statements of Enanta Pharmaceuticals, Inc. |      |             |                         |             | Х        |

This Exhibit has been filed separately with the commission pursuant to an application for confidentiality treatment. The confidential portions of this Exhibit have been omitted and are marked by asterisks.

#### ENANTA PHARMACEUTICALS, INC.

#### SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: February 9, 2016

ENANTA PHARMACEUTICALS, INC.

/s/ Paul J. Mellett

Paul J. Mellett Chief Financial Officer (Principal Financial and Accounting Officer)

#### ENANTA PHARMACEUTICALS, INC.

#### EXHIBIT INDEX

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This Exhibit has been filed separately with the commission pursuant to an application for confidentiality treatment. The confidential portions of this Exhibit have been omitted and are marked by asterisks.

Enanta has requested that portions of this document be accorded confidential treatment pursuant to Rule 24b-2 promulgated under the Securities Exchange Act of 1934, as amended.

Exhibit 10.1 EXECUTION VERSION

#### COLLABORATIVE DEVELOPMENT AND LICENSE AGREEMENT

#### by and between

#### ENANTA PHARMACEUTICALS, INC.

and

#### ABBOTT LABORATORIES

#### November 27, 2006

Confidential materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote such omission.

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#### List of Exhibits and Schedules

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Confidential materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote such omission.

#### COLLABORATIVE DEVELOPMENT AND LICENSE AGREEMENT

This COLLABORATIVE DEVELOPMENT AND LICENSE AGREEMENT (this "<u>Agreement</u>") is entered into as of November 27th, 2006, by and between Enanta Pharmaceuticals, Inc., with principal offices at 500 Arsenal Street, Watertown, Massachusetts 02472 ("<u>Enanta</u>") and Abbott Laboratories, having a place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064 ("<u>Abbott</u>"). Each of Abbott and Enanta is sometimes referred to individually herein as a "<u>Party</u>" and collectively as the "<u>Parties</u>."

WHEREAS, Enanta Controls certain Technology and/or Proprietary Materials related to or otherwise useful in the discovery and development of HCV NS3 or NS3/4A protease inhibitors (as those terms are defined below);

WHEREAS, Abbott has expertise in discovering, developing, testing, obtaining regulatory approvals with respect to, manufacturing and marketing human therapeutic products; and

WHEREAS, Enanta and Abbott desire to enter into a collaboration for the purpose of identifying, developing and commercializing Enanta's proprietary HCV NS3 or NS3/4A protease inhibitors and/or certain of Abbott's proprietary protease inhibitors as more fully described herein,

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the Parties hereto, intending to be legally bound, hereby agree as follows:

#### 1. **DEFINITIONS**

Whenever used in this Agreement with an initial capital letter, the terms defined in this Section 1 shall have the meanings specified.

1.1 "Abandoned Compounds" means all Products designated as Abandoned Compounds by Enanta pursuant to Section 11.3.6.

1.2 "<u>Abbott Background Technology</u>" means any Technology related to the Field used by Abbott, or provided by Abbott for use, in the Research Program or the Development Program that is (a) Controlled by Abbott as of the Effective Date or (b) developed or conceived by employees of, or consultants to, Abbott after the Effective Date in the conduct of activities outside the Research Program or Development Program.

1.3 "<u>Abbott Compounds</u>" means the HCV protease inhibitors Controlled by Abbott and listed on <u>Schedule 1</u> attached hereto, and any direct analogs thereof created during the Research Program.

1.4 "<u>Abbott Decision</u>" means any decision that is not an Enanta Decision and relates solely to the Development of a Candidate or Commercialization of a Product

Confidential materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote such omission. 1.5 "<u>Abbott Improvement</u>" means any Abbott Program Technology or Abbott's interest in any Joint Technology that contains one or more claims that covers the composition or use of any HCV protease inhibitor. The Parties understand that the term Abbott Improvement (a) shall not include any Abbott Program Technology or Abbott's interest in any Joint Technology that relates to the [\*\*\*\*\*] discovered by Abbott and (b) shall include any Abbott Patent Rights that contain one or more claims that cover Abbott Program Technology and/or Abbott's interest in any Joint Technology whether such Abbott Patent Rights are filed during, or, subject to Section 10.1, following the expiration of the Research Program Term.

1.6 "<u>Abbott Materials</u>" means any Proprietary Materials that are Controlled by Abbott and used by Abbott, or provided by Abbott for use, in the Research Program or the Development Program.

1.7 "<u>Abbott Patent Rights</u>" means any Patent Rights containing one or more claims that cover Abbott Technology. All Abbott Patent Rights existing as of the Effective Date are described on <u>Schedule 2</u> attached hereto. For clarification, the Abbott Compounds listed in Schedule 1 will be covered under Abbott Patent Rights.

1.8 "<u>Abbott Program Technology</u>" means any Program Invention conceived or first reduced to practice by employees of, or consultants to, Abbott, alone or jointly with any Third Party.

1.9 "Abbott Research Activities" means any research activities specified to be conducted by Abbott in any Research Plan.

1.10 "Abbott Technology" means, collectively, Abbott Background Technology and Abbott Program Technology.

1.11 "<u>Adverse Event</u>" means any untoward medical occurrence in a human clinical trial subject or in a patient who is administered a Product, whether or not considered related to the Product including, without limitation, any undesirable sign (including abnormal laboratory findings of clinical concern), symptom or disease associated with the use of such Product.

1.12 "<u>Affiliate</u>" means, with respect to any Party, any Person that, directly or through one or more Affiliates, controls, or is controlled by, or is under common control with, such Party. For purposes of this definition, "control" means (a) ownership of more than fifty percent (50%) of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or more than fifty percent (50%) of the equity interests in the case of any other type of legal entity, (b) status as a general partner in any partnership, or (c) any other arrangement whereby a Person controls or has the right to control the Board of Directors or equivalent governing body of a corporation or other entity.

1.13 "Annual Net Sales" means the aggregate Net Sales during a particular Calendar Year.

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1.14 "<u>Applicable Laws</u>" means all Federal, state, local, national and supra-national laws, statutes, rules and regulations, including any rules, regulations, guidelines or requirements of Regulatory Authorities, national securities exchanges or securities listing organizations that may be in effect from time to time during the Term and applicable to a particular activity hereunder.

1.15 "<u>Approval Date</u>" means the date when both (a) the waiting period (or any extension thereof) applicable to this Agreement under the HSR Act (as defined in Section 14.16) has been terminated or has expired, and (b) the Abbott Board, Abbott's Chief Executive Officer and the Enanta Board have provided approvals described in Section 14.17.

1.16 "<u>Calendar Quarter</u>" means the period beginning on the Effective Date and ending on the last day of the calendar quarter in which the Effective Date falls, and thereafter each successive period of three (3) consecutive calendar months ending on March 31, June 30, September 30 or December 31. For purposes of this definition, the Calendar Quarter for all activities outside the United States by Abbott shall be the three (3) consecutive calendar months ending February 28, May 31, August 31 or November 30.

1.17 "<u>Calendar Year</u>" means each successive period of twelve (12) months commencing on January 1 and ending on December 31; provided, that, the initial Calendar Year shall commence on the Effective Date and end on December 31, 2007. For purposes of this definition, the Calendar Year for all activities conducted outside the United States by Abbott pursuant to this Agreement, shall be the twelve (12) month period commencing on December 1 and ending on November 30.

1.18 "<u>Candidate</u>" means any Compound and/or any Abbott Compound designated by the JSC pursuant to Sections 2.1.4(h) and 3.6 to proceed into GLP toxicity studies and enter the Development Program.

1.19 "Change of Control" means, with respect to a Party (a) a merger, consolidation, share exchange or other similar transaction involving such Party and any Third Party which results in the holders of the outstanding voting securities of such Party immediately prior thereto ceasing to hold more than fifty percent (50%) of the combined voting power of the surviving, purchasing or continuing entity immediately after such merger, consolidation, share exchange or other similar transaction, (b) any transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of such Party, other than in connection with a bona fide financing transaction provided by financial and/or venture capital investors to such Party, or (c) the sale or other transfer to a Third Party of all or substantially all of such Party's assets which relate to this Agreement.

1.20 "CTA" means a notification submitted to EU Regulatory Authorities prior to the initiation of clinical trials in the EU.

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1.21 "CTN" means the notification submitted to the Japanese Ministry of Health, Labor and Welfare prior to the Initiation of a Clinical Trial in Japan.

1.22 "<u>Co-Developed Product</u>" means any Product with respect to which Enanta has exercised a Co-Development and Profit Share Option as described in Section 5.1.

1.23 "<u>Co-Development and Profit Share Option Exercise Date</u>" means, with respect to each Co-Developed Product, the date of exercise by Enanta of the Co-Development and Profit Share Option applicable to such Co-Developed Product.

1.24 "<u>Co-Development and Profit Share Option Exercise Period</u>" means, with respect to each Compound or Candidate, as the case may be, the period commencing on the Approval Date and continuing until [\*\*\*\*\*] days after Enanta receives a study summary, including all primary statistical analyses, with respect to the first Phase Ib/2a Clinical Trial for such Candidate. All raw data, both positive and negative, which would be reasonable to be considered in formulating such summary will be made available to Enanta promptly upon Enanta's request.

1.25 "Co-Development Territory" means the United States of America and its territories and possessions.

1.26 "<u>Collaboration</u>" means the alliance of Enanta and Abbott established pursuant to this Agreement for the purpose of identifying Compounds, Developing Candidates and Commercializing Products in the Field in the Territory.

1.27 "<u>Combination Product</u>" means any commercialized HCV therapeutic that contains or comprises a Product and one or more other ingredients that are therapeutically or biologically active and are not themselves Products.

1.28 "<u>Commercialization</u>" or "<u>Commercialize</u>" means any and all activities directed to the commercialization of a Product, including pre-launch and post-launch marketing, manufacturing for commercial sale, promoting, Detailing (as defined in <u>Schedule 5</u> hereof), distributing, offering to sell and selling a Product, importing a Product for sale, conducting additional human clinical studies other than those that are required due to post-approval regulatory commitments (but not pre-clinical studies) and interacting with Regulatory Authorities regarding the foregoing. When used as a verb, "Commercializing" means to engage in Commercialization and "Commercialized" has a corresponding meaning.

1.29 "<u>Commercially Reasonable Efforts</u>" means (a) with respect to activities of either Party in the Research Program, the efforts and resources typically used by companies that are similar in size to such Party in the performance of research programs of comparable research compounds and (b) with respect to the Development by Abbott of a particular Candidate or the Commercialization by Abbott of a particular Product, the efforts and resources typically used by Abbott in the development of product candidates or the commercialization of products of

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comparable market potential, taking into account all relevant factors including, as applicable and without limitation, stage of development, mechanism of action, efficacy and safety relative to competitive products in the marketplace, actual or anticipated Regulatory Authority approved labeling, the nature and extent of market exclusivity (including patent coverage and regulatory exclusivity), cost and likelihood of obtaining Commercialization Regulatory Approval actual or projected profitability and availability of capacity to manufacture and supply for commercial sale.

1.30 "<u>Commercialization Regulatory Approval</u>" means, with respect to any Product, the Regulatory Approval required by Applicable Laws in any country or region in the Territory in order to sell such Product for use in the Field in such country or region. "Commercialization Regulatory Approval" in the United States shall mean final approval of an NDA or sNDA permitting marketing of the applicable Product in interstate commerce in the United States, "Commercialization Regulatory Approval" in the European Union shall mean marketing authorization for the applicable Product, including price reimbursement approval, pursuant to Council Directive 2001/83/EC, as amended, or Council Regulation 2309/93/EEC, as amended and "Commercialization Regulatory Approval" in Japan shall mean final approval of an application submitted to the Ministry of Health, Labor and Welfare and the publication of a New Drug Approval Information Package permitting marketing of the applicable Product, including price reimbursement approval, in Japan, as any of the foregoing may be amended from time to time.

1.31 "Compound" means any HCV NS3 or HCV NS3/4A protease inhibitor Controlled by Enanta, other than the Excluded Compounds.

1.32 "<u>Co-Promote</u>" or "<u>Co-Promotion</u>" means, with respect to any Co-Developed Product, the joint promotion and Detailing of such Co-Developed Product in the Co-Developed Territory using a coordinated sales force consisting of representatives of both Parties.

1.33 "<u>Confidential Information</u>" means: (a) with respect to Enanta, all tangible embodiments of Enanta Technology; (b) with respect to Abbott, all tangible embodiments of Abbott Technology; and (c) with respect to each Party, (i) all tangible embodiments of Joint Technology and (ii) all information, Technology and Proprietary Materials disclosed or provided by of on behalf of such Party (the "<u>Disclosing Party</u>") pursuant to this Agreement or the Existing Agreements to the other Party (the "<u>Receiving Party</u>") or to any of the Receiving Party's employees, consultants, Affiliates or sublicensees; provided that none of the foregoing shall be Confidential Information if: (A) as of the date of disclosure, it is known to the Receiving Party or its Affiliates, as demonstrated by credible written documentation, other than by virtue of a prior confidential disclosure to such Receiving Party or its Affiliates; (B) as of the date of disclosure it is in the public domain, or it subsequently enters the public domain through no fault of the Receiving Party or its Affiliates; (C) it is obtained by the Receiving Party from a Third Party having a lawful right to make such disclosure free from any obligation of confidentiality to the Disclosing Party; or (D) it is independently developed by or for the Receiving Party without reference to or use of any Confidential Information of the Disclosing

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Party as demonstrated by credible written documentation. Further, (y) any scientific, technical or financial information of a Disclosing Party disclosed at any meeting of any of the committees or teams established pursuant to this Agreement or disclosed through an audit report prepared pursuant to this Agreement shall constitute Confidential Information of the Disclosing Party and (z) the terms of this Agreement shall constitute Confidential Information of each Party.

1.34 "<u>Control</u>" or "<u>Controlled</u>" means (a) with respect to Technology (other than Proprietary Materials) or Patent Rights, the possession by a Party of the right to grant a license or sublicense to such Technology or Patent Rights without violating the terms of any agreement or arrangement with, any Third Party and (b) with respect to Proprietary Materials, the possession by a Party of the right to supply such Proprietary Materials to the other Party without violating the terms of any agreement or arrangement with, any Third Party and (b) with respect to Proprietary Materials, the possession by a Party of the right to supply such Proprietary Materials to the other Party without violating the terms of any agreement or arrangement with, any Third Party.

1.35 "Designated Senior Officer" means, with respect to a Party, the senior officer designated by such Party to have final decision-making authority over Disputed Matters, which shall be (a) the Chief Executive Officer of Enanta and (b) the Executive Vice President of the Pharmaceutical Products Group for Abbott.

1.36 "Development" or "Develop" means, with respect to each Candidate, all non-clinical and clinical activities required to obtain Regulatory Approval of such Candidate in accordance with this Agreement on and after the Approval Date and up to and following the obtaining of Commercialization Regulatory Approval of such Candidate. These activities include, without limitation, test method development and stability testing, regulatory toxicology, animal studies, formulation, process development, manufacturing, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, and clinical trial design and operations. When used as a verb, "Developing" means to engage in Development and "Developed" has a corresponding meaning.

1.37 "Development Costs" means, with respect to a Co-Developed Product, the reasonable out-of-pocket costs and internal costs incurred by either Party (or for its account by an Affiliate or a Third Party) on and after the exercise by Enanta of the applicable Co-Development and Profit Share Option that are generally consistent with the respective Development activities allocated to such Party in the applicable Development Plan and are specifically attributable to the Development of such Co-Developed Product in the Co-Development Territory. For purposes of this definition (a) out-of-pocket costs means the costs attributable to specific external development activities applicable to a Co-Developed Product, [\*\*\*\*\*] and (b) internal costs means all direct labor costs to the extent attributable to the Development of a Co-Developed Product in accordance with the Development Plan, [\*\*\*\*\*]. Development Costs (y) shall include the costs incurred by Abbott in conducting clinical trials with respect to a Co-Developed Product, including clinical trials conducted as a result of post-approval regulatory commitments and (z) shall not include [\*\*\*\*\*].

1.38 "Development Plan" means, with respect to each Candidate and Calendar Year, the written plan for the Development activities for such Candidate for such Calendar Year, as

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such written plan may be amended, modified or updated. Each Development Plan shall include: (a) the specific Development objectives, projected milestones, resource allocation requirements and activities to be performed over such period; (b) the Party responsible for such activities; (c) a timeline for such activities; (d) an estimate of the expected Development costs to be incurred over such period; (e) the expected Regulatory Filings to be required and prepared, and the expected timetable for making such Regulatory Filings; and (f) the manufacturing strategy, budget and proposed timelines for manufacturing scale-up, formulation, filling and/or shipping. The initial Development Plan shall be prepared within ninety (90) days of the Approval Date and in any event, on or prior to the initiation of Development prepared by Abbott and reviewed and/or approved by the JSC, shall specifically state that it is an amendment, modification or update to the Development Plan and shall be attached to the minutes of the meeting of the JSC at which such amendment, modification or update to be Development Plan shall be updated at least once prior to the end of each Calendar Year to describe the Development activities to be carried out by each Party during the next Calendar Year pursuant to this Agreement.

1.39 "Development Program" means the set of activities outlined in the Development Plan aimed at achieving regulatory approval for a Candidate.

1.40 "Drug Approval Application" means, with respect to a Candidate in a particular country or region, an application for Commercialization Regulatory Approval for such Candidate in such country or region, including without limitation: (a) an NDA or sNDA; (b) a counterpart of an NDA or sNDA (including, without limitation, a CTN) in any country or region in the Territory; and (c) all supplements and amendments to any of the foregoing.

1.41 "Effective Date" means the date first set forth above.

1.42 "EMEA" means the European Medicines Evaluation Agency, or any successor thereto, which coordinates the scientific review of human pharmaceutical products under the centralized licensing procedures of the European Union.

1.43 "Enanta Background Technology" means any Technology used by Enanta, or provided by Enanta for use, in the Research Program or the Development Program that is (a) Controlled by Enanta as of the Effective Date or (b) developed or conceived by employees of, or consultants to, Enanta after the Effective Date in the conduct of activities outside the Research Program or the Development Program.

1.44 "Enanta Co-Development Percentage" means forty percent (40%).

1.45 "Enanta Decision" means any decision with respect to the application by Enanta of FTEs to the research of Compounds under the Research Program.

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1.46 "Enanta Materials" means any Proprietary Materials that are Controlled by Enanta and used by Enanta, or provided by Enanta for use, in the Research Program or the Development Program. For purposes of clarity, (a) Enanta Materials shall include all Compounds provided by Enanta for use in the Research Program or Candidates used in the Development Program and (b) all other Enanta Materials shall be listed in the Research Plan or the Development Plan.

1.47 "Enanta Patent Rights" means any Patent Rights that contain one or more claims that cover Enanta Technology.

1.48 "Enanta Program Technology" means any Program Invention conceived or first reduced to practice by employees of, or consultants to, Enanta, alone or jointly with any Third Party.

1.49 "Enanta Research Activities" means any research activities specified to be conducted by Enanta in any Research Plan.

1.50 "Enanta Technology," means, collectively, Enanta Background Technology and Enanta Program Technology.

1.51 "European Union" or "EU" means the member states (whether on the Effective Date or later admitted) of the European Union.

1.52 "Excluded Compounds" means (a) the compounds listed on <u>Schedule 3</u> attached hereto and incorporated herein by reference, and (b) the compounds licensed from Chiron under the License and Option Agreement between Chiron Corporation and Enanta, dated May 4<sup>th</sup>, 2005.

1.53 "Existing Agreements" means the [\*\*\*\*\*].

1.54 "FDA" means the United States Food and Drug Administration or any successor agency or authority thereto.

1.55 "FDCA" means the United States Federal Food, Drug, and Cosmetic Act, as amended.

1.56 "Field" means the prevention and treatment of viral infections in humans.

1.57 "<u>First Commercial Sale</u>" means, with respect to a Product in any country after Regulatory Approval in the Territory, the first sale, transfer or disposition of such Product for value in such country.

1.58 "Force Majeure" means any occurrence beyond the reasonable control of a Party that (a) prevents or substantially interferes with the performance by such Party of any of its obligations hereunder and (b) occurs by reason of any act of God, flood, fire, explosion,

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earthquake, strike, lockout, labor dispute, casualty or accident, or war, revolution, civil commotion, act of terrorism, blockage or embargo, or any injunction, law, order, proclamation, regulation, ordinance, demand or requirement of any government or of any subdivision, authority or representative of any such government.

1.59 "**FTE**" means one (1) or more qualified employees of a Party who collectively spend time and effort conducting Enanta Research Activities or Abbott Research Activities, as the case may be, pursuant to the Research Plan or any Development Plan equivalent to the time and effort of one (1) full-time employee for one (1) Calendar Year based on at least [\*\*\*\*\*] hours of work/[\*\*\*\*\*] weeks per Calendar Year/forty (40) hours per week of work (less public holidays).

1.60 "FTE Cost" means, for any Calendar Quarter during the Research Program Term, the FTE Rate divided by 4, multiplied by the applicable number of FTEs applied during such Calendar Quarter.

1.61 "**FTE Rate**" means during the Research Program Term, [\*\*\*\*\*] per Calendar Year, or any prorated portion thereof. Notwithstanding the foregoing, if the Parties agree to any extension of the Research Program pursuant to Section 3.8, then, as of the date of such extension and on each anniversary thereafter, the FTE Rate shall be increased by multiplying the FTE Rate applicable on December 31 of the immediately preceding Calendar Year by 1 + ((CPIx -CPIy) / CPIy), where CPIx is the Consumer Price Index for All Urban Consumers in the Boston Metropolitan Area published by the Bureau of Labor Statistics of the United States Department of Labor for December in the immediately preceding Calendar Year and CPIy is the Consumer Price Index for All Urban Consumers in the Boston Metropolitan Area published by the Bureau of Labor Statistics of the United States Department of Labor for the Bureau of Labor Statistics of the United States Department of Labor for the Bureau of Labor Statistics of the United States Department of Labor for the Bureau of Labor Statistics of the United States Department of Labor for the Bureau of Labor Statistics of the United States Department of Labor for the December in the immediately preceding Calendar Year less one. Any such increase shall be rounded to the nearest one hundred US Dollars (\$100).

1.62 "GAAP" means generally accepted accounting principles as in effect in the United States from time to time.

1.63 "<u>GLP</u>" means the then current Good Laboratory Practice Standards promulgated or endorsed by the FDA or in the case of foreign jurisdictions, comparable regulatory standards promulgated or endorsed by the applicable Regulatory Authority, including those procedures expressed or implied in the Regulatory Filings.

1.64 "<u>GMP</u>" means the then current Good Manufacturing Practices in accordance with the GMP standards of the European Union and the FDA, as amended from time to time.

1.65 "Hatch-Waxman Act" means the Drug Price Competition and Patent Term Restoration Act of 1984, as amended.

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1.66 "HCV Tool Patent License Agreement" means any license agreement with respect to the practice of HCV Tool Patent Rights by and between either Party and [\*\*\*\*\*] or any successor entity or predecessor in interest.

1.67 "**IND**" means: (a) an Investigational New Drug Application, as defined in the FDCA and the regulations promulgated thereunder, or any successor application or procedure required to initiate clinical testing of a Compound, Candidate or Product in humans in the United States; (b) a counterpart of an Investigational New Drug Application that is required in any other country or region in the Territory before beginning clinical testing of a Compound, Candidate or Product in humans in such country or region; and (c) all supplements and amendments to any of the foregoing.

1.68 "Initiation" means, with respect to a human clinical trial, the first date that a subject is dosed in such clinical trial.

1.69 "Joint Co-Development and Commercialization Committee" or "JDCC" means the committee of Enanta and Abbott representatives established pursuant to Section 2.3 to coordinate the Development and Commercialization activities of Co-Developed Products within the Co-Development Territory.

1.70 "Joint Patent Rights" means Patent Rights that contain one or more claims that cover Joint Technology. For clarification, patents filed before or during the Research Program that cover the Abbott Compounds will be Joint Patent Rights, but excluding the Abbott Compounds listed in Schedule 1.

1.71 "Joint Steering Committee" or "JSC" means the committee of Enanta and Abbott representatives established pursuant to Section 2.1 to oversee the conduct and progress of the Research Program, the Development Program and the Commercialization of Products.

1.72 "Joint Technology" means any Program Invention (a) conceived or first reduced to practice jointly by employees of, or consultants to, Abbott and employees of, or consultants to, Enanta or (b) conceived or first reduced to practice solely by employees of, or consultants to, one Party with the use in any material respect of any Technology, Patent Rights or Proprietary Materials of the other Party. For purposes of clarity, Joint Technology shall include any and all Technology conceived or reduced to practice by Abbott in its conduct of any chemistry activities with respect to Compounds or Abbott Compounds (other than the Abbott Compounds listed in Schedule 1) as part of the Research Program.

1.73 "Knowledge" means the [\*\*\*\*\*] of the chief executive officer or any vice president of Enanta.

1.74 "Licensed Patent Rights" means any Enanta Patent Rights and any of Enanta's interest in Joint Patent Rights that contain one or more claims that cover any Compound,

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Candidate or Product. All Licensed Patent Rights existing as of the Effective Date are described on Schedule 4 attached hereto.

1.75 "<u>MAA</u>" means an application filed with the EMEA, or through the mutual recognition procedures in the European Union, for Regulatory Approval to Commercialize a Product as a drug in the European Union, or in any country or territory therein, including decentralized procedures or mutual recognition procedures.

#### 1.76 "Major Market Country" [\*\*\*\*\*].

1.77 "Marketing and Sales Plan" means, with respect to each Co-Developed Product, the written plan for the Commercialization of such Co-Developed Product in the Co-Development Territory prepared in accordance with Section 4.2.1, which shall include, without limitation, (a) a regulatory and Commercialization strategy with proposed timelines and sales forecasts, that are, in each case, applicable to such Co-Developed Product and (b) the written plan for the manufacture of such Co-Developed Product in the Co-Development Territory, including, without limitation, expected manufacturing scale-up, formulating, and filing activities to be conducted for such Co-Developed Product as well as a budget and proposed timelines for such activities, as such plan may be amended or updated from time to time.

1.78 "<u>Materially Used</u>" means, with respect to Shared Clinical Trial Data, the inclusion of such Shared Clinical Trial Data in the core efficacy registration package of an NDA or equivalent registration package used outside of the Co-Development Territory (as defined as Phase II Clinical Trials and Phase DI Clinical Trials required by a Regulatory Authority to substantiate evidence of both safety and efficacy).

1.79 "NDA" means a New Drug Application, as defined in the FDCA and applicable regulations promulgated thereunder, or any successor application or procedure required to sell a Product in the United States.

1.80 "<u>Net Sales</u>" means the total amount billed or invoiced on sales of the Product by Abbott or its Affiliates or Sublicensees (including invoiced royalties and any other compensation of any other kind whatsoever) to independent, unrelated Third Parties, including wholesalers, in bona fide arm's length transactions, less the following deductions, in each case related specifically to the Product and incurred in the ordinary course of business and actually allowed or taken by such Third Parties and not otherwise recovered by or reimbursed to Abbott or its Affiliates:

(i) trade, cash and quantity discounts, allowances, adjustments, and rejections, rebates, recalls and returns;

(ii) price reductions or rebates, retroactive or otherwise, imposed by governmental authorities;

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(iii) sales, excise, turnover, inventory, value-added, and similar taxes assessed on sales of the Product, but not including any income tax paid by or assessed against Abbott or its Affiliates;

(iv) transportation, importation, shipping, insurance and other handling expenses directly chargeable to the sale of the Product, including any fees for services provided by wholesalers and warehousing chains related to the distribution of the Product;

(v) chargebacks granted to Third Party distributors based on sales to their customers; and

(vi) the portion of any management fees or administration fees paid during the relevant time period to group purchasing organizations, pharmaceutical benefit managers and/or Medicare prescription drug plans relating specifically to the Product.

Subject to the above, Net Sales will be calculated in accordance with Abbott's standard internal policies and procedures, which must be in accordance with GAAP. If consideration in addition to or in lieu of money is received for the sale of the Product on an arm's-length transaction, the fair market value of such consideration must be included in the determination of Net Sales for such a sale. Net Sales will not include sales between or among Abbott and its Affiliates.

For purposes of calculating Net Sales, all Net Sales will be converted into Dollars using the conversion methodology set forth in Section 6.5.7 (Foreign Currency Exchange) consistent with GAAP. The standard conversion methodology is based on monthly averages (the spot rate at the end of the month immediately prior to the reporting month plus the spot rate at the end of the reporting month, divided by two) using open market rates.

If Abbott or its Affiliates appoint Third Party distributors for the Product or grant a license or sublicense to any Person (other than Abbott or any of its Affiliates) for manufacturing and selling the Product, Net Sales will include the Net Sales invoiced by Abbott or its Affiliates to such third party distributors and the royalties or other compensation of any other kind whatsoever invoiced by Abbott or its Affiliates to any such other Person, but it will not include any sales of the Product made by any such third party distributors or other Person.

In addition, Net Sales are subject to the following:

(i) [\*\*\*\*\*].

(ii) [\*\*\*\*\*].

(iii) For purposes of clarity, the use of any Product in (A) clinical trials, pre-clinical studies or other research or development activities, or disposal or transfer of Products for purposes of a commercially reasonable sampling program, shall not give rise to any Net Sales

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and (B) a compassionate use program shall not give rise to any deemed sale for purposes of this definition unless [\*\*\*\*\*].

1.81 "Patent Rights" means the rights and interests in and to issued patents and pending patent applications in the HCV protease inhibition area (which, for purposes of this Agreement, include certificates of invention, applications for certificates of invention and priority rights) in any country or region, including all provisional applications, substitutions, continuations, in-part, divisions, renewals, all letters patent granted thereon, and all reissues, reexaminations and extensions thereof including Hatch-Waxman patent term extensions, Supplemental Protection Certificates, and all foreign counterparts of any of the foregoing.

1.82 "**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision, department or agency of a government.

1.83 "Phase I Clinical Trial" means a clinical trial conducted in any country or countries that generally provides for the first introduction into humans of an investigational drug with the purpose of assessing its safety, tolerability, toxicity, metabolism, absorption, elimination or other pharmacological action as more fully defined in 21 C.F.R. 312.21(a).

1.84 "Phase Ib/IIa Clinical Trial" means the initial clinical trial conducted with a Candidate in HCV infected patients designed to assess virologic potency, pharmacokinetics and tolerability and to support the decision to advance development to Phase IIb.

1.85 "Phase II Clinical Trial" means a clinical trial conducted in any country or countries in patients with a particular disease or condition with the purpose of further assessing the safety and tolerability of an investigational drug and initially exploring its efficacy for such disease or condition, as more fully defined in 21 C.F.R. 312.21(b).

1.86 **Phase IIb Clinical Trial**" means, as to a particular Product and indication, the portion of a Phase II Clinical Trial which contains a sufficient number of subjects to generate sufficient data (if successful) to commence a Phase III Clinical Trial of such Product for such indication.

1.87 "<u>Phase III Clinical Trial</u>" means a clinical trial conducted in any country or countries in patients with a particular disease or condition with the purpose of establishing the safety and tolerability of an investigational drug and confirming or establishing its efficacy for such disease or condition, as more fully defined in 21 C.F.R. 312.21(c).

1.88 "**Product**" means any pharmaceutical dosage form that is comprised of a Candidate that has obtained Commercialization Regulatory Approval (whether or not such

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Candidate is the sole active ingredient). The term Product shall include Co-Developed Products and Royalty-Bearing Products.

1.89 "**Product Trademark**" means (a) any trademark or trade name, whether or not registered, or any trademark application, renewal, extension or modification thereto, in the Territory, or any trade dress and packaging, that is applied to or used with Products by Abbott and (b) all goodwill associated therewith, and any promotional materials relating thereto.

1.90 "Program Invention" means any Technology (including, without limitation, any process, method of manufacture or composition of matter) that is conceived or first reduced to practice in the conduct of the Research Program or the Development Program.

1.91 "Program Patent Rights" means any Patent Rights that contain one or more claims that cover Program Inventions.

1.92 "<u>Proprietary Materials</u>" means tangible chemical, biological or physical materials that are furnished by or on behalf of one Party to the other Party in connection with this Agreement, whether or not specifically designated as proprietary by the transferring Party.

1.93 "<u>Regulatory Approval</u>" means, with respect to any country or region in the Territory, any approval (including, without limitation, any pricing approval), product and establishment license, registration or authorization of any Regulatory Authority required for the manufacture, use, storage, importation, export, transport or sale of a Product in such country or region.

1.94 "<u>Regulatory Authority</u>" means the FDA, or any counterpart of the FDA outside the United States, or any other national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity with authority over the distribution, importation, exportation, manufacture, production, use, storage, transport, clinical testing or sale of a Candidate or Product.

1.95 **"<u>Regulatory Filings</u>"** means, collectively: (a) all INDs, NDAs, establishment license applications, drug master files, applications for designation of a Product as an "Orphan Product(s)" under the Orphan Drug Act, for "Fast Track" status under Section 506 of the FDCA (21 U.S.C. § 356) or for a Special Protocol Assessment under Section 505(b)(4)(B) and (C) of the FDCA (21 U.S.C. § 355(b)(4)(B)) or all other similar filings (including, without limitation, any counterparts of any of the foregoing in any country region in the Territory) as may be required by any Regulatory Authority for the Development of a Candidate or Commercialization of a Product; (b) all supplements and amendments to any of the foregoing; and (c) all data contained in, and correspondence relating to, any of the foregoing.

1.96 "<u>Relative Market Size</u>" means (a) with respect to any Shared Clinical Trial Data derived from a Shared Clinical Trial conducted outside of the Co-Development Territory and Materially Used in the Co-Development Territory, the result obtained by [\*\*\*\*\*] and (b) with

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respect to any Shared Clinical Trial Data derived from a Shared Clinical Trial conducted within the Co-Development Territory and Materially Used in a Regulatory Filing made in a country outside of the Co-Development Territory, the result obtained by [\*\*\*\*\*]. For purposes of clarity, the [\*\*\*\*\*] as promptly as possible following the date of the Shared Clinical Trial Notice by a Third Party entity reasonably acceptable to the Parties that performs such market analyses for the biotechnology or pharmaceutical industry.

1.97 **"Research Plan**" means the written plan describing the research activities to be carried out by each Party during each Calendar Year during the Research Program Term in conducting the Research Program pursuant to this Agreement, as such written plan may be amended, modified or updated. The initial Research Plan is attached hereto as <u>Exhibit A</u>, which describes the research activities, and the specific research objectives, milestones and resource allocation requirements, to be carried out by each Party during the first full or partial Calendar Year following the Approval Date. Each amendment, modification and update to the Research Plan shall be set forth in a written document prepared by, or at the direction of, the JSC and approved by the JSC, shall specifically state that it is an amendment, modification or update to the Research Plan and shall be attached to the minutes of the meeting of the JSC at which such amendment, modification or updated was approved by the JSC. Without limiting the nature or frequency of any other amendments, modifications or updates of the Research Plan that may be approved by the JSC, the Research Plan shall be updated at least once prior to the end of each Calendar Year to describe the research activities to be carried out by each Party, and the specific research objectives, milestones and resource allocation requirements, during the next Calendar Year during the Research Program Term in conducting the Research Program pursuant to this Agreement.

1.98 "**Research Program**" means the collaborative research program commencing on the Approval Date and conducted by the Parties pursuant to Section 3.1 and the Research Plan for the purpose of identifying and researching Candidates.

1.99 "<u>Research Program Term</u>" means the period beginning on the Approval Date and, subject to Section 3.7, ending on the third anniversary of the Approval Date.

1.100 "**Royalty-Bearing Product**" means (a) any Product that is not a Co-Developed Product and (b) any Co-Developed Product to the extent sold outside of the Co-Development Territory.

1.101 "**Royalty-Bearing Territory**" means (a) with respect to Co-Developed Products, all countries outside of the Co-Development Territory and (b) with respect to Products, all countries within the Territory.

1.102 "**Royalty Term**" means, with respect to each Royalty-Bearing Product in each country in the Royalty-Bearing Territory, the period beginning on the date of First Commercial Sale of such Royalty-Bearing Product in such country and continuing until the later of (a) the last date on which the manufacture, use or sale of such Royalty-Bearing Product in such country

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would infringe a Valid Claim included in the Licensed Patent Rights but for the license granted hereunder, (b) ten (10) years from the date of the First Commercial Sale of such Royalty-Bearing Product in such country.

1.103 "Shared Clinical Trial" means any clinical trial conducted by or on behalf of a Party the results of which are Materially Used in the Regulatory Filings for a Co-Developed Product that is Commercialized both in the Co-Development Territory and outside of the Co-Development Territory.

1.104 "<u>Shared Clinical Trial Costs</u>" means the reasonable out-of-pocket costs and internal costs incurred by a Party (or for its account by an Affiliate or a Third Party) that are specifically attributable to the conduct of a Shared Clinical Trial.

1.105 "Shared Clinical Trial True-Up Percentage" means, (a) with respect to any Shared Clinical Trial Data derived from a Shared Clinical Trial conducted outside of the Co-Development Territory and Materially Used in the Co-Development Territory, the result obtained by [\*\*\*\*\*], and (b) with respect to any Shared Clinical Trial Data derived from a Shared Clinical Trial conducted within the Co-Development Territory and Materially Used of the Co-Development Territory, [\*\*\*\*\*]. A Shared Clinical Trial will be considered conducted within the Co-Development Territory if such trial is filed under a US IND.

1.106 "Shared Clinical Trial Data" means all data, results and information produced in the conduct of a Shared Clinical Trial.

1.107 "sNDA" means a Supplemental New Drug Application, as defined in the FDCA and applicable regulations promulgated thereunder.

1.108 "Sublicensee" means any Third Party to which Abbott grants a sublicense in accordance with Section 8.3.

1.109 "Sublicense Agreement" means any agreement by and between Abbott or its Affiliates and a Sublicensee with respect to a Product.

1.110 "Sublicense Income" means all payments (including all upfront payments, milestone payments, other consideration and the reasonable monetary value of all non-monetary consideration) received by Abbott from any Sublicensee under a Sublicense Agreement less that portion of the Development Costs incurred by Abbott that is attributable to the conduct of Development activities with respect to the Product in the country or countries covered by the Sublicense Agreement through the date of the grant of the applicable sublicense, and excluding: (a) royalty payments paid by such Sublicensee to Abbott; (b) payments made by a Sublicensee to Abbott in consideration of the issuance of equity or debt securities of Abbott to the extent that the price paid for such equity does not exceed the then fair market value of such equity; and (c) payments made by a Sublicensee to support or fund research and development activities to be undertaken by Abbott pursuant to a budget for sponsored research which has been agreed to with

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the Sublicensee and based on full-time equivalent or other cost-accounting methodologies that are consistent with then current industry practices.

1.111 "Successful Completion of Phase Ib/IIa Clinical Study" means, with respect to any Candidate, the date of [\*\*\*\*\*]with respect to, all [\*\*\*\*\*]from the conduct of a Phase Ib/IIa Clinical Trial or other comparable clinical study in any country in the Territory with respect to such Candidate [\*\*\*\*\*].

1.112 "<u>Technology</u>" means, collectively, inventions, discoveries, improvements, trade secrets and proprietary methods, whether or not patentable, including without limitation: (a) methods of production or use of, and structural and functional information pertaining to, chemical compounds; and (b) compositions of matter, data, formulations, processes, techniques, know-how and results (including any negative results).

1.113 **"<u>Territory</u>**" means all countries of the world.

1.114 "Third Party" means any Person other than Abbott and Enanta and their respective Affiliates.

1.115 "<u>Valid Claim</u>" means any claim of an issued unexpired patent that (a) has not been finally cancelled, withdrawn, abandoned or rejected by any administrative agency or other body of competent jurisdiction, (b) has not been permanently revoked, held invalid, or declared unpatentable or unenforceable in a decision of a court or other body of competent jurisdiction that is unappealable or unappealed within the time allowed for appeal, (c) has not been rendered unenforceable through disclaimer or otherwise, and (d) is not lost through an interference proceeding.

Additional Definitions. In addition, each of the following definitions shall have the respective meanings set forth in the section of this Agreement indicated below:

| DefinitionAbbott BoardAbbott IndemniteesAcquired PartyAcquiring PartyAdditional Co-Developed Product[*****]Additional ProductADRAlliance ManagerAnnual Operating IncomeAnnual Research PaymentApplicable Percentage | Section<br>14.17<br>13.1<br>14.2(a)<br>14.2(a)<br>6.4.1(d)<br>[*****]<br>6.4.1(b)<br>Exhibit D<br>2.2<br>Schedule 6<br>6.3.1<br>6.5.3 |
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| Definition                             | Section      |
|--|--------------|
| Candidate Designation                  | 3.6          |
| Change of Control Notice               | 14.2(a)      |
| Claims                                 | 13.1         |
| Co-Development and Profit Share Option | 5.1          |
| Co-Development Term                    | 6.5.2        |
| Co-Promotion Agreement                 | 5.7.1        |
| CPR                                    | Exhibit D    |
| Disputed Matter                        | 2.1.6        |
| Enanta Board                           | 14.17        |
| Enanta Indemnitees                     | 13.2         |
| Generic Product                        | 6.5.1(d)     |
| HSR Act                                | 14.16        |
| Indemnified Party                      | 13.3         |
| Indemnifying Party                     | 13.3         |
| Infringement                           | 10.2.1(a)(i) |
| Infringement Notice                    | 10.2.1(a)(i) |
| Initial Co-Developed Product           | 6.4.1(c)     |
| Initial Press Release                  | 7.2          |
| Initial Product                        | 6.4.1(a)     |
| Losses                                 | 13.1         |
| Novartis                               | 3.3.2        |
| Operating Income Payments              | 6.5.2        |
| [*****]                                | [*****]      |
| [*****]                                | [*****]      |
| [*****]                                | [*****]      |
| [*****]                                | [*****]      |
| Patent Coordinator                     | 9.5          |
| Quarterly Research Payment             | 6.3.1        |
| Recipient Party                        | 3.7          |
| Roll-Over Payment                      | 5.4          |
| Royalty Payments                       | 6.5.1(a)     |
| Shared Clinical Trial Notice           | 5.4.1        |
| Shares                                 | 6.2          |
| Stock Purchase Agreement               | 6.2          |
| Sublicense Income Payments             | 6.5.3        |
| Term                                   | 11.1         |
| Third Party Payments                   | 6.5.1(b)     |
| Transferring Party                     | 3.7          |
| 5 7                                    |              |

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# 2. <u>ADMINISTRATION OF THE RESEARCH PROGRAM, DEVELOPMENT PROGRAM AND COMMERCIALIZATION</u>

## 2.1 Joint Steering Committee.

2.1.1 **<u>Establishment</u>**. Enanta and Abbott hereby establish the Joint Steering Committee. The JSC shall have and perform the responsibilities set forth in Section 2.1.4.

2.1.2 **Membership.** Each of Enanta and Abbott shall designate an equal (not less than two (2)) number of representatives to the JSC who shall be members of senior management with decision-making authority. Unless otherwise agreed by the Parties, one (1) representative of each Party shall be designated as Co-Chairs of the JSC. Each Party shall have the right at any time to substitute individuals, on a permanent or temporary basis, for any of its previously designated representatives to the JSC by giving written notice to the other Party; provided such substitute has similar decision-making authority within that Party's organization as the individual being replaced.

## 2.1.3 Meetings.

(a) <u>Schedule of Meetings; Agenda</u>. The JSC shall establish a schedule of times for regular meetings, taking into account the planning needs of the Research Program and Development Program and the responsibilities of the JSC. Special meetings of the JSC may be convened by any member upon not less than [\*\*\*\*\*] business days (or, if such meeting is proposed to be conducted by teleconference, upon not less than [\*\*\*\*\*] business days) written notice to the other members; provided that (i) notice of any such special meeting may be waived in writing at any time, either before or after such meeting and (ii) attendance of any member at a special meeting shall constitute a valid waiver of notice from such member, unless such member attends the meeting for the express purpose of objecting to its conduct for failure to provide valid notice. In no event shall the JSC meet less frequently than [\*\*\*\*\*]. Regular and special meetings of the JSC may be held in person or by teleconference or videoconference; provided that (i) meetings held in person shall alternate between the respective offices of the Parties in Watertown, Massachusetts and Abbott Park, Illinois, or such other locations mutually agreeable to the JSC members and (ii) not less than one (1) meeting per Calendar Year shall be held in person. The Co-Chairs shall alternate responsibility for preparing and circulating to each JSC member an agenda for each JSC meeting not later than [\*\*\*\*\*] week prior to such meeting.

(b) <u>Quorum; Voting; Decisions</u>. At each JSC meeting, (i) the presence in person of at least one (1) member designated by each Party shall constitute a quorum and (ii) each member who is present shall have one (1) vote on all matters before the JSC at such meeting. All decisions of the JSC shall be made by majority vote; provided, that, any member designated by a Party shall have the right to cast the votes of any of such Party's members on the JSC who are absent from the meeting. Alternatively, the JSC may act by written consent signed by at least one (1) member designated by each Party. Whenever any action by the JSC is called for hereunder during a time period in which the JSC is not scheduled to meet, either Co-Chair

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shall cause the JSC to take the action in the requested time period by calling a special meeting or by circulating a written consent. Representatives of each Party or of its Affiliates who are not members of the JSC may attend JSC meetings as non-voting observers with the consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed.

(c) <u>Minutes</u>. The JSC shall keep minutes of its meetings that record all decisions and all actions recommended or taken in reasonable detail. Drafts of the minutes shall be prepared and circulated to the members of the JSC within a reasonable time after the meeting, not to exceed [\*\*\*\*\*] business days, and the Chairs shall alternate responsibility for the preparation and circulation of draft minutes. Each member of the JSC shall have the opportunity to provide comments on the draft minutes. The minutes shall be approved, disapproved and revised as necessary at the next JSC meeting or within [\*\*\*\*\*] days of the meeting, whichever occurs first. Upon approval, the Chair with responsibility for preparing minutes shall circulate the final minutes of each meeting to the members of the JSC.

(d) <u>Expenses</u>. Enanta and Abbott shall each bear all expenses of their respective JSC representatives related to their participation on the JSC and attendance at JSC meetings.

2.1.4 **Responsibilities.** The JSC shall be responsible for overseeing the conduct and progress of the Research Program, the Development Program and the Commercialization of Products. Without limiting the generality of the foregoing, the JSC shall have the following responsibilities:

(a) Reviewing each Research Plan, Development Plan and Marketing and Sales Plan (including all budgets applicable thereto);

(b) with respect to (i) any Research Plan, (ii) any Development Plan that covers a Co-Developed Product, or (iii) any Marketing and Sales Plan that covers a Co-Developed Product, approving such Research Plan, Development Plan and Marketing and Sales Plan;

(c) directing the preparation of and reviewing any amendment to any Research Plan, Development Plan and/or Marketing and Sales Plan and/or budget applicable thereto;

(d) with respect to any amendment to (i) any Research Plan, (ii) any Development Plan that covers a Co-Developed Product, or (iii) any Marketing and Sales Plan that covers a Co-Developed Product, approving such amendment;

(e) monitoring the progress of each Research Plan, Development Plan and Marketing and Sales Plan, and of each Party's activities thereunder;

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(f) providing a forum for consensual decision-making with respect to the (i) Research Program, (ii) Development Program for Co-Developed Products and (iii) Commercialization of Co-Developed Products;

(g) reviewing data, reports or other information submitted by either Party with respect to work conducted in the Research Program and the Development Program;

(h) designating Compounds and Abbott Compounds to be Candidates eligible to enter the Development Program in accordance with Section 3.6, and reviewing prioritization of the Development activities in the event multiple Candidates are selected to enter the Development Program;

(i) monitoring the progress of the Commercialization of each Product in accordance with the applicable Marketing and Sales Plan, including, without limitation, reviewing and, to the extent it covers a Co-Developed Product, approving, each annual update to each Marketing and Sales Plan and reviewing all sales forecasts and the results of all efforts in the Co-Development Territory provided by the JDCC;

(j) resolving any dispute as to whether a milestone event for a Product under this Agreement has occurred;

(k) implementing a mutually acceptable mechanism for reporting Adverse Events between the Parties for each Candidate and Product;

(l) developing and discussing strategies for the promotion and marketing of all Co-Developed Products;

(m) implementing the Marketing and Sales Plan that covers any Co-Developed Product;

(n) resolving all issues referred to the JSC by the Alliance Managers and the JDCC; and

(o) making any other decisions as may be delegated to the JSC pursuant to this Agreement or by mutual written agreement of the Parties after the Approval Date and performing such activities as may be delegated to the JSC pursuant to this Agreement, or by mutual written agreement of the Parties after the Approval Date.

2.1.5 **Interests of the Parties.** Notwithstanding any other provisions of this Agreement, all decisions made and all actions taken by the JSC shall be made or taken in the best interest of the Collaboration.

2.1.6 **Dispute Resolution**. The JSC members shall use reasonable efforts to reach agreement on any and all matters for which the JSC is responsible pursuant to Section 2.1.4. In the event that, despite such reasonable efforts, agreement on a particular matter cannot

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be reached by the JSC within [\*\*\*\*\*] days after the JSC first meets to consider such matter (each such matter, a "**Disputed Matter**"), then: (a) if the Disputed Matter involves an Enanta Decision, one of the Enanta members of the JSC shall have the right to make the final decision on such Disputed Matter, but shall only exercise such right in good faith after full consideration of the positions of both Parties; and (b) if the Disputed Matter involves an Abbott Decision or any other matter that is not an Enanta Decision, the Disputed Matter shall be referred to the Designated Senior Officer of each Party, who shall promptly initiate discussions in good faith to resolve the Disputed Matter. If the Disputed Matter is not resolved by such Designated Senior Officers within the first to occur of [\*\*\*\*\*] days after the date the Designated Senior Officers first met to consider such Disputed Matter or [\*\*\*\*\*] days after the date the Disputed Matter shall be referred for resolution to the Executive Vice President of Abbott's Pharmaceutical Products Group, who shall have the right to make the final decision on such Disputed Matter, but shall only exercise such right in good faith after full consideration of such Designated Senior of the positions of both Parties and shall base any such decision, in part, on the principle of maximizing the commercial potential of each Product, but shall not base such decision on providing economic advantage to one Party over the other Party.

2.2 <u>Affiance Managers</u>. Each Party shall appoint a person with experience in and abilities with respect to project management and coordination and communication among various divisions and disciplines who shall oversee contact between the Parties for all matters related to the Collaboration between meetings of the JSC (each, an "<u>Alliance Manager</u>"). The Alliance Managers shall have such responsibilities as the Parties may mutually agree in writing. Each Party may replace its Alliance Manager at any time by notice in writing to the other Party.

# 2.3 Joint Co-Development and Commercialization Committee.

2.3.1 **Establishment**. As soon as practicable following the exercise by Enanta of a Co-Development and Profit-Share Option with respect to a Compound or Candidate, as the case may be, in accordance with Section 5.1, Enanta and Abbott shall establish the Joint Co-Development and Commercialization Committee which shall have and perform the responsibilities set forth in Section 2.3.4.

2.3.2 **Membership.** Each of Enanta and Abbott shall designate an equal (not less than two (2)) number of representatives to the JDCC. Unless otherwise agreed by the Parties, Abbott shall designate one (1) of its designees as the Chairman. Each Party shall have the right at any time to substitute individuals, on a permanent or temporary basis, for any of its previously designated representatives to the JDCC by giving written notice to the other Party.

## 2.3.3 Meetings.

(a) <u>Schedule of Meetings; Agenda</u>. The JDCC shall establish a schedule of times for regular meetings, taking into account, without limitation, its responsibilities

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hereunder and the planning needs for the Co-Developed Products. Special meetings may be convened by any member of the JDCC upon [\*\*\*\*\*] days (or, if such meeting is proposed to be conducted by teleconference, upon [\*\*\*\*\*] days) written notice to the other members; provided that (1) notice of any such special meeting may be waived in writing at any time, either before or after such meeting, and (ii) attendance of any member at a special meeting shall constitute a valid waiver of notice from such member, unless such member attends the meeting for the express purpose of objecting to its conduct for failure to provide valid notice. If formed, in no event shall the JDCC meet less frequently than [\*\*\*\*\*]. Regular and special meetings of the JDCC may be held in person or by teleconference or videoconference; provided, that, meetings held in person shall alternate between the respective offices of the Parties in Watertown, Massachusetts and Abbott Park, Illinois. The Chairman shall prepare and circulate to each JDCC member an agenda for each JDCC meeting not later than one (1) week prior to such meeting.

(b) <u>Quorum; Voting; Decisions</u>. At each JDCC meeting, (i) the presence in person of at least one (1) member designated by each Party shall constitute a quorum and (ii) each member who is present shall have one (1) vote on all matters before the JDCC at such meeting. All decisions of the JDCC shall be made by majority vote; provided, that, any member designated by a Party shall have the right to cast the votes of any of such Party's members on the JDCC who are absent from the meeting. Alternatively, the JDCC may act by written consent signed by at least one (1) member designated by each Party. Whenever any action by the JDCC is called for hereunder during a time period in which the JDCC is not scheduled to meet, the Chairman shall cause the JDCC to take the action in the requested time period by calling a special meeting or by circulating a written consent. Representatives of each Party or of its Affiliates who are not members of the JDCC may attend JDCC meetings as non-voting observers with the consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed.

2.3.4 **<u>Responsibilities</u>**. The JDCC shall be responsible for overseeing the Development and Commercialization of Co-Developed Products in the Co-Development Territory. Without limiting the generality of the foregoing, the JDCC shall have the following responsibilities:

(a) the development and discussion of strategies for the Development and Commercialization of each Co-Developed Product in the Co-Development Territory, including allocation of responsibilities for such Development and Commercialization activities;

(b) reviewing and discussing a Marketing and Sales Plan for each Co-Developed Product in the Co-Development Territory;

(c) coordinating the Development and Commercialization efforts of both Parties in the Co-Development Territory with respect to Co-Developed Products. For purposes of clarity, the JDCC shall not be responsible for coordinating communications with Regulatory Authorities, which is the sole responsibility of Abbott, however, Abbott will work directly with a regulatory liaison to be designated by Enanta on coordinating key regulatory FDA

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communications on Co-Developed Products and will keep Enanta's liaison informed as to other regulatory proceedings on Co-Developed Products that will materially affect approvals or product labeling in the Co-Developed Territory. For clarity, this would not apply to routine regulatory submissions or communications necessary to ensure regulatory compliance with FDA guidelines. Abbott will keep the JDCC informed of key regulatory communications involving key regulatory filings and milestone meetings as specified in Section 4.5.5.

(d) reviewing and providing input in the preparation of a Marketing and Sales Plan containing a Co-Promotion Plan for each Co-Developed Product in the Co-Development Territory;

(e) reviewing and providing input on the short-term and long-term sales forecasts for Co-Developed Products in the Co-Developed Territory;

(f) presenting sales forecasts and the results of all efforts in the Co-Development Territory to the JSC as needed, but no less often than two (2) times per Calendar Year;

(g) coordinating the Detailing efforts of both Parties in the Co-Development Territory with respect to Co-Developed Products;

(h) overseeing all recalls, market withdrawals and any other corrective actions related to Co-Developed Products in the Co-Development

# Territory;

(i) receiving and providing to the Parties sales reports pertaining to Co-Developed Products in the Co-Developed Territory;

(j) approving all Third Parties to be engaged by either Party to provide Representatives to Co-Promote Co-Developed Products in the Co-Developed Territory;

(k) reviewing and approving any ingredients that are therapeutically or biologically active that are proposed by either Party for inclusion with a Co-Developed Product to create a Combination Product; and

(l) performing such activities as may be delegated to the JDCC pursuant to this Agreement, or by mutual written agreement of the Parties after the Approval Date.

2.3.5 **Dispute Resolution.** The JDCC members shall use reasonable efforts to reach agreement on any and all matters for which the JDCC is responsible pursuant to Section 2.3.4. In the event that, despite such reasonable efforts, agreement on a particular matter cannot be reached by the JDCC within [\*\*\*\*\*] days after the JDCC first meets to consider such matter, then the Chairman of the JDCC shall bring such matter to the JSC for a final decision in accordance with Section 2.1.6.

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## 3. RESEARCH PROGRAM

3.1 **<u>Objectives of the Research Program</u>**. The objectives of the Research Program shall be the identification of one (1) or more Compounds or Abbott Compounds suitable for further Development as Candidates and for Commercialization as Products.

3.2 **Research Plan.** The initial Research Plan is attached hereto as <u>Exhibit A</u>. For each Calendar Year during the Research Program Term commencing with the second full Calendar Year, the Research Plan shall be amended and updated by the Parties, which amendments and updates shall be submitted to and approved by the JSC in accordance with Section 2.1.4. Each such amendment shall: (a) set forth (i) the research objectives and activities to be performed for the Calendar Year covered by the update with reasonable specificity; (ii) the Party that shall be responsible for performing such activities; (iii) a timeline and budget for such activities; and (iv) with respect to Enanta Research Activities, the number of FTEs estimated to be required to perform such Enanta Research Activities; and (b) shall be consistent with the terms of this Agreement.

## 3.3 Conduct of Research Program.

3.3.1 **Abbott Responsibilities.** During the Research Program Term, Abbott will (a) use Commercially Reasonable Efforts to conduct the Abbott Research Activities assigned to it in each Research Plan and (b) commit such other resources as are reasonably necessary to conduct such Abbott Research Activities and achieve the goals of the Research Program.

3.3.2 <u>Enanta Responsibilities</u>. During the Research Program Term, Enanta will (a) use Commercially Reasonable Efforts to conduct the Enanta Research Activities assigned to it in each Research Plan and (b) commit to the Research Program at least [\*\*\*\*\*] FTEs for each of the first [\*\*\*\*\*] years of the Research Program Term and such other resources for the remainder of the Research Term as are reasonably necessary to conduct such Enanta Research Activities and achieve the goals of the Research Program; provided, that, Enanta shall not be required to commit FTEs to the Research Program prior to the Approval Date.

3.3.3 **Compliance**. Each Party shall perform its obligations under each Research Plan in good scientific manner and in compliance in all material respects with all Applicable Laws. With respect to each activity performed under the Research Plan that will or could reasonably be expected to be submitted to a Regulatory Authority in support of a Regulatory Filing or Drug Application Approval, the Party performing such activity shall comply in all material respects with the regulations and guidance of the FDA that constitute Good Laboratory Practice or Good Manufacturing Practice or, if and as appropriate under the circumstances, International Conference on Harmonization (ICH) guidance or other comparable regulation and guidance of any Regulatory Authority in any country or region in the Territory. Each Party shall be solely responsible for paying the salaries and benefits of its employees and consultants conducting its activities under the Research Plan.

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3.3.4 <u>Cooperation</u>. Scientists at Enanta and Abbott shall cooperate in the performance of the Research Program and, subject to the terms of this Agreement and any confidentiality obligations to Third Parties, shall exchange such data, information and materials as is reasonably necessary for the other Party to perform its obligations under the Research Plan.

## 3.4 <u>Records</u>.

# 3.4.1 Record Keeping.

(a) <u>Research Program Records</u>. Each Party shall maintain records of its activities under the Research Program in sufficient detail, in good scientific manner and otherwise in a manner that reflects all work done and results achieved in the performance of the Research Program. Subject to Article 7, each Party shall provide the other Party with access during normal business hours and upon reasonable advance notice to inspect and copy such records to the extent reasonably required for the performance of the requesting Party's obligations and exercise of its rights under this Agreement.

(b) <u>Record Keeping Policies</u>. Without limiting the generality of Section 3.4.1(a), each Party agrees to maintain a policy that requires its employees and consultants to record and maintain data and information developed during the Research Program in standard laboratory notebooks that are dated and corroborated by non-inventors on a regular, contemporaneous basis and otherwise in a manner designed to establish the earliest date of invention or reduction to practice.

3.5 **Reports.** The Parties shall keep the JSC regularly informed of the progress of the Research Program and shall present to the JSC all data and results generated from such efforts. Without limiting the generality of the foregoing, each Party shall, at least once each Calendar Quarter during the Research Program Term, provide: (a) reports to the JSC in reasonable detail regarding the status of its activities under such Research Program; (b) advise the JSC of its identification of any Compound or Abbott Compound it reasonably determines should be Developed as a Candidate and provide the JSC with any supporting data applicable to such Compound or Abbott Compound so as to enable the JSC to determine whether such Compound or Abbott Compound should be approved by the JSC as a Candidate; and (c) provide such additional information that it has in its possession as may be reasonably requested from time to time by the JSC.

3.6 <u>Selection of Candidates</u>. Within [\*\*\*\*\*] days after its receipt of each report from a Party pursuant to Section 3.5(b) identifying a Compound or Abbott Compound which such Party determines be Developed as a Candidate, the JSC shall (i) review such supporting data and information using standards and criteria to be developed by the JSC, and (ii) if it determines that a Candidate has been identified, notify the Parties in writing of such determination (each, a "<u>Candidate Designation</u>"). Upon the issuance by the JSC of a Candidate Designation for a Compound or Abbott Compound, (a) such Compound or Abbott Compound shall be deemed to be a Candidate for purposes of this Agreement and (b) the Parties shall, as

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promptly as possible, prepare and submit to the JSC for its review and, if such Candidate is a Co-Developed Product for its approval, a Development Plan with respect to the Development activities to be conducted with respect to such Candidate. For purposes of clarity, the Parties hereby acknowledge and agree that no Compound or Abbott Compound may be Developed under the Development Program unless and until it is designated as a Candidate by the JSC.

3.7 <u>Supply of Proprietary Materials</u>. From time to time during the Research Program Term, either Party (a "<u>Transferring Party</u>") may supply the other Party (a "<u>Recipient Party</u>") with Proprietary Materials of the Transferring Party for use in the Research Program. In connection therewith, each Recipient Party hereby agrees that: (a) it shall not use such Proprietary Materials for any purpose other than exercising its rights or performing its obligations hereunder; (b) it shall use such Proprietary Materials only in compliance with all Applicable Laws; (c) it shall not transfer any such Proprietary Materials to any Third Party without the prior written consent of the Transferring Party, except as expressly permitted hereby; (d) it shall not acquire any right, title or interest in or to such Proprietary Materials as a result of such supply by the Transferring Party; and (e) upon the expiration or termination of the Research Program Term, it shall, if and as instructed by the Transferring Party, either destroy or return any such Proprietary Materials that are not the subject of the grant of a continuing license hereunder.

3.8 **Research Program Term.** Subject to Section 11.2.1, the Research Program may be extended (a) for an additional period of one (1) year by Abbott by providing not less than six (6) months' prior written notice to Enanta and (b) for one (1) or more periods of one (1) year each thereafter by either Party providing not less than six (6) months' prior written notice to the other Party, subject to the Parties reaching mutual agreement on all of the terms and conditions applicable to any such extension. In the event this Agreement is terminated prior to the end of the Research Program Term, the effective date of termination of the Research Program Term shall be the same date as the termination of this Agreement.

## 4. DEVELOPMENT AND COMMERCIALIZATION

### 4.1 Development of Candidates.

4.1.1 **Development Plans.** A Development Plan and budget for each Candidate for the balance of the Calendar Year during which the Compound or Abbott Compound is designated by the JSC as a Candidate shall be prepared by Abbott and submitted to the JSC promptly after the designation of such Compound or Abbott Compound as provided in Sections 2.1.4(h) and 3.6. Thereafter, for each Calendar Year during the Development Program, an updated Development Plan and budget for each Candidate shall be prepared by Abbott and submitted to the JSC as provided in Section 2.1.4(a) or (b), as applicable. To the extent JSC approval is required, the Parties shall manage the preparation of each Development Plan and budget in a manner designed to obtain such JSC approval no later than [\*\*\*\*\*] days prior to the end of the then-current Calendar Year. Each Development Plan and amendment thereto shall: (a) set forth (i) the Development objectives, activities, priorities, timelines, budget and resources for the Calendar Year covered by the Development Plan with reasonable specificity, (ii) the

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Development objectives and activities to be performed for each Calendar Year period covered by the Development Plan with reasonable specificity, broken down by Calendar Quarters, (iii) the Party that shall be responsible for performing such activities, (iv) a timeline for such activities and (v) the expected Development Costs over such Calendar Year; and (b) be consistent with the other terms of this Agreement.

4.1.2 **Responsibility for the Development of Candidates.** Unless otherwise set forth in any Development Plan; Abbott shall have the sole right and responsibility for all aspects of the Development of Candidates in accordance with the applicable Development Plan in the Territory, including, without limitation, (a) the conduct of: (i) all IND-enabling non-clinical studies for Candidates; and (ii) all activities related to the conduct of human clinical trials (including, without limitation, Phase I Clinical Trials, Phase II Clinical Trials and Phase III Clinical Trials), including the manufacture of all clinical trial materials, (b) making all Regulatory Filings for Candidates and filing all Drug Approval Applications and otherwise seeking all Regulatory Approvals for Candidates, as well as all correspondence and communications with Regulatory Authorities regarding such matters, subject in each case to Section 4.5.5, and (c) reporting all Adverse Events to Regulatory Authorities, if and to the extent required by Applicable Laws. Abbott shall own all Regulatory Filings and Drug Approval Applications for Candidates, subject to Section 11.3.

## 4.2 Commercialization of Products.

4.2.1 <u>Marketing and Sales Plans</u>. Within [\*\*\*\*\*] days of the Initiation of a Phase III Clinical Trial with respect to each Candidate, Abbott shall prepare and provide to the JSC for its review a Marketing and Sales Plan for each Candidate, and approval, if such Marketing and Sales Plan pertains to a Co-Developed Product. Thereafter, for each Calendar Year during the Term, the Marketing and Sales Plan for each Candidate or Product, as the case may be, shall be updated by Abbott and submitted to the JSC for its approval in accordance with Section 2.1.4(a) or (b), as applicable. Each update to the Marketing and Sales Plan shall set forth: (a) the Commercialization objectives and activities to be performed for the Calendar Year covered by the Marketing and Sales Plan with reasonable specificity; (b) the manufacturing scale-up, formulating and filing requirements for each Candidate or Product, as the case may be, to be performed for the Calendar Year with reasonable specificity: and (c) a timeline for such activities.

4.2.2 **Responsibility for Commercialization of Products.** Subject to the exercise by Enanta of a Co-Development and Profit Share Option and unless otherwise set forth in any Marketing and Sales Plan, Abbott shall have the sole right and responsibility for all aspects of the Commercialization of Products, in accordance with the applicable Marketing and Sales Plan in the Field. Without limiting the foregoing, Abbott shall have the sole right and responsibility for (a) the conduct of: (i) all activities relating to the manufacture and supply of Products (including all required process development and scale up work with respect thereto); and (ii) all pre-marketing, marketing, promotion, FDA DDMAC interactions, sales, distribution, import and export activities (including securing reimbursement, sales and marketing and

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conducting any post-marketing trials or post-marketing safety surveillance or maintaining databases), subject to the oversight of the JSC and (b) for: (i) subject to Section 4.5.5, making all Regulatory Filings for Candidates and filing all Drug Approval Applications and otherwise seeking all Regulatory Approvals for Products, as well as all correspondence and communications with Regulatory Authorities regarding such matters; (ii) reporting all Adverse Events to Regulatory Authorities if and to the extent required by Applicable Laws; and (iii) subject to making the Co-Development Payments to Enanta for Co-Developed Products contemplated by Section 6.4.1(b). Abbott shall own all Regulatory Approvals for Products, subject to Section 11.3.

4.2.3 <u>Manufacture and Supply of Products</u>. Abbott shall be responsible for manufacturing or having manufactured through Third Party contract manufacturers, any materials (including, without limitation, all Candidates) as may be required for all pre-clinical and clinical studies necessary to obtain Regulatory Approval of Products and any materials and quantities of each Candidate as may required for all pre-clinical and clinical studies applicable to such Candidates.

4.3 Development and Commercialization Diligence. Abbott shall use Commercially Reasonable Efforts during the Term to Develop Candidates and Commercialize Products in the Field and in the Territory. Without limiting the foregoing, Abbott shall seek Regulatory Approvals for, and Commercialize, each Product in all of the Major Market Countries and in every other country in the Territory identified in the Marketing and Sales Plan. If Enanta at any time believes that Abbott is not meeting its diligence obligations pursuant to this Section 4.3, Enanta may give written notice to Abbott requesting written justification, in the form of detailed reasons, that would support the proposition that Abbott is meeting such diligence obligations. In such event, Abbott shall provide such written justification to Enanta within [\*\*\*\*\*] days after such notice is given. In the event that Enanta does not receive such justification within such [\*\*\*\*\*] day period or does not agree with such justification, then Enanta shall have the right, in its sole discretion, to pursue a declaration of breach and seek available remedies under Section 11.3.6 or any or all other rights or remedies that it may have under this Agreement, at law or in equity.

4.4 <u>Compliance</u>. Each Party shall perform its obligations under each Development Plan in good scientific manner and under each Marketing and Sales Plan using Commercially Reasonable Efforts, and both in compliance in all material respects with all Applicable Laws; provided that with respect to each activity performed under a Development Plan and under a Marketing and Sales Plan that will or would reasonably be expected to be submitted to a Regulatory Authority in support of a Regulatory Filing or Drug Approval Application, such Party shall comply in all material respects with, if and as applicable, the regulations and guidance of the FDA that constitute Good Laboratory Practice, Good Manufacturing Practice or Good Clinical Practice (or, if and as appropriate under the circumstances, International Conference on Harmonization (ICH) guidance or other comparable regulation and guidance of any Regulatory Authority in any country or region in the Territory).

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## 4.5 Reports; Information; Updates.

4.5.1 **Development Reports.** Abbott shall keep the JSC regularly informed of the progress of its efforts to Develop Compounds in the Field and in the Territory. Without limiting the generality of the foregoing, Abbott shall, at least once per Calendar Quarter, provide the JSC with reports in reasonable detail regarding the status of all pre-clinical IND-enabling studies and activities (including toxicology and pharmacokinetic studies), clinical trials and other activities conducted under each Development Plan, together with summary data and results and raw data made available if requested for each such pre-clinical IND-enabling study or activity, clinical trial and such additional information that it has in its possession as may be reasonably requested from time to time by the JSC.

4.5.2 **Commercialization Reports.** Abbott shall keep the JSC regularly informed of the progress of its efforts to Commercialize Products in the Field and in the Territory. Without limiting the generality of the foregoing, Abbott shall provide Enanta with semi-annual written updates to each Marketing and Sales Plan, which shall (a) summarize Abbott's efforts to Commercialize Products, (b) identify the Regulatory Filings and Drug Approval Applications with respect to Candidates that Abbott or any of its Affiliates or Sublicensees have filed in the prior twelve (12) month period, (c) identify the Regulatory Approvals with respect to Products that Abbott or any of its Affiliates or Sublicensees have obtained in the prior twelve (12) month period or reasonably expect to obtain in the following twelve (12) month period, and (d) summarize all clinical and other data generated by Abbott with respect to Products. In addition, Abbott shall provide such additional information that it has in its possession as may be reasonably requested from time to time by the JSC regarding the Commercialization of any Product.

4.5.3 <u>Supply of Products for Development and Commercialization</u>. Abbott shall be solely responsible, at its sole cost for manufacturing or having manufactured through Third Party contract manufacturers, any and all Products for Commercialization. For purposes of clarification, manufacturing costs for Co-Developed Products are referenced in Sec. 1.37 "Development Costs" and Schedule 6 "Cost of Goods".

4.5.4 <u>Adverse Event Reports</u>. Within ninety (90) days after the date of this Agreement, the Parties shall enter into an agreement to initiate a process for the exchange of adverse event safety data in a mutually agreed format, including, but not limited to, post-marketing spontaneous reports received by the Party or its Affiliates in order to monitor the safety of the Product and to meet reporting requirements with any applicable Regulatory Authority.

# 4.5.5 Preparation and Review of Regulatory Filings and Correspondence.

(a) <u>Preparation of Drug Approval Applications</u>. Abbott shall consult with Enanta in good faith in the preparation of all Drug Approval Applications for Candidates.

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Abbott shall consider all comments of Enanta in good faith, taking into account the best interests of the Collaboration and of the Development of the applicable Candidate and Commercialization of the corresponding Product on a global basis.

(b) <u>Regulatory Meetings</u>; <u>Review of Regulatory Filings and Correspondence</u>. Abbott shall use Commercially Reasonable Efforts to provide Enanta with at least [\*\*\*\*\*] days advance notice of any key meetings with the FDA or other Regulatory Authority regarding a Drug Approval Application relating to, or Regulatory Approval for, any Candidate or Product, as the case may be, and provide Enanta with material related to such meeting. Enanta may elect to send one (1) individual reasonably acceptable to Abbott to participate as an observer (at Enanta's sole cost and expense) in meetings with the FDA. In addition, Abbott shall provide Enanta with initial IND filings or Drug Approval Applications sufficiently in advance of submission so that Enanta may review and comment on the substance of such Regulatory Filing or other document or correspondence. In addition, Abbott shall promptly provide Enanta with copies of any FDA milestone meetings or NDA labeling discussions pertaining to any Candidate or Product. If Enanta has not commented on such Regulatory Filing or other documents or correspondence. Abbott shall consider all comments of Enanta shall be deemed to have no comments on such Regulatory Filing or other documents or correspondence. Abbott shall consider all comments of Enanta in good faith, taking into account the best interests of the Collaboration and of the Development of the applicable Candidate or Commercialization of the corresponding Product on a global basis.

For a Co-Developed Product, Abbott shall notify Enanta of any material communication with any Regulatory Authority regarding drug approval, drug labeling, or safety matters and shall promptly provide copies of any material document or other material correspondence received from any Regulatory Authority.

4.6 **Product Recalls.** In the event that any Regulatory Authority issues or requests a recall or takes similar action in connection with a Co-Developed Product, or in the event a Party reasonably believes that an event, incident or circumstance has occurred that may result in the need for a recall, market withdrawal or other corrective action regarding a Co-Developed Product, such Party shall promptly advise the other Party thereof by telephone or facsimile. Following such notification, Abbott shall decide and have control of whether to conduct a recall or market withdrawal (except in the event of a recall or market withdrawal mandated by a Regulatory Authority, in which case it shall be required) or to take other corrective action in any country and the manner in which any such recall, market withdrawal or corrective action shall be conducted; provided that Abbott shall keep Enanta regularly informed regarding any such recall, market withdrawal or corrective action. Abbott shall bear all expenses of any such recall, market withdrawal or corrective action and return of the affected Co-Developed Product and any refund to customers); provided, that, any such expenses shall be allocable as Co-Developed Costs or Commercialization Expenses and shared by the Parties in accordance with Section 5.3.

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4.7 **Product Labeling.** All product labels for Products shall include the names and logos of both Abbott and Enanta, to the extent consistent with the Applicable Laws of any country in which Products are sold.

# 5. <u>CO-DEVELOPMENT AND PROFIT SHARE OPTION</u>

5.1 <u>Exercise of Co-Development and Profit Share Option</u>. Enanta shall have the option (the "<u>Co-Development and Profit Share Option</u>"), but not the obligation, to co-develop and share in the profits of any Product in the Co-Development Territory by providing written notice to Abbott at any time during the Co-Development and Profit Share Option Period, which notice shall identify the Compound or Candidate, as the case may be.

5.2 Effect of Exercise. If Enanta exercises the Co-Development and Profit Share Option with respect to a Compound or Candidate, as the case may be, as described in Section 5.1 then: (a) that Compound or Candidate, as the case may be, will thereafter be deemed to be a Co-Developed Product for purposes of this Agreement; (b) the Parties shall prepare and provide to the JSC for its review and approval a Marketing and Sales Plan for such Co-Developed Product within the Co-Development Territory which shall be updated and submitted by the Parties to the JSC not less than annually; (c) Abbott shall provide Enanta, as promptly as possible thereafter, with Abbott's revised non-binding, good faith estimate of Development Costs it expects to incur with respect to the allocation of Shared Clinical Trial Costs in accordance with Section 5.4, Enanta shall be responsible for the Enanta Co-Development Percentage of all Development Costs applicable to that Co-Developed Product incurred on and after the Co-Development and Profit Share Option Exercise Date within the Co-Development Percentage; (f) the Parties shall negotiate a Co-Promotion Agreement for such Co-Developed Product in accordance with Section 5.7; and (g) Enanta shall receive the Enanta Co-Development Percentage of all Operating Income derived from that Co-Developed Product in accordance with Section 6.5.2. The Parties hereby acknowledge and agree that either Party shall have the right to propose the addition of other therapeutically or biologically active ingredients for inclusion with a Co-Developed Product to create a Combination Product. Enanta and Abbott will negotiate in good faith on the terms for the development and commercialization of a Combination Product created from a Co-Developed Product that have not been contemplated in this Agreement.

## 5.3 Reconciliation and Auditing of Development Costs.

5.3.1 **Reconciliation of Development Costs.** Within [\*\*\*\*\*] days following the end of each Calendar Quarter following the exercise of the Co-Development and Profit Share Option applicable to a given Co-Developed Product, Abbott shall submit to JSC a written report setting forth in reasonable detail all Development Costs incurred by Abbott over such Calendar Quarter. Within [\*\*\*\*\*] days following the JSC's receipt of such written reports, the JSC shall

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prepare and submit to Enanta a written report setting forth in reasonable detail the calculation of the net amount owed by Enanta to Abbott in order to ensure the appropriate sharing of the Development Costs in accordance with the Enanta Co-Development Percentage and the Abbott Co-Development Percentage, respectively. Enanta shall pay the net amount to Abbott within [\*\*\*\*\*] days after the distribution by the JSC of such written report.

5.3.2 Records; Audit Rights. Abbott shall keep and maintain for [\*\*\*\*\*] years complete and accurate records of Development Costs incurred with respect to Co-Developed Products in sufficient detail to allow confirmation of same by Enanta. Enanta shall have the right for a period of [\*\*\*\*\*] years after such Development Cost is reconciled in accordance with Section 5.2 to inspect or audit, or to appoint, at its expense, an independent certified public accountant reasonably acceptable to Abbott to inspect or audit, the relevant records of Abbott and its Affiliates to verify that the amount of such Development Costs was correctly determined. Abbott and its Affiliates shall each make its records available for inspection or audit by such independent certified public accountant during regular business hours at such place or places where such records are customarily kept, upon reasonable notice from Enanta, solely to verify that Development Costs hereunder were correctly determined; provided that Enanta shall not have the right to inspect or audit any Calendar Year more than [\*\*\*\*\*] or more than [\*\*\*\*\*] years after the end of such Calendar Year or to conduct more than [\*\*\*\*\*] such audit in any [\*\*\*\*\*] month period. All records made available for inspection or audit shall be deemed to be Confidential Information of Abbott. The results of each inspection or audit, if any, shall be binding on both Parties. In the event there was an error in the amount of Development Costs reported by Abbott hereunder, (a) if the amount of Development Costs was over-reported, Abbott shall promptly (but in any event no later than [\*\*\*\*\*] days after Abbott's receipt of the independent accountant's report so concluding) make payment to Enanta of the over-reported amount and (b) if the amount of Development Costs was underreported, Enanta shall promptly (but in any event no later than [\*\*\*\*\*] days after Enanta's receipt of the independent accountant's report so concluding) make payment to Abbott of the underreported amount. Enanta shall bear the full cost of such audit unless such audit discloses an over-reporting by Abbott of more than [\*\*\*\*\*] of the aggregate amount of Development Costs reportable in any Calendar Year, in which case Abbott shall reimburse Enanta for all costs incurred by Enanta in connection with such inspection or audit.

#### 5.4 Allocation of Shared Clinical Trial Costs.

5.4.1 <u>Use of Shared Clinical Trial Data</u>. On and after the date of exercise by Enanta of its Co-Development and Profit Share Option for a Co-Developed Product and continuing for the Term of this Agreement [\*\*\*\*\*], whichever date is earlier, each Party shall provide written notice to the other Party to the extent it Materially Used any Shared Clinical Trial Data (the "<u>Shared Clinical Trial Notice</u>").

5.4.2 <u>True- Up of Clinical Trial Costs</u>. Within [\*\*\*\*\*] days of the end of each Calendar Year following the date of the Shared Clinical Trial Notice, each Party shall submit to JSC a written report setting forth in reasonable detail all Shared Clinical Trial Costs

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incurred by such Party over such Calendar Year. Within [\*\*\*\*\*] days following the JSC's receipt of such written reports, the JSC shall prepare and submit to each Party a written report setting forth in reasonable detail the calculation of the net amount owed by a Party to the other Party in order to ensure the appropriate sharing of the Shared Clinical Trial Costs [\*\*\*\*\*]. The net amount payable shall be due within [\*\*\*\*\*] days after receipt of any such accounting.

5.4.3 **Data Audit**. Promptly following the submission of each Regulatory Filing, and any amendments or supplements thereto, the Party making such submission shall provide a full and complete copy of such filing to the other Party for purposes of determining whether the submitting Party has Materially Used the other Party's Shared Clinical Trial Data without having paid its applicable Shared Clinical Trial Cost Sharing Percentage associated with such Shared Clinical Trial Data. In the event that a Party Materially Used the other Party's Shared Clinical Trial Data. In the event that a Party Materially Used the other Party's Shared Clinical Trial Data in such submission, the submitting Party shall immediately pay its applicable Shared Clinical Trial Cost Sharing Percentage to the other Party upon written request by the other Party.

5.5 **Roll-Over Payments.** If, in any Calendar Quarter, the actual Development Costs incurred by Enanta with respect to a Co-Developed Product for that Calendar Quarter exceeds by greater than [\*\*\*\*\*] Abbott's good faith estimate of Development Costs for that Co-Developed Product for that Calendar Quarter, Enanta may, upon written notice to Abbott, delay payment of its share of any such excess until the subsequent Calendar Year (the "**Roll-Over Payment**"). Enanta shall make the Roll-Over Payment in two (2) equal amounts over the first two (2) consecutive Calendar Quarters of the subsequent Calendar Year.

5.6 [\*\*\*\*\*].

# 5.7 Co-Promotion.

5.7.1 **Preparation and Execution of Co-Promotion Agreement.** As soon as practicable but no later than the date of completion of a Phase III Clinical Trial with respect to a Co-Developed Product, the Parties shall complete and execute a Co-Promotion Agreement (the "**Co-Promotion Agreement**") which shall provide for the terms applicable to such Co-Promotion and shall conform in all material respects with the terms and conditions set forth in <u>Schedule 5</u> attached hereto and such additional provisions as are usual and customary for inclusion in a co-promotion agreement between companies in the pharmaceutical industry of comparable sizes to the respective Parties. Such additional terms shall supplement and shall not materially expand, limit or change the terms set forth on <u>Schedule 5</u>. The Parties shall negotiate the Co-Promotion Agreement in good faith and with sufficient diligence as is required to execute and deliver the Co-Promotion Agreement within [\*\*\*\*\*] days of commencing negotiations.

5.7.2 **Dispute Resolution**. In the event the Parties fail to execute and deliver the Co-Promotion Agreement within the [\*\*\*\*\*] day period described in Section 5.6.1, the Parties shall (a) use reasonable efforts to complete such negotiations and to execute and deliver the Co-Promotion Agreement as soon as possible after such [\*\*\*\*\*] day period and (b) without

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limiting the generality of the foregoing, after the expiration of such [\*\*\*\*\*] day period, each produce a list of issues on which they have failed to reach agreement and submit its list to the JSC to be resolve in accordance with Section 2.1.6. Notwithstanding the foregoing, the Parties shall, upon the request by either Party during the negotiation period, discuss in good faith whether to enter into an agreement with a Third Party to Co-Promote the Co-Developed Product, in which case, Enanta shall share in the consideration received from such Third Party in accordance with the Enanta Co-Development Percentage.

5.7.3 **Co-Promotion Plan.** The JDCC shall prepare a Co-Promotion Plan for each Co-Developed Product for the Co-Development Territory which shall include, but not be limited to, (a) demographics and market dynamics, market strategies, and estimated launch date of such Co-Developed Product in the Co-Development Territory, (b) a sales and expense forecast (including at least five (5) years of estimated sales and expenses), manufacturing plans and targeted label claims for such Co-Developed Product in the Co-Development Territory, (c) a marketing plan (including five (5) year advertising and Detailing forecasts and pricing strategies) for such Co-Developed Product in the Co-Development Territory, and (d) a five (5) year budget for such Co-Developed Product for the Co-Development Territory. The Co-Promotion Plan and annual written updates thereto shall be submitted to the JDCC for review by a date to be established by the JDCC, taking into account Abbott's and Enanta's annual budget planning calendars, but no later than December 31 of each Calendar Year.

# 6. CONSIDERATION AND FUNDING

6.1 <u>Upfront Fee</u>. On the Approval Date, Abbott shall be obligated to pay Enanta a non-refundable, non-creditable fee in the amount of Forty-Four Million Seven Hundred Thousand Dollars (US \$44,700,000). [\*\*\*\*\*] of this fee is payable by wire transfer of immediately available funds on the first business day following the Approval Date. [\*\*\*\*\*] of this fee is payable by wire transfer on the first anniversary of the first business day following the Approval Date.

6.2 <u>Purchase of Equity; Participation Right</u>. In partial consideration of the rights granted by Enanta to Abbott hereunder, Abbott agrees to purchase from Enanta, and Enanta hereby agrees to issue and sell to Abbott, shares of Series G Preferred Stock, \$.001 par value per share (the "<u>Shares</u>"), of Enanta for an aggregate purchase price of Twelve Million Five Hundred Thousand Dollars (US \$12,500,000). Abbott shall be obligated to make such payment to Enanta on the Approval Date. Such payment is payable by wire transfer of immediately available funds on the first business day following the Approval Date and pursuant to the terms and subject to the conditions set forth in the Stock Purchase Agreement attached hereto as <u>Exhibit B</u> (the "<u>Stock Purchase</u> <u>Agreement</u>").

#### 6.3 R&D Funding.

6.3.1 <u>FTE Costs</u>. Beginning on the first day of the third year of the Research Program Term and on the first day of each subsequent Calendar Quarter during the Research

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Program Term, Abbott shall make a payment equal to [\*\*\*\*\*] ("Quarterly Research Payment", which is equal to [\*\*\*\*\*] per Calendar Year (the "<u>Annual</u> <u>Research Payment</u>")). For the third year of the Research Program Term (and any subsequent years of the Research Program Term, if extended as per Section 3.8), Enanta shall provide Abbott with an annual reconciliation statement that specifies the actual number of FTEs for that third (and subsequent, if applicable) year of the Research Program Tern. If, with respect to that third (and subsequent, if applicable) year of the Research Program Term, the FTE Cost attributable to the number of FTEs specified in the annual reconciliation statement for such third (and subsequent, if applicable) year of the Research Program Term, Abbott shall have the right to apply the excess paid by it towards the FTE Cost due to Enanta in subsequent years of the Research Program Tern, Abbott shall have the right to apply the excess paid by it towards the FTE Cost due to Enanta in subsequent years of the Research Program Term, due to the Research Program Term ends before such balance is zero, Enanta will pay such excess payment to Abbott within thirty (30) days after the end of the Research Program Term. If, with respect to that third (and subsequent, if applicable) year of the Research Program Term is more than the Annual reconciliation statement for such third (and subsequent, if applicable) year of the Research Program Term is more than the Annual Research Payment for such third (and subsequent, if applicable) year of the Research Program Term is more than the Annual Research Payment for such third (and subsequent, if applicable) year of the Research Program Term is more than the Annual Research Payment for such third (and subsequent, if applicable) year of the Research Program Term is more than the Annual Research Payment for such third (and subsequent, if applicable) year of the Research Program Term, Enanta shall be solely responsible for such excess FTE Cost.

6.3.2 Research Funding Audit Rights. Enanta shall keep complete and accurate books and financial records pertaining to its costs and expenses of conducting the Research Program, which books and financial records shall be kept in accordance with GAAP and shall be retained by Enanta until [\*\*\*\*\*] years after the end of the Calendar Year to which they pertain. Abbott shall have the right to appoint, at its expense, an independent certified public accountant reasonably acceptable to Enanta to inspect or audit, the books and financial records of Enanta relating to its costs and expenses of conducting the Research Program during any Calendar Year; provided that Abbott shall not have the right to inspect or audit any Calendar Year more than [\*\*\*\*\*] or more than [\*\*\*\*\*] years after the end of such Calendar Year or to conduct more than [\*\*\*\*\*] such audit in any [\*\*\*\*\*] month period. All books and financial records made available for inspection or audit shall be deemed to be Confidential Information of Enanta. The results of each inspection or audit, if any, shall be binding on both Parties. In the event there was an error in the amount of FTE Costs reported by Enanta hereunder, (a) if the amount of FTE Costs was over-reported, Enanta shall promptly (but in any event no later than [\*\*\*\*\*] days after Enanta's receipt of the independent accountant's report so concluding) make payment to Abbott of the over-reported amount and (b) if the amount of FTE Costs was underreported, Abbott shall promptly (but in any event no later than [\*\*\*\*\*] days after Abbott's receipt of the independent accountant's report so concluding) adjust its records to reduce the balance of any excess payment to the under-reported amount. Abbott shall bear the full cost of such audit unless such audit discloses an over-reporting by Enanta of more than [\*\*\*\*\*] of the aggregate amount of FTE Costs reportable in any Calendar Year, in which case Enanta shall reimburse Abbott for all costs incurred by Abbott in connection with such inspection or audit.

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## 6.4 Milestone Payments.

## 6.4.1 Milestones.

(a) <u>First Product</u>. Abbott shall make each of the following non-refundable, non-creditable payments to Enanta within thirty (30) days after the occurrence of each of the following milestone events for the first Candidate or Product, as the case may be, that is not a Co-Developed Product (the <u>"Initial Product</u>"):

| Milestone Event   | Mile | stone Payment |
|---|------|---------------|
| Successful Completion of Phase Ib/IIa Clinical Study        | \$   | 40 million    |
| Initiation of first Phase III Clinical Trial                | \$   | 15 million    |
| Filing of first NDA in the United States                    | \$   | 20 million    |
| Filing of first Regulatory filing in the European Union     | \$   | 20 million    |
| Commercialization Regulatory Approval in the United States  | \$   | 75 million    |
| Commercialization Regulatory Approval in the European Union | \$   | 50 million    |
| Commercialization Regulatory Approval in Japan              | \$   | 30 million    |

(b) <u>Additional Products</u>. To the extent that one (1) or more additional Candidates or Products, as the case may be, are Developed and Commercialized following receipt of Commercialization Regulatory Approval of the first Product, Abbott shall make each of the following non-refundable, non-creditable payments to Enanta within thirty (30) days after the occurrence of each of the following milestone events for each additional Product that is not a Co-Developed Product (each, an "<u>Additional Product</u>"):

| [****]  | [*****] |
|---------|---------|
| [*****] | [*****] |
| [*****] | [*****] |

(c) **<u>First Co-Developed Product</u>**. In lieu of the payments to be made by Abbott pursuant to Section 6.4.1(a), Abbott shall make each of the following non-refundable, non-creditable payments to Enanta within thirty (30) days after the occurrence of each of the following milestone events in the event the first Candidate or Product, as the case may be, is a Co-Developed Product (the "<u>Initial Co-Developed Product</u>"):

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| Milestone Event | Milestone Payment |
|-----------------|-------------------|
| [****]          | [****]            |
| [*****]         | [*****]           |
| [*****]         | [****]            |
| [****]          | [*****]           |

Notwithstanding the foregoing, in the event that Enanta exercises a Co-Development and Profit-Share Option with respect to a Candidate or Product, as the case may be, the milestone payments applicable under this Section 6.4.1(c) shall be reduced in the aggregate by [\*\*\*\*\*] for the first to occur of (i) filing of the first Regulatory Filing for such Co-Developed Product in the European Union, (ii) the first Commercialization Regulatory Approval in Japan received for such Co-Developed Product and (iii) the first Commercialization Regulatory Approval in the European Union received for such Co-Developed Product. The forgoing reduction shall only apply to the Initial Co-Developed Product.

(d) <u>Additional Co-Developed Products</u>. In lieu of the payments to be made by Abbott pursuant to Section 6.4.1(b), to the extent that one (1) or more Co-Developed Products are Developed and Commercialized following receipt of Commercialization Regulatory Approval of the first Product, regardless of whether the first Product is an Initial Product or an Initial Co-Developed Product, Abbott shall make each of the following non-refundable, non-creditable payments to Enanta within thirty (30) days after the occurrence of each of the following milestone events for each additional Co-Developed Product (each, an "<u>Additional Co-Developed Product</u>"):

| [*****] | [****]  |
|---------|---------|
| [*****] | [*****] |

6.4.2 <u>Milestone Payments and Notices</u>. Abbott shall provide Enanta with prompt written notice upon each achievement of a milestone event set forth in Section 6.4.1, which notice shall include a description of the applicable milestone event. In the event that, notwithstanding the fact that Abbott has not given such a notice, Enanta believes any such milestone event has occurred, it shall so notify Abbott in writing and shall provide to Abbott data, documentation or other information that supports its belief. Any dispute under this Section 6.4.2 that relates to whether a milestone event has been achieved shall be referred to the JSC to be resolved in accordance with Section 2.1.6. In the event Abbott proceeds to the next stage of Development for a Candidate, any milestone payments that were not paid for any prior stages of Development that are otherwise applicable to such Candidate, shall also be due and payable. For example, if a Phase IIb Clinical Trial is initiated without payment of the Successful Completion of Phase Clinical Study, then the Successful Completion of Phase Ib/IIa Clinical Study will be deemed to have occurred and will be paid in full upon payment of the milestone payable upon the submission of the first NDA filing.

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## 6.5 Payment of Royalties; Operating Income Payments; Sublicense Income Payments; Accounting and Records.

## 6.5.1 Payment of Royalties.

(a) <u>Payment of Royalties</u>. Abbott shall pay Enanta a royalty based on Annual Net Sales of each Royalty-Bearing Product commencing with the Calendar Year (or partial Calendar Year) in which the First Commercial Sale of such Royalty-Bearing Product occurs and ending upon the expiration of the Royalty Term for such Royalty-Bearing Product, at the following rates (such royalty payments, the "<u>Royalty Payments</u>"):

| Annual Net Sales   | <b>Royalty Rate</b> |
|--|---------------------|
| Up to (but not including) [*****]                                      | 10%                 |
| Equal to or greater than [*****] and up to (but not including) [*****] | [*****]             |
| Equal to or greater than [*****] and up to (but not including) [*****] | [*****]             |
| Equal to or greater than [*****] and up to (but not including) [*****] | [*****]             |
| Equal to or greater than [*****]                                       | 20%                 |

For example, if Annual Net sales of a Royalty-Bearing Product were [\*\*\*\*\*], the royalty payment would be [\*\*\*\*\*].

(b) <u>Offsets for Third Party Payments</u>. In the event Abbott, in order to practice the license granted to it under Section 8.2.1 of this Agreement in any country in the applicable portion of the Territory in which royalties are payable as provided in Section 6.5.1, is required to and actually makes royalty payments to any Third Party ("<u>Third Party Payments</u>") in order to obtain a license to an issued patent or patents in the absence of which the Compound portion of the Royalty Bearing Product could not legally be researched, Developed, manufactured, imported, sold, exported, or otherwise exploited in such country (as evidenced, to the extent reasonably requested by Enanta, by an opinion of patent counsel), then the royalties payable to Enanta for such Royalty-Bearing Product under this Agreement with respect to such country may be reduced by [\*\*\*\*\*] of the amount of such Third Party Payments. Notwithstanding the foregoing, (i) [\*\*\*\*\*], and (ii) such reductions shall in no event reduce the royalty that would otherwise be payable for such Royalty-Bearing Product under Section 6.5.1 with respect to such country by more than [\*\*\*\*\*] of the amount otherwise payable with respect to Net Sales of such Royalty-Bearing Product in such country.

(c) <u>No Patent Coverage</u>. Notwithstanding Section 6.5.1(a), if any Royalty-Bearing Product is sold in a country and is not covered by a Valid Claim of the Licensed

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Patent Rights, Abbott Patent Rights or Joint Patent Rights in such country, the royalty rate in such country shall be reduced by [\*\*\*\*\*] of the rates set forth above, continuing until the last day of the Royalty Term with respect to such Royalty-Bearing Product; provided, that, in the event the royalty rate on a Royalty-Bearing Product is reduced in a country under this Section 6.5.1(c) and is subsequently covered by a Valid Claim under the Licensed Patent Rights, Abbott Patent Rights or Joint Patent Rights in such country, (i) the full royalty rates otherwise applicable under Section 6.5.1(a) shall be reinstated for the remainder of the Royalty Term, and (ii) for any period of time that the royalty rate on a Royalty-Bearing Product is reduced but a pending patent application exists which subsequently results in such Valid Claim, Abbott shall make a one-time payment to Enanta in an amount equal to the difference between (A) the amounts that would have been payable under full royalty rates applicable under Section 6.5.1(a) during such time, and (B) amounts that were paid under the royalty rates applicable under this Section 6.5.1(c) during such time.

(d) <u>Generic Products</u>. In the event one or more Third Parties sell a Generic Product (as defined below) in a country in which a Royalty-Bearing Product is then being sold, then, during the period in which sales of the Generic Product by such Third Parties in the aggregate are equal to at least [\*\*\*\*] of Abbott's volume-based or revenue-based market share of the Royalty-Bearing Product in such country (as measured by prescriptions or other similar information available in such country), all applicable royalties in effect with respect to such Royalty-Bearing Product in such country as specified in Section 6.4.1 shall be reduced by [\*\*\*\*\*]. Notwithstanding the foregoing, Abbott's obligation to pay royalties at the full royalty rates shall be reinstated on the first day of the Calendar Quarter immediately following the Calendar Quarter in which sales of such Generic Product account for less than [\*\*\*\*\*] of Abbott's volume-based or revenue-based market share in such country. For purposes of this Section 6.5.1(d), a "<u>Generic Product</u>" means a pharmaceutical product that (i) is not covered by a Valid Claim under the Licensed Patent Rights, Abbott Patent Rights or Joint Patent Rights in the relevant country, (ii) contains the same active ingredient as a Royalty-Bearing Product and (iii) is bioequivalent to such Royalty-Bearing Product.

(e) <u>Combination Products</u>. For each Royalty-Bearing Product that is a Combination Product, the Parties shall, on a country-by-country basis, agree to an appropriate adjustment to Net Sales to reflect a good faith determination of the relative value of each pharmaceutically active ingredient, based on the estimated fair market value of each such therapeutically or biologically active ingredient, as follows: (a) In the case of a Combination Product for which a Royalty-Bearing Product and each of the other therapeutically or biologically active ingredients contained in the Combination Product are sold separately in such country by Abbott, Net Sales shall be determined by [\*\*\*\*\*]; (b) In the case of a Combination Product for which the Royalty-Bearing Product is sold separately in such country but the non-Royalty-Bearing Product therapeutically or biologically active ingredients contained in the Combination Product are not sold separately by Abbott in such country, Net Sales shall be calculated by [\*\*\*\*\*]; and (c) If in a country neither the Royalty-Bearing Product nor the therapeutically or biologically active ingredients contained in the combination product are sold separately in said country by Abbott, Net Sales of the Royalty-Bearing Product are sold separately in said country by Abbott, Net Sales of the Royalty-Bearing Product are sold separately in said country by Abbott, Net Sales of the Royalty-Bearing Product are sold separately in said country by Abbott, Net Sales of the Royalty-Bearing Product fanning part of

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the Combination Product shall be reasonably determined by [\*\*\*\*\*]. In the case where the Parties are unable to agree on [\*\*\*\*\*], the Parties shall agree upon an internationally recognized independent certified public accountant who shall make such determination and whose determination shall be final and binding on the Parties.

(f) <u>Know-How Payments</u>. The Parties hereby acknowledge and agree that any royalties that are payable for a Royalty-Bearing Product under 6.5.1 (c) for which no Patent Rights exist shall be in consideration of: (i) Enanta's expertise and know-how concerning the identification of Compounds in the Field, and its other Compound-related development activities conducted prior to the Effective Date; (ii) the performance by Enanta of the Research Program; (iii) the disclosure by Enanta to Abbott of results obtained in the Research Program; (iv) the licenses granted to Abbott hereunder with respect to Licensed Technology and Joint Technology that are not within the claims of any Patent Rights Controlled by Enanta; (v) the restrictions on Enanta in Section 8.5; and (vi) the "head start" afforded to Abbott by each of the foregoing.

(g) <u>Payment Dates and Reports</u>. Abbott shall make Royalty Payments within [\*\*\*\*\*]. All payments shall be made by wire transfer to the credit of such bank account as shall be designated in writing from time to time by Enanta. Abbott shall also provide, at the same time each such payment is made, a report showing: (i) the Net Sales of each Royalty-Bearing Product by country in the Territory; (ii) the basis for any deductions from gross amounts billed or invoiced to determine Net Sales; (iii) the applicable royalty rates for such Royalty-Bearing Product; (iv) the exchange rates used in calculating any of the foregoing; and (v) a calculation of the amount of royalty due to Enanta.

6.5.2 **Operating Income Payments.** Enanta shall receive from Abbott, in lieu of receiving any Royalty Payments with respect to each Co-Developed Product in the Co-Development Territory, the Enanta Co-Development Percentage of all Annual Operating Income derived from sales of that Co-Developed Product in the Co-Development Territory (such payments, the "**Operating Income Payments**") for as long as there are sales by Abbott, its Affiliates and Sublicensees of such Co-Developed Product (the "**Co-Development Term**"). Within thirty (30) days following the end of each Calendar Quarter commencing on and after the date of First Commercial Sale of each Co-Developed Product, (a) Enanta shall submit to the JSC a statement identifying all Commercialization Expenses and License Fees incurred by it with respect to such Co-Developed Product in the Co-Development Territory and (b) Abbott shall submit to the JSC a statement identifying the Net Sales, Cost of Goods, freight, Third Party Payments, R&D and all Commercialization Expenses incurred by it with respect to such Co-Developed Product. Within forty-five (45) days following the end of the Calendar Quarter, the JSC shall submit to the Parties a written report setting forth in reasonable detail (c) the calculation of Operating Income, determined in accordance with <u>Schedule 6</u> attached hereto and (d) the calculation of the amount of Operating Income payable to Enanta in accordance with the Enanta Co-Development Percentage for that Co-Developed Product taking into account Enanta's expenditures for the period. Abbott shall make the Operating Income Payments to Enanta within thirty (30) days following the issuance of such written report.

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6.5.3 <u>Sublicense Income Payments</u>. Abbott shall pay Enanta the Applicable Percentage of all Sublicense Income received by Abbott under Sublicense Agreements with respect to Products ("<u>Sublicense Income Payments</u>"). As used herein, the term "<u>Applicable Percentage</u>" shall mean [\*\*\*\*\*]. Abbott shall make all Sublicense Income Payments within thirty (30) days of the end of the Calendar Quarter commencing with the first Calendar Quarter in which any Sublicense Income is received.

6.5.4 Records; Audit Rights. Abbott and its Affiliates and Sublicensees shall keep and maintain for [\*\*\*\*\*] years from the date of each Royalty Payment, Operating Income Payment and Sublicense Income Payment complete and accurate records of gross sales and Net Sales by Abbott and its Affiliates and Sublicensees of each Product, in sufficient detail to allow Royalty Payments, Operating Income Payments and Sublicense Income Payments to be determined accurately. Enanta shall have the right for a period of [\*\*\*\*\*] years after receiving any such payment to inspect or audit, or to appoint at its expense an independent certified public accountant reasonably acceptable to Abbott to inspect or audit the relevant records of Abbott and its Affiliates and Sublicensees to verify that the amount of such payment was correctly determined. Abbott and its Affiliates and Sublicensees shall each make its records available for inspection or audit by such independent certified public accountant during regular business hours at such place or places where such records are customarily kept, upon reasonable notice from Enanta, solely to verify that Royalty Payments and Sublicense Income Payments were correctly accounted for or determined. Enanta shall not exercise such inspection or audit right [\*\*\*\*\*]. All records made available for inspection or audit shall be deemed to be Confidential Information of Abbott. The results of each inspection or audit, if any, shall be binding on both Parties. In the event there was an underpayment by Abbott, Abbott shall promptly (but in any event no later than [\*\*\*\*\*] days after Abbott's receipt of the independent accountant's report so concluding) make payment to Enanta of any shortfall, together with the interest payment as provided in Section 6.5.5. In the event that there was an overpayment by Abbott, Enanta shall promptly (but in any event no later than [\*\*\*\*\*] days after Enanta's receipt of the independent accountant's report so concluding) refund to Abbott the excess amount. Enanta shall bear the full cost of such audit unless such audit discloses an underreporting by Abbott of more than [\*\*\*\*\*] of the aggregate amount of Royalty Payment or Sublicense Income Payments payable in any Calendar Year, in which case Abbott shall reimburse Enanta for all costs incurred by Enanta in connection with such inspection or audit.

6.5.5 **Overdue Royalties, Operating Income Payments and Milestones.** All Royalty Payments, Operating Income Payments and Sublicense Income Payments not made within the time period set forth in Section 6.5.1, 6.5.2 and 6.5.3, and all milestone payments not made within the time period specified in Section 6.4.1, shall bear interest at a rate of [\*\*\*\*\*] percent ([\*\*\*\*\*]%) per month from the due date until paid in full or, if less, the maximum interest rate permitted by Applicable Laws. Any such overdue Royalty Payment, Sublicense Income Payment, Operating Income Payment or milestone payment shall, when made, be accompanied by, and credited first to, all interest so accrued.

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6.5.6 <u>Withholding Taxes.</u> All payments made by Abbott hereunder shall be free and clear of any taxes, duties, levies, fees or charges except for applicable withholding taxes, if any. Abbott shall make any applicable withholding payments due from Enanta on its behalf and shall promptly thereafter provide Enanta with written documentation of any such payment sufficient to enable Enanta to satisfy the requirements of the United States Internal Revenue Service with regard to an application for a foreign tax credit for such payment.

6.5.7 <u>Foreign Currency Exchange</u>. All Royalty Payments, Operating Income Payments and Sublicense Income Payments shall be payable in full in United States Dollars, regardless of the countries in which sales are made. For the purpose of computing Net Sales for Products sold in any currency other than United States Dollars, the quarterly Royalty Payment will be calculated as follows:

(A/B) x C= United States Dollars Royalty Payment on Net Sales sold in any currency other than United States Dollars during a Calendar Quarter, where

A= foreign "Net Sales" (as defined above) in such Calendar Quarter expressed in such foreign currency;

B= foreign exchange conversion rate, expressed in local currency of the foreign country per United States Dollar (using, as the applicable foreign exchange rate, the average of the monthly average rates for that Calendar Quarter as published by Bloomberg, and if Bloomberg is not available then another similar third party source); and

C= the royalty rate(s) applicable to such Net Sales under this Agreement.

6.6 **No Other Compensation.** The Parties hereby agree that the terms of this Agreement and the Stock Purchase Agreement fully define all consideration, compensation and benefits, monetary or otherwise, to be paid, granted or delivered by each Party to the other Party in connection with the transactions contemplated herein. Neither Party has previously paid or entered into any other commitment to pay, whether orally or in writing, any employee of the other Party, directly or indirectly, any consideration, compensation or benefits, monetary or otherwise, in connection with the transactions contemplated herein.

6.7 **Enanta Payments.** Notwithstanding anything to the contrary in any of Section 6.4 or Section 6.5, Enanta shall be solely responsible for any and all payments to be made to [\*\*\*\*\*] pursuant to the terms and conditions set forth in that certain [\*\*\*\*\*] by and between Enanta and [\*\*\*\*\*], other than any payments for use of [\*\*\*\*\*] HCV Tool Patent License under the terms of such [\*\*\*\*\*] existing on the Effective Date, which will be the sole responsibility of Abbott to the extent that the HCV Tool Patent License is used by either Party pursuant to this Agreement.

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## 7. TREATMENT OF CONFIDENTIAL INFORMATION; PUBLICITY; NON-SOLICITATION

## 7.1 Confidentiality.

7.1.1 <u>Confidentiality Obligations</u>. Enanta and Abbott each recognizes that the other Party's Confidential Information constitutes highly valuable assets of such other Party. Enanta and Abbott each agrees that, subject to Section 7.1.2, during the Term and for an additional five (5) years thereafter, it will not disclose or use, and will cause its Affiliates and sublicensees not to disclose or use, any Confidential Information of the other Party, except as expressly permitted hereunder. In fulfilling its obligations of confidentiality under this Article 7, each Party shall take such action, and shall cause its Affiliates and sublicensees to take such action, to preserve the confidentiality of the other Party's Confidential Information as such Party would customarily take to preserve the confidentiality of its own Confidential Information.

7.1.2 Limited Disclosure. Enanta and Abbott each agrees (a) that disclosure of its Confidential Information or any transfer of its Proprietary Materials may be made by the other Party to any employee, consultant, director or Affiliate of such other Party to enable such other Party to exercise its rights or to carry out its responsibilities under this Agreement; provided that any such disclosure or transfer shall only be made to Persons who are bound by written obligations as described in Section 7.1.3, and (b) disclosure of its Confidential Information may be made by the other Party (1) on a need-to-know basis to such other Party's legal and financial advisors, or (ii) as reasonably necessary in connection with an actual or potential (A) permitted sublicense of such other Party's rights hereunder, (B) debt or equity financing of such other Party or (C) Change of Control involving such other Party, provided, in any case, the Person receiving such Confidential Information of the other Party agrees in writing to maintain the confidentiality of such Confidential Information of the other Party with terms at least as restrictive as those contained in Section 7.1.1. In addition, each Party agrees that the other Party may disclose such Party's Confidential Information (a) as reasonably necessary to file, prosecute or maintain Patent Rights, or to file, prosecute or defend litigation related to Patent Rights, in accordance with this Agreement or (b) as required by Applicable Laws; provided that, in the case of any disclosure and provide the other Party with an opportunity to comment on any such required disclosure, (ii) if requested by such other Party, seek, or cooperate in all reasonable respects with such other Party's efforts to obtain, confidential treatment or a protective order with respect to any such disclosure to the extent available at such other Party's expense, and (iii) use good faith efforts to incorporate the comments of such other Party in any such disclosure or request for confidential treatment or pro

7.1.3 <u>Employees and Consultants</u>. Enanta and Abbott each represents that all of its employees and consultants, and all of the employees and consultants of its Affiliates or sublicensees, who participate in the activities of the Collaboration or have access to Confidential Information of the other Party are or will, prior to their participation or access, be bound by written obligations to maintain such Confidential Information in confidence and not to use such

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information except as expressly permitted hereunder. Each Party agrees to use, and to cause its Affiliates and sublicensees to use, reasonable efforts to enforce such obligations.

7.2 **Publicity.** The Parties acknowledge that the terms of this Agreement constitute Confidential Information of each Party and may not be disclosed except as permitted by Section 7.1.2. Notwithstanding anything to the contrary in Section 7.1, the Parties, after approval of this Agreement by the Abbott Board, Abbott's Chief Executive Officer and the Enanta Board and agreement by both Parties, shall file the press release attached hereto as <u>Exhibit C</u> (the "<u>Initial Press Release</u>") and, once the Initial Press Release is disclosed by either Party, then either Party may make subsequent public disclosure of the specific contents of such press release without further approval of the other Party. Thereafter, except as may be required by Applicable Laws, neither Party shall publish, present or otherwise disclose publicly any material related to the Research Program, the Development of a Candidate or the Commercialization of a Product without the prior written consent of the other Party; provided, that notwithstanding the foregoing, (a) either Party shall be permitted to publish such material in scientific journals or present such material at scientific conferences in accordance with Section 7.3, (b) Abbott shall control interactions with the FDA DDMAC regarding publicity of marketed products, as provided in Section 4.2.2, and (c) Abbott and Enanta agree that it shall not unreasonably withhold, condition or delay its consent to any request by the other Party to publish, present or otherwise announce publicly developments in the Research Program, the Development of Candidates or the Commercialization of Products.

7.3 **Publications and Presentations.** The Parties acknowledge that scientific publications must be strictly monitored to prevent any adverse effect from premature publication or dissemination of results of the activities hereunder. Except as required by Applicable Laws, each Party agrees that it shall not publish or present, or permit to be published or presented, the results of the Research Program, the Development of a Candidate or the Commercialization of a Product, including, but not limited to, studies or clinical trials carried out by such Party as part of the Collaboration, without the prior review by and the approval of the JSC in accordance with Section 2.1. Each Party shall provide to the JSC the opportunity to review any of the submitting Party's proposed abstracts, manuscripts or presentations (including information to be presented verbally) which relate to the Research Program, the Development of a Candidate or the Commercialization of a Product at least [\*\*\*\*\*] days prior to its intended presentation or submission for publication, and such submitting Party agrees, upon written request from the TSC within such [\*\*\*\*\*] day period, not to submit such abstract or manuscript for publication or to make such presentation until the other Party is given up to [\*\*\*\*\*] days from the date of such written request to seek appropriate patent protection for any material in such publication or presentations which the JSC reasonably believes is patentable. Once such abstracts, manuscripts or presentations have been reviewed by the JSC, the same abstracts, manuscripts or presentations do not have to be provided again to the JSC for review for a later submission for publication. Each Party also shall have the right to require that its Confidential Information that is disclosed in any such proposed publication or presentation be deleted prior to such publication or presentation. In any permitted publication or presentation by a Party, the other Party's

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contribution shall be duly recognized, and co-authorship shall be determined in accordance with customary industry standards.

7.4 **Prohibition on Solicitation**. Without the written consent of the other Party, neither Party nor its Affiliates shall, for a period of [\*\*\*\*\*] years from the Approval Date, solicit (directly or indirectly) any employee of the other Party or its Affiliates who participated in the Research Program at any time. This provision shall not restrict either Party or its Affiliates from advertising employment opportunities in any manner that does not directly target the other Party or its Affiliates.

## 8. LICENSE GRANTS; EXCLUSIVITY

#### 8.1 Research Licenses.

8.1.1 <u>Enanta Grant</u>. Enanta hereby grants to Abbott and its Affiliates during the Research Term a non-exclusive, royalty-free, worldwide license, with the limited right to grant sublicenses as provided in Section 8.3.1(a), under Enanta Technology, Enanta Patent Rights, Licensed Patent Rights and Enanta's interest in Joint Technology and Joint Patent Rights for the sole purpose of conducting Abbott Research Activities under the Research Program in accordance with the Research Plan.

8.1.2 **Abbott Grant.** Abbott hereby grants to Enanta and its Affiliates during the Research Term, a non-exclusive, royalty-free, worldwide license, with the limited right to grant sublicenses as provided in Section 8.3.1(b), under Abbott Technology, Abbott Patent Rights and Abbott's interest in Joint Technology and Joint Patent Rights for the sole purpose of conducting Enanta Research Activities under the Research Program in accordance with the Research Plan.

#### 8.2 Development and Commercialization Licenses.

8.2.1 <u>Enanta Grant</u>. Enanta hereby grants to Abbott during the Term an exclusive, royalty-bearing license, including the right to grant sublicenses as provided in Section 8.3, under Enanta Technology, Enanta Patent Rights, Licensed Patent Rights and Enanta's interest in Joint Technology and Joint Patent Rights, for the sole purpose of Developing Candidates and Commercializing Products in the Field in the Territory; provided, that, Enanta shall retain such rights as may be necessary to Develop and Commercialize Co-Developed Products in the Field and in the Co-Development Territory.

#### 8.2.2 Abbott Grants.

(a) <u>Commercialization License</u>. Abbott hereby grants to Enanta during the Term a co-exclusive (together with Abbott), royalty-free, fully paid license, without the right to grant sublicenses, under Abbott Technology, Abbott Patent Rights and Abbott's interest in Joint Technology and Joint Patent Rights for the sole purpose of Developing and Commercializing Co-Developed Products in the Field in the Co-Development Territory.

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(b) <u>Abbott Improvements</u>. Subject to Section 8.5, Abbott hereby grants to Enanta a co-exclusive (together with Abbott), fully paid, royalty-free license, including the right to grant sublicenses, under Abbott's interest in Abbott Improvements to develop, make, have made, use, sell, have sold, offer for sale, import, have imported, export and have exported, and otherwise exploit for all uses in the Field, any product that is not a Compound, Candidate or Product.

## 8.3 Right to Sublicense.

## 8.3.1 Research Licenses.

(a) <u>Abbott Right to Sublicense</u>. Abbott shall have the right to grant sublicenses under the license granted to it under Section 8.1.1 solely to Third Party subcontractors engaged by Abbott to perform designated support functions related to the conduct of Abbott Research Activities under the Research Program and the Development of Candidates under the Development Program; provided however, that (i) Abbott shall obtain the prior approval of the JSC to each sublicense grant; (ii) Abbott shall remain responsible for the satisfactory accomplishment of such work in accordance with the teuus and conditions of this Agreement; and (iii) each such subcontractor shall enter into a written agreement binding such subcontractor to the obligations Abbott has to Enanta under this Agreement (and containing such other provisions as are normal and customary for similar types of agreements).

(b) <u>Enanta Rights to Sublicense</u>. Enanta shall have the right to grant sublicenses under the license granted to it under Section 8.1.2 solely to Third Party subcontractors engaged by Enanta to perform designated support functions related to the conduct of Enanta Research Activities under the Research Program; provided however, that (i) Enanta shall obtain the prior approval of the JSC to each sublicense grant; (ii) Enanta shall remain responsible for the satisfactory accomplishment of such work in accordance with the terms and conditions of this Agreement; and (iii) each such subcontractor shall enter into a written agreement binding such subcontractor to the obligations Enanta has to Abbott under this Agreement (and containing such other provisions as are normal and customary for similar types of agreements).

8.3.2 <u>Commercialization License</u>. Abbott shall have the right to grant sublicenses under the license granted to it under Section 8.2.1 to any Affiliate of Abbott and to any Third Party with respect to any Product, other than any Co-Developed Product in the Co-Development Territory after which time Enanta has exercised its Co-Development and Profit Share Option with respect to such Co-Developed Product; provided, that: (a) it shall be a condition of any such sublicense that such Sublicensee agrees to be bound by all terms of this Agreement applicable to the Development of Candidates and the Commercialization of Products in the Field in the Territory (including, without limitation, Article 7); (b) Abbott shall provide written notice to Enanta of any such proposed sublicense at least thirty (30) days prior to such execution; and (c) Abbott shall not be relieved of any of its obligations pursuant to this Agreement as a result of such sublicense.

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8.4 **No Other Rights.** Abbott shall have no rights to use or otherwise exploit Enanta Technology, Enanta Patent Rights or Enanta Materials, and Enanta shall have no rights to use or otherwise exploit Abbott Technology, Abbott Patent Rights or Abbott Materials, in each case, except as expressly set forth herein.

## 8.5 Exclusivity.

#### 8.5.1 Enanta.

(a) <u>Exclusivity</u>. During the Research Term, and thereafter during the remainder of the Term for so long as a Candidate or Product is being actively Developed or Commercialized, respectively, for use in the Field, Enanta shall not, and shall cause each of its Affiliates to not: (a) conduct any activity, either on its own, or with, for the benefit of, or sponsored by any Third Party, that is designed to research, Develop or Commercialize any Compound or any Candidate or Product derived therefrom for use in the Field; (b) grant any license or other rights to any Third Party to utilize any Technology or Patent Rights Controlled by Enanta or any of its Affiliates for the express purpose of researching, Developing or Commercializing any Compound or Candidate or Product derived therefrom for use in the Field; or (c) in-license from any Third Party any Technology or Patent Rights Controlled by such Third Party, for the express purpose of researching, Developing or Commercializing any Compound or any Candidate or Product derived therefrom for use in the Field; any Compound or any Candidate or Product derived therefrom for use in the Field; or (c) in-license from any Third Party any Technology or Patent Rights Controlled by such Third Party, for the express purpose of researching, Developing or Commercializing any Compound or any Candidate or Product derived therefrom for use in the Field, except in any case as is necessary to advance the Research Program, the Development Program or the Commercialization of Products as set forth herein. Without limiting the generality of the foregoing, there shall be no restriction on Enanta hereunder with regard to (y) the use of Abandoned Compounds outside the Field during the Term or (b) the use of Abandoned Compounds, whether within or outside of the Field, after the expiration of the Term.

(b) <u>Exclusivity Exception</u>. Notwithstanding anything to the contrary in this Agreement, Section 8.5.1(a) shall not be deemed to restrict or prevent Enanta from conducting any activity under that certain License and Option Agreement dated as of May 4, 2005 by and between Enanta and Chiron Corporation.

#### 8.5.2 Abbott.

(a) <u>Exclusivity</u>. During the Research Term, and thereafter during the remainder of the Term for so long as a Candidate or Product is being actively Developed or Commercialized, respectively, for use in the Field, Abbott shall not, and shall cause each of its Affiliates to not: (a) conduct any activity, either on its own, or with, for the benefit of, or sponsored by any Third Party, that is designed to research, Develop or Commercialize any Compound or any Candidate or Product derived therefrom for use in the Field; (b) grant any license or other rights to any Third Party to utilize any Technology or Patent Rights Controlled by Abbott or any of their respective Affiliates for the express purpose of researching, Developing or Commercializing any Compound or any Candidate or Product derived therefrom for use in the Field; or (c) in-license from any Third Party any Technology or Patent Rights Controlled by such

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Third Party, for the express purpose of researching, Developing or Commercializing any Compound or any Candidate or Product derived therefrom for use in the Field, except in any case as is necessary to advance the Research Program, the Development Program or the Commercialization of Products as set forth herein and as described in Section 8.5.2(b).

(b) <u>Exclusivity Exception</u>. Notwithstanding anything to the contrary in this Agreement, Section 8.5.2(a) shall not be deemed to restrict or prevent Abbott from entering into non-exclusive license agreements with Third Parties with respect to the use of [\*\*\*\*\*], Abbott shall (i) provide Enanta with written notice of such license grant and (ii) pay Enanta a royalty equal to [\*\*\*\*\*] of all royalty payments received by Abbott under such license agreement for a co-formulation of an Additional Compound in each country in the Territory in which a Product is then being Commercialized, commencing with the Calendar Year (or partial Calendar Year) in which the First Commercial Sale of such Additional Compound occurs and ending upon the date on which the Product or the Additional Product is no longer being Commercialized in such country.

## 9. INTELLECTUAL PROPERTY RIGHTS

9.1 <u>Disclosure of Program Inventions</u>. Each of Enanta and Abbott shall promptly provide the other Party, through the Patent Coordinators (as defined in Section 9.5), with written notice concerning all Program Inventions that are conceived or reduced to practice by employees or consultants of such Party or its Affiliates, alone or jointly with employees or consultants of the other Party or its Affiliates or any Third Party.

9.2 Enanta Intellectual Property Rights. Enanta shall have sole and exclusive ownership of all right, title and interest on a worldwide basis in and to any and all Enanta Technology and Enanta Patent Rights.

9.3 <u>Abbott Intellectual Property Rights</u>. Abbott shall have sole and exclusive ownership of all right, title and interest on a worldwide basis in and to any and all Abbott Technology and Abbott Patent Rights,

9.4 Joint Technology Rights. Abbott and Enanta shall jointly own all Joint Technology and Joint Patent Rights, subject to the rights of, and the licenses granted to, each Party hereunder.

9.5 <u>Patent Coordinators</u>. Enanta and Abbott shall each appoint a patent coordinator reasonably acceptable to the other Party (each, a "<u>Patent</u> <u>Coordinator</u>"), who shall serve as such Party's primary liaison with the other Party on matters relating to patent filing, prosecution, maintenance and enforcement. Each Party may replace its Patent Coordinator at any time by notice in writing to the other Party.

9.6 **Inventorship**. In case of a dispute between Enanta and Abbott over inventorship, such dispute shall be resolved by application of United States patent law by patent counsel

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selected by the JSC who (and whose firm) is not at the time of the dispute, and was not at any time during the five (5) years prior to such dispute, performing services for either of the Parties. The Parties shall share equally the expenses of such patent counsel.

# 10. FILING, PROSECUTION AND MAINTENANCE OF PATENT RIGHTS

10.1 **Patent Filing, Prosecution and Maintenance.** Subject to the foregoing, the responsibility for filing, prosecuting and maintaining Patent Rights shall be as follows:

10.1.1 Licensed Patent Rights. Subject to Section 10.1.3, Enanta, acting through patent counsel or agents of its choice, shall be solely responsible, at its sole cost and expense, for the preparation, filing, prosecution and maintenance of the Licensed Patent Rights. In accordance with Section 10.1.5, Enanta will collaborate with Abbott on the preparation, filing and prosecution of the Licensed Patent Rights worldwide by providing Abbott with copies of any substantive office actions and setting up meetings with respective Patent Coordinators to discuss strategies and responses.

10.1.2 **Enanta Patent Rights.** Enanta, acting through patent counsel of its choice, shall be responsible, at its sole cost and expense, for the preparation, filing, prosecution and maintenance of all Enanta Patent Rights.

10.1.3 **Abbott Patent Rights.** Abbott, acting through patent counsel of its choice, shall be responsible, at its sole cost and expense, for the preparation, filing, prosecution and maintenance (a) of all Abbott Patent Rights and (b) commencing on the date of receipt of Commercialization Regulatory Approval with respect to a Product and continuing for the remainder of the applicable Royalty Term, of any Licensed Patent Rights that contain one or more claims that cover such Product.

10.1.4 **Joint Patent Rights.** The JSC shall determine the jurisdictions within the Territory in which patent applications will be filed with respect to Joint Patent Rights and the Party that shall be responsible for the preparation, filing, prosecution and maintenance of Joint Patent Rights. The Parties will share equally all expenses incurred by the filing Party for the preparation, filing, prosecution and maintenance of such Joint Patent Rights.

10.1.5 **Information and Cooperation**. Each filing Party shall (a) regularly provide the other Party with copies of all patent applications filed hereunder and other material submissions and correspondence with the patent offices, in sufficient time to allow for review and comment by the other Party and (b) provide the other Party and its patent counsel with an opportunity to consult with the filing Party and its patent counsel regarding the filing and contents of any such application, amendment, submission or response. The filing Party hereby agrees that the advice and suggestions of the other Party and its patent counsel shall be taken into reasonable consideration by the filing Party and its patent counsel in connection with each filing. Each Party shall, upon request from the filing Party and at the filing Party's sole cost, reasonably cooperate with the filing Party in connection with such patent filing activities.

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10.1.6 **Abandonment.** If either Party decides to expressly abandon or to allow to purposely lapse any of the Patent Rights covering any Program Inventions in any country or region in the Territory that specifically cover any Compound, Candidate or Product or specifically cover the manufacture or formulation or the delivery or use of a Compound, Candidate or Product in the Field, such Party shall inform the other Party of such decision promptly and, in any event, so as to provide the other Party a reasonable amount of time to meet any applicable deadline to establish or preserve such Patent Rights in such country or region. The other Party shall have the right to assume responsibility for continuing the prosecution of such Patent Rights in such country or region and paying any required fees to maintain such Patent Rights in such country or region or defending such Patent Rights, in the latter case only at the other Party's sole expense, through patent counsel or agents of its choice. The Party taking over the responsibility for prosecuting, maintaining and defending any of the Patent Rights to the other Party under this Section 10.1.6, the transferring Party's responsibility for prosecuting and execute all documents reasonably necessary for the other Party to assume such prosecution, maintenance and defense.

#### 10.2 Legal Actions.

# 10.2.1 Third Party Infringement.

#### (a) In General.

(i) <u>Notice</u>. In the event either Party becomes aware of (A) any possible infringement of any Licensed Patent Rights, Enanta Program Patent Rights or Abbott Program Patent Rights through the Development of a Candidate or the Commercialization of a Product, or (B) the submission by any Third Party of an abbreviated new drug application under the Hatch-Waxman Act for a product that includes a Compound, Candidate or a Product (each, an "<u>Infringement</u>"), that Party shall promptly notify the other Party and provide it with all details of such Infringement of which it is aware (each, an "<u>Infringement Notice</u>").

(ii) <u>Licensed Patent Rights</u>. Both Abbott and Enanta shall have the unilateral right to enforce any and all Licensed Patent Rights on any Product following the First Commercial Sale of such Product. All costs, including, without limitation, attorneys' fees, relating to such legal proceedings or other action shall be borne by the party enforcing such rights. In the event such an Infringement relates to any Licensed Patent Rights on any Compound, Candidate or Product prior to the First Commercial Sale of such Product, Enanta shall have the first right (not the obligation) to enforce such claim with respect to such Infringement. All costs, including, without limitation, attorneys' fees, relating to such legal proceedings or other action shall be borne by Enanta. If Enanta does not take or initiate commercially reasonable steps to initiate legal proceedings or take other actions regarding the Infringement within (A) twenty (20) days from any Infringement Notice in the case of an

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Infringement resulting from the submission by any Third Party of an abbreviated new drug application under the Hatch-Waxman Act, and (B) one hundred twenty (120) days from any Infringement Notice that relates to any other Licensed Patent Rights, then Abbott shall have the right and option to do so at its expense; provided, that Abbott shall not admit the invalidity or unenforceability of any such Licensed Patent Rights without Enanta's prior written consent.

(iii) <u>Enanta Patent Rights</u>. In the event such an Infringement relates to any Enanta Patent Rights, Enanta shall have the first right and option to initiate legal proceedings or take other actions regarding such Infringement by reasonable steps. All costs, including, without limitation, attorneys' fees, relating to such legal proceedings or other action shall be borne by Enanta. If Enanta does not take or initiate commercially reasonable steps to initiate legal proceedings or take other actions regarding the Infringement (A) within ten (10) days from any Infringement Notice if the Infringement relates to a Product being Commercialized by Abbott; (B) (twenty (20) days in the case of an Infringement resulting from the submission by any Third Party of an abbreviated new drug application under the Hatch-Waxman Act); and (C) one hundred twenty (120) days for any other Infringement, then in each such case, Abbott shall have the right and option to do so at its expense.

(iv) <u>Abbott Patent Rights</u>. In the event such an Infringement relates to any Abbott Patent Rights, Abbott shall have the first right and option to initiate legal proceedings or take other actions regarding such Infringement by reasonable steps. All costs, including, without limitation, attorneys' fees, relating to such legal proceedings or other action shall be borne by Abbott. If Abbott does not take or initiate commercially reasonable steps to initiate legal proceedings or take other actions regarding the Infringement within thirty (30) days from any Infringement Notice (or twenty (20) days in the case of an Infringement resulting from the submission by any Third Party of an abbreviated new drug application under the Hatch-Waxman Act), then Enanta shall have the right and option to do so at its expense.

(v) <u>No Settlement</u>. Neither Party shall settle any Infringement claim or proceeding under Sections 10.2.1(a)(iii) or (iv) or 10.2.1(b) without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed.

(vi) <u>Representation</u>. Each Party shall have the right to be represented by counsel that it selects in any legal proceedings or other action instituted under Sections 10.2.1(a)(iii) or (iv) or 10.2.1(b) by the other Party. If a Party with the right to initiate legal proceedings under Section 10.2.1 regarding an Infringement lacks standing to do so and the other Party has standing to initiate such legal proceedings, then the Party with standing shall initiate such legal proceedings at the request and expense of the other Party.

(b) <u>Joint Patent Rights</u>. In the event of an Infringement of a Joint Patent Right, the Parties shall enter into discussions as to whether to initiate legal proceedings or take other actions regarding the Infringement. Unless otherwise agreed by the Parties: (i) each Party shall bear an equal share of the cost of any action, suit or proceeding instituted under this

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Section 10.2.1(b); and (ii) all amounts recovered shall be allocated pursuant to Section 10.2.1(e). If the Parties are unable to determine whether and how to institute an action, suit or proceeding for infringement of any such Joint Patent Right, either Party shall have the right to prosecute such Infringement, in which event that Party shall bear all of the expense and be entitled to retain all amounts that it recovers.

(c) <u>Right to Representation</u>. Each Party shall have the right to participate, and be represented by counsel that it selects, in any legal proceedings or other action instituted under this Section 10.2.1 by the other Party. If a Party with the right to initiate legal proceedings under Section 10.2.1 regarding an Infringement lacks standing to do so and the other Party has standing to initiate such legal proceedings, then the Party with standing shall initiate such legal proceedings at the request and expense of the other Party.

(d) <u>Cooperation</u>. In any action, suit or proceeding instituted under this Section 10.2.1, the Parties shall cooperate with and assist each other in all reasonable respects. Upon the reasonable request of the Party instituting such action, suit or proceeding, the other Party shall join therein and shall be represented using counsel of its own choice, at the requesting Party's expense.

(e) <u>Allocation of Recoveries</u>. Any amounts recovered by either Party pursuant to actions under Sections 10.2.1(a)(iii) or (iv) or 10.2.1(b) with respect to any Infringement through the development or sale of a Compound or Product, whether by settlement or judgment, shall be allocated in the following order: (i) first, to reimburse Enanta and Abbott for their reasonable out-of-pocket expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses); and (ii) then, to Enanta and Abbott in the same proportion as Abbott's historic profits on Net Sales of the Product or Products affected by the Infringement bears to Abbott's historic royalties hereunder in respect of such Net Sales, in each case as determined in good faith.

10.2.2 **Defense of Claims.** In the event that any action, suit or proceeding is brought against either Party or any Affiliate or sublicensee of either Party alleging the infringement of the Technology or Patent Rights of a Third Party by reason of the conduct of the Research Program, the Development Program or the Commercialization of any Product: (a) Abbott shall have the obligation to defend such action, suit or proceeding at its sole expense; (b) Enanta shall have the right to separate counsel at its own expense in any such action, suit or proceeding; and (c) the Parties shall cooperate with each other in all reasonable respects in any such action, suit or proceeding relates to a Co-Developed Product in the Co-Development Territory, the cost and expense of the above shall be used to calculate Development Costs for that Co-Developed Product. Each Party shall provide the other Party with prompt written notice of the commencement of any such suit, action or proceeding, or of any allegation of infringement that is received by such Party. Nothing in this Section 10.2.2 shall affect the right of Enanta to defend itself in any such action, suit or proceeding. Abbott shall not compromise, settle or otherwise

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dispose of any such suit, action or proceeding that involves the use of Enanta Patent Rights, without Enanta's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed.

10.3 **Trademark Prosecution**. Abbott, at is sole expense, shall be responsible for the filing, prosecution, defense and maintenance before all trademark offices of the Product Trademarks.

## 11. TERM AND TERMINATION

11.1 **Term.** This Agreement shall commence on the Effective Date and shall continue in full force and effect until the end of the Research Program Term and, if Abbott is Developing a Candidate or Commercializing a Product arising out of the Research Program, thereafter until (a) such time as Abbott is no longer Developing a Candidate for use in the Field and in the Territory or (b) if, as of the time Abbott is no longer Developing any Candidates, Abbott is Commercializing a Product, until such time as all Royalty Terms for all Products and all Co-Development Terms for all Co-Developed Products have ended, unless earlier terminated in accordance with the provisions of this Article 11 (the "**Term**").

11.2 Termination. This Agreement may be terminated at any time by either Party, or by the Party specified, as follows:

11.2.1 **Unilateral Right to Terminate**. Abbott may terminate this Agreement at any time by giving written notice to Enanta not less than [\*\*\*\*\*] months prior to any anniversary of the Approval Date.

11.2.2 **Termination for Breach.** Either Party may terminate this Agreement by providing written notice to the other Party, and such termination will be effective [\*\*\*\*\*] days after the written notice, if the other Party commits a material breach of this Agreement unless the other Party has cured the asserted material breach during such [\*\*\*\*\*]-day period. If the breach has been cured prior to expiration of the [\*\*\*\*\*]-day cure period, the notice of termination will be void. In lieu of seeking termination of this Agreement, the Party asserting the material breach may seek compensatory damages and/or equitable relief as a remedy of an uncured material breach by the other Party. Notwithstanding the foregoing, a material breach by a Party shall not give rise to the termination right under this Section 11.2.2 to the extent such material breach arises from a Force Majeure event described in Section 14.12; provided, that the Party allegedly breaching the Agreement shall have the burden of demonstrating the occurrence of the Force Majeure event.

11.2.3 **Termination for Insolvency.** In the event either Party files for protection under the bankruptcy laws, makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it which is not discharged within sixty (60) days of the filing thereof, then the other Party may terminate this Agreement effective

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immediately upon written notice to such Party. In connection therewith, all rights and licenses granted under this Agreement are, and shall be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(56) of the United States Bankruptcy Code.

11.3 <u>**Consequences of Termination of Agreement</u>**. In the event this Agreement is terminated pursuant to Section 11.2, the following provisions shall apply, as applicable:</u>

11.3.1 **Termination by Abbott Pursuant to Section 11.2.1**. If this Agreement is terminated by Abbott pursuant to Section 11.2.1, the following provisions shall apply:

(a) If Abbott terminates the Agreement prior to the first anniversary of the first business day following the Approval Date, it shall make a [\*\*\*\*\*] time payment to Enanta of [\*\*\*\*\*] to complete the Upfront Fee as provided in Section 6.1;

(b) the licenses granted to Abbott pursuant to Sections 8.1.1 and 8.2.1 shall terminate upon the effective date of such termination;

(c) Abbott shall be deemed to have granted to Enanta, on and after the date of termination, (i) a non-exclusive, perpetual, fully-paid, worldwide, royalty-free license, with the rights to sublicense, under Abbott Program Technology and Abbott Patent Rights and (ii) an exclusive (even as to Abbott), perpetual, fully-paid, worldwide, royalty-free license, with the rights to sublicense, under Abbott's interest in Joint Technology and Joint Patent Rights, in either case, to Develop and have Developed Candidates resulting from Compounds and Abbott Compounds, other than Abbott Compounds listed on Schedule 1, and Commercialize Products derived from such Candidates;

(d) all exclusivity obligations of Enanta under Section 8.5.1 shall terminate upon the effective date of such termination and Enanta shall thereafter have the right to Develop Candidates and Commercialize Products for any and all uses within the Field;

(e) each Party shall promptly return all Confidential Information of the other Party that is not subject to a continuing license hereunder; provided that each Party may retain one (1) copy of the Confidential Information of the other Party in its archives solely for the purpose of establishing the contents thereof and ensuring compliance with its obligations hereunder;

(f) upon request of Enanta, Abbott shall promptly, and in any event within sixty (60) days after Enanta's request: (i) transfer to Enanta all right, title and interest in and to all Product Trademarks and registrations thereof, if any; (ii) transfer to Enanta all of its right, title and interest in all Regulatory Filings, Drug Approval Applications and Regulatory Approvals then in its name applicable to any Candidate or Product, and all material aspects of Confidential Information Controlled by it as of the date of termination relating to Regulatory Filings, Drug Approval Applications and Regulatory Approvals; provided that Enanta shall as of

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the date of such transfer, assume all obligations and liabilities associated with such Regulatory Filings, Drug Approval Applications and Regulatory Approvals; (iii) notify the applicable Regulatory Authorities and take any other action reasonably necessary to effect such transfer; (iv) provide Enanta with copies of all correspondence between Abbott and such Regulatory Authorities relating to such Regulatory Filings, Drug Approval Applications and Regulatory Approvals; (v) unless expressly prohibited by any Regulatory Authority, transfer control to Enanta of all clinical trials of any Candidate or Product being conducted as of the effective date of termination, and upon such transfer Enanta shall assume all obligations and liabilities associated with continuing such clinical trials; (vi) assign (or cause its Affiliates to assign) to Enanta all agreements with any Third Party with respect to the conduct of clinical trials for any Candidate or Product including, without limitation, agreements with contract research organizations, clinical sites and investigators, unless expressly prohibited by any such agreement (in which case Abbott shall cooperate with Enanta in all reasonable respects to secure the consent of such Third Party to such assignment); (vii) provide Enanta with all supplies of any Candidate or Product in the possession of Abbott or any Affiliate or contractor of Abbott; and (viii) provide Enanta with copies of all reports and data generated or obtained by Abbott or its Affiliates pursuant to this Agreement that relate to any Candidate or Product that has not previously been provided to Enanta; and

(g) if Abbott has manufactured, is manufacturing or having manufactured any Candidate or Product or any intermediate thereof as of the effective date of termination: (i) Abbott shall, if requested by Enanta, supply Enanta with its requirements for all such Candidate or Product and intermediate for up to [\*\*\*\*\*] months following such termination [\*\*\*\*\*]; and (ii) within sixty (60) days after Enanta's request, Abbott shall provide to Enanta or its designee all information in its possession with respect to the manufacture of each such Candidate, Product or intermediate.

11.3.2 **Termination by Enanta Pursuant to Section 11.2.2.** If this Agreement is terminated by Enanta pursuant to Section 11.2.2, the following provisions shall apply:

(a) the licenses granted to Abbott pursuant to Sections 8.1.1 and 8.2.1 shall terminate upon the effective date of such termination;

(b) Abbott shall be deemed to have granted to Enanta, on and after the date of termination, (i) a non-exclusive, perpetual, fully-paid, worldwide, royalty-free license, with the rights to sublicense, under Abbott Program Technology and Abbott Patent Rights with respect to Abbott Program Technology and (ii) an exclusive (even as to Abbott), perpetual, fully-paid, worldwide, royalty-free license, with the rights to sublicense, under Abbott's interest in Joint Technology and Joint Patent Rights, in either case, to Develop and have Developed Candidates resulting from Compounds and Abbott Compounds, other than Abbott Compounds listed on Schedule 1, and Commercialize Products derived from such Candidates;

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(c) all exclusivity obligations of Enanta under Section 8.5.1 shall terminate upon the effective date of such termination and Enanta shall thereafter have the right to Develop Candidates and Commercialize Products for any and all uses within the Field;

(d) each Party shall promptly return all Confidential Information of the other Party that are not subject to a continuing license hereunder; provided that each Party may retain one (1) copy of the Confidential Information of the other Party in its archives solely for the purpose of establishing the contents thereof and ensuring compliance with its obligations hereunder;

(e) upon request of Enanta, Abbott shall promptly, and in any event within sixty (60) days after Enanta's request: (i) transfer to Enanta all right, title and interest in and to all Product Trademarks and registrations thereof, if any; (ii) transfer to Enanta all of its right, title and interest in all Regulatory Approval Applications and Regulatory Approvals then in its name applicable to any Candidate or Product, and all material aspects of Confidential Information Controlled by it as of the date of termination relating to Regulatory Filings, Drug Approval Applications and Regulatory Approvals; provided that Enanta shall as of the date of such transfer, assume all obligations and liabilities associated with such Regulatory Filings, Drug Approval Applications and Regulatory Approvals; (ii) notify the applicable Regulatory Authorities and take any other action reasonably necessary to effect such transfer; (iv) provide Enanta with copies all correspondence between Abbott and such Regulatory Authorities relating to such Regulatory Filings, Drug Approval Applications and Regulatory Approvals; (v) unless expressly prohibited by any Regulatory Authorities relating to such Regulatory Filings, Drug Approval Applications and Regulatory Approvals; (v) unless expressly prohibited by any Regulatory Authorities relating to such Regulatory Filings, Drug Approval Applications and Regulatory Approvals; (v) unless expressly prohibited by any Regulatory Authorities relating to such Regulatory Filings, Drug Approval Applications and Regulatory Approvals; (v) unless expressly prohibited by any Regulatory Authorities relating assume all obligations and liabilities associated with continuing such clinical trials; (vi) assign (or cause its Affiliates to assign) to Enanta all agreements with any Third Party with respect to the conduct of clinical trials for any Candidate or Product including, without limitation, agreements with contract research organizations, clinical sites and investigators, unless expressly prohibited by any such

(f) if Abbott has manufactured, is manufacturing or having manufactured any Candidate or Product or any intermediate thereof as of the effective date of termination: (i) Abbott shall, if requested by Enanta, supply Enanta with its requirements for all such Candidate or Product and intermediate for up to [\*\*\*\*\*] months following such termination [\*\*\*\*\*], and (ii) within sixty (60) days after Enanta's request, Abbott shall provide to Enanta or its designee all information in its possession with respect to the manufacture of each such Candidate, Product or intermediate.

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11.3.3 **<u>Termination by Abbott Pursuant to Section 11.2.2</u>**. If this Agreement is terminated by Abbott pursuant to Section 11.2.2, the following provisions shall apply:

(a) Abbott shall continue to have the licenses set forth in Sections 8.1.1 and 8.2.1 to Develop Candidates being Developed by Abbott as of the effective date of termination, if any, and to Commercialize Products being Commercialized by Abbott as of the effective date of termination, if any, and to Commercialize Products that were Candidates at the time of termination, subject to a determination by the neutral in ADR of the level at which the milestone payments and Royalty Payments continue, it being understood by the Parties that the milestone payments and royalty rates set forth in this Agreement shall be modified with respect to a given Candidate or Product only to the extent the ADR determines that the material breach that resulted in the termination by Abbott of this Agreement materially affected the Development of such Candidate and/or the Commercialization of such Product.

(b) all rights (including, without limitation, the Co-Development and Profit Share Option) and licenses granted to Enanta pursuant to Article 5 and Sections 8.1.2 and 8.2.2 shall terminate upon the effective date of such termination;

(c) Enanta shall be deemed to have granted to Abbott, on and after the date of termination, (i) a non-exclusive, perpetual, fully-paid, worldwide, royalty-free license, with the rights to sublicense, under Enanta Program Technology and Enanta Patent Rights and (ii) an exclusive (even as to Enanta), perpetual, fully-paid, worldwide, royalty-free license, with the rights to sublicense, under Enanta's interest in Joint Technology and Joint Patent Rights, in either case, to Develop and have Developed Candidates and Commercialize Products derived from such Candidates;

(d) all exclusivity obligations of Abbott under Section 8.5.2 shall terminate upon the effective date of such termination and Abbott shall thereafter have the right to Develop Candidates and Commercialize Products for any and all uses within the Field; and

(e) each Party shall promptly return all Confidential Information of the other Party that are not subject to a continuing license hereunder; provided that each Party may retain one (1) copy of the Confidential Information of the other Party in its archives solely for the purpose of establishing the contents thereof and ensuring compliance with its obligations hereunder.

11.3.4 **Termination by Enanta Pursuant to Section 11.2.3**. If Enanta terminates this Agreement pursuant to Section 11.2.3, to the extent not prohibited by Applicable Laws, the provisions of Section 11.3.1 shall apply to such termination.

11.3.5 **Termination by Abbott Pursuant to Section 11.2.3.** If Abbott terminates this Agreement pursuant to Section 11.2.3, to the extent not prohibited by Applicable Laws, the provisions of Section 11.3.3 shall apply to such termination.

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11.3.6 **Breach of Compound or Product Diligence.** If after Enanta followed the procedure set forth in Section 11.2.2 for asserting a breach of contract and Abbott does not cure its breach for failure to use Commercially Reasonable Efforts to Develop a Candidate or Commercialize a Product in any Major Market Country, then Enanta shall have the right, in its sole discretion upon ten (10) days written notice to Abbott, to designate such Candidate or Product as a Abandoned Compound. In such event:

(a) the licenses granted to Abbott under Section 8.2 of this Agreement to Commercialize such Product shall terminate upon the effective date of such reversion;

(b) subject to the other terms of this Agreement, Abbott shall be deemed to have granted to Enanta and its Affiliates (i) an exclusive, royalty-free, paid-up, worldwide license, with the right to grant sublicenses, under Abbott Patent Rights and Abbott's interest in Joint Patent Rights that would be infringed by the making, using in the Field, importing or selling of such Abandoned Compound (or, for purposes of clarity, a Product derived therefrom) in the absence of a license to research, develop, make, have made, use, offer for sale, distribute for sale, sell, import and have imported Abandoned Compounds in the Field and (ii) a non-exclusive, royalty-free, paid-up, worldwide license, with the right to grant sublicenses, under Abbott Technology and Abbott's interest in Joint Technology to research, develop, have developed, make, have made, use, distribute for sale, sell, offer for sale, import and have imported such Abandoned Compound in the Field, subject in each case to the restrictions on Enanta pursuant to Section 8.5.1;

(c) upon request of Enanta, Abbott shall promptly, and in any event within sixty (60) days after Enanta's request: (i) grant to Enanta an exclusive, worldwide, royalty-free, paid-up license under all Product Trademarks applicable to such Product, if any; (ii) provide Enanta with access to, and grant Enanta the right and license to use and to reference, all Regulatory Filings and Regulatory Approvals then in its name applicable to the Commercialization of such Product and all material aspects of Confidential Information Controlled by it as of the date such Compound or Product relating to such Regulatory Filings and Regulatory Approvals is designated as a Abandoned Compound; (iii) provide Enanta with copies of all correspondence between Abbott and such Regulatory Authorities relating to such Regulatory Filings and Regulatory Approvals; (iv) assign to Enanta all agreements between Abbott and any Third Party with respect to the conduct of clinical trials for such Product, including, without limitation, agreements or contracts with contract research organizations, clinical sites and investigators, unless expressly prohibited by any such agreement; and (v) provide Enanta with copies of all reports and data obtained by Abbott or its Affiliates pursuant to this Agreement that relate to the Commercialization of such Product; and

(d) if Abbott has manufactured, is manufacturing or is having manufactured such Product or any intermediate of such Product as of the date such Candidate or Product is designated as a Abandoned Compound, upon request of Enanta, (i) Abbott shall supply Enanta with its requirements of such Product or intermediate for up to twenty-four (24) months following such removal at a transfer price equal to Abbott's Cost of Goods for the supply

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of such Product or intermediate plus fifteen percent (15%), and (ii) Abbott shall provide to Enanta or its designee all information in its possession with respect to the manufacture of such Product.

11.4 Surviving Provisions. Termination or expiration of this Agreement for any reason shall be without prejudice to:

(a) the rights and obligations of the Parties provided in Sections 5.3.2, 6.3.2, 6.4, 6.5, 6.6, 6.7, 11.3, 11.4 and Articles 7, 12, 13 and 14 (including all other Sections or Articles referenced in any such Section or Article and including Article 1), all of which shall survive such termination;

(b) any other rights or remedies provided at law or equity which either Party may otherwise have.

#### 12. REPRESENTATIONS AND WARRANTIES

12.1 Mutual Representations and Warranties. Enanta and Abbott each represents and warrants to the other, as of the Effective Date, as follows:

12.1.1 **Organization**. It is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver and perform this Agreement.

12.1.2 **Authorization**. Upon receipt of the approval by the Abbott Board and Abbott's Chief Executive Officer, the execution and delivery of this Agreement and the performance by Abbott of the transactions contemplated hereby will have been duly authorized by all necessary corporate action. Upon receipt of the approval by the Enanta Board and Enanta's Chief Executive Officer, the execution and delivery of this Agreement and the performance by Enanta of the transactions contemplated hereby will necessary corporate action.

12.1.3 **No Violations**. The transactions contemplated hereby and the performance by it of the transactions contemplated hereby will not violate (a) such Party's certificate of incorporation or bylaws, (b) any agreement, instrument or contractual obligation to which such Party is bound in any material respect, (c) any requirement of any Applicable Law, or (d) any order, writ, judgment, injunction, decree, determination or award of any court or governmental agency presently in effect applicable to such Party.

12.1.4 **<u>Binding Agreement</u>**. This Agreement is a legal, valid and binding obligation of such Party enforceable against it in accordance with its terms and conditions.

12.1.5 <u>No Inconsistent Obligation</u>. It is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any respect with the terms of this

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Agreement or that would impede the diligent and complete fulfillment of its obligations hereunder.

12.2 Additional Representations of Enanta. Enanta further represents and warrants to Abbott, as of the Effective Date, as follows:

12.2.1 <u>Enanta Licensed Patent Rights</u>. All Licensed Patent Rights are existing and, to Enanta's Knowledge, no Licensed Patent Rights are invalid or unenforceable.

12.2.2 <u>Claims or Judgments</u>. There are no claims, judgments or settlements against Enanta pending, or to Enanta's Knowledge, threatened, that invalidate or seek to invalidate the Licensed Patent Rights.

12.2.3 **<u>Right to Technology</u>**. Enanta has the right to (a) use the Licensed Technology and Licensed Patent Rights existing as of the Effective Date as is necessary to fulfill its obligations under this Agreement; and (b) grant the licenses under the Licensed Patent Rights granted pursuant to this Agreement; and (c) without limiting the foregoing, and with respect to both clauses (a) and (b) of this Section 12.2.3, [\*\*\*\*\*].

12.2.4 No Infringement. To Enanta's Knowledge, no Third Party is infringing, or threatening to infringe, the Licensed Patent Rights.

12.2.5 <u>No Litigation</u>. There is no pending or, to Enanta's Knowledge, threatened, litigation that alleges that Enanta's proposed activities under this Agreement would infringe or misappropriate any intellectual property rights of any Third Party.

## 13. **INDEMNIFICATION**

13.1 **Indemnification of Abbott by Enanta**. Enanta shall indemnify, defend and hold harmless Abbott, its Affiliates, their respective directors, officers, employees and agents, and their respective successors, heirs and assigns (the "**Abbott Indemnitees**"), against all liabilities, damages, losses and expenses (including reasonable attorneys' fees and expenses of litigation) (collectively, "**Losses**") incurred by or imposed upon the Abbott Indemnitees, or any one of them, as a direct result of any claims, suits, actions, demands or judgments of Third Parties, including, without limitation, personal injury and product liability matters and claims of suppliers and Enanta employees (collectively, "**Claims**") arising out of (a) any action by Enanta in the conduct of the Research Program other than any action that is a Disputed Matter and is approved by the JSC as an Abbott Decision pursuant to Section 2.1.6, (b) the Development or Commercialization of a Co-Developed Product, or (c) a breach of any representation or warranty made by Enanta pursuant to Section 12.2; provided that, with respect to any Claim for which Enanta has an obligation to any Abbott Indemnitee pursuant to this Section 13.1 and Abbott has an obligation to any Enanta Indemnitee pursuant to Section 13.2, each Party shall indemnify each of the other Party's Indemnitees for its Losses to the extent of its responsibility for the facts underlying the Claim relative to the other Party.

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13.2 Indemnification of Enanta by Abbott. Abbott shall indemnify, defend and hold harmless Enanta, its Affiliates, their respective directors, officers, employees and agents, and their respective successors, heirs and assigns (the "Enanta Indemnitees"), against any Losses incurred by or imposed upon the Enanta Indemnitees, or any one of them, as a direct result of any Claims arising out of (a) any action by Abbott in the conduct of the Research Program, (b) the Development (including, without limitation, the conduct of clinical research) by Abbott of any Candidate, or (c) the Commercialization (including, without limitation, manufacture, promotion, import, sale or use by any Person) of any Product that is manufactured or sold by Abbott or by an Affiliate, Sublicensee, distributor or agent of Abbott; provided that with respect to any Claim for which Enanta has an obligation to any Abbott Indemnitee pursuant to Section 13.1 and Abbott has an obligation to any Enanta Indemnitee pursuant to this Section 13.2, each Party shall indemnify each of the other Party's Indemnitees for its Losses to the extent of its responsibility for the facts underlying the Claim relative to the other Party.

13.3 **Conditions to Indemnification.** A Person seeking recovery under this Article 13 (the "**Indemnified Party**") in respect of a Claim shall give prompt notice of such Claim to the Party from which recovery is sought (the "**Indemnifying Party**") and, provided that the Indemnifying Party is not contesting its obligation under this Article 13, shall permit the Indemnifying Party to control any litigation relating to such Claim and the disposition of such claim; provided that the Indemnifying Party shall (a) act reasonably and in good faith with respect to all matters relating to the settlement or disposition of such Claim as the settlement or disposition relates to Parties being indemnified under Article 13, (b) not settle or otherwise resolve such claim without the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). The Indemnified Party shall cooperate with the Indemnifying Party in its defense of any such Claim in all reasonable respects and shall have the right to be present in person or through counsel at all legal proceedings with respect to such Claim.

13.4 <u>Warranty Disclaimer</u>. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY WARRANTY WITH RESPECT TO ANY TECHNOLOGY, GOODS, SERVICES, RIGHTS OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND EACH PARTY HEREBY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEIVIENT.

13.5 <u>No Warranty of Success</u>. Nothing contained in this Agreement shall be construed as a warranty on the part of either Party that (a) the Research Program will yield any Compound or will otherwise be successful, or (b) the outcome of the Research Program or the Development Program will be commercially exploitable in any respect.

13.6 <u>Limited Liability</u>. EXCEPT WITH RESPECT TO INDEMNIFICATION OBLIGATIONS FOR THIRD PARTY CLAIMS SET FORTH IN SECTION 13.1 AND SECTION 13.2, AND EXCEPT WITH RESPECT TO A BREACH OF CONFIDENTIALITY

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OBLIGATIONS, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES FOR (a) ANY SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING, WITHOUT LIMITATION, LOST PROFITS OR LOST REVENUES, OR (b) COST OF PROCUREMENT OF SUBSTITUTE GOODS, TECHNOLOGY OR SERVICES, WHETHER UNDER ANY CONTRACT, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY.

13.7 **Insurance**. Not later than thirty (30) days before the date on which Abbott or any Affiliate or Sublicensee of Abbott shall, on a commercial basis, make, use, or sell any Products, and at all times thereafter until the expiration of all applicable statutes of limitation pertaining to any such manufacture, marketing, possession, use, sale of other disposition of any Products, Abbott will, at its expense, and Enanta will, at its expense, with respect only to Co-Developed Products, obtain and maintain in full force and effect, comprehensive general liability insurance, including product liability insurance and clinical trial insurance protecting the other Party, subject to Section 13.1 or 13.2, as the case may be, against all claims, obligations, liabilities, and damages, based upon or arising out of actual or alleged bodily injury, personal injury, death, or any other damage to or loss of persons or property, cause by any such manufacture, marketing, possession, use, sale, or other disposition. Notwithstanding the foregoing, Abbott may elect to self-insure with respect to any insurance coverage it is required to obtain hereunder.

## 14. MISCELLANEOUS

14.1 <u>Arbitration</u>. In the event of any dispute, difference or question arising between the Parties in connection with this Agreement, the construction thereof, or the rights, duties or liabilities of either Party hereunder, other than any Disputed Matter that is submitted for resolution as provided in Section 2.1.6 (each, an "<u>Arbitration Matter</u>"), the Parties shall initiate an arbitration proceeding to be conducted in accordance with the procedures set forth in <u>Exhibit D</u> attached hereto.

#### 14.2 Change of Control.

(a) <u>Notice</u>. If either Enanta or Abbott enters into an agreement that results or, if the transaction contemplated thereby is completed, would result in a Change of Control ("<u>Acquired Party</u>"), the Acquired Party shall provide the other Party with prompt written notice describing such Change of Control in reasonable detail (the "<u>Change of Control Notice</u>"). The Change of Control Notice shall be provided by the Acquired Party prior to execution of such agreement, if permitted under Applicable Laws and not prohibited by the terms of any agreement between the Acquired Party and any Third Party (the "<u>Acquiring Party</u>"), and otherwise as soon as practicable thereafter and, in any event, not later than promptly following the consummation of the transaction contemplated by such agreement.

(b) <u>Effect of Change of Control</u>. Notwithstanding any provision hereof, in the event of a Change of Control, the exclusivity obligations of the Acquired Party

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described in Section 8.5 shall not apply to any compound or product owned or controlled by the Acquiring Party as of the date of consummation of the Change of Control.

14.3 **Notices.** All notices and communications shall be in writing and delivered personally or by courier providing evidence of delivery or mailed via certified mail, return receipt requested, addressed as follows, or to such other address as may be designated from time to time:

| If to Abbott:  |
|--|
| Abbott Laboratories<br>100 Abbott Park Road<br>Building AP34, Dept. R50A<br>Abbott Park, IL 60064-3500<br>Fax: [*****]<br>Attention: [*****] |
|  |

With a copy to:

Abbott Laboratories Building AP6D, D-364 100 Abbott Park Road Abbott Park, IL 60064-3500 Fax: [\*\*\*\*\*] Attention: [\*\*\*\*\*] If to Enanta:

Enanta Pharmaceuticals, Inc. 500 Arsenal Street Watertown, MA 02472 Tel: [\*\*\*\*\*] Fax: [\*\*\*\*\*] Attention: [\*\*\*\*\*]

With a copy to:

[\*\*\*\*\*]

Except as otherwise expressly provided in this Agreement or mutually agreed in writing, any notice, communication or document (excluding payment) required to be given or made shall be deemed given or made and effective upon actual receipt, in each case addressed to a Parties at its address stated above or to such other address as such Party may designate by written notice in accordance with this Section 14.3.

14.4 <u>Governing Law</u>. This Agreement shall be governed by and construed in accordance with the laws of the State of New York (USA), without regard to the application of principles of conflicts of law.

14.5 **<u>Binding Effect</u>**. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective legal representatives, successors and permitted assigns.

14.6 Headings. Section and subsection headings are inserted for convenience of reference only and do not form a part of this Agreement.

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14.7 **Counterparts.** This Agreement may be executed simultaneously in two (2) or more counterparts, each of which shall be deemed an original and both of which, together, shall constitute a single agreement.

14.8 <u>Amendment; Waiver</u>. This Agreement may be amended, modified, superseded or canceled, and any of the terms of this Agreement may be waived, only by a written instrument executed by each Party or, in the case of waiver, by the Party or Parties waiving compliance. The delay or failure of any Party at any time or times to require performance of any provisions shall in no manner affect the rights at a later time to enforce the same. No waiver by any Party of any condition or of the breach of any term contained in this Agreement, whether by conduct, or otherwise, in any one or more instances, shall be deemed to be, or considered as, a further or continuing waiver of any such condition or of the breach of such term or any other term of this Agreement.

14.9 No Third Party Beneficiaries. Except as set forth in Sections 13.1, and 13.2, no Third Party (including, without limitation, employees of either Party) shall have or acquire any rights by reason of this Agreement.

14.10 **<u>Purposes and Scope</u>**. The Parties hereto understand and agree that this Collaboration is limited to the activities, rights and obligations as set forth in this Agreement. Nothing in this Agreement shall be construed (a) to create or imply a general partnership between the Parties, (b) to make either Party the agent of the other for any purpose, (c) to alter, amend, supersede or vitiate any other arrangements between the Parties with respect to any subject matters not covered hereunder, (d) to give either Party the right to bind the other, (e) to create any duties or obligations between the Parties except as expressly set forth herein, or (f) to grant any direct or implied licenses or any other right other than as expressly set forth herein.

14.11 <u>Assignment and Successors</u>. Neither this Agreement nor any obligation of a Party hereunder may be assigned by either Party without the consent of the other which shall not be unreasonably withheld, except that each Party may assign this Agreement and the rights, obligations and interests of such Party, in whole or in part, to any of its Affiliates, or subject to Section 14.2(b), to any purchaser of all of its assets and/or all of its assets to which this Agreement relates or to any successor corporation resulting from any merger or consolidation of such Party with or into such corporation.

14.12 **Force Majeure**. Neither Abbott nor Enanta shall be liable for failure of or delay in performing obligations set forth in this Agreement, and neither Party shall be deemed in breach of its obligations, if such failure or delay is due to a Force Majeure. In event of such Force Majeure event, the Party affected thereby shall use reasonable efforts to cure or overcome the same and resume performance of its obligations hereunder.

14.13 **Interpretation**. The Parties hereto acknowledge and agree that: (a) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (b) the rule of construction to the effect that any ambiguities are

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resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (c) the terms and provisions of this Agreement shall be construed fairly as to all Parties and not in a favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement.

14.14 **Integration; Severability.** This Agreement and the Existing Agreements are the entire agreement with respect to the subject matter hereof and supersedes all other agreements and understandings between the Parties with respect to such subject matter. If any provision of this Agreement is or becomes invalid or is ruled invalid by any court of competent jurisdiction or is deemed unenforceable, it is the intention of the Parties that the remainder of the Agreement shall not be affected.

14.15 **Further Assurances**. Each of Enanta and Abbott agrees to duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including, without limitation, the filing of such additional assignments, agreements, documents and instruments, as the other Party may at any time and from time to time reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes of, or to better assure and confirm unto such other Party its rights and remedies under, this Agreement.

14.16 **HSR Filing.** Each Party shall, no later than November 30, 2006 (or such later time as the Parties mutually agree in writing), file with the Federal Trade Commission any filing required under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the "**HSR Act**"), in connection with the transactions contemplated hereby. The Parties shall cooperate with each other to the extent necessary in the preparation of any such filing. Each party shall request early termination of such filing by the Federal Trade Commission. Neither Party shall be required in connection with any filing under the HSR Act to commit or agree to any action, to obtain any consents, approvals, permits or authorizations to remove any impediments or to resort to or respond to litigation or to agree to hold separate or divest any business or assets.

Abbott shall be responsible for paying any fees required to be paid to governmental authorities in connection with its filings as a licensee, Enanta shall be responsible for paying any fees associated with its filings as a licensor and each Party shall bear its own expenses, including but not limited to legal fees associated with preparing any such filing, subject to Section 14.17 below.

14.17 **Board Approvals**. The obligation of Enanta to effect the transactions contemplated by this Agreement is subject to the receipt of approval by Enanta's Board of Directors (the "<u>Enanta Board</u>") and Enanta's Chief Executive Officer. The obligation of Abbott to effect the transactions contemplated by this Agreement is subject to the receipt of approval by Abbott's Board of Directors (the "<u>Abbott Board</u>") and Abbott's Chief Executive Officer. In the event that such Abbott approvals are not obtained on or before December 8, 2006, (a) Abbott shall reimburse Enanta for any fees or expenses incurred by Enanta in

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connection with the filing under the HSR Act described in Section 14.16, including but not limited to legal fees associated with preparing such filing, and (b) this Agreement shall be terminated with no further force and effect. Each Party shall provide the other with evidence or certification of its Board of Directors or Chief Executive Officer approval, as applicable, upon request.

# [Remainder of page intentionally left blank.]

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IN WITNESS WHEREOF, The Parties have caused this Agreement, to be executed by their duly authorized representatives.

# ENANTA PHARMACEUTICALS, INC.

| By:    | /s/ Jay R. Luly                       |
|--------|---------------------------------------|
| Name:  | Jay Luly, Ph.D                        |
| Title: | President and Chief Executive Officer |

# ABBOTT LABORATORIES

| By:    | /s/ William G. Dempsey                                  |
|--------|---|
| Name:  | William G. Dempsey                                      |
| Title: | Executive Vice President, Pharmaceutical Products Group |

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#### **RESEARCH PLAN**

The Research Program will involve the research and development of Enanta's proprietary HCV protease inhibitor program identified in PCT nos. WO 2005010029 Al; WO 2004/093798 A2; WO 2004/072243 A2; WO 2004 113365 A2 and any HCV protease inhibitors identified by Enanta in the conduct of the Research Program and any other patent applications included in Schedule 4 as part of the Licensed Patent Rights.

Enanta, with input from the JSC, will be primarily responsible for discovery activities including, but not limited to, medicinal chemistry, enzyme, replicon and cytotoxicity assays, and initial metabolism and pharmacokinetic screens associated with the identification of [\*\*\*\*\*] during the Research Program Term. With approval of JSC, Abbott FTEs may be applied to Candidate identification research to expand scope of chemistry or to otherwise improve the competitive position of the program. Abbott will have primary responsibility for Candidate selection activities including virology, pharmacokinetics, pharmaceutics, metabolism and safety studies needed for the identification of [\*\*\*\*\*]. Abbott will have primary responsibility for process research, and the planning and execution of all preclinical IND-enabling studies on Candidate compounds.

Abbott personnel will be responsible for preparation of data-summary documentation and presentations necessary to support internal assignment of Abbott resources to support characterization of lead Compounds and IND-enabling pre-clinical research on Candidates.

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# FORM OF STOCK PURCHASE AGREEMENT

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# SERIES G CONVERTIBLE PREFERRED STOCK PURCHASE AGREEMENT

by and among

# ENANTA PHARMACEUTICALS, INC.

and

# THE INVESTORS LISTED ON THE

# SCHEDULE OF INVESTORS attached hereto

# Dated [•], 20

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# **Schedules**

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# Exhibits

- Exhibit 1 Fourth Amended and Restated Certificate of Incorporation of Enanta Pharmaceuticals, Inc.
- Exhibit 4.22A Third Amended and Restated Registration Rights Agreement
- Exhibit 4.22B Third Amended and Restated Voting Agreement
- Exhibit 4.22C Third Amended and Restated Stock Restriction Agreement
- Exhibit 4.22D Investor Rights Agreement
- Exhibit 4.29A Employee Confidentiality, Inventions and Noncompetition Agreement
- Exhibit 4.29B Consultant Confidentiality and Inventions Agreement
- Exhibit 6.1(e) Form of Legal Opinion of Palmer & Dodge LLP

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## SERIES G CONVERTIBLE PREFERRED STOCK PURCHASE AGREEMENT

THIS SERIES E CONVERTIBLE PREFERRED STOCK PURCHASE AGREEMENT ("<u>Agreement</u>") is made as of  $[\bullet]$ , 20 , by and among Enanta Pharmaceuticals, Inc., a Delaware corporation (the "<u>Corporation</u>"), the investors named on the <u>Schedule of Investors</u> attached hereto (the "<u>Initial Investors</u>") and the additional investors added from time to time to the Schedule of Investors in accordance with Section 23 below (the "<u>Additional Investors</u>," and together with the Initial Investors, the "<u>Investors</u>").

WHEREAS, the Investors wish to purchase from the Corporation, and the Corporation wishes to sell to the Investors, up to an aggregate of [•] shares of the Corporation's Series G Convertible Preferred Stock, par value \$.01 per share (the "Series G Preferred Stock").

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements herein contained, the parties hereby agree as follows:

**SECTION 1.** Fourth Amended and Restated Certificate of Incorporation. On or prior to the date hereof, the Corporation shall have filed with the Secretary of State of the State of Delaware its Fourth Amended and Restated Certificate of Incorporation (the "Restated Certificate"), a copy of which is attached hereto as Exhibit 1 (the Restated Certificate as in effect on the date hereof being hereinafter sometimes also referred to as the "Certificate of Incorporation"), for the purpose of amending the authorized capital stock of the Corporation and setting forth the designations and the powers, preferences and rights, and the qualifications, limitations and restrictions thereof, granted to or imposed upon the capital stock of the Corporation or the holders thereof, including the Series G Preferred Stock.

# SECTION 2. Purchase and Sale of the Series G Preferred Stock.

**2.1** <u>Initial Series G Shares</u>. Subject to the terms and conditions of this Agreement, at the Initial Closing (as defined in Section 3.1), the Corporation agrees to issue and sell an aggregate of [•] shares of Series G Preferred Stock (the "<u>Initial Series G Shares</u>") to the Initial Investors, and each Initial Investor, acting severally and not jointly, agrees to purchase from the Corporation the number of Initial Series G Shares set forth opposite the name of such Initial Investor on the <u>Schedule of Investors</u> under the column heading "Initial Series G Shares," at a purchase price of \$[•] per share.

# 2.2 Additional Series G Shares.

(a) Subject to the terms and conditions of this Agreement, at each Scheduled Additional Closing (as defined in Section 3.2), the Corporation agrees to issue and sell an aggregate of [•] shares of Series G Preferred Stock (the "Initial Investor Additional Series G Shares" and, together with the Initial Series G Shares, the "Initial Investor Series G Shares") to the Initial Investors, and each Initial Investor, acting severally and not jointly, agrees to purchase

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from the Corporation the number of Initial Investor Additional Series G Shares set forth opposite the name of such Initial Investor on the <u>Schedule of</u> <u>Investors</u> under the column headings "Second Closing Series G Shares," "Third Closing Series G Shares," "Fourth Closing Series G Shares," and "Fifth Closing Series G Shares," all at a purchase price of  $[\bullet]$  per share.

(b) The Corporation may issue and sell an aggregate of up to [•] shares of Series G Preferred Stock (the "<u>Additional Investor Series G Shares</u>" and, together with the Initial Investor Additional Series G Shares, the "<u>Additional Series G Shares</u>") to one or more Additional Investors, each of which purchases Additional Investor Series G Shares at or before the date of the first Scheduled Additional Closing and agrees to purchase additional shares of the Additional Investor Series G Shares in proportionate amounts on the same terms as the Initial Investors. Any Additional Investor shall be either (i) an existing stockholder of or an affiliate of an existing stockholder of the Corporation or (ii) a new investor reasonably acceptable to the Corporation with the consent of the Corporation's Series C-G Directors (as defined in the Restated Certificate). The Initial Investor Series G Shares and the Additional Investor Series G Shares.

(c) [The Corporation may, in its discretion, cancel any Additional Closing upon written notice to the Initial Investors and any Additional Investors who had previously agreed to participate in such Additional Closing. In the event the Corporation cancels any Additional Closing, the number of Series G Shares to have been purchased by each Investor at such Additional Closing shall thereafter be added to the number of Series G Shares to be purchased by each Investor at the (next Additional Closing scheduled to take place after such cancelled Additional Closing.)

#### SECTION 3. Closing.

**3.1** <u>Initial Closing</u>. The closing of the sale and purchase of the Initial Series G Shares (the "<u>Initial Closing</u>") shall take place simultaneously with the execution of this Agreement at the offices of Palmer & Dodge LLP, 111 Huntington Avenue, Boston, Massachusetts, U.S.A., or at such other location as may be agreed upon among the Initial Investors and the Corporation. At the Initial Closing, the Corporation shall issue and deliver to each Initial Investor a certificate or certificates for shares of Series G Preferred Stock, registered in the name of such Initial Investor, in the amount representing the number of Initial Series G Shares being purchased by such Initial Investor at the Initial Closing, against payment by such Initial Investor to the Corporation of the aggregate purchase price therefor in the form of (a) a wire transfer to a bank account designated by the Corporation or (b) such other method of payment as the Corporation, in its sole discretion, may accept.

**3.2** <u>Additional Closings</u>. The closing of the sale and purchase of the Additional Series G Shares shall occur at (i) [•] additional closings (each, a "<u>Scheduled Additional Closing</u>") to take place at the offices of Palmer & Dodge LLP, 111 Huntington Avenue, Boston, Massachusetts, U.S.A., or at such other location as may be agreed upon among the Investors participating in such Scheduled Additional Closing, on each of [•] and (ii) one or more

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additional closings (each, an "<u>Additional Investor Additional Closing</u>" and together with the Scheduled Additional Closings, each an "<u>Additional Closing</u>") to take place no later than December 15, 2005 at the offices of Palmer & Dodge LLP, 111 Huntington Avenue, Boston, Massachusetts, U.S.A., or at such other location as may be agreed upon among the Corporation and the Investors participating in such Additional Investor Additional Closing. At each Additional Closing, the Corporation shall issue and deliver to each Investor participating in such Additional Closing a certificate or certificates for shares of Series G Preferred Stock, registered in the name of such Investor, in the amount representing the number of Series G Shares being purchased by such Investor to the Corporation of the aggregate purchase price therefor in the form of (a) a wire transfer to a bank account designated by the Corporation or (b) such other method of payment as the Corporation, in its sole discretion, may accept.

**SECTION 4. Representations and Warranties of the Corporation**. Except as set forth on <u>Schedule 4</u>, the Corporation hereby makes the representations and warranties contained in this Section 4 to the Investors. The information contained on <u>Schedule 4</u> shall be deemed to be representations and warranties of the Corporation and shall make explicit reference to the particular representation or warranty (by reference to a subsection hereof) as to which exception is taken, provided that the information on <u>Schedule 4</u> shall qualify as disclosure with respect to other representations or warranties for which the appropriateness of such disclosure is reasonably apparent.

**4.1** <u>**Organization**</u>. The Corporation is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware and has all requisite corporate power and authority to own and lease its properties, to carry on its business as presently conducted and as proposed to be conducted and to carry out the transactions contemplated by the Transaction Documents (as defined in Section 4.22 hereof). The Corporation is duly qualified as a foreign corporation and is in good standing in all such jurisdictions in which the conduct of its business or its ownership or leasing of property requires such qualification.

## 4.2 **Capitalization**. The entire authorized capital stock of the Corporation consists of:

(a) [•] shares of Corporation's Common Stock, par value \$.01 per share ("<u>Common Stock</u>"), of which (i) 3,794,270 shares have been issued and are outstanding, and are duly authorized, validly issued, fully paid and nonassessable; (ii) no shares are held as treasury shares; (iii) 822,830 shares have been reserved for issuance upon exercise of options granted or to be granted under the Corporation's 1998 Equity Performance Plan (the "<u>Equity Performance Plan</u>"), of which [•] shares have been issued as restricted stock or upon the exercise of options granted pursuant to the Equity Performance Plan and are included in the 3,794,270 shares of Common Stock that are issued and outstanding; [•] shares are subject to currently outstanding options to purchase Common Stock; and [•] shares are reserved for future issuance; (iv) [•] shares have been reserved for issuance under the Corporation's 1995 Equity Incentive Plan (the "<u>1995 Equity Plan</u>"), of which [•] shares have been issued as restricted stock or upon the

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exercise of options granted pursuant to the 1995 Equity Plan, all of which are included in the 3,794,270 shares of Common Stock that are issued and outstanding; [•] shares are subject to currently outstanding options to purchase Common Stock; and [•] shares are reserved for future issuance; (v) 379,450 shares have been reserved for issuance upon conversion of the Corporation's Series A Convertible Preferred Stock, par value \$.01 per share ("Series A Preferred Stock"); (vi) 187,000 shares have been reserved for issuance upon conversion of the Corporation's Series B Convertible Preferred Stock, par value \$.01 per share ("Series B Preferred Stock"); (vii) 2,563,603 shares have been reserved for issuance upon conversion of the Corporation's Series C Convertible Preferred Stock, par value \$.01 per share ("Series C Preferred Stock") (viii) 116,638 shares have been reserved for issuance upon exercise of certain Common Stock Purchase Warrants dated December 1998 and May and August of 1999; (ix) 7,902,121 shares have been reserved for issuance upon conversion of the Corporation's Series D Convertible Preferred Stock, par value \$.01 per share ("Series D Preferred Stock"), including [•] additional shares that have been reserved for issuance as a result of the reduction of the Series D Conversion Price (as defined in the Restated Certificate) to \$[•] as a result of the deemed issuance and sale by the Corporation of [•] shares of Series G Preferred Stock; (x) 161,600 shares have been reserved for issuance upon exercise of certain Common Stock Purchase Warrants dated October 2000 and January and May of 2001; (xi) 21,238,570 shares have been reserved for issuance upon conversion of the Corporation's Series E Convertible Preferred Stock, par value \$.01 per share ("Series E Preferred Stock") including 2,473,308 shares that have been reserved for issuance upon conversion of the shares of Series E Preferred Stock issuable upon exercise of the warrants to purchase shares of Series E Preferred Stock issued by the Corporation to the holders of Notes issued in March 2002, July, October and November 2003 and March 2004 and to Silicon Valley Bank in December 2002; (xiii) 6,894,966 shares have been reserved for issuance upon conversion of the Corporation's Series F Convertible Preferred Stock par value \$.01 per share ("Series F Preferred Stock"); and [•] shares have been reserved for issuance upon conversion of the Series G Preferred Stock;

(b) 379,450 shares of Series A Preferred Stock, all of which have been issued and are outstanding, and are duly authorized, validly issued, fully paid and nonassessable;

(c) 187,000 shares of Series B Preferred Stock, all of which have been issued and are outstanding, and are duly authorized, validly issued, fully paid and nonassessable;

(d) 2,563,603 shares of Series C Preferred Stock, all of which have been issued and are outstanding, and are duly authorized, validly issued, fully paid and nonassessable;

(e) 5,988,334 shares of Series D Preferred Stock, all of which have been issued and are outstanding, and are duly authorized, validly issued, fully paid and nonassessable;

(f) 16,158,953 shares of Series E Preferred Stock, of which (i) 14,261,598 shares have been issued and are outstanding, and are duly authorized, validly issued, fully paid and nonassessable and (ii) 1,879,715 shares have been reserved for issuance upon exercise of the Series E Preferred Stock Warrants;

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(g) 6,894,966 shares of Series F Preferred Stock, all of which have been issued and are outstanding, and are duly authorized, validly issued, fully paid and nonassessable; and

(h) [•] shares of Series G Preferred Stock, of which (i) [•] shares are being issued at the Initial Closing and immediately thereafter will be issued and outstanding, and will be duly authorized, validly issued, fully paid and nonassessable and will be held of record by the Initial Investors and (ii) [•] shares have been reserved for issuance to the Initial Investors and one or more Additional Investors at the Additional Closings and immediately thereafter will be issued and outstanding, and will be duly authorized, validly issued, fully paid and nonassessable and will be held of record by the Initial Investors.

Except as set forth in this Section 4.2 or in the Restated Certificate or the Transaction Documents: (I) there are no outstanding shares of capital stock of the Corporation or warrants, options, agreements, convertible securities, rights or other commitments pursuant to which the Corporation is or may become obligated to issue any shares of its capital stock or other securities of the Corporation; (II) there are no preemptive or similar rights to purchase or otherwise acquire shares of capital stock of the Corporation from the Corporation pursuant to any provision of law, the Certificate of Incorporation or the by-laws, as amended to date, of the Corporation (the "<u>By-laws</u>") or, any agreement to which the Corporation is a party, or otherwise; (III) there are no redemption or similar rights whereby the Corporation is obligated, contractually or otherwise, to repurchase, redeem, or otherwise acquire any shares of capital stock of the Corporation or encumbrance with respect to the registration, transfer, sale or voting of any shares of the Corporation's capital stock (whether outstanding or issuable upon conversion or exercise of outstanding securities).

The Corporation has not violated the Securities Act of 1933, as amended (the "<u>Securities Act</u>") or any securities law of any state or other jurisdiction in connection with the issuance of any securities prior to the date hereof. All of the outstanding shares of the Corporation's capital stock and all other securities of the Corporation were offered, issued, and sold, the Series G Shares (which have been sold at any Closing (as defined in Section 6)) will be offered, issued and sold, and the Reserved Shares (as defined below) will be issued in compliance with (i) all applicable preventive or similar rights of all persons and (ii) all applicable provisions of the Securities Act and the rules and regulations thereunder, and all applicable state securities laws and the rules and regulations thereunder. No person has any valid right to rescind any purchase of any shares of capital stock or other securities of the Corporation.

**4.3** <u>Equity Investments; Subsidiaries</u>. The Corporation does not currently own, directly or indirectly, any capital stock or other proprietary interest in any corporation, association, trust, partnership, limited liability company, limited liability partnership, joint venture or other entity. The Corporation does not have any subsidiaries or own any legal and/or beneficial interests in any other person.

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**4.4** <u>Financial Statements</u>. The audited balance sheet (the "<u>Balance Sheet</u>") for the Corporation as of September 30, 2004 (the "<u>Balance Sheet Date</u>") and the related audited statements of income, stockholders' equity and cash flows for the year then ended (collectively, the "<u>Financial Statements</u>") (a) are in accordance with the books and records of the Corporation and (b) present fairly the financial position and results of operations of the Corporation as of the date and for the periods indicated in accordance with generally accepted accounting principles ("<u>GAAP</u>") applied on a consistent basis.

**4.5** <u>Absence of Undisclosed Liabilities</u>. The Corporation has no material liabilities or obligations of any nature, whether accrued, absolute, contingent, or otherwise (including without limitation liabilities as guarantor or otherwise with respect to obligations of others) and whether due or to become due, except as incurred in the ordinary course of business.

**4.6** <u>Absence of Changes</u>. Since the Balance Sheet Date there has not been (a) any material adverse change in the financial condition, results of operations, assets, liabilities, business or prospects of the Corporation, (b) any material asset or property of the Corporation made subject to a lien of any kind, except liens for taxes not yet due and payable or non-consensual purchase money liens arising by operation of law and in the ordinary course of business, (c) any waiver of any valuable right of the Corporation, or the cancellation of any debt or claim held by the Corporation, (d) any payment of dividends on, or other distribution with respect to, or any direct or indirect redemption or acquisition of, any shares of the capital stock of the Corporation, except in the ordinary course of business, (f) any loan by the Corporation to, or any loan to the Corporation from, any officer, director, employee or stockholder of the Corporation, or any agreement or commitment therefor, (g) any damage, destruction or loss (whether or not covered by insurance) materially and adversely affecting the assets, property or business of the Corporation, or (h) any change in the accounting methods or practices followed by the Corporation.

**4.7** <u>Encumbrances</u>. The Corporation has good and marketable title to all of its property and assets, real, personal or mixed, tangible or intangible, free and clear of all liens, security interests, charges and other encumbrances of any kind, except liens for taxes not yet due and payable. The Corporation enjoys peaceful and undisturbed possession under all leases under which it is operating, and all said leases are valid and subsisting and in full force and effect.

# 4.8 Intellectual Property Rights.

(a) The Corporation owns or has the legally enforceable right to use, and has the right to bring actions for infringement of, all Intellectual Property Rights (as defined below) necessary or required for the conduct of its business as presently conducted or as proposed to be conducted.

(b) The Corporation has no obligation to compensate any person for the use of any of its Intellectual Property Rights and the Corporation has not granted any person any license

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or other rights to use any of such Intellectual Property Rights, whether requiring the payment of royalties or not.

(c) No product or process presently used, marketed or sold or proposed to be used, marketed or sold by the Corporation and no Intellectual Property Rights proposed to be licensed by the Corporation as licensor violate or will violate any license or infringe or will infringe any Intellectual Property Rights of another, nor has the Corporation received any notice that any of its Intellectual Property Rights or the operation or proposed operation of the Corporation's business conflicts or will conflict with the rights of others; and to the Corporation's knowledge, none of the Intellectual Property Rights have been or are being infringed or violated by others.

(d) There are no claims pending or, to the Corporation's knowledge, threatened to the effect that any of the Intellectual Property Rights owned or licensed by the Corporation, or which the Corporation otherwise has rights to use, is invalid or unenforceable, or that would otherwise interfere in any material respect with the Corporation's right to use any Intellectual Property Rights being used in the Corporation's business as currently conducted or as proposed to be conducted, nor does there exist any basis therefor.

(e) All personnel of the Corporation, including employees, agents, consultants and contractors, who have contributed to or participated in the conception or development of any of the Intellectual Property Rights owned by the Corporation have entered into an agreement that conveys to the Corporation full, effective and exclusive ownership of all tangible and intangible property thereby arising.

(f) The Corporation has not entered into any agreement to indemnify any other person against any charge of infringement of any Intellectual Property Rights.

As used herein, the term "Intellectual Property Rights" means all patents, trademarks, service marks, trade names, copyrights, inventions, trade secrets, licenses, know-how, proprietary processes and formulae, applications for patents, trademarks, service marks and copyrights, and other industrial and intellectual property rights.

**4.9** <u>Litigation</u>. There is no action, suit, claim, proceeding or investigation, at law, in equity or otherwise, or by or before any governmental instrumentality or other agency, now pending, or, to the Corporation's knowledge, threatened against or affecting the Corporation, nor is there any basis therefor known to the Corporation.

**4.10** No Defaults. The Corporation is not in violation or breach of, or in default under, any provision of (a) the Certificate of Incorporation or the By-Laws or (b) any material note, indenture, mortgage, lease, contract, purchase order or other instrument, document or agreement to which the Corporation is a party or by which it or any of its property is bound or affected or any ruling, writ, injunction, order, judgment or decree of any court, administrative agency or other governmental body. To the Corporation's knowledge, there exists no condition, event or

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act which, after notice, lapse of time, or both, may constitute a violation or breach of, or a default under, any of the foregoing.

**4.11** <u>Employment of Officers, Employees and Consultants</u>. To the Corporation's knowledge, no third party may assert any valid claim against the Corporation, any Investor, or any Designated Person (as defined below) with respect to (a) the continued employment by or association with the Corporation of any of the present officers or employees of, or consultants to, the Corporation (collectively, the "Designated Persons</u>"), or (b) the use or disclosure by the Corporation or any Designated Person of any information which the Corporation or any Designated Person would be prohibited from using or disclosing under any prior agreements or arrangements or under any laws, including, without limitation, laws applicable to unfair competition, trade secrets or proprietary information.</u>

The Corporation is in compliance in all material respects with all applicable federal and state laws respecting employment and employment practices, terms and conditions of employment, wages and hours, and nondiscrimination in employment, and is not engaged in any unfair labor practice. None of the employees of the Corporation is covered by any collective bargaining agreement, and no collective bargaining agreement is currently being negotiated by it.

**4.12** <u>Taxes</u>. The Corporation has filed all federal, state, local and foreign tax returns which are required to be filed by it and all such returns are true and correct. The Corporation has paid all taxes pursuant to such returns or pursuant to any assessments received by it or which it is obligated to withhold from amounts owing to any employee, creditor or third party, except, in each case, for those which are not yet due and payable pursuant to such returns. There are no liens for taxes (other than current taxes not yet due and payable) on the assets of the Corporation. The Corporation has established adequate reserves for all taxes accrued but not yet payable to the extent required by GAAP. All material tax elections of any type which the Corporation has made as of the date hereof are set forth in the financial statements referred to in Section 4.4. No deficiency assessment with respect to or, proposed adjustment of the Corporation nor any of its present or former stockholders has ever filed an election pursuant to Section 1362 of the Internal Revenue Code of 1986 (the "Code"), that the Corporation be taxed as an S corporation.

## 4.13 [Reserved.]

**4.14** <u>Material Agreements</u>. The Corporation has delivered or caused to be delivered to those Investors who have so requested in writing correct and complete copies of each Material Agreement (as defined below), each as amended to date. Each such agreement, instrument, and commitment is a valid, binding and enforceable obligation of the Corporation, and to the Corporation's knowledge, of the other party or parties thereto (in each case, except as enforceability may be limited by bankruptcy, insolvency, or similar laws and except as the availability of equitable remedies is subject to the discretion of the court before they are sought), and is in full force and effect. Neither the Corporation, nor to the best of its knowledge, any

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other party thereto, is, or is considered by any other party thereto to be, in breach of or not in compliance with any term of any such agreement, instrument, or commitment (nor, to the Corporation's knowledge, is there any basis for any of the foregoing), except for any breach or noncompliance that singly or in the aggregate would not have a material adverse effect on the financial condition, results of operations, assets, liabilities, business or prospects of the Corporation. No claim, change order, request for equitable adjustment, or request for contract price or schedule adjustment, between the Corporation and any supplier or customer, relating to any Material Agreement is pending or, to the Corporation's knowledge, threatened, nor, to the Corporation's knowledge, is there any basis for any of the foregoing. No Material Agreement includes or incorporates any provision, the effect of which may be to enlarge or accelerate any of the obligations of the Corporation or to give additional rights to any other party thereto, or will terminate, lapse, or in any other way be affected, by reason of the transactions contemplated by this Agreement.

As used in this Agreement, "Material Agreement" means any:

(a) agreement for the purchase, sale, lease, or license by or from it of services, products, or assets, requiring total payments by or to it in excess of \$50,000 in any instance, or entered into other than in the ordinary course of business;

(b) agreement requiring it to purchase all or substantially all of its requirements for a particular product or service from a particular supplier or suppliers, or requiring it to supply all of a particular customer's or customers' requirements for a certain service or product;

(c) agreement or other commitment pursuant to which it has agreed to indemnify or hold harmless any other person, other than standard indemnification obligations with respect to the Corporation's directors, employees and consultants;

(d) (i) employment agreement, (ii) consulting agreement, or (iii) agreement providing for severance payments or other additional rights or benefits (whether or not optional) in the event of the sale or other change in control of it;

(e) agreement with any current or former "affiliate" (as defined in the Securities Act), stockholder, officer, director, employee, or consultant of the Corporation, or with any person in which any such affiliate has an interest;

(f) joint venture or partnership agreement;

(g) agreement with any domestic or foreign government or agency or executive office thereof or any subcontract between it and any third party relating to a contract between such third party and any domestic or foreign government or agency or executive office thereof;

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(h) agreement imposing non-competition or exclusive dealing obligations on it;

(i) contract with any labor union;

(j) bonus, pension, profit-sharing, retirement, stock purchase, stock option, hospitalization, medical insurance or similar plan, contract or understanding in effect with respect to its employees or the employees of others;

(k) agreement or indenture relating to the borrowing of money or to the mortgaging, pledging or otherwise placing a lien on any assets of the Corporation;

(l) guaranty of any obligation for borrowed money or otherwise;

(m) lease or agreement under which the Corporation is lessee of or holds or operates any property, real or personal, owned by any other party;

(n) lease or agreement under which the Corporation is lessor of or permits any third party to hold or operate any property, real or personal, owned or controlled by the Corporation;

(o) license or lease agreement with respect to any Intellectual Property Rights;

(p) agreement or other commitment for capital expenditures in excess of \$50,000;

(q) distributor, dealer or manufacturer's representative contract or agreement which is not terminable on less than ninety (90) days' notice without cost or other liability to the Corporation;

(r) sales agreement which entitles any customer to a rebate or right of set-off, to return any product to the Corporation after acceptance thereof or to delay the acceptance thereof, or which varies in any material respect from the Corporation's standard form contracts;

(s) agreement with any supplier containing any provision permitting any party other than the Corporation to renegotiate the price or other terms, or containing any pay-back or other similar provision, upon the occurrence of a failure by the Corporation to meet its obligations under the agreement when due or the occurrence of any other event;

(t) agreement for the future purchase of fixed assets or for the future purchase of materials, supplies or equipment in excess of its normal operating requirements;

(u) agreement, or group of related agreements with the same party or any group of affiliated parties, under which the Corporation has advanced or agreed to advance money, has agreed to lease any real property as lessee or lessor, or has agreed to lease any

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personal property as lessee or lessor if such lease for personal property was not entered into in the ordinary course of business;

(v) contract, agreement or commitment under which the Corporation is obligated to pay any broker's fees, finder's fees or any such similar fees, to any third party;

(w) except as set forth above, any other agreement or group of related contracts with the same party continuing over a period of more than six months from the date or dates thereof (including renewals or extensions of options with another party), which agreement or group of agreements is not terminable by the Corporation without penalty upon notice of thirty (30) days or less, but excluding any agreement or group of agreements with a customer of the Corporation for the sale, lease or rental of the Corporation's products or services if such agreement or group of agreements was entered into by the Corporation in the ordinary course of business; or

(x) any other contract, agreement, arrangement or understanding which is material to the business of the Corporation or which is material to a prudent investor's understanding of the business of the Corporation.

**4.15 ERISA**. The Corporation does not now sponsor, maintain, have any obligation to contribute to or have any liability under, and never has sponsored, maintained, had any obligation to contribute to, or had any liability under, and is not now and has never otherwise been a party to, any Benefit Plan. For purposes of this Agreement, "Benefit Plan" shall mean any plan, fund, program, policy, arrangement or contract, whether formal or informal, which is in the nature of (i) an employee pension benefit plan (as defined in Section (2) of the Employee Retirement Income Security Act of 1974, as amended ("<u>ERISA</u>")), (ii) an employee welfare benefit plan (as defined in section 3(1) of ERISA), (iii) a "multi-employer plan" (as defined in Section 3(37) of ERISA) or (iv) any plan of deferred compensation, medical plan, life insurance plan, long-term disability plan, dental plan or other plan instituted with respect to any of the Corporation's employees or former employees or beneficiaries thereof.

**4.16** <u>U.S. Real Property Holding Corporation</u>. The Corporation is not now, has never been and has no current plans to become a "United States real property holding corporation," as defined in Section 897(c)(2) of the Code and Section 1.897-2(b) of the Regulations promulgated by the Internal Revenue Service, and the Corporation has never filed with the Internal Revenue Service a statement with its United States income tax returns under Section 1.897-2(h) of such Regulations stating that any shares of its capital stock constitute a U.S. real property interest within the meaning of Section 897(c)(1) of the Code.

**4.17** <u>Environmental Protection</u>. The Corporation has not caused or allowed, or contracted with any party for, the generation, use, transportation, treatment, storage or disposal of any Hazardous Substances (as defined below) in connection with the operation of its business or otherwise. The Corporation, the operation of its business, and any real property that the Corporation owns, leases or otherwise occupies or uses (the "<u>Premises</u>") are in compliance with

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all applicable Environmental Laws (as defined below) and orders or directives of any governmental authorities having jurisdiction under such Environmental Laws, including, without limitation, any Environmental Laws or orders or directives with respect to any cleanup or remediation of any release or threat of release of Hazardous Substances. The Corporation has not received any citation, directive, letter or other communication, written or oral, or any notice of any proceeding, claim or lawsuit, from any person arising out of the ownership or occupation of the Premises, or the conduct of its operations, and the Corporation is not aware of any basis therefor. The Corporation has obtained and is maintaining in full force and effect all necessary permits, licenses and approvals required by all Environmental Laws applicable to the Premises and the business operations conducted thereon (including operations conducted by tenants on the Premises), and is in compliance with all such permits, licenses and approvals. The Corporation has not arelease, or a threat of release, of any Hazardous Substance onto, at or near the Premises, and, to the Corporation's knowledge, neither the Premises nor any property at or near the Premises has ever been subject to a release, or a threat of release, of any Hazardous Substance. For the purposes of this Agreement, the term "Environmental Laws" shall mean any federal, state or local law or ordinance or regulation pertaining to the protection of human health or the environment, including, without limitation, the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. Sections 9601, <u>et seq</u>., the Emergency Planning and Community Right-to-Know Act, 42 U.S.C. Sections 11001, <u>et seq</u>., and the Resource Conservation and Recovery Act, 42 U.S.C. Sections 6901, <u>et seq</u>. For purposes of this Agreement, the term "Hazardous Substances" shall include oil and petroleum products, asbestos, polychlorinated biphenyls, urea formaldehyde and other materials classified as hazardo

**4.18** <u>Foreign Corrupt Practices Act</u>. The Corporation has not taken any action which would cause it to be in violation of the Foreign Corrupt Practices Act of 1977, as amended, or any rules and regulations thereunder. To the Corporation's knowledge, there is not now, and there has never been, any employment by the Corporation of, or beneficial ownership in the Corporation by, any governmental or political official in any country in the world.

**4.19** <u>Federal Reserve Regulations</u>. The Corporation is not engaged in the business of extending credit for the purpose of purchasing or carrying margin stock (within the meaning of Regulation U of the Board of Governors of the Federal Reserve System), and no part of the proceeds of the sale of Series G Shares will be used to purchase or carry any margin stock or to extend credit to others for the purpose of purchasing or carrying any margin stock or in any other manner which would involve a violation of any of the regulations of the Board of Governors of the Federal Reserve System.</u>

**4.20** <u>Compliance</u>. The Corporation has complied with, and is in compliance in all material respects with, (i) all laws, statutes, governmental regulations, judicial or administrative tribunal orders, judgments, writs, injunctions, decrees, and similar commands applicable to it and its business, (ii) all unwaived terms and provisions of all agreements, instruments, and commitments to which it is a party or to which it or any of its assets or properties is subject, except for any noncompliances that, both individually and in the aggregate, have not had and

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could not reasonably be expected to have a material adverse effect on the financial condition, results of operations, assets, liabilities, business or prospects of the Corporation, and (iii) its charter documents and By-Laws, each as amended to date. The Corporation has all federal, state, local and foreign governmental licenses, registrations and permits material to or necessary for the conduct of its business as currently conducted, such licenses, registrations and permits are in full force and effect, and there have been no material violations of any such licenses, registrations or permits. No proceeding is pending or, to the Corporation's knowledge, threatened, to revoke or limit any thereof.

**4.21** <u>**Insurance**</u>. No notice from any insurance carrier has been received by the Corporation claiming that the Corporation is in default with respect to any provision contained in any insurance policy.

4.22 Authorization of Transaction Documents. The execution, delivery and performance by the Corporation of (a) this Agreement, (b) the Third Amended and Restated Registration Rights Agreement of even date herewith by and among the Corporation, the Investors and the other parties thereto in the form of Exhibit 4.22A (the "Registration Rights Agreement"), (c) the Third Amended and Restated Voting Agreement of even date herewith by and among the Corporation, the Investors and the other parties thereto in the form of Exhibit 4.22B (the "Voting Agreement"), (d) the Third Amended and Restated Stock Restriction Agreement of even date herewith by and among the Corporation, the Investors and the other parties thereto in the form of Exhibit 4.22C (the "Stock Restriction Agreement") and (e) the Amended and Restated Investor Rights Agreement of even date herewith by and among the Corporation, the Investors and the other parties thereto in the form of Exhibit 4.22D (the "Investor Rights Agreement"; together with this Agreement, the Registration Rights Agreement, the Voting Agreement and the Stock Restriction Agreement, the "Transaction Documents") have been duly authorized by all requisite corporate action. The Corporation has duly authorized, executed and delivered each Transaction Document, and each Transaction Document constitutes the valid and binding obligation of the Corporation, enforceable in accordance with its terms. The execution, delivery and performance of the Transaction Documents, the issuance, sale and delivery of the Series G Shares, and the shares of Common Stock issuable upon conversion of the Series G Shares (the "Reserved Shares"), and compliance with the provisions hereof and thereof by the Corporation do not and will not, with or without the passage of time or the giving of notice or both, violate, conflict with or result in any breach of any of the terms, conditions or provisions of, or constitute a default (or give rise to any right of termination, cancellation or acceleration) under, or result in the creation of any lien, security interest, charge or encumbrance upon any of the properties or assets of the Corporation under, the Certificate of Incorporation or By-Laws, any Material Agreement, or any provision of law, statute, rule or regulation or any ruling, writ, injunction, order, judgment or decree of any court, administrative agency or other governmental body.

**4.23** <u>Authorization of Series G Shares and Reserved Shares</u>. The Restated Certificate has been duly authorized by all requisite corporate action, and has been filed with the Secretary of State of the State of Delaware. The issuance, sale and delivery hereunder by the

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Corporation of the Series G Shares have been duly authorized by all requisite corporate action of the Corporation, and when so issued, sold and delivered the Series G Shares will be validly issued and outstanding, fully paid and nonassessable, and not subject to preemptive or any other similar rights of the stockholders of the Corporation or others. The issuance and delivery of the Reserved Shares have been duly authorized by all requisite corporate action of the Corporation, and the Reserved Shares have been duly reserved for issuance upon conversion of any or all of the Series G Shares, and when so issued and delivered upon conversion of the Series G Shares, the Reserved Shares will be validly issued and outstanding, fully paid and nonassessable, and not subject to preemptive or any other similar rights of the stockholders of the Corporation or others.

**4.24** <u>Related Transactions</u>. No director, officer or employee of the Corporation nor any "associate" (as defined in Rule 405 in the rules and regulations promulgated under the Securities Act) of any such person is indebted to the Corporation, nor is the Corporation indebted (or committed to make loans or extend or guarantee credit) to any such person, nor is any such person a party to any transaction (other than as an employee or consultant) with the Corporation providing for the furnishing of services by, or rental of real or personal property from, or otherwise requiring cash payments to, any such person.

**4.25** <u>Offerees</u>. The Corporation has not, either directly or through any agent, offered any Common Stock, Series G Preferred Stock, or other securities convertible into Common Stock, Series G Preferred Stock, or any security or securities similar to any thereof, for sale to, or solicited any offers to buy any Common Stock, Series G Preferred Stock, or other securities convertible into Common Stock, Series G Preferred Stock, or other securities convertible into Common Stock, Series G Preferred Stock, or other securities convertible into Common Stock, Series G Preferred Stock, or any such similar security or securities from, or otherwise approached or negotiated in respect thereof with, any person or entity other than the Investors.

**4.26** <u>Use of Proceeds</u>. The net proceeds received by the Corporation from the sale of the Series G Shares shall be used by the Corporation solely for the purpose of working capital and such other purposes as may be approved by the Board of Directors (including the approval of all of the Series C-E Directors (as defined in the Investor Rights Agreement).

**4.27** <u>No Governmental Consent or Approval Required</u>. No authorization, consent, approval or other order of, declaration to, or filing with, any governmental agency or body is required to be made or obtained by the Corporation for or in connection with the valid and lawful authorization, execution and delivery by the Corporation of the Transaction Documents, for or in connection with the valid and lawful authorization, issuance, sale and delivery of the Series G Shares or for or in connection with the valid and lawful authorization, except exemptive filings under applicable securities laws that have been made or that are not required to be made until after the Closing and that shall be made on a timely basis.</u>

**4.28** <u>Registration Rights</u>. Except as contemplated by the Registration Rights Agreement, no person has any right to cause the Corporation to effect the registration under the Securities Act of any shares of Common Stock or any other securities of the Corporation.

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**4.29** <u>Employees</u>. Each of the officers of the Corporation, each key employee and each other employee now employed by the Corporation who has access to confidential information of the Corporation has executed an agreement regarding confidentiality, inventions and noncompetition, and such agreements are in full force and effect. No officer or key employee of the Corporation has advised the Corporation (orally or in writing) that he intends to terminate employment with the Corporation. The Corporation has complied in all material respects with all applicable laws relating to the employment of labor, including provisions relating to wages, hours, equal opportunity, collective bargaining and the payment of Social Security and other taxes, and with ERISA.

**4.30** <u>Exemptions from Securities Laws</u>. Subject to the accuracy of the representations and warranties of the Investors set forth in Section 5 hereof, the provisions of Section 5 of the Securities Act are inapplicable to the offering, issuance, sale and delivery of the Series G Shares and the Reserved Shares, and no consent, approval, qualification or registration or filing under any state securities laws is required in connection therewith, except exemptive filings that have been made or that are not required to be made until after the Initial Closing or any Additional Closing and that shall be made on a timely basis.

**4.31** [Small Business Concern. The Corporation, taken together with its "affiliates" (as that term is defined in 13 C.F.R. § 121.103) is a "small business concern" within the meaning of 15 U.S.C. § 662(5), that is § 103(5) of the Small Business Investment Act of 1958, as amended (the "<u>SBIC Act</u>"), and the regulations thereunder, including 13 C.F.R. § 107, and meets applicable size eligibility criteria set forth in 13 C.F.R. § 121.301(c)(1) or the industry standard covering the industry in which the Corporation is primarily engaged as set forth in 13 C.F.R. § 13.301(c)(2). The Corporation does not presently engage in any activities for which a small business investment company is prohibited from providing funds by the SBIC Act and the regulations thereunder, including 13 C.F.R. § 107.]

**4.32** <u>Books and Records</u>. The books of account, ledgers, order books, records and documents of the Corporation accurately and completely reflect all material information relating to the business of the Corporation, the location and collection of its assets, and the nature of all transactions giving rise to the obligations or accounts receivable of the Corporation.

**4.33** <u>Disclosure</u>. Neither this Agreement nor any other document, certificate or written statement furnished to the Investors by or on behalf of the Corporation contains any untrue statement of a material fact or omits to state a material fact necessary in order to make the statements contained herein or therein not misleading. To the Corporation's knowledge, there is no fact or circumstance relating specifically to the business or condition of the Corporation that could reasonably be expected to result in a material adverse effect to the financial condition, results of operations, assets, liabilities, business or prospects of the Corporation and that is not disclosed in <u>Schedule 4</u>.

SECTION 5. <u>Representations and Warranties of the Investors</u>. Each of the Investors, severally and not jointly, represents and warrants to the Corporation as follows:

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**5.1** <u>**Purchase for Investment**</u>. Such Investor is acquiring the Series G Shares purchasable by it hereunder for its own account, for investment and not for, with a view to, or in connection with, any distribution or public offering thereof within the meaning of the Securities Act.

**5.2** <u>Unregistered Securities; Legend</u>. Such Investor understands that the Series G Shares and the Reserved Shares (i) have not been, and will not be, registered under the Securities Act or any state securities law, by reason of their issuance in a transaction exempt from the registration requirements of the Securities Act and such laws, (ii) must be held indefinitely unless they are subsequently registered under the Securities Act and such laws or subsequent disposition thereof is exempt from registration and (iii) will be subject to the restrictions on transfer set forth in Section 8. Such Investor further understands that such exemption depends upon, among other things, the bona fide nature of such Investor's investment intent expressed herein.

**5.3** <u>Status of the Investors</u>. Such Investor has not been formed for the specific purpose of acquiring the Series G Shares pursuant to this Agreement. Such Investor understands the term "accredited investor" as used in Regulation D promulgated under the Securities Act and represents and warrants to the Corporation that such Investor is an "accredited investor" for purposes of acquiring the Series G Shares purchasable by it hereunder.

**5.4** <u>Knowledge and Experience; Economic Risk</u>. Such Investor has sufficient knowledge and experience in business and financial matters and with respect to investment in securities of privately held companies so as to enable it to analyze and evaluate the merits and risks of the investment contemplated hereby and is capable of protecting its interest in connection with this transaction. Such Investor is able to bear the economic risk of such investment, including a complete loss of the investment.

**5.5** <u>Access to Information</u>. Such Investor acknowledges that such Investor and its representatives have had the opportunity to ask questions and receive answers from officers and representatives of the Corporation concerning the transactions contemplated by this Agreement, and to obtain any additional information which the Corporation possesses or can acquire in connection with its purchase of the Series G Shares purchasable by it hereunder.

**5.6** <u>Rule 144</u>. Such Investor understands that the exemption from registration afforded by Rule 144 (the provisions of which are known to such Investor) promulgated by the Securities and Exchange Commission (the "<u>Commission</u>") under the Securities Act depends upon the satisfaction of various conditions, and that such exemption is not currently available.

## SECTION 6. Conditions Precedent to Closings by the Investors.

**6.1** <u>**Conditions Precedent to Initial Closing by the Initial Investors**</u>. The obligation of each Initial Investor to purchase and pay for the Initial Series G Shares being

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purchased by such Initial Investor at the Initial Closing is subject to satisfaction (or waiver by such Initial Investor) of the following conditions precedent at or before the Initial Closing:

(a) <u>Corporate Proceedings</u>. All corporate and other proceedings to be taken and all waivers and consents to be obtained in connection with the transactions contemplated by this Agreement shall have been taken or obtained and all documents incident to such transactions shall be reasonably satisfactory in form and substance to the Initial Investors and their counsel, who shall have received all such originals or certified or other copies of such documents as they may reasonably request.

(b) <u>Representations and Warranties Correct</u>. The representations and warranties made by the Corporation in Section 4 hereof shall be true and correct when made, and shall be true and correct at the time of the Initial Closing with the same force and effect as if they had been made at and as of the time of the Initial Closing.

(c) <u>Compliance with Covenants</u>. The Corporation shall have duly complied with and performed all covenants and agreements of the Corporation herein which are required to be complied with and performed at or before the Initial Closing.

(d) <u>Certificate of Compliance</u>. The President and Chief Executive Officer of the Corporation shall have provided to the Initial Investors a certificate, dated the date of the Initial Closing in form and substance reasonably satisfactory to the Initial Investors participating in such Closing, confirming compliance with the conditions set forth in Subsections 6.1(b) and 6.1(c).

(e) <u>Opinion of Counsel</u>. At the Initial Closing, each of the Initial Investors shall have received an opinion of Palmer & Dodge LLP, counsel for the Corporation, addressed to the Initial Investors in the form attached hereto as <u>Exhibit 6.1(e)</u>.

(f) <u>Related Agreements and Documents</u>. At or before the Initial Closing, the parties thereto shall have executed and delivered this Agreement, the Registration Rights Agreement, the Investor Rights Agreement, the Voting Agreement and the Stock Restriction Agreement. In addition, the Initial Investors and their counsel shall have received copies of the following documents: (i) (A) the Certificate of Incorporation, certified as of a recent date by the Secretary of State of the State of Delaware and (B) a certificate of said Secretary dated as of a recent date as to the due incorporation and good standing of the Corporation, the payment of all excise taxes by the Corporation and listing all documents of the Corporation on file with said Secretary; (ii) a certificate of the Secretary or an Assistant Secretary of the Corporation dated the Initial Closing Date and certifying: (A) that attached thereto is a true and complete copy of the By-Laws as in effect on the date of such certification; (B) that attached thereto is a true and complete copy of all resolutions adopted by the Board of Directors or the stockholders of the Corporation authorizing the execution, delivery and performance of the Transaction Documents, the issuance, sale and delivery of the Series G Shares and the reservation, issuance and delivery of the Reserved Shares, and that all such resolutions are in full force and effect and are all the

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resolutions adopted in connection with the transactions contemplated by the Transaction Documents; (C) that the Restated Certificate has not been amended; and (D) to the incumbency and specimen signature of each officer of the Corporation executing any of the Transaction Documents, the stock certificates representing the Series G Shares and any certificate or instrument furnished pursuant hereto, and a certification by another officer of the Corporation as to the incumbency and signature of the officer signing the certificate referred to in this clause (ii); and (iii) such additional supporting documents and other information with respect to the operations and affairs of the Corporation as the Initial Investors or their counsel reasonably may request.

(g) <u>Securities Matters</u>. All consents, approvals, qualifications, registrations, notices and filings required to be obtained or effected as of the Initial Closing under any applicable securities laws of any state or other jurisdiction in connection with the issuance, sale and delivery of the Series G Shares and the Reserved Shares shall have been obtained or effected and copies of the same delivered to each of the Initial Investors.

(h) <u>Delivery of Certificates for Series G Shares</u>. The Corporation shall have delivered to each Initial Investor a certificate for the Series G Shares being purchased by such Initial Investor at the Initial Closing, registered in the name of such Initial Investor.

(i) <u>Purchase by Other Initial Investors</u>. Each Initial Investor shall have purchased and paid for the Initial Series G Shares being purchased by it at the Initial Closing and the aggregate investment of all Initial Investors shall be no less than \$[7,000,000].

**6.2** <u>Conditions Precedent to Scheduled Additional Closings by the Investors</u>. The obligation of each Investor to purchase and pay for the Additional Series G Shares being purchased by such Investor at a Scheduled Additional Closing (together with the Initial Closing and any other Additional Closing(s), each a "Closing") is subject to satisfaction (or waiver by such Initial Investor) of the following conditions precedent at or before such Scheduled Additional Closing:

(a) <u>Completion of Initial Closing</u>. The Initial Closing shall have been consummated in accordance with the terms of this Agreement.

(b) <u>Corporate Proceedings</u>. None of the corporate and other proceedings required to be taken nor the waivers and consents required to be obtained in connection with the Initial Closing shall have been rescinded or amended in a manner that prevents such Scheduled Additional Closing.

(c) <u>Delivery of Certificates for Series G Shares</u>. The Corporation shall have delivered to each Investor a certificate for the Additional Series G Shares being purchased by such Investor at the Scheduled Additional Closing, registered in the name of such Investor.

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**6.3** <u>Conditions Precedent to First Additional Closing by the Additional Investors</u>. The obligation of each Additional Investor to purchase and pay for the Additional Investor Series G Shares being purchased by such Additional Investor at the first Additional Closing in which such Additional Investor participates is subject to satisfaction (or waiver by such Additional Investor) of the following conditions precedent at or before such Additional Closing:

(a) <u>Corporate Proceedings</u>. None of the corporate and other proceedings required to be taken nor the waivers and consents required to be obtained in connection with the Initial Closing shall have been rescinded or amended in a manner that prevents such Additional Closing.

(b) <u>Representations and Warranties Correct</u>. The representations and warranties made by the Corporation in Section 4 hereof shall be true and correct at the time of such Additional Closing with the same force and effect as if they had been made at and as of the time of such Additional Closing, except as set forth in any supplement or update to the Disclosure Schedules reasonably satisfactory to such Additional Investor.

(c) <u>Compliance with Covenants</u>. The Corporation shall have duly complied with and performed all covenants and agreements of the Corporation herein which are required to be complied with and performed at or before such Additional Closing.

(d) <u>Certificate of Compliance</u>. The President and Chief Executive Officer of the Corporation shall have provided to such Additional Investor a certificate, dated the date of such Additional Closing in form and substance reasonably satisfactory to such Additional Investor, confirming compliance with the conditions set forth in Subsections 6.3(b) and 6.3(c).

(e) <u>Delivery of Certificates for Series G Shares</u>. The Corporation shall have delivered to each such Additional Investor a certificate for the Additional Investor Series G Shares being purchased by such Additional Investor at such Additional Closing, registered in the name of such Additional Investor.

**SECTION 7.** <u>Conditions Precedent to Closing by the Corporation</u>. The obligation of the Corporation to issue and sell the Series G Shares being sold to the Investors at any Closing is subject to satisfaction (or the waiver by the Corporation) of the following conditions precedent at or before such Closing:

7.1 <u>Representations and Warranties</u>. The representations and warranties made by each Investor purchasing shares at such Closing in Section 5 hereof shall be true and correct when made, and shall be true and correct in all material respects at the time of such Closing with the same force and effect as if they had been made at and as of the time of such Closing.

**7.2** <u>Tender of Payment</u>. Each Investor purchasing Series G Shares at the Closing shall have tendered payment for such Series G Shares to the Corporation.

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**SECTION 8.** <u>Transfer of Shares; Restricted Shares</u>. "Restricted Shares" means (i) the Series G Shares, (ii) the shares of Common Stock issued or issuable upon conversion of the Series G Shares, (iii) any shares of capital stock of the Corporation acquired by the Investors pursuant to the Investor Rights Agreement, and (iv) any other shares of capital stock of the Corporation issued in respect of such shares (as a result of stock splits, stock dividends, reclassifications, recapitalizations, or similar events); *provided*, however, that shares of Common Stock which are Restricted Shares shall cease to be Restricted Shares (x) upon any sale pursuant to a registration statement under the Securities Act, Section 4(1) of the Securities Act or Rule 144 under the Securities Act or (y) at such time as they become eligible for sale under Rule 144(k) under the Securities Act.

#### 8.1 <u>Requirements for Transfer</u>.

(a) Restricted Shares shall not be sold or transferred unless either (i) they first shall have been registered under the Securities Act or (ii) the Corporation first shall have been furnished with an opinion of legal counsel, reasonably satisfactory to the Corporation, to the effect that such sale or transfer is exempt from the registration requirements of the Securities Act.

(b) Notwithstanding the foregoing, no registration or opinion of counsel shall be required for (i) (A) a transfer by an Investor which is a corporation to the parent or a wholly owned subsidiary of such corporation, (B) a transfer by an Investor which is a partnership to a partner of such partnership or a retired partner of such partnership who retires after the date hereof, or to the estate of any such partner or retired partner, or to an affiliated limited partnership (or other entity) managed by the same management company or managing general partner, (C) a transfer by an Investor which is a trust to any beneficiary of the trust, (D) a transfer by an Investor which is a limited liability company to a member of such limited liability company or a retired member, or to an affiliated limited liability company (or other entity) managed by the same management of such Investor or by an entity managed by the same management company or managing general partner, (C) a transfer by an Investor which is a trust to any beneficiary of the trust, (D) a transfer by an Investor which is a limited liability company to a member of such limited liability company or a retired member who resigns after the date hereof or to the estate of any such member or retired member, or to an affiliated limited liability company (or other entity) managed by the same management company or managing member of such Investor or by an entity which controls, is controlled by, or is under common control with, such management or by an entity which controls, is controlled by, or is under common control with, such management or by an entity which controls, is controlled by, or is under common control with, such management company or by an entity which controls, is controlled by, or is under common control with, such management company or managing member.

**8.2** <u>Legend</u>. Each certificate representing Restricted Shares shall bear a legend substantially in the following form:

"The shares represented by this certificate have not been registered under the Securities Act of 1933, as amended (the "Act"), and may not be offered, sold or otherwise transferred, pledged or hypothecated unless and until such shares are registered under such Act, or, if requested by the Company, an opinion of counsel satisfactory to the Company is obtained to the effect that such registration is not required."

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The foregoing legend shall be removed from the certificates representing any Restricted Shares, at the request of the holder thereof, at such time as they become eligible for resale pursuant to Rule 144(k) under the Securities Act.

## SECTION 9. Fees; Brokers.

9.1 <u>Fees</u>. The Corporation shall pay, and save the Investors harmless against all liability for the payment of:

(a) all costs and other expenses incurred by the Corporation in connection with the preparation of the Transaction Documents and the Corporation's performance of and compliance with all agreements and conditions contained herein and therein on its part to be performed or complied with; and

(b) all costs and other expenses incurred by the Corporation in connection with delivering to the Investors the Series G Shares and the Reserved Shares.

The Corporation further agrees that it shall pay, and shall save the Investors harmless from, any and all liability with respect to any stamp, issue or similar taxes which may be determined to be payable in connection with the execution, delivery and performance of this Agreement, the issuance of the Series G Shares or the Reserved Shares or any modification, amendment or alteration of the terms or provisions of this Agreement.

**9.2** <u>Brokers</u>. The Corporation represents and warrants to the Investors that (a) neither the Corporation nor any of its officers, directors, employees or stockholders, has employed any broker or finder in connection with the transactions contemplated by this Agreement, and (b) no person or entity will have, as a result of the transactions contemplated by this Agreement, any right to, interest in, or claim against or upon the Corporation or any Investor for, any commission, fee or other compensation as a finder or broker because of any act or omission by the Corporation or any agent of the Corporation. The Corporation agrees that it shall pay, and shall save the Investors harmless from, any and all liability with respect to any commission, fee or other compensation payable to any broker or finder in connection with the transactions contemplated by this Agreement.

**SECTION 10.** <u>Remedies</u>. In case any one or more of the representations, warranties, covenants or agreements set forth in this Agreement shall have been breached by the Corporation, the Investors may proceed to protect and enforce their rights either by suit in equity or by action at law, including, but not limited to, an action for damages as a result of any such breach or an action for specific performance of any such covenant or agreement contained in this Agreement. No failure or delay on the part of any party to this Agreement in exercising any right, power or remedy hereunder shall operate as a waiver thereof; nor shall any single or partial exercise of any such right, power or remedy preclude any other or further exercise thereof or the exercise of any other right, power or remedy hereunder. The remedies herein provided are cumulative and not exclusive of any remedies provided by law.

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**SECTION 11.** Exchanges; Lost, Stolen or Mutilated Certificates. Upon surrender by any Investor to the Corporation of any certificate representing Series G Shares or Reserved Shares, the Corporation at its expense shall issue in exchange therefor, and deliver to such Investor, new certificates representing such Series G Shares or Reserved Shares, as the case may be, in such amounts or denominations as may be requested by such Investor. Upon receipt of evidence satisfactory to the Corporation of the loss, theft, destruction or mutilation of any certificate representing any Series G Shares or Reserved Shares and in case of any such loss, theft or destruction, upon delivery of an indemnity agreement satisfactory to the Corporation, or in case of any such mutilation, upon surrender and cancellation of such certificate, the Corporation at the Investor's expense shall issue and deliver to such Investor a new certificate for such Series G Shares or Reserved Shares, of like tenor, in lieu of such lost, stolen or mutilated certificate.

**SECTION 12.** <u>Survival of Representations, Warranties and Agreements</u>. The covenants, representations and warranties of the parties contained herein shall survive the Closings hereunder. Each of the parties may rely on such covenants, representations and warranties irrespective of any investigation made, or notice or knowledge held by, it or any other person. All statements contained in any certificate or other instrument delivered by any party pursuant to this Agreement or in connection with the transactions contemplated by this Agreement shall constitute representations and warranties by such party under this Agreement, subject to the qualifications set forth herein and therein.

**SECTION 13.** <u>Successors and Assigns</u>. This Agreement shall be binding upon, and inure to the benefit of, each of the parties hereto and, except as otherwise expressly provided herein, each other person who shall become a registered holder named in a certificate evidencing Series G Shares or Reserved Shares transferred to such holder by any of the Investors or their permitted transferees, and (except as aforesaid) their respective legal representatives, successors and assigns. Notwithstanding the foregoing, the Corporation shall not have the right to assign its rights hereunder with respect to the Investors' commitment to make an investment at an Additional Closing without the prior written consent of the holders of at least two-thirds of the voting power of the then outstanding Series G Shares and Reserved Shares, voting together on an as-if converted to Common Stock basis.

**SECTION 14.** <u>Entire Agreement; Effect on Prior Documents</u>. This Agreement and the other documents referred to herein or delivered pursuant hereto contain the entire agreement among the parties with respect to the financing transactions contemplated hereby and supersede all prior negotiations, commitments, agreements and understandings among them with respect thereto. Nothing in this Agreement or the transactions hereby contemplated is intended to confer upon any other person any rights or remedies of any nature whatsoever.

**SECTION 15.** <u>Notices</u>. All notices, requests, consents and other communications hereunder ("<u>Notices</u>") to any party shall be contained in a written instrument addressed to such party at the address set forth below or such other address as may hereafter be designated in writing by the addressee to the addressor listing all parties and shall be deemed given (a) when delivered in person or duly sent by fax showing confirmation of receipt, (b) three days after being duly sent

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by first class mail postage prepaid (other than in the case of Notices to or from any non-U.S. resident), or (c) two days after being duly sent by DHL, Federal Express or other recognized express international courier service:

(a) if to the Corporation, to:

Enanta Pharmaceuticals, Inc. 500 Arsenal Street Watertown, MA 02472 Attn: President Fax: [\*\*\*\*\*]

with a copy to:

Nathaniel S. Gardiner Palmer & Dodge LLP 111 Huntington Avenue Boston, MA 02199-7613 Fax: 617-227-4420

(b) if to the Investors, to their respective addresses as set forth on the signature pages of this Agreement.

**SECTION 16.** <u>Amendments; Waivers</u>. This Agreement may be amended, and compliance with the provisions of this Agreement may be omitted or waived, only by the written agreement of the Corporation and Investors or assignees of their rights hereunder holding two-thirds in voting power of the then outstanding Series G Shares and Reserved Shares taken as a whole.

**SECTION 17.** <u>Counterparts</u>. This Agreement may be executed in any number of counterparts, each such counterpart shall be deemed to be an original instrument, and all such counterparts together shall constitute but one agreement. Any such counterpart may contain one or more signature pages.

**SECTION 18.** <u>Headings</u>. The headings of the various sections of this Agreement have been inserted for convenience of reference only and shall not be deemed to be a part of this Agreement.

SECTION 19. <u>Nouns and Pronouns</u>. Whenever the context may require, any pronouns used herein shall include the corresponding masculine, feminine or neuter forms, and the singular form of names and pronouns shall include the plural and vice-versa.

**SECTION 20.** <u>Governing Law</u>. This Agreement shall be governed by, and construed and enforced in accordance with, the substantive laws of the Commonwealth of Massachusetts, without regard to its principles of conflicts of laws.

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**SECTION 21.** <u>Severability</u>. Any provision of this Agreement that is prohibited or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such prohibition or unenforceability without invalidating the remaining provisions hereof, and any such prohibition or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction.

**SECTION 22.** <u>Further Assurances</u>. From and after the date of this Agreement, upon the request of any Investor, the Corporation shall execute and deliver such instruments, documents and other writings as may be reasonably necessary or desirable to confirm and carry out and to effectuate fully the intent and purposes of this Agreement and the Series G Shares.

**SECTION 23.** <u>Additional Investors</u>. The Additional Investors shall become parties to this Agreement, and shall be entitled to all of the benefits to and shall be subject to all of the obligations of "Investors" under this Agreement, all upon execution by such Additional Investor of a counterpart signature page to this Agreement. The Corporation shall be authorized to add the name, amount of investment and number of Additional Investor Series G Shares purchased by each Additional Investor at each Additional Closing to the <u>Schedule of Investors</u>.

**SECTION 24.** <u>Adjustments for Stock Splits, Etc.</u> Wherever in this Agreement there is a reference to a specific number of shares of Common Stock or Series G Preferred Stock or any other class or series of capital stock, then, upon the occurrence of any subdivision, combination or stock dividend of such class or series of stock, the specific number of shares so referenced in this Agreement shall automatically be proportionally adjusted to reflect the affect on the outstanding shares of such class or series of stock by such subdivision, combination or stock dividend.

**SECTION 25.** <u>Aggregation of Stock</u>. All shares held or acquired by affiliated entities or persons shall be aggregated together for the purpose of determining the availability of any rights under this Agreement.

**SECTION 26.** <u>Issuances of Series G Preferred Stock</u>. Except as expressly provided in this Agreement, the Corporation shall not issue or sell any shares of Series G Preferred Stock.

[Remainder of page intentionally left blank.]

Confidential materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote such omission.

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IN WITNESS WHEREOF, the undersigned have executed this Series G Convertible Preferred Stock Purchase Agreement as of the day and year first written above.

## ENANTA PHARMACEUTICALS, INC.

By:

Name:Jay R. LulyTitle:President and Chief Executive Officer

[Signature Page to Series G Convertible Preferred Stock Purchase Agreement]

#### Enanta Pharmaceuticals, Inc. Investor Signature Page

By his, her or its execution and delivery of this signature page, the undersigned Investor hereby joins in and agrees to be bound by the terms and conditions of (i) the Series G Convertible Preferred Stock Purchase Agreement (the "Purchase Agreement") dated as of September , 2005 (the "Effective Date"), by and among Enanta Pharmaceuticals, Inc. (the "Corporation"), and the investors named on the Schedule of Investors thereto, as to the number of shares of Series G Convertible Preferred Stock set forth below, (ii) that certain Third Amended and Restated Voting Agreement dated as of the Effective Date (the "Voting Agreement"), by and among the Corporation, the Founders (as defined therein) and the Investors (as defined therein) as a "Series G Investor" thereunder, and, if the undersigned is also a "Series C Investor," and/or a "Series D Investor" and/or a "Series E Investor" thereunder, as a "Series C Investor," and/or as a "Series D Investor" and/or as a "Series E Investor," as the case may be, thereunder, (iii) that certain Third Amended and Restated Registration Rights Agreement dated as of the Effective Date (the "Registration Rights Agreement"), by and among the Corporation and the Investors (as defined therein) as a "Series G Investor" thereunder, and, if the undersigned is also a "Series C Investor," and/or a "Series D Investor," and/or a "Series E Investor," thereunder, as a "Series C Investor," and/or as a "Series D Investor" and/or as a "Series E Investor," as the case may be, thereunder, (iv) that certain Third Amended and Restated Stock Restriction Agreement dated as of the Effective Date (the "Stock Restriction Agreement"), by and among the Corporation, the Founders (as defined therein) and the Investors (as defined therein) as a "Series G Investor" thereunder, and, if the undersigned is also a "Series C Investor," and/or a "Series D Investor" and/or a "Series E Investor," thereunder, as a "Series C Investor" and/or as a "Series D Investor," and/or as a "Series E Investor", as the case may be, thereunder, and (v) that certain Amended and Restated Investor Rights Agreement dated as of the Effective Date (the "Investor Rights Agreement"), by and among the Corporation and the Investors (as defined therein) as a "Series G Investor" thereunder, and, if the undersigned is also a "Series C Investor," and/or a "Series D Investor" and/or a "Series E Investor," thereunder, as a "Series C Investor," and/or as a "Series D Investor" and/or as a "Series E Investor," as the case may be, thereunder, and authorizes this signature page to be attached as a counterpart to the Purchase Agreement, the Voting Agreement, the Registration Rights Agreement, the Stock Restriction Agreement and the Investor Rights Agreement, or counterparts thereof.

EXECUTED as of this day of

,

By:

Title:

Print Name of Investor Record Address:

Telecopy No.:

Number of Shares of Series G Preferred Stock:

## Schedule of Investors

| Name of Investor     | Aggregate<br>Purchase Price | Initial<br>Series G Shares |   | Second Closing<br>Series G Shares |   | Third Closing<br>Series G Shares |   | Fourth Closing<br>Series G Shares |   | Fifth Closing<br>Series G Shares |   |
|----------------------|-----------------------------|----------------------------|---|-----------------------------------|---|----------------------------------|---|-----------------------------------|---|----------------------------------|---|
| Initial Investors    |                             |                            |   |                                   |   |                                  |   |                                   |   |                                  |   |
| [name]               | \$                          | [                          | ] | [                                 | ] | [                                | ] | [                                 | ] | [                                | ] |
| [name]               | \$                          | [                          | ] | [                                 | ] | [                                | ] | [                                 | ] | [                                | ] |
| [name]               | \$                          | [                          | ] | [                                 | ] | [                                | ] | [                                 | ] | [                                | ] |
| [name]               | \$                          | [                          | ] | [                                 | ] | [                                | ] | [                                 | ] | [                                | ] |
| Subtotal:            | \$                          | [                          | ] | [                                 | ] | [                                | ] | [                                 | ] | [                                | ] |
| Additional Investors |                             |                            |   |                                   |   |                                  |   |                                   |   |                                  |   |
| [name]               | \$                          | -                          |   |                                   |   |                                  |   |                                   |   |                                  |   |
| [name]               | \$                          | -                          | _ |                                   |   |                                  |   |                                   |   |                                  |   |
| Subtotals:           | \$                          | -                          |   |                                   |   |                                  |   |                                   |   |                                  |   |
| TOTALS:              | \$                          | -                          | _ |                                   |   |                                  |   |                                   |   |                                  |   |

#### Schedule 4 Disclosure Schedules

Exhibit 1 Fourth Amended and Restated Certificate of Incorporation of Enanta Pharmaceuticals, Inc.

# Exhibit 4.22A

Third Amended and Restated Registration Rights Agreement

## Exhibit 4.22B Third Amended and Restated <u>Voting Agreement</u>

# Exhibit 4.22C

Third Amended and Restated Stock Restriction Agreement

#### Exhibit 4.22D Amended and Restated Investor Rights Agreement

# Exhibit 6.1(e)

Form of Legal Opinion of Palmer & Dodge LLP

#### FORM OF PRESS RELEASE

## ABBOTT AND ENANTA FORM WORLDWIDE ALLIANCE TO DEVELOP & COMMERCIALIZE HCV PROTEASE INHIBITORS

ABBOTT PARK, Ill., and WATERTOWN, Mass., Dec XX, 2006 – Abbott and Enanta Pharmaceuticals announced today that the companies have signed a worldwide agreement to develop and commercialize hepatitis C virus (HCV) NS3 and NS3/4A protease inhibitors. Enanta has discovered several HCV protease inhibitors that have demonstrated attractive efficacy and pharmacokinetic profiles in pre-clinical studies.

"Abbott's innovative work in the protease inhibitor field against the Human Immunodeficiency Virus (HIV) has provided the momentum and the foundation for our research interest in HCV infection," said John Leonard, M.D., vice president, Global Pharmaceutical Research and Development, Abbott. "Enanta has done compelling work in its HCV protease inhibitor program, and we look forward to working together on the advancement of this global program."

"Abbott is a market leader in the field of antiviral therapies, and we have a shared vision and commitment to the discovery and development of promising HCV therapies that address this high unmet medical need globally," stated Jay R. Luly, President and CEO of Enanta Pharmaceuticals.

Under the terms of the agreement, Abbott gains worldwide access to Enanta's substantial intellectual property position for a variety of different types of compounds, which includes several issued U.S. patents. Abbott also gains access to Enanta's drug discovery capabilities in the HCV NS3 and NS3/4A protease inhibitor field.

Additionally, Enanta will receive an upfront payment of \$57 million, which includes a cash payment and an equity investment. If all potential clinical and regulatory milestones are met, additional payments of up to \$250 million will be made to Enanta, and further payments will be due if multiple products develop from the program. Enanta will receive double-digit royalties and holds an option to fund 40 percent of development costs and U.S. commercialization efforts (sales and promotion costs) in exchange for a 40-percent profit share in the U.S. on medicines from this alliance that result in commercial approval.

"Through this alliance, we will enhance our HCV protease inhibitor program and allow both companies to participate in the long-term value creation of these compounds, by leveraging Enanta's core expertise in chemistry and drug discovery, with Abbott's proven track-record in the discovery, development, and commercialization of antiviral therapies," stated Yujiro S. Hata, Senior Vice President of Business Development at Enanta Pharmaceuticals.

#### Confidential materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote such omission.

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#### About Hepatitis C Virus

Hepatitis C is a liver disease affecting over 170 million people worldwide. The virus is spread through direct contact with the blood of an infected person. Hepatitis C increases a person's risk of developing chronic liver disease, cirrhosis, liver cancer and death. Liver disease associated with HCV infection is growing rapidly, and current therapies only provide sustained benefit in about half of patients with the genotypel form of the virus. Specifically targeted antiviral therapies for HCV, such as NS3/4a protease inhibitors, may have the potential to increase the proportion of patients in whom the virus can be eradicated.

#### **About Enanta**

Enanta Pharmaceuticals is a research and development company that uses its novel chemistry approach and drug discovery capabilities to create best in class small molecule drugs in the anti-infective field. At the heart of Enanta is its commitment to innovative chemistry that surpasses traditional medicinal chemistry approaches. The Company's successful integration of chemistry with biology has created a new class of macrolide antibiotics that overcome bacterial resistance. Antibacterial focus areas include community respiratory tract infections as well as hospital and community infections relating to *MRSA*. Additionally, Enanta has discovered antiviral agents targeted against the Hepatitis C virus (HCV). Enanta is a privately held company with offices in Watertown, MA. More information about the company can be found at www.enanta.com.

#### **About Abbott**

Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs 65,000 people and markets its products in more than 130 countries.

Abbott's news releases and other information are available on the company's web site at www.abbott.com.

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#### ARBITRATION PROCEDURES

The Parties recognize that from time to time a dispute may arise relating to either Party's rights or obligations under this Agreement. The Parties agree that any such dispute shall be resolved by the Alternative Dispute Resolution ("<u>ADR</u>") provisions set forth in this Exhibit, the result of which shall be binding upon the Parties.

To begin the ADR process, a Party first must send written notice of the dispute to the other Party for attempted resolution by good faith negotiations between their respective presidents (or their designees) of the affected subsidiaries, divisions, or business units within twenty-eight (28) days after such notice is received (all references to "days" in this ADR provision are to calendar days). If the matter has not been resolved within twenty-eight (28) days of the notice of dispute, or if the Parties fail to meet within such twenty-eight (28) days, either Party may initiate an ADR proceeding as provided herein. The Parties shall have the right to be represented by counsel in such a proceeding.

1. To begin an ADR proceeding, a Party shall provide written notice to the other Party of the issues to be resolved by ADR. Within fourteen (14) days after its receipt of such notice, the other Party may, by written notice to the Party initiating the ADR, add additional issues to be resolved within the same ADR.

2. Within twenty-one (21) days following the initiation of the ADR proceeding, the parties shall select a mutually acceptable neutral to preside in the resolution of any disputes in this ADR proceeding. If the parties are unable to agree on a mutually acceptable neutral within such period, either party may request the President of the CPR Institute for Dispute Resolution ("**CPR**"), 366 Madison Avenue, 14th Floor, New York, New York 10017, to select a neutral pursuant to the following procedures:

(a) The CPR shall submit to the parties a list of not less than five (5) candidates within fourteen (14) days after receipt of the request, along with a *Curriculum Vitae* for each candidate. No candidate shall be an employee, director, or shareholder of either party or any of their subsidiaries or affiliates.

(b) Such list shall include a statement of disclosure by each candidate of any circumstances likely to affect his or her impartiality.

(c) Each Party shall number the candidates in order of preference (with the number one (1) signifying the greatest preference) and shall deliver the list to the CPR within seven (7) days following receipt of the list of candidates. If a Party believes a conflict of interest exists regarding any of the candidates, that Party shall provide a written explanation of the conflict to the CPR along with its list showing its order of preference for the candidates. Any

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Party failing to return a list of preferences on time shall be deemed to have no order of preference.

(d) If the Parties collectively have identified fewer than three (3) candidates deemed to have conflicts, the CPR immediately shall designate as the neutral the candidate for whom the Parties collectively have indicated the greatest preference. If a tie should result between two candidates, the CPR may designate either candidate. If the Parties collectively have identified three (3) or more candidates deemed to have conflicts, the CPR shall review the explanations regarding conflicts and, in its sole discretion, may either (i) immediately designate as the neutral the candidate for whom the Parties collectively have indicated the greatest preference, in which case the procedures set forth in subparagraphs 2(a) - 2(d) shall be repeated.

3. No earlier than twenty-eight (28) days or later than fifty-six (56) days after selection, the neutral shall hold a hearing to resolve each of the issues identified by the Parties. The ADR proceeding shall take place at a location agreed upon by the parties. If the Parties cannot agree, the neutral shall designate a location other than the principal place of business of either Party or any of their subsidiaries or affiliates.

4. At least seven (7) days prior to the hearing, each Party shall submit the following to the other party and the neutral:

(a) a copy of all exhibits on which such Party intends to rely in any oral or written presentation to the neutral;

(b) a list of any witnesses such Party intends to call at the hearing, and a short summary of the anticipated testimony of each witness;

(c) a proposed ruling on each issue to be resolved, together with a request for a specific damage award or other remedy for each issue. The proposed rulings and remedies shall not contain any recitation of the facts or any legal arguments and shall not exceed one (1) page per issue. The parties agree that neither side shall seek as part of its remedy any punitive damages.

(d) a brief in support of such party's proposed rulings and remedies, provided that the brief shall not exceed twenty (20) pages. This page limitation shall apply regardless of the number of issues raised in the ADR proceeding.

Except as expressly set forth in subparagraphs 4(a) - 4(d), no discovery shall be required or permitted by any means, including depositions, interrogatories, requests for admissions, or production of documents.

5. The hearing shall be conducted on two (2) consecutive days and shall be governed by the following rules:

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(a) Each Party shall be entitled to five (5) hours of hearing time to present its case. The neutral shall determine whether each Party has had the five (5) hours to which it is entitled.

(b) Each Party shall be entitled, but not required, to make an opening statement, to present regular and rebuttal testimony, documents or other evidence, to cross-examine witnesses, and to make a closing argument. Cross-examination of witnesses shall occur immediately after their direct testimony, and cross-examination time shall be charged against the Party conducting the cross-examination.

(c) The Party initiating the ADR shall begin the hearing and, if it chooses to make an opening statement, shall address not only issues it raised but also any issues raised by the responding Party. The responding Party, if it chooses to make an opening statement, also shall address all issues raised in the ADR. Thereafter, the presentation of regular and rebuttal testimony and documents, other evidence, and closing arguments shall proceed in the same sequence.

(d) Except when testifying, witnesses shall be excluded from the hearing until closing arguments.

(e) Settlement negotiations, including any statements made therein, shall not be admissible under any circumstances. Affidavits prepared for purposes of the ADR hearing also shall not be admissible. As to all other matters, the neutral shall have sole discretion regarding the admissibility of any evidence.

6. Within seven (7) days following completion of the hearing, each Party may submit to the other Party and the neutral a post-hearing brief in support of its proposed rulings and remedies, provided that such brief shall not contain or discuss any new evidence and shall not exceed ten (10) pages. This page limitation shall apply regardless of the number of issues raised in the ADR proceeding.

7. The neutral shall rule on each disputed issue within fourteen (14) days following completion of the hearing. Such ruling shall adopt in its entirety the proposed ruling and remedy of one of the parties on each disputed issue but may adopt one Party's proposed rulings and remedies on some issues and the other Party's proposed rulings and remedies on other issues. The neutral shall not issue any written opinion or otherwise explain the basis of the ruling.

8. The neutral shall be paid a reasonable fee plus expenses. These fees and expenses, along with the reasonable legal fees and expenses of the prevailing Party (including all expert witness fees and expenses), the fees and expenses of a court reporter, and any expenses for a hearing room, shall be paid as follows:

(a) If the neutral rules in favor of one Party on all disputed issues in the ADR, the losing Party shall pay 100% of such fees and expenses.

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(b) If the neutral rules in favor of one Party on some issues and the other Party on other issues, the neutral shall issue with the rulings a written determination as to how such fees and expenses shall be allocated between the Parties. The neutral shall allocate fees and expenses in a way that bears a reasonable relationship to the outcome of the ADR, with the Party prevailing on more issues, or on issues of greater value or gravity, recovering a relatively larger share of its legal fees and expenses.

9. The rulings of the neutral and the allocation of fees and expenses shall be binding, non-reviewable, and non-appealable, and may be entered as a final judgment in any court having jurisdiction.

10. Except as provided in paragraph 9 or as required by law, the existence of the dispute, any settlement negotiations, the ADR hearing, any submissions (including exhibits, testimony, proposed rulings, and briefs), and the rulings shall be deemed Confidential Information. The neutral shall have the authority to impose sanctions for unauthorized disclosure of Confidential Information.

11. All ADR hearings shall be conducted in the English language.

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# ABBOTT COMPOUNDS

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# ABBOTT PATENT RIGHTS

None.

## EXCLUDED COMPOUNDS

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# SCHEDULE 4

## LICENSED PATENT RIGHTS

| <u>Title</u><br>Azapeptide   | ENP-<br><u>Numbers</u><br>ENP-057 | Application<br>Number/Patent<br><u>Number</u><br>7,125,845<br>05010029A1<br>[*****]   | <u>Country</u><br>US (Utility)<br>PCT<br>Nationalization<br>[*****]  | Filing<br><u>Date</u><br>03-Jul-2003<br>19-May-2004<br>[*****]  | Patent Issue<br><u>Date</u><br>24-Oct-2006<br>NA<br>[*****]        | <u>Status</u><br>Granted<br>Published<br>[*****]   |  |  |  |
|--|-----------------------------------|---|--|---|--|--|--|--|--|
| Quinoxaline  | ENP-060                           | 10/826,743<br>[*****]<br>[*****]<br>2004800129286<br>04750236.4<br>06104304.7<br>2006-513078<br>1020057019856<br>US04/11841 | US (Utility)<br>[*****]<br>[*****]<br>China<br>European Patent<br>Convention<br>Hong Kong<br>Japan<br>Korea<br>PCT | 16-Apr-2004<br>[*****]<br>[*****]<br>16-Apr-2004<br>16-Apr-2004<br>10-Apr-2004<br>16-Apr-2004<br>16-Apr-2004<br>16-Apr-2004 | NA<br>[*****]<br>[*****]<br>NA<br>NA<br>NA<br>NA<br>NA<br>NA<br>NA | Allowed<br>[*****]<br>[*****]<br>Published<br>Published<br>Pending<br>Published<br>Published |  |  |  |
| Tripeptide   | ENP-065                           | 10/849,107<br>[*****]   | US (Utility)<br>[*****]  | 15-May-2004<br>[*****]  | NA<br>[*****]  | Allowed<br>[*****]   |  |  |  |
| Heteroaryl   | ENP-066                           | 10/774,047<br>[*****]<br>[*****]<br>0480009268.6<br>047090204<br>[*****]  | USUtility)<br>[*****]<br>[*****]<br>China<br>European Patent<br>Convention<br>[*****]                              | [ ]<br>06-Feb-2004<br>[*****]<br>[*****]<br>06-Feb-2004<br>06-Feb-2004  | [ ]<br>NA<br>[*****]<br>[*****]<br>NA<br>NA<br>[*****]             | Published<br>[*****]<br>[*****]<br>Published<br>Published<br>[*****]                         |  |  |  |
| [****]   | [*****]                           | [*****]   | [****  | [*****]   | [*****]  | [*****]  |  |  |  |
| Confidential materials omitted and filed separately with the Securities and Exchange |                                   |   |  |   |  |  |  |  |  |

Confidential materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote such omission.

- 1 -

| Title   | ENP-<br><u>Numbers</u> | Application<br>Number/ Patent<br><u>Number</u><br>[*****]<br>[*****] | Country<br>[*****]<br>[*****] | Filing<br><u>Date</u><br>[*****]<br>[*****] | Patent Issue<br><u>Date</u><br>[*****]<br>[*****] | Status<br>[*****]<br>[*****] |
|---------|------------------------|--|-------------------------------|---|---|------------------------------|
| [****]  | [*****]                | [*****]<br>[*****]   | [*****]<br>[*****]            | [*****]<br>[*****]                          | [*****]<br>[*****]                                | [*****]<br>[*****]           |
| [****]  | [****]                 | [****]   | [****                         | [****]                                      | [****]  | [*****]                      |
| [****]  | [****]                 | [*****]  | [*****]                       | [*****]                                     | [*****]   | [*****]                      |
| [****]  | [****                  | [*****]  | [*****]                       | [*****]                                     | [*****]   | [*****]                      |
| [*****] | [****]                 | [*****]  | [*****]                       | [*****]                                     | [*****]   | [*****]                      |
| [*****] | [****]                 | [*****]  | [*****]                       | [*****]                                     | [*****]   | [*****]                      |
| [****]  | [****                  | [*****]  | [*****]                       | [*****]                                     | [*****]   | [*****]                      |
| [****]  | [****                  | [*****]  | [*****]                       | [*****]                                     | [*****]   | [*****]                      |
| [*****] | [*****]                | [*****]  | [*****]                       | [*****]                                     | [*****]   | [*****]                      |
| [*****] | [*****]                | [*****]  | [*****]                       | [*****]                                     | [*****]   | [*****]                      |
| [****]  | [****                  | [*****]  | [*****]                       | [*****]                                     | [*****]   | [*****]                      |
| [****]  | [****]                 | [*****]  | [*****]                       | [*****]                                     | [*****]   | [*****]                      |
| [****]  | [****]                 | [*****]  | [*****]                       | [*****]                                     | [****]  | [*****]                      |

Confidential materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote such omission.

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#### MATERIAL TERMS TO BE INCLUDED IN CO-PROMOTION AGREEMENT

The Co-Promotion Agreement to be negotiated by the Parties upon exercise by Enanta of a Co-Promotion Option shall contain the following material terms. Capitalized terms used in this <u>Schedule 5</u> and not otherwise defined have the meanings given to them in the Agreement.

#### 1. Co-Promotion Rights.

(a) Enanta and Abbott hereby acknowledge and agree that the overall objective of co-promotion is to reach a broad customer audience, avoid confusion and redundancy of the marketing message for Co-Promoted Products and maximize the particular strengths that the Parties bring to the Co-Promotion of Co-Promoted Products. In connection therewith, it is the expectation of the Parties that each Marketing and Sales Plan shall provide that Enanta will perform up to the Enanta Co-Development Percentage of the total Detailing effort made each Calendar Year applicable to Co-Promoted Products in the Co-Promotion Territory (the "Co-Promotion Detailing Target"); provided, that, the allocation of the Detailing obligations between the Parties shall take into account the position of the Detail, the number of calls and the quality/difficulty and relative importance of the target audience. All such Detailing calls shall be made in such markets as the JDCC reasonably considers to be appropriate for the successful Commercialization of such Co-Promoted Product based on objective, quantifiable information and market research data with the objectives of allocating to each of Enanta and Abbott target audience and accounts from which each such Parties to effect an objective allocation of individual accounts and target audience between the Parties, the Parties recognize that it may be necessary from time to time to reassign individual accounts and/or target audience between the Parties and the JDCC shall be entitled to review the allocation of accounts as it reasonably determines to be appropriate.

(b) The object of Co-Promotion is to increase Co-Promotion efforts to the Co-Promotion Target Audience with a consistent marketing message. It is recognized that the Parties bring particular strengths to the ongoing Commercialization of Co-Promoted Products in the Co-Promotion Territory. With respect to each Co-Promoted Product, the JDCC will assign to each Party a role in Commercialization functions and activities as the JDCC considers to be reasonably appropriate for the successful Commercialization of such Co-Promoted Product.

(c) Abbott shall grant to Enanta a co-exclusive (together with Abbott and its Affiliates), royalty-free license, with the right to grant sublicenses solely to Affiliates, under the Abbott Technology and Abbott Patent Rights, to Co-Promote Co-Promoted Products in the Co-Promotion Territory.

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(d) Enanta and Abbott shall use an integrated sales force to Detail each Co-Promoted Product. In connection therewith, neither Party will, without the other Party's prior written consent, use a Representative to Detail a Co-Promoted Product if that Representative is also Detailing a product that is approved for an indication that is directly competitive with the Co-Promoted Product. Enanta and Abbott hereby agree that each such Party shall be responsible for ensuring that its Representatives Detail each Co-Promoted Product in a manner consistent with the Marketing and Sales Plan and/or the decisions of the JDCC. Notwithstanding the foregoing, in performing their respective Detailing obligations hereunder, each of the Parties agrees to (a) use Representatives with an experience profile appropriate for the target audience and Detailing role as described in the Marketing and Sales Plan; (b) provide its own sales management organization and infrastructure for its Representatives and (c) Detail the Co-Promoted Product in the first or second position.

2. <u>Commercialization Efforts</u>. Each Party shall use commercially reasonable efforts to execute its obligations under each Co-Promotion Marketing and Sales Plan, consistent with the applicable Co-Promotion Commercialization Budget, and to cooperate diligently with each other in carrying out such Co-Promotion Marketing and Sales Plan.

#### 3. Co-Promotion Marketing and Sales Plan and Budget.

(a) Preparation of Plan and Budget. Abbott, in good faith consultation with Enanta, shall develop a Marketing and Sales Plan ("Co-Promoted Product Marketing and Sales Plan") for each Co-Promoted Product for the Co-Promotion Territory, and each such Co-Promotion Marketing and Sales Plan shall be reviewed and approved by the JDCC; provided that each such Co-Promotion Marketing and Sales Plan shall be consistent with Enanta's rights under the Agreement. Each Co-Promotion Marketing and Sales Plan shall include but not be limited to: (i) demographics and market dynamics, market strategies, estimated launch date(s) in the Co-Promotion Territory, a sales and expense forecast (including at least three (3) years of estimated sales and expenses) for the Co-Promotion Territory, manufacturing plans and expected product profile; (ii) a market plan (including Advertising (to be defined in the Co-Promotion Agreement) and Detailing forecasts and pricing strategies pertaining to discounts, samples and nominal price sales) for the Co-Promotion Territory; (iii) a commercialization budget ("Co-Promotion Commercialization Budget") for each Co-Promoted Product for the Co-Promotion Territory, including the Third Parties proposed to be utilized and, to the extent practicable, any proposed Third Party arrangements. Each Co-Promotion Marketing and Sales Plan. Each Co-Promotion Marketing and Sales Plan and Co-Promotion Budget shall be submitted to the JDCC for review and approval by a date to be established by the JDCC, taking into account Abbott's and Enanta's annual budget planning calendars, but no later than December 31 of each year. It is contemplated that each Co-Promotion Marketing and Sales Plan and Co-Promotion Commercialization Budget will become more comprehensive as the Co-Promotion of the applicable Co-Promoted Product evolves.

(b) <u>Changes to Plans/Budgets</u>. Any significant change in a Co-Promotion Marketing and Sales Plan or Co-Promotion Commercialization Budget during the course of the

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year will be communicated promptly to the JDCC. In addition, Abbott shall provide an update on each Co-Promotion Marketing and Sales Plan and Co-Promotion Commercialization Budget to the JDCC in a manner consistent (with respect to timing and content) with such updates as are reported internally by Abbott or its Affiliates on its or their other products at such time, but no less frequently than semi-annually.

(c) <u>Detail Audit Rights</u>. Each of Abbott and Enanta shall maintain electronic records of Details performed for a period of [\*\*\*\*\*] years from the date of performance. Each such Party shall have the right to inspect such records of the other Party to verify Detailing reports provided to the JDCC under this Agreement. Each Audited Party shall make its records available for inspection by appropriate representatives of the Auditing Party during regular business hours at such place or places where such records are customarily kept, upon reasonable notice from the Auditing Party, solely to verify the accuracy of such statements. All information concerning such statements, and all information learned in the course of any audit or inspection, shall be Confidential Information of the Audited Party. The Auditing Party shall pay the costs of such inspections, except that in the event there is any downward adjustment in the number of Details shown by such inspection of more than [\*\*\*\*\*] of the number of Details reported in such statement, the Audited Party shall pay the costs of such inspection.

### 4. Control Over Advertising and Detailing.

(a) Neither Party shall engage in any Advertising or use any label, package, literature or other written material (other than General Public Relations (to be defined in the Co-Promotion Agreement) in connection with a Co-Promoted Product in the Co-Promotion Territory, unless the specific form and content thereof is approved by the JDCC.

(b) General Public Relations on the part of either Party need to be approved by the JDCC, and all representations and statements pertaining to Co-Promoted Products that appear in General Public Relations of Enanta or Abbott and include subject matter not previously approved by the JDCC shall be subject to the approval of the JDCC.

(c) All Advertising and Detailing undertaken by either Party hereto shall be undertaken in good faith with a view towards maximizing the sales of the applicable Co-Promoted Product.

(d) Except with the prior written consent of the other Party, neither Party shall use the name of the other Party or any Affiliate of the other Party in Advertising, Detailing or General Public Relations.

(e) Abbott shall have the sole responsibility for (i) deciding on pricing and for obtaining all pricing approvals as may be required for all Co-Promoted Products, (ii) conducting all billing and collections for Co-Promoted Products; and (iii) overseeing and implementing all other reimbursement matters but shall, in all such cases, consult with, and reasonably consider the views of, the JDCC with respect to the foregoing.

(f) Abbott shall have sole responsibility for arranging for the distribution and warehousing of Co-Promoted Products.

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(g) Neither Party shall engage in any Advertising or use any label, package, literature or other written material (other than General Public Relations) in connection with a Co-Promoted Product unless the specific form and content thereof is approved by the JDCC. Without the prior written consent of the other party, no Party shall use the name of the other Party or any Affiliate of the other Party in General Public Relations.

5. <u>Sales Efforts in the Co-Promotion Territory</u>. As part of each Co-Promotion Marketing and Sales Plan for the Co-Promotion Territory, the JDCC shall determine the targeted level of sales of the applicable Co-Promoted Product for the Co-Promotion Target Audience for the Calendar Year covered by such Co-Promotion Marketing and Sales Plan. Each Co-Promotion Marketing and Sales Plan shall provide each Party the opportunity to perform a percentage of the Detailing calls to the Co-Promotion Target Audience each calendar year as the JDCC reasonably considers to be appropriate for the successful Commercialization of such Co-Promoted Product. The Parties shall allocate physicians in the Co-Promotion Target Audience in an unbiased manner based on objective, quantifiable information and market research data with the objectives of allocating to each Party those physicians in the Co-Promotion Target Audience with the appropriate Detailing frequency to optimize the penetration of such Co-Promoted Product and achieve such Co-Promotion's sales target. Notwithstanding the commercially reasonable efforts of the Parties to effect an objective allocation between them, the Parties recognize that it may be necessary from time to time to reassign individual medical professionals in the Co-Promotion Target Audience as it reasonably determines to be appropriate.

6. <u>Training Program</u>. The Parties shall (a) develop a training program for the promotion of all Products (including, without limitation, all Co-Promoted Products in the Co-Promotion Territory) and (b) train all Representatives of both Parties to be used for the Co-Promotion of Co-Promoted Products in the Co-Promotion Territory as soon as practicable after the approval of the Marketing and Sales Plan by the JDCC. The Parties agree to utilize such training programs on an ongoing basis to assure a consistent, focused promotional strategy and all such training shall be carried out at a time that is mutually acceptable to Enanta and Abbott. No Representative of either Party may Detail a Co-Promotion Product specific training, the internal costs and the out-of-pocket costs of such training programs (including without limitation the out-of-pocket costs of the development, production, printing of such training materials) shall not be included as a Development Cost under this Agreement and shall be treated as a Commercialization Expense.

7. <u>Trademarks</u>. Abbott shall select the Product Trademark under which each Co-Promoted Product shall be marketed. The Parties shall market each Co-Promoted Product in the Co-Promotion Territory exclusively under such Product Trademark (all such trademarks being hereinafter referred to as the "Co-Promotion Trademarks"), and Abbott shall grant Enanta a license to use such Co-Promotion Trademarks solely for such Co-Promotion. Abbott shall register the Co-Promotion Trademarks in the Co-Promotion Territory and shall take all such actions as are required to continue and maintain in full force and effect in the Co-Promotion Territory the Co-Promotion Trademarks and the registrations thereof, and shall be solely

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responsible for all expenses incurred in connection therewith. As between the Parties, Abbott shall be the exclusive owner of the Co-Promotion Trademarks in the Co-Promotion Territory.

8. Product Recalls. In the event that any Regulatory Authority issues or requests a recall or takes similar action in connection with a Co-Promoted Product, or in the event a Party reasonably believes that an event, incident or circumstance has occurred that may result in the need for a recall, market withdrawal or other corrective action regarding a Co-Promoted Product, such Party shall promptly advise the other Party thereof by telephone or facsimile. Following such notification, Abbott shall decide and have control of whether to conduct a recall or market withdrawal (except in the event of a recall or market withdrawal mandated by a Regulatory Authority, in which case it shall be required) or to take other corrective action in any country and the manner in which any such recall, market withdrawal or corrective action shall be conducted, subject to the oversight of the JDCC and provided that Abbott shall keep Enanta regularly informed regarding such recall, market withdrawal or corrective action, the final decision on such matter shall be made by Abbott. In the event that Enanta disagrees with any such decision for reasons related to safety of a Co-Promoted Product, Enanta may elect to terminate its Co-Promotion of such Co-Promoted Product immediately by written notice to Abbott. Abbott shall bear all expenses of any such recall, market withdrawal or corrective action and return of the affected Co-Promoted Product and any refund to customers of amounts paid for such Co-Promoted Product).

#### 9. Co-Promotion Mechanism.

(a) <u>Sales</u>. All sales of Co-Promoted Products in the Co-Promotion Territory shall be booked by Abbott. If, during the term of the Co-Promotion Agreement, Enanta receives orders from customers for a Co-Promoted Product, it shall refer such orders to Abbott.

#### (b) Processing of Orders for Co-Promoted Products.

(i) All orders for Co-Promoted Products received and accepted by Abbott during the term of the Co-Promotion Agreement shall be executed by Abbott in a reasonably timely manner consistent with the general practices applied by it in executing orders for other pharmaceutical products sold by it or its Affiliates.

(ii) Abbott shall have the discretion to reject any order received by it for a Co-Promoted Product; provided, however, that Abbott shall not reject such orders on an arbitrary basis, but only with reasonable justification and consistent with the general policies applied by it with respect to orders for other pharmaceutical products sold by it or its Affiliates.

### (iii) Abbott shall comply with all Applicable Laws in selling any Co-Promoted Product.

10. <u>Termination of Co-Promotion Participation</u>. In addition to its termination right under Section 8, at the end of any Calendar Quarter, Enanta shall have the right, exercisable

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upon three (3) Calendar Quarters prior written notice (the "Co-Promotion Termination Notice Period") to Abbott, to terminate its Co-Promotion of any Co-Promoted Product.

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#### **CALCULATION OF OPERATING INCOME**

"Advertising" means the advertising and promotion of the Co-Developed Products in the Co-Development Territory through any means, including, without limitation, (i) television and radio advertisements; (ii) advertisements appearing in journals, newspapers, magazines or other media; (iii) seminars and conventions; (iv) packaging design; (v) professional education programs; (vi) samples (including related costs for manufacturing, shipping, and use taxes), visual aids and other selling materials; (vii) hospital formulary committee presentations; and (viii) presentations to state and other governmental formulary committees; provided, however, that Advertising shall exclude Detailing and General Public Relations. With regard to advertising and promotion that include products other than Co-Developed Products, the JDCC shall determine the percentage of such advertising and promotion that will be deemed Advertising for the purposes of this Agreement.

"Annual Operating Income" means the Operating Income derived in any Calendar Year.

**"Commercialization Expense"** means the sum of (a) Promotion Expense; (b) Marketing Expense; (c) any reasonable internal and out-of-pocket costs, expenses and fees incurred in prosecuting, maintaining, enforcing and defending the Product Trademark, Licensed Patent Rights, and/or Abbott Patent Rights covering a Co-Developed Product; (d) the cost of preparing and filing Drug Approval Applications with respect to Co-Developed Products; and (e) any other out-of-pocket cost or expense expressly stated to be a Commercialization Expense in this Agreement or under the Marketing and Sales Plan.

"Cost of Goods" will be consistent with Abbott's accounting practices used for its other products and means the fully absorbed manufacturing costs attributable to the manufacture of a Co-Developed Product calculated in accordance with GAAP and consistent with the Marketing and Sales Plan and includes, without limitation, [\*\*\*\*\*].

**"Detail"** means, with respect to a Co-Developed Product, an interactive, live, face-to-face contact of a Representative within the Co-Development Territory with a medical professional with prescribing authority or other individuals or entities that have a significant impact or influence on prescribing decisions, in an effort to increase physician prescribing preferences of such Co-Developed Product for its approved uses within the Co-Development Territory, which shall involve (a) a primary product presentation (i.e. a Detail in which the Co-Developed Product is given an important emphasis) or (b) a secondary product presentation (i.e. a non-primary product presentation; provided, however, the emphasis is not less than that placed upon other products presented), in each case as measured by the relevant Party's internal recording of such activity. When used as a verb, "Detailing" means performing Details.

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**"Distribution Costs"** means all freight and distribution costs incurred in connection with, and directly attributable to, the distribution of a Co-Developed Product to the extent not otherwise included in Commercialization Expense.

"General Public Relations" means any public relations activity (including a press release or image piece) which (i) promotes generally the business of a company or deals in a general manner with the activities of such company in a general pharmaceutical market; and (ii) mentions in an incidental manner the fact that such company or its Affiliates markets or sells one or more of the Co-Developed Products or provides other incidental information concerning one or more of the Co-Developed Products. Announcements related to this Agreement or that concern primarily the relationship of either Party to each other are not General Public Relations and must be agreed upon by both Parties in writing prior to release.

**"Marketing Expense"** means all reasonable out-of-pocket costs and all internal costs on an FTE basis equal to Abbott's then applicable FTE Rate, annually for those individuals fully dedicated to the Product incurred by the Parties that are directly attributable to the following functions for the sale, promotion and marketing of a Co-Developed Product in the Co-Development Territory: (a) market research on such Co-Developed Product, (b) marketing communications, (c) corporate accounts, (d) managed care, (e) sales force training, (f) product hotlines, (g) reimbursement support, (h) contracting, (i) pricing, (j) conducting compassionate use programs and for domestic Phase IV studies for Co-Developed Products (including without limitation fully absorbed manufacturing costs for any Co-Developed Product utilized in such compassionate use programs) and (k) telemarketing services. Marketing Expense shall not include any General Public Relations or any other activities that promote the business of Abbott or Abbott as a whole without specifically referencing any Co-Developed Product.

**"Operating Income"** means, with respect to a Co-Developed Product, Net Sales minus (a) Cost of Goods of such Co-Developed Product; (b) any Commercialization Expense applicable to the Co-Developed Product; (c) Third Party Royalties and (d) Distribution Costs, in each case, incurred in that Calendar Quarter for that Co-Developed Product. For purposes of clarity, "Net Sales" with respect to Co-Developed Products shall not include [\*\*\*\*].

"Net Sales" has the meaning provided in Article 1.

"Personnel Costs" means the reasonable costs of employment of personnel employed by or under contract to a Party including, but not limited to, salaries, benefits (including the costs of cars or allowances therefore), travel, lodging, meals and office and computing supplies.

"Product Trademark" has the meaning provided in Article 1.

**"Promotion Expense"** means all reasonable out-of-pocket costs and expenses incurred by Abbott and directly attributable to the promotion of a Co-Developed Product in the Co-Development Territory to the extent that such costs are not included in Marketing Expense including, but not limited to (i) marketing, Advertising and promoting of Co-Developed Products (including, without limitation, educational expenses, advocate development programs and symposia, sales meetings, direct to consumer/patient advertising, samples, agency fees for the

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development of promotional materials and printing of promotional materials) and (ii) training and communication materials for the Co-Developed Products.

**"Representative"** means an individual (a) employed and trained by Abbott or Enanta or (b) employed by a Third Party or self-employed and trained by or on behalf of Abbott or Enanta, in either case, to Detail a Product.

"Third Party Royalties" means royalty payments made to any Third Party pursuant to an agreement by and between a Party and such Third Party that are necessary to make, use, or sell such Co-Developed Product in the Co-Development Territory.

An example of a calculation of Operating Income is set forth in <u>Exhibit I</u> to this Schedule . In calculating the Operating Income the following principles shall apply:

- 1. There shall be no double counting of any costs or expenses or of any revenues, and to the extent a cost or expense has been included in one category or sub-category, it shall not be included in another; similarly, to the extent any revenue has been taken into account in one category or sub-category it shall not be taken into account in another.
- 2. When allocating costs and expenses under this Agreement, each Party shall utilize the same policies and principles as it utilizes consistently within its group and business units when making internal cost allocations.
- 3. To the extent an item of income or revenue is received by a Party or a cost or expense is incurred by a Party, and is necessary and specifically and directly identifiable, attributable and allocable to the Commercialization of Co-Developed Product and is not otherwise accounted for in the calculation of Operating Income, such Party shall credit such income or revenue and shall be permitted to charge such cost or expense to the Operating Income.
- 4. All costs and expenses shall be determined, and all calculations shall be made, in accordance with GAAP.
- 5. [\*\*\*\*\*].
- 6. To the extent a Co-Developed Product that is sold in the Co-Development Territory contains or comprises a Product and one or more other ingredients that were [\*\*\*\*\*], the Parties shall negotiate in good faith whether an adjustment should be made to the determination of Net Sales for such Co-Developed Product, and the amount of any such adjustment, based upon [\*\*\*\*\*]. In the case where the Parties are unable to agree on whether, or the amount of, such adjustment, the Parties shall submit the matter to arbitration in accordance with Section 14.1.

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# EXAMPLE OF OPERATING INCOME/OPERATING LOSS CALCULATION FOR CO-DEVELOPED PRODUCT

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#### FIRST AMENDMENT TO COLLABORATIVE DEVELOPMENT AND LICENSE AGREEMENT

This First Amendment (this "First Amendment"), made this 27th day of January, 2009 to the Collaborative Development and License Agreement dated November 27, 2006 (the "Agreement"), is entered into by and between Abbott Laboratories, having its principal office at 100 Abbott Park Road, Abbott Park, IL 60064-3500 (together with its affiliates, "Abbott") and Enanta Pharmaceuticals, Inc., with principal offices at 500 Arsenal Street, Watertown, Massachusetts 02472 ("Enanta").

NOW THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the Parties hereto intending to be legally bound hereby agree as follows:

A. Any capitalized terms used and not otherwise defined herein shall have the meanings set forth in the Agreement,

B. In Sections 1.18, 1.72, 2.1.4(h), 3.1, 3.5, 3,6, 4.1.1, 11.3.1(c), and 11.3.2(b) of the Agreement, any occurrence of the words (whether in the singular or the plural) "Compound or Abbott Compound" or "Compound and/or Abbott Compound" (and in the case of Sections 1.67, 1.74, 2.3.1, 4.5.1, 5.1, 5.2, 6.5.1(b), 10.2.1, and 11.3.6(c) the occurrence of the word "Compound") shall be changed to the words "Compound, Abbott Compound, compound covered by Joint Patent Rights or compound covered by Joint Technology." In addition, each occurrence of the word "Compound" in Sections 8.2.2(b), 8.5.1(a), 8.5.2(a), 10.1.6, 11.3.2(e) and 12.2.3 shall be changed to "Compound covered by Joint Technology."

C. Section 1.29(a) of the Agreement is hereby deleted in its entirety, and the following Section 1.29(a) is inserted in lieu of the deleted Section:

"(a) with respect to activities of either Party in the Research Program and/or the conduct by Abbott of evaluation activities pursuant to Section 3.9, the efforts and resources typically used by companies that are similar in size to such Party in the performance of research programs with respect to, and/or the evaluation of, comparable research compounds, and"

D. A new section 3.9 shall be added to the Agreement, as follows:

3.9 **Evaluation Period**. Notwithstanding anything in this Agreement to the contrary, during the period commencing upon the termination or expiration of the Research Program Term (including any extensions thereto) continuing for a period of six (6) months (as so extended, the "Evaluation Period"), Abbott shall have the right to analyze any Compounds, Abbott Compounds, compounds

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covered by Joint Patent Rights or compound covered by Joint Technology that were synthesized prior to the termination or expiration of the Research Program Term (each, an "Evaluation Compound") solely for the purpose of identifying one or more Compounds, Abbott Compounds, compounds covered by Joint Patent Rights or compounds covered by Joint Technology suitable for further Development as Candidates. Either Party may nominate any Evaluation Compound as a Candidate by providing written notice to the JSC pursuant to Section 3.5 and the JSC may select any Evaluation Compound so nominated as a Candidate pursuant to Section 3.6, subject to all applicable provisions of this Agreement (including, but not limited to, applicable provisions in Article 2 and Sections 3.3, 3.4, 3.5, 3.6 and 3.7 and this Section 3.9), which provisions shall survive the termination or expiration of the Research Program Term. During the Evaluation Period, (a) chemistry scale-up of Evaluation Compounds is permitted (including, but not limited to, the use of Enanta Technology and/or Program Technology), but no further medicinal chemistry will be conducted by Abbott under this Agreement; and (b) Section 8.1.1 and Section 8.3.1 shall apply to the evaluation activities conducted pursuant to this Section 3.9. Abbott shall pay Enanta a non-refundable, non-creditable evaluation fee in the amount of [\*\*\*\*\*] by wire transfer of immediately available funds on the date of commencement of the Evaluation Period and fund [\*\*\*\*\*] Enanta FTEs during the Evaluation Period at an annualized rate of [\*\*\*\*\*] per FTE. All amounts due hereunder for FTEs shall be payable on the first day of each calendar quarter occurring during the Evaluation Period. In addition to the foregoing:

(a) As to each patent or patent application of a Joint Patent Right, Abbott and Enanta shall agree to apportion each such patent or patent application into: (i) patent(s) and application(s) claiming only HCV NS3 or HCV NS3/4A protease inhibitor compounds, pharmaceutical compositions containing such compounds, methods for manufacturing such compounds and/or methods of using such compounds in treating HCV infections; and/or (ii) patent(s) and application(s) claiming subject matter not set forth in the foregoing subsection 3.9(a)(i), including, without limitation, formulation technology, compounds other than compounds set forth in subsection 3.9(a)(i), compositions containing compounds other than compounds set forth in subsection 3.9(a)(i), and/or methods of manufacturing compounds other than compounds set forth in subsection 3.9(a)(i). Upon the expiration or termination of the Term (except if the Agreement is terminated pursuant to Section 11.3.3, 11.2.3, or is otherwise terminated for reasons of a Party's bankruptcy or insolvency), Abbott shall be deemed to have assigned, and hereby does assign, to Enanta all of Abbott's right, title and interest solely to patents/patent applications set forth in subsection 3.9(a)(i) above, Patents and patent applications set forth in subsection 3.9(a)(ii) shall be jointly owned upon the expiration or termination of the Term. Upon expiration or termination of the Term (except if the Agreement is terminated for reasons of a Party's bankruptcy or insolvency), Abbott shall be compound and patent applications set forth in subsection 3.9(a)(ii) shall be jointly owned upon the expiration or termination of the Term. Upon expiration or termination of the Term (except if the Agreement is terminated for reasons of a Party's bankruptcy or insolvency), Abbott shall grant Enanta an exclusive (even as to Abbott), perpetual, fully-paid, royalty-free, world-wide license, with the

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right to sublicense, under the patents and patent applications set forth in subsection 3.9(a)(ii) to Develop and Commercialize HCV NS3 or HCV NS3/4A protease inhibitor compounds claimed by such patents and patent applications as set forth in subsection 3.9(a)(i) in the Field. In the event that Abbott commercializes in the Field any HCV protease inhibitors conceived after the Term as a result of utilizing the technology claimed in patents/patent applications set forth in subsection 3.9(a)(ii), Abbott shall pay Enanta a royalty on products containing such HCV protease inhibitors as described in section 6.5.1; and in such event, Enanta shall grant Abbott an exclusive (even as to Enanta), perpetual, world-wide license, with the right to sublicense, under the patents/patent applications set forth in subsection 3.9(a)(ii) to make, use, sell, offer to sell, or have made the aforesaid HCV protease inhibitors. In the event that Abbott and Enanta do not agree in apportioning claims in such patents and patent applications, then such dispute shall be resolved by joint patent counsel selected by the JSC who (and whose firm) is not at the time of the dispute, and was not at any time during the five (5) years prior to the dispute, performing services for either of the Parties. The Parties shall share equally in the expenses of such patent counsel.

(b) During the Evaluation Period, at Abbott's request: (i) Enanta shall render reasonable assistance (including, but not limited to, providing to Abbott available quantities of Compounds, compounds covered by Joint Patent Rights and compounds covered by Joint Technology) to Abbott to facilitate Abbott's activities undertaken pursuant to this Section 3.9; and (ii) the words "Evaluation Period" shall be inserted after the words "Research Term" in each of Sections 8.5.1(a) and 8.5.2(a).

(c) During the Evaluation Period, Abbott shall use Commercially Reasonable Efforts to undertake its activities pursuant to this Section 3.9 and shall comply with the reporting requirements of Section 3.5 of this Agreement.

(d) After expiration of the Evaluation Period and continuing for the remainder of the Term, the Parties may nominate and designate Evaluation Compounds as Candidates under the applicable provisions set forth in this Agreement, including, but not limited to Section 3.6. Upon the termination or expiration of the Term, the Parties' respective rights to nominate and designate Evaluation Compounds under Section 3.9 shall terminate.

#### E. A new section 3.10 shall be added to the Agreement, as follows:

3.10 <u>External Compounds</u>. Either Party (a "Providing Party") may, in its sole discretion, provide the other Party (a "Receiving Party") with access to any proprietary compound Controlled by such Providing Party that is not a Compound, Abbott Compound, compound covered by Joint Patent Rights or compound covered by Joint Technology (each an "External Compound" and collectively, the "External Compounds") solely to enable the Receiving Party to

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conduct research activities involving the combination of such External Compound with a Compound, Abbott Compound, compound covered by Joint Patent Rights or compound covered by Joint Technology ("Combination Activities"). In addition, a Providing Party may, in its sole discretion, conduct Combination Activities itself with an External Compound Controlled by such Providing Party. Prior to conducting any Combination Activities hereunder the Parties shall obtain approval from the other Party. Notwithstanding anything in this Agreement to the contrary: (i) the Providing Party shall retain all right, title and interest in and to any such External Compound; (ii) the Receiving Party shall receive no right, title or interest in or to, nor any express or implied license to use, such External Compound in any way, other than to perform Combination Activities expressly authorized by the Providing Party; (iii) the Providing Party shall have no limitation on its ability, in its sole discretion, to withhold access under this Section 3.10 to any of its External Compounds, or to withdraw the Receiving Party's access to any of its External Compounds at any time for any or no reason immediately upon written notice; (iv) the Providing Party shall have sole and exclusive ownership of all right, title and interest in and to any Technology other than technology covered by Joint Combination Patent Rights (as defined below), that is conceived or first reduced to practice by either Party in the conduct of Combination Activities that relates solely to the External Compound of the Providing Party or its use; (v) the Providing Party and the Receiving Party shall jointly own any patent right that is conceived or first reduced to practice by either Party in the conduct of Combination Activities that relates solely to the use of an External Compound specifically in combination with a Compound, Abbott Compound, compound covered by Joint Patent Rights or compound covered by Joint Technology ("Joint Combination Patent Right"); (vi) no Joint Technology, Joint Patent Rights or Abbott Improvements shall result from any activities conducted by any Party with External Compounds; and (vii) the Providing Party, acting through patent counsel of its choice, shall be solely responsible for the preparation, filing, prosecution and maintenance of Joint Combination Patent Rights; provided, that, for purposes of determining the remaining rights and obligations of the Parties with respect to the filing, prosecution and maintenance of any such patent rights by the Providing Party, such patent rights shall be deemed to be Joint Patent Rights for purposes of this Agreement and shall be governed by Article 10. Subject to Article 8 of this Agreement, the Providing Party shall have no limitation on its ability, in its sole discretion, to conduct or direct any research, development, commercialization or any other activities with respect to any External Compound. In addition to the foregoing:

(a) all data and results (including raw data and reports) produced or generated by either Party in the conduct of Combination Activities will be shared with the other Party as soon as it is available and may be used by both Parties subject to the limitations set forth in this Agreement. In addition, if the Receiving Party or the Providing Party will be conducting Combination Activities with respect to an External Compound, the Providing Party shall provide the Receiving Party with detailed scientific data relating to such External Compound, including

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any preclinical and clinical data, but excluding compound structure with respect to the type of Combination Activities to be conducted at least [\*\*\*\*\*] business days in advance of proposed start date of the Combination Activities; provided, that all such data shall be treated as Confidential Information of the Providing Party. By way of example, it is the understanding of the Parties that the Providing Party will be obligated under this Section 3.9(a) to provide virology data to the Receiving Party only to the extent that the Combination Activities to be conducted by the Receiving Party involve virology activities and to provide toxicology data to the Receiving Party only to the extent that the Combination Activities to be conducted by the Receiving Party involve toxicology activities.

(b) The Providing Party or Receiving Party, as the case may be, shall provide written notice to the other Party at least [\*\*\*\*\*] business days in advance of the proposed start date of any proposed Combination Activities.

#### F. A new section 3.11 shall be added to the Agreement, as follows:

3.11 <u>Confidentiality of Information Concerning External Compounds</u>. For purposes of clarity, subject to Section 1.33, all information provided by a Providing Party to a Receiving Party regarding any External Compound pursuant to Section 3.10, and any information regarding any External Compound ascertained in connection with activities authorized under Section 3.10, shall be Confidential Information of the Providing Party for purposes of this Agreement. Notwithstanding Article 7 of the Agreement, each of Abbott and Enanta agree that during the Term and for an additional [\*\*\*\*\*] years thereafter, they shall not disclose (except only to employees to the extent necessary to enable such employees to perform the activities authorized under Section 3.10 above) or use (except as specifically allowed under Section 3.10 above and Section 7.1.2), any Confidential Information provided by the Providing Party regarding any External Compound, or any Confidential Information regarding any External Compound ascertained in connection with activities authorized under Section 3.10 without, in either case, the prior written authorization of the Providing Party.

#### G. Section 10.1.4 of the Agreement is hereby deleted in its entirety, and the following Section 10.1.4 is inserted in lieu of the deleted Section:

10.1.4 Joint Patent Rights. The JSC shall determine the jurisdictions within the Territory in which patent applications will be filed with respect to Joint Patent Rights as well as the patent counsel that shall represent both Enanta and Abbott for the preparation, filing, prosecution and maintenance of Joint Patent Rights. Each Party will independently select which countries it will financially support with respect to the preparation, filing, prosecution and maintenance of Joint Patent Rights. The Parties shall share (at a rate of [\*\*\*\*\*] of the total costs with respect to each country) in the expenses incurred for the preparation, filing prosecution and maintenance of Joint Patent Rights in each country independently selected by both Parties. The expenses incurred for the preparation, filing,

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prosecution and maintenance of Joint Patent Rights in any country that is selected by one Party but not by the other Party shall be borne solely by the Party selecting that country. For purposes of clarity, (a) neither Party shall be obligated to share in the expenses incurred in the preparation, filing, prosecution and maintenance of any Patent Rights under this Agreement and (b) any decision by a Party not to share in the expenses incurred for the preparation, filing, prosecution and maintenance of Joint Patent Rights in any country shall not affect the rights of such Party with respect to such Joint Patent Rights in such country.

H. Section 11.1 of the Agreement is hereby deleted in its entirety, and the following Section 11.1 is inserted in lieu of the deleted Section:

11.1 **Term**. This Agreement shall commence on the Effective Date and shall continue in full force and effect until the end of the Evaluation Period and, if at the end of the Evaluation Period, Abbott is Developing a Candidate or Commercializing a Product arising out of the Research Program, thereafter until (a) such time as Abbott is no longer Developing a Candidate for use in the Field and in the Territory or (b) if, as of the time Abbott is no longer Developing any Product, until such time as all Royalty Terms for all Products and all Co-Development Terms for all Co-Developed Products have ended, unless earlier terminated in accordance with the provisions of this Article 11 (the "**Term**").

I. Abbott and Enanta agree that this First Amendment shall be annexed to and made part of the Agreement. Any conflicts arising between this First Amendment and the Agreement shall be resolved in favor of the provisions of this First Amendment. Except as herein provided, all of the terms and conditions in the Agreement remain unchanged and are hereby reaffirmed.

J. This First Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, Abbott and Enanta have each caused this First Amendment to be executed by a duly authorized representative as of the day and year first above written.

| ABBOTT LABORATORIES |   | ENANTA PHARMACEUTICALS, INC. |                   |
|---------------------|---|------------------------------|-------------------|
| By:                 | /s/ John M. Leonard                                       | By:                          | /s/ Jay R. Luly   |
| Name:               | /s/ John M. Leonard                                       | Name:                        | Jay R. Luly       |
| Title:              | Senior VP, Global Pharmaceutical Research and Development | Title:                       | President and CEO |

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#### SECOND AMENDMENT TO COLLABORATIVE DEVELOPMENT AND LICENSE AGREEMENT

This Second Amendment (this "Second Amendment"), made this 9th day of December, 2009 ("Second Amendment Effective Date") to the Collaborative Development and License Agreement dated November 27, 2006 (as previously amended, the "Agreement"), is entered into by and between Abbott Laboratories, having its principal office at 100 Abbott Park Road, Abbott Park, IL 60064-3500 (together with its affiliates, "Abbott") and Enanta Pharmaceuticals, Inc., with principal offices at 500 Arsenal Street, Watertown, Massachusetts 02472 ("Enanta").

WHEREAS on November 27, 2006, the parties entered into a Collaborative Development and License Agreement;

WHEREAS on January 27, 2009, the parties amended the November 27, 2006 Collaborative Development and License Agreement in a First Amendment to Collaborative Development and License Agreement;

WHEREAS under the terms of the Agreement, the Research Program Term is set to expire and Abbott and Enanta both desire to extend the Research Program Term;

NOW THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the Parties hereto intending to be legally hound hereby agree as follows:

A. Any capitalized term used and not otherwise defined herein shall have the meaning set forth in the Agreement.

B. Section 1.99 of the Agreement is hereby deleted in its entirety and replaced by the following Section 1.99:

1.99 "Research Program Term" means the period beginning on the Approval Date and, subject to Section 3.8, ending on December 15, 2010.

C. Notwithstanding anything in the Agreement to the contrary, Enanta shall commit to the Research Program at least [\*\*\*\*\*] FTEs during the period beginning on the Second Amendment Effective Date and ending December 15, 2010.

D. The words "if extended as per Section 3.8" shall be deleted from the second sentence of Section 6.3.1 in the Agreement.

E. [\*\*\*\*\*].

F. Abbott and Enanta agree that this Second Amendment shall be annexed to and made part of the Agreement. Any conflicts arising between this Second Amendment and the Agreement shall be resolved in favor of the provisions of this Second Amendment. Except as herein provided, all of the terms and conditions in the Agreement remain unchanged.

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G. This Second Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, Abbott and Enanta have each caused this Second Amendment to be executed by a duly authorized representative as of the day and year first above written.

| ABBOTT LABORATORIES  |   | ENANTA PHARMACEUTICALS, INC. |                        |  |
|--|---|------------------------------|------------------------|--|
| By:  | /s/ John M. Leonard   | By:                          | /s/ Yujiro Hata        |  |
| Name:  | John M. Leonard, M.D.   | Name:                        | Yujiro Hata            |  |
| Title:   | Senior Vice President, Pharmaceuticals Research and Development | Title:                       | Chief Business Officer |  |
| Confidential materials omitted and filed separately with the Securities and Exchange |   |                              |                        |  |

Commission. Asterisks denote such omission.

#### THIRD AMENDMENT TO THE COLLABORATIVE <u>DEVELOPMENT AND LICENSE AGREEMENT</u>

This THIRD AMENDMENT TO THE COLLABORATIVE DEVELOPMENT AND LICENSE AGREEMENT (this "Third Amendment") is entered into as of October 20, 2014, by and between Enanta Pharmaceuticals, Inc., with principal offices at 500 Arsenal Street, Watertown, Massachusetts 02472 ("Enanta") and AbbVie Inc., having a place of business at 1 North Waukegan Road, North Chicago, Illinois 60064 ("AbbVie"). AbbVie and Enanta are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

WHEREAS, Enanta and AbbVie's predecessor, Abbott Laboratories ("Abbott"), entered into the Collaborative Development and License Agreement (the "Original Agreement"), dated November 27, 2006, for the purpose of identifying, developing and commercializing Enanta's proprietary HCV NS3 or NS3/4A protease inhibitors and/or certain of Abbott's proprietary protease inhibitors as more fully described within the Original Agreement;

WHEREAS, Enanta and Abbott entered into a First Amendment to the Original Agreement, dated January 27, 2009, and a Second Amendment to the Original Agreement dated December 9, 2009 (such amendments, together with the Original Agreement, being collectively the "Agreement");

WHEREAS, pursuant to the Agreement, the Parties intend to develop and commercialize Combination Products containing Products and one or more other ingredients that are therapeutically or biologically active and are not themselves Products, as those terms are defined in the Agreement; and

WHEREAS, the Parties wish to define further the terms for the co-development and commercialization of Combination Products created from a Product and for appropriate adjustments to Net Sales to reflect a good faith determination of the relative value of each pharmaceutically active ingredient in a Combination Product.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, and for other good and valuable consideration, the Parties hereto, intending to be legally bound, hereby agree as follows:

A. Any capitalized terms used and not otherwise defined herein shall have the meanings set forth in the Agreement.

B. When used in the Agreement and this Third Amendment, "Abbott" or "Abbott Laboratories" shall mean AbbVie.

C. The following new terms and definitions shall be added to Section 1 (Definitions) of the Agreement:

1.116 "DAA" means any protease inhibitor, NS5A inhibitor, non-nuc polymerase inhibitor, nucleoside or nucleotide polymerase inhibitor, or any other

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direct acting antiviral agent, but for clarity does not include, without limitation, ritonavir, interferon, or ribavirin.

1.117 "<u>Non-DAA</u>" means any active pharmaceutical ingredient other than a DAA. For purposes of clarity, a non-DAA includes, without limitation, ritonavir, interferon, and ribavirin.

1.118 "First Generation Product" means any Combination Product containing or comprising the compound known as ABT-450 (parataprevir), a Product that is an HCV NS3/4 protease inhibitor, and one or more other ingredients that are therapeutically or biologically active and are not themselves Products. For purposes of clarity, the First Generation Product may consist of more than one combination, each containing ABT-450, including, without limitation, the 3D Regimen and the 2D Regimen, each as defined below.

1.119 **"<u>3D Regimen</u>"** means the First Generation Product combination comprising the co-formulation of the compounds ABT-450, ABT-267 (ombitasvir), and ritonavir (the "<u>Co-Formulation</u>"), plus the co-administered compound ABT-333 (dasabuvir) [\*\*\*\*\*].

1.120 "<u>2D Regimen</u>" means the First Generation Product combination comprising the Co-Formulation for use in the treatment of HCV without co-administration of the compound ABT-333 (dasabuvir).

1.121 [\*\*\*\*\*].

1.122 "<u>Second Generation Product</u>" means any Combination Product containing or comprising the compound known as ABT-493, a Product that is an HCV NS3/4A protease inhibitor, and one or more other ingredients that are therapeutically or biologically active and are not themselves Products. For purposes of clarity, a Second Generation Product may consist of more than one combination, each containing ABT-493.

D. Section 1.44 (Enanta Co-Development Percentage) of the Agreement is hereby deleted in its entirety, and the following Section 1.44 is inserted in lieu of the deleted Section:

1.44 "Enanta Co-Development Percentage" means forty percent (40%) for any Co-Developed Product. Notwithstanding the foregoing, for the Second Generation Product, the Parties agree that the Enanta Co-Development Percentage means forty percent (40%) divided by the total number of DAAs comprising the Second Generation Product. If one or more Non-DAAs is added to the Second Generation Product, then the Parties will negotiate in good faith further adjustments to the Enanta Co-Development Percentage for the Second Generation Product based on the relative value of the Non-DAA(s) to the product, using the same formulas as set forth in Section 6.5.1(e)(iii) to the extent applicable.

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E. Section 1.78 (Materially Used) of the Agreement is hereby deleted in its entirety, and the following Section 1.78 is inserted in lieu of the deleted Section:

1.78 <u>"Materially Used</u>" means, with respect to Shared Development Costs, the inclusion in the core efficacy registration package in the NDA of any data, results, and/or information produced in the conduct of a clinical trial.

F. Section 1.96 (Relevant Market Size) of the Agreement is hereby deleted in its entirety, and the following Section 1.96 is inserted in lieu of the deleted Section:

1.96 "U.S. Relative Market Size" means the result obtained by [\*\*\*\*\*].

G. Section 1.103 (Shared Clinical Trial) of the Agreement is hereby deleted in its entirety, and the following Section 1.103 is inserted in lieu of the deleted Section:

1.103 "<u>Global Development Costs</u>" means any Development Costs incurred by a Party (or for its account by an Affiliate or a Third Party) that are intended to support approval both in the Co-Development Territory and outside of the Co-Development Territory, regardless of where those costs are physically incurred. For purposes of clarity, Global Development Costs do not include (a) any filing fees required for, and other costs associated with, any Regulatory Filings for a particular country or (b) clinical studies conducted solely to support approval in a specific country or countries (i.e., U.S. Development Costs or Ex-U.S. Development Costs as defined below).

H. Section 1.104 (Shared Clinical Trial Costs) of the Agreement is hereby deleted in its entirety, and the following Section 1.104 is inserted in lieu of the deleted Section:

1.104 "<u>U.S. Development Costs</u>" means any Development Costs (including, without limitation, any filing fees required for, and other costs associated with, any Regulatory Filings) incurred by a Party (or for its account by an Affiliate or a Third Party) that are solely intended to support approval of the Co-Developed Product within the Co-Development Territory, regardless of where those costs are physically incurred.

I. Section 1.105 (Shared Clinical Trial True-Up Percentage) of the Agreement is hereby deleted in its entirety, and the following Section 1.105 is inserted in lieu of the deleted Section:

1.105 "<u>Sharing Percentage</u>" means [\*\*\*\*\*]. For purposes of clarity, the Sharing Percentage will be [\*\*\*\*\*] and solely for purposes of calculating what portion of Global Development Costs are Shared Development Costs.

J. Section 1.106 (Shared Clinical Trial Data) of the Agreement is hereby deleted in its entirety, and the following Section 1.106 is inserted in lieu of the deleted Section:

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1.106 "Shared Development Costs" for a Co-Developed Product means the sum of (a) the Global Development Costs times the Sharing Percentage [\*\*\*\*\*] and (b) the U.S. Development Costs, in each case only to the extent such costs applicable to the Co-Developed Product were incurred on or after its Co-Development and Profit Share Option Exercise Date. For purposes of clarity, Shared Development Costs will not include any Development Costs incurred by a Party (or for its account by an Affiliate or a Third Party) that are solely intended to support approval of the Co-Developed Product outside the Co-Development Territory, regardless of where those costs are physically incurred ("<u>Ex-U.S. Development Costs</u>").

K. Section 4.1.1 (Development Plans) of the Agreement is hereby deleted in its entirety, and the following Section 4.1.1 is inserted in lieu of the deleted Section:

4.1.1 **Development Plans**. A Development Plan and budget for each Candidate for the balance of the Calendar Year during which the Compound or Abbott Compound is designated by the JSC as a Candidate shall be prepared by Abbott and submitted to the JSC promptly after the designation of such Compound or Abbott Compound as provided in Sections 2.1.4(h) and 3.6. Thereafter, for each Calendar Year during the Development Program, an updated Development Plan and budget for each Candidate shall be prepared by Abbott and submitted to the JSC as provided in Section 2.1.4(a) or (b), as applicable. To the extent JSC approval is required, the Parties shall manage the preparation of each Development Plan and budget in a manner designed to obtain such JSC approval no later than [\*\*\*\*\*] days prior to the end of the then-current Calendar Year. Each Development Plan and amendment thereto shall: (a) set forth (i) the Development objectives, activities, priorities, timelines, budget and resources for the Calendar Year covered by the Development Plan with reasonable specificity, (ii) the Development objectives and activities to be performed for each Calendar Year period covered by the Development Plan with reasonable specificity, broken down by Calendar Quarters, (iii) the Party that shall be responsible for performing such activities, (iv) a timeline for such activities and (v) the expected Development Costs over such Calendar Year, including the U.S. Development Costs and the Global Development Costs; and (b) be consistent with the other terms of this Agreement.

L. Section 5.2 (Effect of Exercise) of the Agreement is hereby deleted in its entirety, and the following Section 5.2 is inserted in lieu of the deleted Section:

5.2 <u>Effect of Exercise</u>. If Enanta exercises the Co-Development and Profit Share Option with respect to a Compound or Candidate, as the case may be, as described in Section 5.1 then: (a) that Compound or Candidate, as the case may be, will thereafter be deemed to be a Co-Developed Product for purposes of this Agreement; (b) the Parties shall prepare and provide to the JSC for its review and approval a Marketing and Sales Plan for such Co-Developed Product within the Co-Development Territory which shall be updated and submitted by the Parties to

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the JSC not less than annually; (c) Abbott shall provide Enanta, as promptly as possible thereafter, with Abbott's revised non-binding, good faith estimate of Development Costs it expects to incur with respect to that Co-Developed Product within the Co-Development Territory for each Calendar Quarter for the next five (5) Calendar Years; (d) except in accordance with Section 5.4, Enanta shall be responsible for the Enanta Co-Development Percentage of all Shared Development Costs applicable to that Co-Developed Product incurred on and after the Co-Development and Profit Share Option Exercise Date; (e) Enanta shall have the right to employ a number of Enanta Representatives to Co-Promote such Co-Developed Product, such number to equal the Enanta Co-Development Percentage of the total sales force the JDCC has reasonably determined is appropriate for the successful commercialization of the Co-Developed Product in the Co-Development Territory; (f) the Parties shall negotiate a Co-Promotion Agreement for such Co-Developed Product in accordance with Section 5.7; and (g) Enanta shall receive the Enanta Co-Development Percentage of all Operating Income derived from that Co-Developed Product in accordance with Section 6.5.2. The Parties hereby acknowledge and agree that either Party shall have the right to propose the addition of other therapeutically or biologically active ingredients for inclusion with a Co-Developed Product to create a Combination Product. Enanta and Abbott will negotiate in good faith on the terms for the development and commercialization of a Combination Product created from a Co-Developed Product that have not been contemplated in this Agreement.

M. Section 5.3.1 (Reconciliation of Development Costs) of the Agreement is hereby deleted in its entirety, and the following Section 5.3.1 is inserted in lieu of the deleted Section:

5.3.1 **Reconciliation of Development Costs.** Within [\*\*\*\*\*] days following the end of each Calendar Quarter following the exercise of the Co-Development and Profit Share Option applicable to a given Co-Developed Product, Abbott shall submit to JSC a written report setting forth in reasonable detail all Shared Development Costs incurred by Abbott over such Calendar Quarter. Within [\*\*\*\*\*] days following the JSC's receipt of such written reports, the JSC shall prepare and submit to Enanta a written report setting forth in reasonable detail the calculation of the net amount owed by Enanta to Abbott in order to ensure the appropriate sharing of the Shared Development Costs in accordance with the Enanta Co-Development Percentage. Enanta shall pay the net amount to Abbott within [\*\*\*\*\*] days after the distribution by the JSC of such written report.

N. Section 5.4 (Allocation of Shared Clinical Trial Costs) of the Agreement is hereby deleted in its entirety, and the following Section 5.4 is inserted in lieu of the deleted Section:

## 5.4 Allocation of Shared Development Costs.

5.4.1 <u>Development Plan Corrections</u>. On and after the date of exercise by Enanta of its Co-Development and Profit Share Option for a Co-Developed

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Product and continuing for the Term of this Agreement [\*\*\*\*\*], whichever date is earlier, Abbott shall provide written notice to Enanta to the extent any Shared Development Cost (a) previously designated as a Global Development Cost is now intended solely to support approval in the Co-Development Territory or solely to support approval outside of the Co-Development Territory; or (b) previously designated as a U.S. Development Cost or an Ex-U.S. Development Cost is now intended to support approval both in the Co-Development Territory and outside of the Co-Development Territory and otherwise qualifies as a Shared Development Cost (the "Development Plan Correction Notice"). Further, [\*\*\*\*\*], Abbott shall provide a Development Plan Correction Notice within [\*\*\*\*\*] days following the filing of the core efficacy registration package for a Co-Developed Product in the Co-Development Territory (1) if any clinical trials (a) intended to support approval both in the Co-Development Territory and outside of the Co-Development Territory or (b) intended to support approval solely in the Co-Development Territory was not Materially Used in that core efficacy registration package, or (2) if any clinical trial intended to support approval solely outside the Co-Development Territory was Materially Used in that core efficacy registration package. Within [\*\*\*\*\*] days after the end of the quarter in which Abbott provides a Development Plan Correction Notice (or as soon as reasonably possible thereafter), Abbott will include in its reconciliation of Shared Development Costs report pursuant to Section 5.3.1 (or in a separate report as soon as reasonably possible thereafter) a statement indicating any amounts owed by Abbott or Enanta necessary to adjust Enanta's contribution to Shared Development Costs to reflect the amount Enanta would have paid had the Development Costs subject to the Development Plan Correction Notice been correctly allocated from the date of exercise by Enanta of its Co-Development and Profit Share Option. For example, for purposes of clarity, if the Development Plan Correction Notice identifies a Development Cost previously designated as a Global Development Cost that should now be designated as an Ex-U.S. Development Cost, then Enanta would receive a credit in the next quarterly cost statement provided pursuant to Section 5.3.1 (or in a separate report as soon as reasonably possible thereafter) in the amount of its prior contribution to those Shared Development Costs and would not share in those costs going forward.

5.4.2 Initial True-Up of Shared Development Costs. Within [\*\*\*\*\*] days after the end of the Calendar Year following the filing of the core efficacy registration package in the NDA for a Co-Developed Product in the Co-Development Territory, a Third Party entity reasonably acceptable to the Parties that performs such market analyses for the biotechnology or pharmaceutical industry will determine the U.S. Relative Market Size. Within [\*\*\*\*\*] days of that determination, Abbott shall submit to JSC a written report setting forth in reasonable detail all Shared Development Costs incurred through the end of the Calendar Year in which the filing of the core efficacy registration package in the NDA for the Co-Development Territory occurred (the "Initial Period") and the amount Enanta has paid in Shared Development Costs for the Initial Period under Section 5.2. Within [\*\*\*\*\*] days following the JSC's receipt of such written

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reports, the JSC shall prepare and submit to each Party a written report setting forth in reasonable detail the calculation of the net amount owed by a Party to the other Party in order to ensure the appropriate sharing of Shared Development Costs [\*\*\*\*\*]. The net amount payable shall be due within [\*\*\*\*\*] days after receipt of any such accounting. [\*\*\*\*\*].

5.4.3 Annual True-Up of Shared Development Costs. Within [\*\*\*\*\*] days of the end of each Calendar Year following the year in which the core efficacy registration package was filed in the Co-Development Territory (the "Subsequent Calendar Year"), to the extent Shared Development Costs are incurred during the Subsequent Calendar Year, a Third Party entity reasonably acceptable to the Parties that performs such market analyses for the biotechnology or pharmaceutical industry will determine whether any changes to the U.S. Relative Market Size are warranted. If any changes are warranted, Abbott shall submit to JSC a written report setting forth in reasonable detail all Shared Development Costs incurred during that Subsequent Calendar Year and the amount Enanta has paid in Shared Development Costs for that Subsequent Calendar Year under Section 5.2. Within [\*\*\*\*\*] days following the JSC's receipt of such written report, the JSC shall prepare and submit to each Party a written report setting forth in reasonable detail the calculation of the net amount owed by a Party to the other Party in order to ensure the appropriate sharing of Shared Development Costs as if the adjusted U.S. Relative Market Size had been the Sharing Percentage during the entire Subsequent Calendar Year. The net amount payable shall be due within [\*\*\*\*\*] days after receipt of any such accounting. The U.S. Relative Market Size so determined for the Annual-True Up for any year would be the U.S. Relative Market Size for the subsequent calendar year, subject to annual true-up as provided above, which process would repeat for as long as Shared Development Costs are incurred.

O. Section 5.5 (Roll-Over Payments) of the Agreement is hereby deleted in its entirety, and the following Section 5.5 is inserted in lieu of the deleted Section:

5.5 Roll-Over Payments. If, in any Calendar Quarter, the actual amount of Shared Development Costs incurred and owed by Enanta with respect to a Co-Developed Product for that Calendar Quarter exceeds by greater than [\*\*\*\*\*] Abbott's good faith estimate of Shared Development Costs for that Co-Developed Product for that Calendar Quarter, Enanta may, upon written notice to Abbott, delay payment of its share of any such excess until the subsequent Calendar Year (the "Roll-Over Payment"). Enanta shall make the Roll-Over Payment in two (2) equal amounts over the first two (2) consecutive Calendar Quarters of the subsequent Calendar Year. For purposes of clarity, this Section does not affect the timing of any true-up payments owed by Enanta pursuant to Section 5.4 above.

P. Section 5.6 ([\*\*\*\*\*]) of the Agreement is hereby deleted in its entirety, and the following Section 5.6 is inserted in lieu of the deleted Section:

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# 5.6 [\*\*\*\*\*].

Q. The following provision shall be inserted at the end of Section 6.4.1 (Milestones) of the Agreement:

(e) <u>Next Generation Products</u>. If Enanta elects to exercise the Co-Development and Profit Share Option with respect to any Next Generation Product (such as the Second Generation Product) [\*\*\*\*\*].

R. Section 6.5.1(e) (Combination Products) of the Agreement is hereby deleted in its entirety, and the following Section 6.5.1(e) is inserted in lieu of the deleted Section:

#### (e) Combination Products.

(i) In calculating royalties owed on the First Generation Product in the form of the 2D Regimen and the 3D Regimen, Net Sales throughout the world shall be adjusted as follows: (A) the total Net Sales of the 3D Regimen shall be multiplied by 0.3, and (B) the total Net Sales of the 2D Regimen shall be multiplied by 0.45. [\*\*\*\*\*]. If the Parties cannot agree on such an adjustment, a Third Party entity that is reasonably acceptable to the Parties and that performs such market estimates of pharmaceutical usage for the biotechnology or pharmaceutical industry shall make such determination, which determination shall be final and binding upon the Parties.

(ii) In calculating royalties owed on the Second Generation Product, Net Sales shall be divided by the total number of DAAs comprising the Second Generation Product. In the event that the Second Generation Product comprises or contains one or more Non-DAAs, then the Parties will negotiate in good faith further adjustments to the Net Sales for the Second Generation Product based on the relative value of the Non-DAA(s) to the product using the same formulas as set forth in Section 6.5.1(e)(iii) to the extent applicable.

(iii) For any Royalty-Bearing Product that is a Combination Product other than a First Generation Product addressed in Section 6.5.1(e)(i) above or a Second Generation Product addressed in Section 6.5.1(e)(ii) above, the Parties shall, on a country-by-country basis, agree to an appropriate adjustment to Net Sales to reflect a good faith determination of the relative value of each pharmaceutically active ingredient, based on the estimated fair market value of each such therapeutically or biologically active ingredient, as follows: (a) In the case of a Combination Product for which the Royalty-Bearing Product and each of the other therapeutically or biologically active ingredients contained in the Combination Product are sold separately in such country by Abbott, Net Sales shall be determined by [\*\*\*\*\*]; (b) In the case of a Combination Product for which the Royalty-Bearing Product is sold separately in such country but the non-Royalty-Bearing Product therapeutically or biologically active ingredients contained in the Combination Product are not sold separately by Abbott in such country, Net Sales shall be calculated by [\*\*\*\*\*]; and (c) If in a country neither

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the Royalty-Bearing Product nor all of the therapeutically or biologically active ingredients contained in the combination product are sold separately in said country by Abbott, Net Sales of the Royalty-Bearing Product forming part of the Combination Product shall be reasonably determined by [\*\*\*\*\*]. In the case where the Parties are unable to agree on [\*\*\*\*\*], the Parties shall agree upon an internationally recognized independent certified public accountant who shall make such determination and whose determination shall be final and binding on the Parties.

S. Section 6.5.1(g) (Payment Dates and Reports) of the Agreement is hereby deleted in its entirety, and the following Section 6.5.1(g) is inserted in lieu of the deleted Section:

(g) Payment Calculation, Dates and Reports. Abbott shall make Royalty Payments within [\*\*\*\*\*] days after the end of each Calendar Quarter commencing with the Calendar Quarter in which the First Commercial Sale of each Royalty-Bearing Product occurs. The Royalty Payment for each Calendar Quarter [\*\*\*\*\*] is to be calculated as the total royalties due Enanta for the Calendar Year through the end of that Calendar Quarter ("Calendar Year To Date") less any Royalty Payments made by Abbott for any prior Calendar Quarter of the same Calendar Year. For example, the Royalty Payment for the Third Quarter will be the total royalties owed for the Calendar Year To Date less Royalty Payments made for the First and Second Calendar Quarters. If the total Royalty Payments for the prior Calendar Quarters of the same Calendar Year exceed the royalties due Enanta for the Calendar Year To Date, then Abbott will receive a credit in following Calendar Quarter, unless no further royalties are owed under the Agreement for any Royalty-Bearing Product, in which case Enanta would pay any outstanding credits owed to Abbott within [\*\*\*\*\*] days of receipt of an invoice therefor. All payments shall be made by wire transfer to the credit of such bank account as shall be designated in writing from time to time by Enanta. Abbott shall also provide, at the same time each such payment is made, a report showing: (i) the Net Sales of each Royalty-Bearing Product by country in the Territory; (ii) an explanation of the methodology Abbott used to calculate Net Sales from gross amounts billed or invoiced (and for clarity not including transaction-level data); (iii) the applicable royalty rates for such Royalty-Bearing Product; (iv) the exchange rates used in calculating any of the foregoing; and (v) a calculation of the amount of royalty due to Enanta. For the First Generation Product, this report shall include [\*\*\*\*\*].

T. Section 6.5.2 (Operating Income) of the Agreement is hereby deleted in its entirety, and the following Section 6.5.2 is inserted in lieu of the deleted Section:

6.5.2 **Operating Income Payments.** Enanta shall receive from Abbott, in lieu of receiving any Royalty Payments with respect to each Co-Developed Product in the Co-Development Territory, the Enanta Co-Development Percentage of all Annual Operating Income derived from sales of that Co-Developed Product in the Co-Development Territory (such payments, the

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"Operating Income Payments") for as long as there are sales by Abbott, its Affiliates and Sublicensees of such Co-Developed Product (the "Co-Development Term"). For purposes of clarity, if Operating Income is negative for any Co-Developed Product in any Calendar Quarter, for example, due to commercialization expenses incurred before sales of the Co-Developed Product, Enanta shall pay its applicable share of the negative Operating Income; [\*\*\*\*\*]. Within thirty (30) days following the end of each Calendar Quarter commencing on and after the date of First Commercial Sale of each Co-Developed Product, (a) Enanta shall submit to the JSC a statement identifying all Commercialization Expenses and License Fees incurred by it with respect to such Co-Developed Product in the Co-Development Territory and (b) Abbott shall submit to the JSC a statement identifying the Net Sales, Cost of Goods, freight, Third Party Payments, R&D and all Commercialization Expenses incurred by it with respect to such Co-Developed Product. Within forty-five (45) days following the end of the Calendar Quarter, the JSC shall submit to the Parties a written report setting forth in reasonable detail (c) the calculation of Operating Income, determined in accordance with Schedule 6 attached hereto and (d) the calculation of the amount of Operating Income payable to Enanta in accordance with the Enanta Co-Development Percentage for that Co-Developed Product taking into account Enanta's expenditures for the period. Abbott shall make the Operating Income Payments to Enanta within thirty (30) days following the issuance of such written report.

U. Enanta hereby waives its Co-Development and Profit Share Option with respect to ABT-493.

V. Enanta and Abbott agree that this Third Amendment shall be annexed to and made part of the Original Agreement. Any conflicts arising between this Third Amendment and the Agreement shall be resolved in favor of the provisions in this Third Amendment, including any terms and/or definitions modified and/or made obsolete by this Third Amendment. Except as herein provided, all of the terms and conditions in the Agreement remain unchanged and are hereby reaffirmed.

W. This Third Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, AbbVie and Enanta have each caused this Third Amendment to be executed by a duly authorized representative as of the day and year first above written.

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| ABBVIE INC.                   | ENANTA PHARMACEUTICALS, INC. |  |  |
|-------------------------------|------------------------------|--|--|
| By: /s/ William J. Chase      | By: /s/ Jay R. Luly          |  |  |
| Name: William J. Chase        | Name: Jay R. Luly            |  |  |
| Executive Vice President, CFO | Title: President and CEO     |  |  |

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\_\_\_\_\_

#### CERTIFICATION

I, Jay R. Luly, Ph.D., certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Enanta Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 9, 2016

/s/ Jay R. Luly, Ph.D.

Jay R. Luly, Ph.D. Chief Executive Officer

#### CERTIFICATION

I, Paul J. Mellett, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Enanta Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 9, 2016

/s/ Paul J. Mellett

Paul J. Mellett Chief Financial Officer

#### ENANTA PHARMACEUTICALS, INC.

#### Certification of Periodic Financial Report Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Each of the undersigned officers of Enanta Pharmaceuticals, Inc. ("Enanta") certifies, to his knowledge and solely for the purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q of Enanta for the three months ended December 31, 2015 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of Enanta.

Dated: February 9, 2016

By: /s/ Jay R. Luly, Ph.D.

Jay R. Luly, Ph.D. Chief Executive Officer

By: /s/ Paul J. Mellett

Paul J. Mellett Chief Financial Officer

Dated: February 9, 2016