

SECURITIES AND EXCHANGE COMMISSION

FORM 10-Q

Quarterly report pursuant to sections 13 or 15(d)

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FILER

**ANADYS PHARMACEUTICALS INC**

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D. C. 20549

FORM 10-Q

(MARK ONE)

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2011

OR

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

FOR THE TRANSITION PERIOD FROM            TO            .

COMMISSION FILE NUMBER: 0-50632

**ANADYS PHARMACEUTICALS, INC.**

*(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)*

Delaware

*(STATE OR OTHER JURISDICTION OF  
INCORPORATION OR ORGANIZATION)*

22-3193172

*(I.R.S. EMPLOYER  
IDENTIFICATION NO.)*

5871 Oberlin Drive, Suite 200

San Diego, California

*(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES)*

92121

*(ZIP CODE)*

Registrant's telephone number, including area code: 858-530-3600

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  No

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 (§ 232.405 of this chapter) 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

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a 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  No

The number of shares of common stock outstanding as of the close of business on October 28, 2011:

<b>Class</b>	<b>Number of Shares Outstanding</b>
Common Stock, \$0.001 par value	57,438,114

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### PART I. FINANCIAL INFORMATION

#### Item 1. Financial Statements

**ANADYS PHARMACEUTICALS, INC.**  
**Condensed Consolidated Balance Sheets**  
**(In thousands, except share and per share amounts)**

	September 30, 2011 <u>(Unaudited)</u>	December 31, 2010 <u>(Note)</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 1,081	\$ 7,617
Securities available-for-sale	18,083	30,367
Prepaid expenses and other current assets	902	1,319
Total current assets	20,066	39,303
Property and equipment, net	107	234
Total assets	<u>\$ 20,173</u>	<u>\$ 39,537</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 6,898	\$ 2,970
Common stock warrant liability	460	1,881
Deferred rent	14	-
Total current liabilities	7,372	4,851
Other long-term liabilities	1	13
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at September 30, 2011 and December 31, 2010; no shares issued and outstanding at September 30, 2011 and December 31, 2010	-	-
Common stock, \$0.001 par value; 90,000,000 shares authorized at September 30, 2011 and December 31, 2010; 57,176,285 and 57,141,223 shares issued and outstanding at September 30, 2011 and December 31, 2010, respectively	57	57
Additional paid-in capital	335,623	334,298
Accumulated other comprehensive gain (loss)	12	(1 )
Accumulated deficit	(322,892 )	(299,681 )
Total stockholders' equity	12,800	34,673
Total liabilities and stockholders' equity	<u>\$ 20,173</u>	<u>\$ 39,537</u>

See accompanying notes to unaudited condensed consolidated financial statements.

Note: The balance sheet at December 31, 2010 has been derived from audited financial statements at that date but does not include all of the disclosures required by U.S. generally accepted accounting principles for complete financial statements.

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**ANADYS PHARMACEUTICALS, INC.**  
**Condensed Consolidated Statements of Operations**  
**(In thousands, except per share amounts)**  
**(Unaudited)**

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2011</u>	<u>2010</u>	<u>2011</u>	<u>2010</u>
<b>Operating Expenses:</b>				
Research and development	\$ 7,991	\$ 2,488	\$ 19,999	\$ 9,273
General and administrative	1,670	1,510	4,739	4,752
Total operating expenses	9,661	3,998	24,738	14,025
<b>Other Income (Expense):</b>				
Interest income and other, net	26	22	106	115
Gain (loss) from valuation of common stock warrant liability	497	(767 )	1,421	(13 )
Total other income (expense), net	523	(745 )	1,527	102
Net loss	<u>\$ (9,138 )</u>	<u>\$ (4,743 )</u>	<u>\$ (23,211 )</u>	<u>\$ (13,923 )</u>
Net loss per share, basic and diluted	<u>\$ (0.16 )</u>	<u>\$ (0.11 )</u>	<u>\$ (0.41 )</u>	<u>\$ (0.35 )</u>
Shares used in calculating net loss per share, basic and diluted	<u>57,176</u>	<u>43,214</u>	<u>57,159</u>	<u>39,970</u>

See accompanying notes to unaudited condensed consolidated financial statements.

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**ANADYS PHARMACEUTICALS, INC.**  
**Condensed Consolidated Cash Flow Statements**  
**(In thousands)**  
**(Unaudited)**

	<u>Nine months ended September 30,</u>	
	<u>2011</u>	<u>2010</u>
<b>Cash Flows from Operating Activities:</b>		
Net loss	\$ (23,211 )	\$ (13,923 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	157	308
Share-based compensation expense	1,290	1,457
(Gain)loss on valuation of common stock warrant liability issued in connection with equity financing	(1,421 )	13
Gain from the sale of property and equipment	-	(6 )
Amortization of discount on securities available-for-sale	357	248
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	417	(295 )
Other assets	-	60
Accounts payable and accrued expenses	3,928	(632 )
Deferred rent	14	-
Other current and long-term liabilities	(12 )	(9 )
Net cash used in operating activities	(18,481 )	(12,779 )
<b>Cash Flows from Investing Activities:</b>		
Purchases of securities available-for-sale	(10,535 )	(17,476 )
Proceeds from the sale and maturity of securities available-for-sale	22,475	16,160
Purchases of property and equipment	(30 )	(7 )
Proceeds from the sale of property and equipment	-	6
Net cash provided by (used in) investing activities	11,910	(1,317 )
<b>Cash Flows from Financing Activities:</b>		
Proceeds from equity financing, net of issuance costs	-	11,373
Proceeds from exercise of stock options and employee stock purchase plan	35	118
Net cash provided by financing activities	35	11,491
Net decrease in cash and cash equivalents	(6,536 )	(2,605 )
Cash and cash equivalents at beginning of period	7,617	4,497
Cash and cash equivalents at end of period	<u>\$ 1,081</u>	<u>\$ 1,892</u>
<b>Supplemental Disclosure of Non-Cash Investing and Financing Activities:</b>		
Unrealized loss on securities available-for-sale	\$ 13	\$ (38 )

See accompanying notes to unaudited condensed consolidated financial statements.

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### ANADYS PHARMACEUTICALS, INC. Notes to Condensed Consolidated Financial Statements (Unaudited)

#### 1. Organization and Basis of Presentation

##### *Organization and Business*

The accompanying unaudited condensed consolidated financial statements of Anadys Pharmaceuticals, Inc. (together with its wholly owned subsidiaries, Anadys Pharmaceuticals Europe GmbH and Anadys Development Limited, the Company) should be read in conjunction with the audited consolidated financial statements and related disclosures included in the Company's 2010 Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) on March 4, 2011. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP) for interim financial information, in accordance with the instructions to Form 10-Q and the guidance in Article 10 of Regulation S-X. Accordingly, since they are interim financial statements, the accompanying unaudited condensed consolidated financial statements do not include all of the information and disclosures required by U.S. GAAP for complete financial statements. The accompanying unaudited condensed consolidated financial statements reflect all adjustments, consisting of normal recurring adjustments, that are, in the opinion of management, necessary for the fair statement of the results of operations for the interim periods presented. Interim results are not necessarily indicative of results to be expected for the year ended December 31, 2011 or for any other period(s).

On October 16, 2011, the Company entered into an Agreement and Plan of Merger (the Merger Agreement) with Hoffmann-La Roche Inc., a New Jersey corporation, Bryce Acquisition Corporation, a Delaware corporation and a wholly owned subsidiary of Hoffman-La Roche, Inc. and, solely for purposes of Section 9.13 therein, Roche Holdings, Inc., a Delaware corporation and the parent of Hoffman-La Roche, Inc. (collectively referred to as Roche), pursuant to which, and on the terms and subject to the conditions thereof, among other things, Roche initiated on October 25, 2011, a cash tender offer to acquire all of the outstanding shares of common stock of the Company, par value \$0.001 per share at a price of \$3.70 per share, net to the selling stockholder in cash, without interest and less any required withholding taxes. Following the completion of the tender offer and subject to the satisfaction or waiver of certain conditions set forth in the Merger Agreement, including, if required, receipt of approval by the stockholders of the Company, Bryce (Roche's acquisition subsidiary) will merge with and into the Company, with the Company surviving as a wholly owned subsidiary of Roche.

##### *Use of Estimates*

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect amounts reported in the financial statements and notes thereto. Actual results could differ materially from those estimates.

##### *Securities Available-for-Sale*

Investments with an original maturity of more than three months when purchased have been classified by management as securities available-for-sale. Such investments are carried at fair value, with unrealized gains and losses included as a component of accumulated other comprehensive gain (loss) in stockholders' equity. Realized gains and losses and declines in value judged to be other-than-temporary (of which there have been none to date) on available-for-sale securities are included in interest income. The cost of securities sold is based on the specific-identification method. The Company views its available-for-sale securities as available for use in current operations. Accordingly, the Company has classified all investments as short-term, even though the stated maturity date may be one year or more beyond the current balance sheet date.

##### *Subsequent Events*

The Company evaluated all events or transactions that occurred after the balance sheet date of September 30, 2011 through the date it issued these financial statements. Subsequent to September 30, 2011 but prior to the issuance of these financial statements, the Company entered into an Agreement and Plan of Merger with Roche. See additional information related to the Merger Agreement at



footnote 7 to these financial statements. No other subsequent events were identified during the Company' s evaluation that require disclosure.

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### 2. Net Loss Per Share

Basic net loss per share was calculated by dividing the net loss for the period by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share was calculated by dividing the net loss for the period by the weighted-average number of common stock equivalents outstanding during the period determined using the treasury-stock method. For purposes of this calculation, options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted earnings per share when their effect is dilutive.

The Company has excluded the following outstanding options and warrants from the calculation of diluted net loss per share because the effect would be anti-dilutive for all periods presented (in thousands):

	As of September 30,	
	2011	2010
Options to purchase common stock	7,761	7,158
Common stock warrants	2,944	2,944
	<u>10,705</u>	<u>10,102</u>

### 3. Comprehensive Loss

Comprehensive loss is comprised of net loss adjusted for changes in market values in securities available-for-sale. Below is a reconciliation of net loss to comprehensive loss for the periods presented (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2011	2010	2011	2010
Net loss	\$ (9,138 )	\$ (4,743 )	\$ (23,211 )	\$ (13,923 )
Unrealized gain (loss) on securities available-for-sale	(2 )	(5 )	13	(38 )
Comprehensive loss	<u>\$ (9,140 )</u>	<u>\$ (4,748 )</u>	<u>\$ (23,198 )</u>	<u>\$ (13,961 )</u>

### 4. Share-Based Compensation

Share-based compensation expense for stock options granted to employees and non-employee directors is estimated at the grant date based on the stock option's fair value as calculated by a Black-Scholes pricing model and the portion that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service period. The Company accounts for compensation expense for options granted to non-employees other than directors based on the fair value of the options issued using the Black-Scholes pricing model and these options are periodically re-measured as the underlying options vest.

A summary of the Company's stock options and related information as of September 30, 2011 is as follows:

	Options Outstanding (in thousands)	Weighted Average Exercise Price	Weighted- Average Remaining Contractual Term in Years	Aggregate Intrinsic Value (in thousands)
Balance at September 30, 2011	<u>7,761</u>	<u>\$ 3.01</u>	<u>6.26</u>	<u>\$ 24</u>
Exercisable at September 30, 2011	<u>5,291</u>	<u>\$ 3.72</u>	<u>5.07</u>	<u>\$ -</u>

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The Company has reported the following amounts of share-based compensation expense in the unaudited condensed consolidated Statements of Operations (in thousands, except per share data):

	Three months ended September 30,		Nine months ended September 30,	
	2011	2010	2011	2010
Research and development expense	\$ 234	\$ 206	\$ 606	\$ 643
General and administrative expense	199	289	684	814
Total share-based compensation expense	<u>\$ 433</u>	<u>\$ 495</u>	<u>\$ 1,290</u>	<u>\$ 1,457</u>
Net share-based compensation expense, per common share basic and diluted	<u>\$ 0.01</u>	<u>\$ 0.01</u>	<u>\$ 0.02</u>	<u>\$ 0.04</u>

As of September 30, 2011, there was an additional \$1.6 million of total unrecognized compensation cost related to unvested stock options granted under the Company's stock option plans. This unrecognized compensation cost is expected to be recognized over a weighted-average period of 2.16 years.

The following assumptions were used to estimate the fair value of stock options granted during the three and nine months ended September 30, 2011 and 2010:

	Three months ended September 30,		Nine months ended September 30,	
	2011	2010	2011	2010
Stock options granted in each period	106,000	50,000	974,205	140,000
<b>Assumptions:</b>				
Dividend yield	0.00 %	0.00 %	0.00 %	0.00 %
Expected volatility	84.70 %	84.56 %	84.70 %	84.56 %
Risk-free interest rate	2.11 %	2.42 %	2.11 %	2.42 %
Expected life of the option term (in years)	6.35	6.09	6.35	6.09

Share-based compensation expense is based on awards ultimately expected to vest, and therefore is reduced by expected forfeitures. The Company estimates forfeitures based upon historical forfeiture rates, and will adjust its estimate of forfeitures in future periods if actual forfeitures differ, or are expected to differ, from such estimates. Changes in forfeiture estimates impact share-based compensation expense in the period in which the change in estimate occurs.

During the three months ended September 30, 2011, no stock options expired. During the nine months ended September 30, 2011, 151,461 stock options expired. There were no stock options that expired during the three and nine month periods ended September 30, 2010.

## 5. Securities Available-for-Sale

Securities available-for-sale consisted of the following as of September 30, 2011 and December 31, 2010 (in thousands):

	September 30, 2011			
	Amortized Cost	Unrealized		Market Value
		Gain	Loss	
Commercial paper	\$300	\$-	\$-	\$300
Municipal bonds	3,986	1	-	3,987
U.S. government sponsored enterprise securities	10,984	10	-	10,994
Corporate debt securities	2,801	2	(1)	2,802
	<u>\$18,071</u>	<u>\$13</u>	<u>\$(1)</u>	<u>\$18,083</u>

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	December 31, 2010			
	Amortized	Unrealized		Market
	Cost	Gain	Loss	Value
Commercial paper	\$10,018	\$-	\$(1)	\$10,017
Municipal bonds	1,654	-	-	1,654
U.S. government sponsored enterprise securities	15,983	7	(5)	15,985
Corporate debt securities	2,713	-	(2)	2,711
	<u>\$30,368</u>	<u>\$7</u>	<u>\$(8)</u>	<u>\$30,367</u>

The amortized cost and estimated fair value of the Company's securities available-for-sale by contractual maturity as of September 30, 2011 and December 31, 2010 are shown below (in thousands):

	September 30, 2011			
	Amortized	Unrealized		Market
	Cost	Gain	Loss	Value
Within one year	\$17,809	\$11	\$(1)	\$17,819
After one year	262	2	-	264
	<u>\$18,071</u>	<u>\$13</u>	<u>\$(1)</u>	<u>\$18,083</u>

	December 31, 2010			
	Amortized	Unrealized		Market
	Cost	Gain	Loss	Value
Within one year	\$23,731	\$ 2	\$(5)	\$23,728
After one year	6,637	5	(3)	6,639
	<u>\$30,368</u>	<u>\$ 7</u>	<u>\$(8)</u>	<u>\$30,367</u>

As of September 30, 2011, the Company performed a review of all of the securities in its portfolio with an unrealized loss position to determine if any other-than-temporary impairments were required to be recorded. Factors considered in the Company's assessment included but were not limited to the following: the Company's ability and intent to hold the security until maturity, the number of months until the security's maturity, the number of quarters that each security was in an unrealized loss position, ratings assigned to each security by independent rating agencies, the magnitude of the unrealized loss compared to the face value of the security and other market conditions. No other-than-temporary impairments were identified as of September 30, 2011 related to securities currently in the Company's portfolio. The Company also noted that none of the securities as of September 30, 2011 had been in an unrealized loss position for greater than one year.

### 6. Fair Value Disclosures

As of September 30, 2011, the Company had \$19.2 million of cash equivalents and marketable securities consisting of money market funds, commercial paper, municipal bonds, U.S. government sponsored enterprise securities and corporate debt securities with maturities that range from one day to 18.3 months with an overall average time to maturity of 4.5 months. The Company has the ability to liquidate these investments without restriction or penalty. The Company determines fair value for marketable securities with Level 1 inputs through quoted market prices. The Company determines fair value for marketable securities with Level 2 inputs through broker or dealer quotations or alternative pricing sources with reasonable levels of price transparency. The Company's Level 2 marketable securities have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, typically utilizing third party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market based approaches and observable market inputs to determine value. These observable market inputs include reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, and other industry and economic events.

The Company's Level 3 inputs are unobservable inputs based on the Company's assessment of what market participants would use in pricing the instruments.

On June 3, 2009, the Company sold warrants to purchase 2.9 million shares of common stock to institutional investors as part of an equity financing. The Company accounts for the common stock warrants which may potentially be settled with cash as a liability. The Company determines fair value for the common stock warrants with Level 3 inputs through a Black-Scholes pricing model.

There have been no transfers of assets or liabilities between the fair value measurement classifications.

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The following table presents the Company's assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2011 (in thousands):

Description	September 30, 2011	Fair Value Measurements at Reporting Date Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds	\$ 857	\$ 857	\$ –	\$ –
Commercial paper	300	–	300	–
Municipal bonds	3,987	–	3,987	–
U.S. government sponsored enterprise securities	10,994	–	10,994	–
Corporate debt securities	2,802	–	2,802	–
<b>Total financial assets</b>	<b>\$ 18,940</b>	<b>\$ 857</b>	<b>\$ 18,083</b>	<b>\$ –</b>
Liabilities:				
Common stock warrants	\$ 460	\$ –	\$ –	\$ 460
<b>Total financial liabilities</b>	<b>\$ 460</b>	<b>\$ –</b>	<b>\$ –</b>	<b>\$ 460</b>

The Company reassesses the fair value of the common stock warrants at each reporting date utilizing a Black-Scholes pricing model. The following inputs were utilized in the Black-Scholes pricing model at September 30, 2011 and 2010:

	September 30,	
	2011	2010
Risk-free interest rate	0.43 %	0.96 %
Dividend yield	0.00 %	0.00 %
Expected volatility	79.43%	91.76%
Weighted-average expected life of warrant (in years)	2.7	3.7

As a result of the Company's reassessment of the fair value of the common stock warrants, the Company recorded a gain of \$0.5 million and a loss of \$0.8 million for the three months ended September 30, 2011 and 2010, respectively. As a result of the Company's reassessment of the fair value of the common stock warrants, the Company recorded a gain of \$1.4 million and a loss of \$0.01 million for the nine months ended September 30, 2011 and 2010, respectively. The gain (loss) is reflected in the Company's unaudited condensed consolidated statement of operations as a component of other income (expense), net.

The following table is a roll forward of the fair value of the common stock warrants, as to which fair value is determined by Level 3 inputs (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2011	2010	2011	2010
Beginning balance	\$ 957	\$ 3,143	\$ 1,881	\$ 3,897
Purchases, issuances, and settlements	–	–	–	–
Realized gain (loss) included in net loss	497	(767)	1,421	(13)

Ending balance	<u>\$ 460</u>	<u>\$ 3,910</u>	<u>\$ 460</u>	<u>\$ 3,910</u>
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## 7. Subsequent Events

On October 16, 2011, the Company entered into a Merger Agreement with Roche, pursuant to which, and on the terms and subject to the conditions thereof, among other things, Roche agreed to commence a cash tender offer (the Offer), which was initiated on October 25, 2011, to acquire all of the outstanding shares of common stock of the Company, par value \$0.001 per share (the Shares) at a price of \$3.70 per share (the Offer Price), net to the selling stockholder in cash, without interest and less any required withholding taxes. Following the completion of the tender offer and subject to the satisfaction or waiver of certain conditions set forth in the Merger Agreement, including, if required, receipt of approval by the stockholders of the Company, the Company will be a wholly owned subsidiary of Roche. If and when the Merger is effected, the shares not purchased pursuant to the Offer (other than shares held by the Company, Roche, any subsidiary of Roche or by stockholders of the Company who have perfected their statutory rights of appraisal under Delaware law) will be converted into the right to receive an amount in cash equal to the Offer Price, without interest, and less any required withholding taxes. In addition, each unexpired and unexercised option to purchase Shares then in effect, whether vested or unvested, will be cancelled, terminated and extinguished in exchange for the right to receive the excess, if any, of the Offer Price over the exercise price of such Option immediately prior to the effective time of the Merger.

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Roche' s obligation to accept for payment and pay for Shares tendered in the Offer is subject to certain conditions, including, among other things, (i) that the number of Shares validly tendered pursuant to the Offer (and not properly withdrawn prior to any then scheduled expiration date of the Offer), together with Shares then beneficially owned by Roche, represents at least a majority of (a) all Shares then outstanding plus (b) all Shares issuable upon the exercise, conversion or exchange of any options, warrants or other rights to acquire Shares then outstanding (other than options, warrants or other rights that have a per share exercise price that is equal to or greater than the Offer Price) regardless of whether or not then vested, (ii) the expiration or termination of any applicable waiting period under any applicable antitrust law, including the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and (iii) that the other conditions set forth in Annex I to the Merger Agreement have been satisfied or waived.



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### **Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

This discussion and analysis should be read in conjunction with our unaudited condensed consolidated financial statements and notes included in this Quarterly Report on Form 10-Q (this Quarterly Report) and the audited consolidated financial statements and notes as of and for the year ended December 31, 2010 included with the our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) on March 4, 2011. Operating results are not necessarily indicative of results that may occur in future periods.

This Quarterly Report contains forward-looking statements. These forward-looking statements involve a number of risks and uncertainties. Such forward-looking statements include statements about our strategies, objectives, discoveries, clinical trials, development programs, financial forecasts and other statements that are not historical facts, including statements which may be preceded by the words "intend," "will," "plan," "expect," "anticipate," "estimate," "aim," "seek," "believe," "hope" or similar words. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Readers of this Quarterly Report are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date on which they are made. We undertake no obligation to update publicly or revise any forward-looking statements. Actual events or results may differ materially from our expectations. Important factors that could cause actual results to differ materially from those stated or implied by our forward-looking statements include, but are not limited to, the risk factors identified in our SEC reports, including this Quarterly Report.

#### **Overview**

##### *Background*

Anadys Pharmaceuticals, Inc. is a biopharmaceutical company dedicated to improving patient care by developing novel medicines for the treatment of hepatitis C. We believe hepatitis C represents a large unmet medical need in which meaningful improvements in treatment outcomes may be attainable with the introduction of new medicines. We are currently focusing most of our efforts on the development of setrobuvir, a direct-acting antiviral (DAA) for the treatment of hepatitis C. We are currently conducting a Phase IIb study of setrobuvir in combination with pegylated interferon alfa and ribavirin for the treatment of hepatitis C. We believe that this study, which is being conducted in patients infected with hepatitis C virus (HCV), should form a basis for future testing of setrobuvir in combination with other DAAs.

##### *Agreement and Plan of Merger*

On October 16, 2011, the Company entered into an Agreement and Plan of Merger (the Merger Agreement) with Hoffmann-La Roche Inc., a New Jersey corporation, Bryce Acquisition Corporation, a Delaware corporation and a wholly owned subsidiary of Hoffman-La Roche, Inc. and, solely for purposes of Section 9.13 therein, Roche Holdings, Inc., a Delaware corporation and the parent of Hoffman-La Roche, Inc. (collectively referred to as Roche), pursuant to which, and on the terms and subject to the conditions thereof, among other things, Roche agreed to commence a cash tender offer (the Offer), which was initiated on October 25, 2011, to acquire all of the outstanding shares of common stock of Anadys, par value \$0.001 per share (the Shares) at a price of \$3.70 per share (the Offer Price), net to the selling stockholder in cash, without interest and less any required withholding taxes. Following the completion of the tender offer and subject to the satisfaction or waiver of certain conditions set forth in the Merger Agreement, including, if required, receipt of approval by the stockholders of the Company, the Company will be a wholly owned subsidiary of Roche. At the effective time of the Merger (the Effective Time), the Shares not purchased pursuant to the Offer (other than shares held by Anadys, Roche or any subsidiary of Roche or by stockholders of Anadys who have perfected their statutory rights of appraisal under Delaware law) will be converted into the right to receive an amount in cash equal to the Offer Price, without interest, and less any required withholding taxes. In addition, each unexpired and unexercised option to purchase Shares then in effect (such options, the Options), whether vested or unvested, will be cancelled, terminated and extinguished in exchange for the right to receive the excess, if any, of the Offer Price over the exercise price of such Option immediately prior to the Effective Time.

Roche's obligation to accept for payment and pay for Shares tendered in the Offer is subject to certain conditions, including, among other things, (i) that the number of Shares validly tendered pursuant to the Offer (and not properly withdrawn prior to any then scheduled expiration date of the Offer), together with Shares then beneficially owned by Roche (if any), represents at least a majority of

(a) all Shares then outstanding plus (b) all Shares issuable upon the exercise, conversion or exchange of any options, warrants or other rights to acquire Shares then outstanding (other than options, warrants or other rights that have a per share exercise price that is equal to or greater than the Offer Price) regardless of whether or not then vested, (ii) the expiration or termination of any applicable waiting period under any applicable antitrust law, including the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and (iii) that the other conditions set forth in Annex I to the Merger Agreement have been satisfied or waived.

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### *Development Program Update Setrobuvir*

On October 13, 2011, we announced the following preliminary data from our on-going Phase IIb study with setrobuvir in combination with pegylated interferon alfa and ribavirin (P/R). 78% of treatment-naïve patients and 76% of patients who had responded inadequately to, or relapsed after, prior treatment with P/R had undetectable virus at week 12 (cEVR) while receiving setrobuvir plus P/R, compared to 56% and 44%, respectively, for patients who received placebo plus P/R. 71% of treatment-naïve patients who received setrobuvir plus P/R had undetectable virus at week 8 and met the initial response-guided criteria for shortening treatment in this study to 28 weeks from the traditional 48 weeks for treatment with P/R alone. 29% of patients who had no appreciable response to prior treatment with P/R (null responders) achieved cEVR with setrobuvir plus P/R, and the percentage of patients with undetectable virus continued to climb in this hard-to-treat population to 36% at week 18. No prior null responders received placebo plus P/R in this trial. The viral breakthrough rate through 12 weeks on setrobuvir plus P/R was low in both treatment naïve patients (2.9%) and patients who had responded inadequately to, or relapsed after, prior treatment with P/R (3.6%). Setrobuvir has been generally well-tolerated in the study. The profile of adverse events has been similar between the setrobuvir and control groups, with reported adverse events being typical for patients treated with interferon and ribavirin.

### *Development Program Update ANA773*

As we previously announced, we have plans to conduct a 28 day combination study of ANA773, an oral, small-molecule inducer of endogenous interferons that acts via the Toll-like receptor 7 pathway, with ribavirin. In light of our proposed merger with Roche, we have decided to postpone initiation of this clinical study.

### *Future Operations*

We have incurred significant operating losses since our inception and, as of September 30, 2011, our accumulated deficit was \$322.9 million. In the event that we do not complete the Merger with Roche, we expect to incur substantial losses for at least the next several years as we:

- continue the development of setrobuvir for the treatment of HCV;
- optimize methods for and scale-up manufacturing of setrobuvir for clinical trials and potential commercialization;
- explore the potential to further develop ANA773 for the treatment of HCV;
- commercialize any product candidates that receive regulatory approval; and
- potentially in-license technology and acquire or invest in businesses, products or technologies that are synergistic with our own.

## **Critical Accounting Policies**

Our discussion and analysis of our financial condition and results of operations are based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and related disclosure of contingent assets and liabilities. We review our estimates on an on-going basis and make adjustments to the financials statements as considered necessary. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ materially from these estimates under different assumptions or conditions.

*Drug Development Costs.* Drug development costs include costs associated with the development of our product candidates including the manufacturing of clinical trial material, payments to clinical trial investigators, payments to clinical research organizations and certain non-clinical activities. We review and accrue drug development costs based on work performed. We estimate work performed utilizing factors such as subject enrollment, estimated timeline for completion of studies and other factors. These costs and estimates vary based on the type, scope and length of non-clinical and clinical studies as well as other factors. Drug development cost

accruals are subject to revisions as studies, projects and trials progress to completion. Expense is adjusted for revisions in the period in which the facts that give rise to the revision become known.

*Common Stock Warrant Liability.* We account for common stock warrants which may potentially be settled with cash as a liability. The common stock warrants have been recorded at their fair value at issuance and will continue to be recorded at fair value each subsequent balance sheet date until such time that they are exercised or are otherwise modified to remove the provisions that

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require this treatment, at which time the warrants will be adjusted to fair value and reclassified from liabilities to stockholders' equity. Any change in value between reporting periods will be recorded as other income (expense), net at each reporting date. The fair value of the warrants is estimated using the Black-Scholes pricing model.

*Share-Based Compensation.* Share-based compensation cost is estimated at the grant date based on the award's fair-value as calculated by a Black-Scholes pricing model and the portion that is expected to vest is recognized as expense evenly over the requisite service period. The determination of the fair value of share-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, our expected stock price volatility over the term of the awards, the risk-free interest rate, the expected term of the awards and expected forfeitures. If any of the assumptions used in the model change significantly, share-based compensation expense may differ materially in the future from that recorded in the current period.

### **New Accounting Pronouncements**

In June 2011, the Financial Accounting Standards Board issued Accounting Standards Update (ASU) No. 2011-05, "Comprehensive Income (Topic 220)" (ASU 2011-05). This accounting standard (1) eliminates the option to present the components of other comprehensive income (loss) as part of the statement of changes in stockholders' equity; (2) requires the consecutive presentation of the statement of net income (loss) and other comprehensive income (loss); and (3) requires an entity to present reclassification adjustments on the face of the financial statements from other comprehensive income (loss) to net income (loss). The amendments in this ASU do not change the items that must be reported in other comprehensive income (loss) or when an item of other comprehensive income (loss) must be reclassified to net income (loss) nor do the amendments affect how earnings (loss) per share is calculated or presented. This ASU is required to be applied retrospectively and is effective for fiscal years and interim periods within those years beginning after December 15, 2011. As this accounting standard only requires enhanced disclosure, the adoption of this standard will not impact our financial position or results of operations.

### **Results of Operations**

#### **Three Months Ended September 30, 2011 and 2010**

*Research and Development Expenses.* Research and development expenses were \$8.0 million for the three months ended September 30, 2011 compared to \$2.5 million for the three months ended September 30, 2010. The \$5.5 million increase was primarily attributable to a \$5.0 million increase in setrobuvir development costs and a \$0.6 million increase in ANA773 development costs. During the three months ended September 30, 2011, our development costs associated with setrobuvir were primarily associated with our ongoing Phase IIb combination study, which began in the first quarter of 2011, and to a lesser extent, our now completed Phase IIa combination study. During the three months ended September 30, 2010, development costs for setrobuvir were primarily associated with our now completed Phase IIa combination study. Our ANA773 development costs during the three months ended September 30, 2011 were comprised primarily of clinical trial setup and clinical trial material manufacturing costs associated with our planned Phase IIa combination study. In light of our proposed merger with Roche, we have decided to postpone initiation of this study. Our infrastructure, support personnel and other costs have decreased \$0.1 million primarily due to lower depreciation expense. Our non-cash share-based compensation expense associated with share-based payments granted to our research and development employees was \$0.2 million for each of the three months ended September 30, 2011 and 2010.

The following summarizes our research and development expenses for the three months ended September 30, 2011 and 2010. Facility costs, depreciation and amortization, research and development support personnel and other indirect personnel related costs are included as a component of infrastructure and support personnel.

	<b>Three months ended September 30,</b>	
	<b>2011</b>	<b>2010</b>
	<b>(In thousands)</b>	
Setrobuvir	\$ 6,586	\$ 1,630
ANA773	684	72

Infrastructure, support personnel and other	487	580
Non-cash employee and non-employee share-based compensation	<u>234</u>	<u>206</u>
Total research and development expense	<u>\$ 7,991</u>	<u>\$ 2,488</u>

*General and Administrative Expenses.* General and administrative expenses were \$1.7 million for the three months ended September 30, 2011 compared to \$1.5 million for the three months ended September 30, 2010. This increase can be primarily attributed to higher legal costs incurred in connection with the Company' s pending merger. Non-cash share-based compensation expense associated with share-based payments granted to our general and administrative employees and non-employee directors was \$0.2 million for each of the three months ended September 30, 2011 and 2010.

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*Interest Income and Other, net.* Interest income and other, net was \$0.02 million for each of the three months ended September 30, 2011 and 2010.

*Gain (Loss) from Valuation of Common Stock Warrant.* Non-operating income associated with the decrease in our common stock warrant liability was \$0.5 million for the three months ended September 30, 2011. The decrease in the fair value of our common stock warrant liability from June 30, 2011 to September 30, 2011 was primarily the result of a decrease in our stock price over the same period of time. During the three months ended September 30, 2010, the non-operating expense associated with the increase in our common stock warrant liability was \$0.8 million. The increase in the fair value of our common stock warrant liability from June 30, 2010 to September 30, 2010 was primarily the result of an increase in our stock price over the same period of time.

Fair values were calculated using the Black-Scholes pricing model and are remeasured at each reporting period. Potential future increases in our stock price will result in losses being recognized in our statement of operations in future periods. Conversely, potential future declines in our stock price will result in gains being recognized in our statement of operations in future periods.

### **Nine Months Ended September 30, 2011 and 2010**

*Research and Development Expenses.* Research and development expenses were \$20.0 million for the nine months ended September 30, 2011 compared to \$9.3 million for the nine months ended September 30, 2010. The \$10.7 million increase was attributable to a \$9.6 million increase in setrobuvir development costs and a \$1.5 million increase in ANA773 development costs. During the nine months ended September 30, 2011, our development costs associated with setrobuvir were primarily associated with our ongoing Phase IIb combination study, and our ANA773 development costs were comprised primarily of clinical trial setup and clinical trial material manufacturing costs associated with our upcoming Phase IIa combination study, for which initiation has been postponed in light of our proposed merger with Roche. During the nine months ended September 30, 2010, our development costs associated with setrobuvir were primarily associated with our Phase IIa combination study, and our development costs associated with ANA773 were primarily related to wrap-up activities associated with our Phase I oncology trial. Infrastructure, support personnel and other expense decreased \$0.3 million due to lower depreciation expense and decreased facility costs under our building lease, the terms of which were modified upon renewal in the first quarter of 2011. Our non-cash share-based compensation expense associated with share-based payments granted to our research and development employees was \$0.6 million for each of the nine months ended September 30, 2011 and 2010.

The following summarizes our research and development expenses for the nine months ended September 30, 2011 and 2010. Facility costs, depreciation and amortization, research and development support personnel and other indirect personnel related costs are included as a component of infrastructure and support personnel.

	<b>Nine months ended September 30,</b>	
	<b>2011</b>	<b>2010</b>
	<b>(In thousands)</b>	
Setrobuvir	16,118	6,567
ANA773	1,758	215
Infrastructure, support personnel and other	1,517	1,848
Non-cash employee and non-employee share-based compensation	606	643
<b>Total research and development expense</b>	<b>\$ 19,999</b>	<b>\$ 9,273</b>

*General and Administrative Expenses.* General and administrative expenses were \$4.7 million for each of the nine months ended September 30, 2011 and 2010. Non-cash share-based compensation expense associated with share-based payments granted to our general and administrative employees and non-employee directors was \$0.7 million and \$0.8 million for the nine months ended September 30, 2011 and 2010, respectively.

*Interest Income and Other, net.* Interest income and other, net was \$0.1 million for each of the nine months ended September 30, 2011 and 2010.

*Gain (Loss) from Valuation of Common Stock Warrant.* Non-operating income associated with the decrease in our common stock warrant liability was \$1.4 million for the nine months ended September 30, 2011. The decrease in the fair value of our common stock warrant liability from December 31, 2010 to September 30, 2011 was primarily the result of a decrease in our stock price over the same period of time. There was no significant change in the fair value of our common stock warrant liability during the nine months ended September 30, 2010.



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Fair values were calculated using the Black-Scholes pricing model and are remeasured at each reporting period. Potential future increases in our stock price will result in losses being recognized in our statement of operations in future periods. Conversely, potential future declines in our stock price will result in gains being recognized in our statement of operations in future periods.

### **Liquidity and Capital Resources**

#### *Overview*

Our September 30, 2011 cash, cash equivalents and securities available-for-sale balance was \$19.2 million. Our cash, cash equivalents and securities available-for sale decreased by \$18.8 million from December 31, 2010 to September 30, 2011. This decrease in cash, cash equivalents and securities available-for-sale is the result of our year-to-date cash utilization to fund operations, including external expenditures associated with our on-going Phase II combination studies of setrobuvir.

As of September 30, 2011, we do not have sufficient cash, cash equivalents and securities available-for-sale to meet our working capital requirements for the next twelve months. In the event we are unable to complete the proposed merger with Roche, we have identified certain cash saving measures that, if implemented, would not be expected to impair our on-going conduct of the Phase IIb study of setrobuvir and would allow us to meet our working capital requirements with our existing cash, cash equivalents and securities available-for-sale through June 30, 2012.

#### *Agreement and Plan of Merger*

On October 16, 2011, we entered into an Agreement and Plan of Merger with Roche, pursuant to which, and on the terms and subject to the conditions thereof, among other things, Roche commenced a cash tender offer on October 25, 2011 to acquire all of the outstanding shares of common stock of Anadys, par value \$0.001 per share at a price of \$3.70 per share, net to the selling stockholder in cash, without interest and less any required withholding taxes. Following the completion of the tender offer and subject to the satisfaction or waiver of certain conditions set forth in the Merger Agreement, including, if required, receipt of approval by the stockholders of the Company, the Company will be a wholly owned subsidiary of Roche.

#### *Future Cash Requirements*

Over time we expect our development expenses to be substantial and to increase as we continue the advancement of our development programs. The lengthy process of completing clinical trials and seeking regulatory approval for our product candidates requires the expenditure of substantial resources. Any failure by us or delay in completing clinical trials or in obtaining regulatory approvals could cause our research and development expenses to increase and, in turn, have a material adverse effect on our results of operations.

Assuming our merger with Roche is not completed, cash to fund our future operations will most likely have to be obtained from one of the following sources: sale of equity securities, a new strategic collaboration agreement, a debt financing or a project financing. We may not be successful in obtaining a strategic alliance or other agreements, or in receiving milestone or royalty payments under those agreements. In addition, we cannot be sure that we will be able to complete an equity or debt financing when needed or that, if available, such financing will be obtained on terms favorable to us or our stockholders. If we raise additional funds through a debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

Our future capital uses and requirements depend on numerous forward-looking factors. These factors may include but are not limited to the following:

- the progress of our clinical trials;
- the progress of our nonclinical development activities;
- our ability to establish and maintain strategic alliances;
- the costs involved in enforcing or defending patent claims and other intellectual property rights;

the costs and timing of regulatory approvals;

the costs of establishing or expanding manufacturing, sales and distribution capabilities;

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the costs related to development and manufacture of non-clinical, clinical and validation lots for regulatory and commercialization of drug supply;

the success of the commercialization of setrobuvir, ANA773 or any other product candidates we may develop; and

the extent to which we acquire or invest in other products, technologies and businesses.

### *Investment Portfolio*

As of September 30, 2011, we had \$18.9 million of marketable securities consisting of money market funds, commercial paper, municipal bonds, U.S. government sponsored enterprise securities and corporate debt securities with maturities that range from one day to 18.3 months with an overall average time to maturity of 4.5 months. We have the ability to liquidate these marketable securities without restriction or penalty. As of September 30, 2011, we did not own any marketable securities which were classified as asset-backed securities or auction rate securities.

### *Fair Value Inputs*

Fair value is a market-based measurement that is determined based on assumptions that market participants would use in pricing an asset. We value our marketable securities by using quoted market prices, broker or dealer quotations or alternative pricing sources with reasonable levels of price transparency. The types of securities valued based on quoted market prices in active markets include money market funds. We do not adjust the quoted price for such securities. The types of instruments valued based on quoted prices in markets that are not active, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency include U.S. government sponsored enterprise securities, municipal bonds, commercial paper and corporate debt securities. The price for each security at the measurement date is sourced from an independent pricing vendor. Periodically, management assesses the reasonableness of these sourced prices by comparing them to the prices provided by our portfolio managers to derive the fair value of these financial instruments. Historically, we have not experienced significant deviation between the prices from the independent pricing vendor and our portfolio managers. Management assesses the inputs of the pricing in order to categorize the financial instruments into the appropriate hierarchy levels. The fair value of the common stock warrants, which may potentially be settled with cash and are therefore treated as a liability, is estimated using the Black-Scholes pricing model.

### *Off-Balance Sheet Arrangements*

As of September 30, 2011 and 2010, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships. We do not have relationships or transactions with persons or entities that derive benefits from their non-independent relationship with us or our related parties.

## **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are in short-term marketable securities. Due to the nature of our short-term investments, we believe that we are not subject to any material market risk exposure. We do not hold any foreign currency or other derivative financial instruments.

## **Item 4. Controls and Procedures**

Our President and Chief Executive Officer and our Vice President, Finance and Operations performed an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 (the Exchange Act)) as of the end of the period covered by this Quarterly Report. Based on that evaluation, our President and Chief Executive Officer and our Vice President, Finance and Operations concluded that as of the date of such evaluation, our disclosure

controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in our periodic reports under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our President and Chief Executive Officer and our Vice President, Finance and Operations, as appropriate, to allow timely decisions regarding required disclosure. It should be noted that the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and can therefore only provide reasonable, not absolute, assurance that the design will succeed in achieving its stated goals.

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There were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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### **PART II. OTHER INFORMATION**

#### **Item 1. Legal Proceedings**

Between October 20 and October 25, 2011, three putative class action lawsuits (entitled (1) *Hammad v. Anadys Pharmaceuticals, Inc.*, Case No. 37-2011-00099789-CU-BT-CTL, (2) *Maestro v. Anadys Pharmaceuticals, Inc.*, Case No. 37-2011-00099895-CU-BT-CTL, and (3) *Shabtai v. Anadys Pharmaceuticals, Inc.*, Case No. 37-2011-00099995-CU-BT-CTL) were filed in San Diego Superior Court against the Company, members of the Anadys board of directors, Hoffmann-La Roche, Inc. (“Roche”), Bryce Acquisition Corporation (“Bryce”), and Roche Holdings, Inc. (“RHI”), arising out of the proposed acquisition of Anadys by Roche (“Proposed Transaction”). These lawsuits generally allege that the Anadys board of directors breached their fiduciary duties of care, loyalty, good faith, and independence to Anadys’ stockholders by entering into the merger agreement because the directors, among other things, (i) failed to maximize stockholder value; (ii) used a process that was unfair and inadequate and tailored to better their own interests at the expense of Anadys’ stockholders; (iii) failed to properly value Anadys; (iv) and agreed to preclusive deal-protection terms. The lawsuits also allege that Anadys, Roche, Bryce, and RHI aided and abetted the Anadys board of directors in breaching their fiduciary duties. Plaintiffs seek to stop or delay the acquisition of Anadys, or rescission of the merger in the event it is consummated, and seek monetary damages in an unspecified amount to be determined at trial. On October 25, 2011, the *Hammad* and *Maestro* lawsuits were consolidated as *In re Anadys Pharmaceuticals Shareholder Litigation*, Lead Case No. 37-2011-00099789-CU-BT-CTL. Defendants believe plaintiffs’ allegations in these actions are without merit and intend to defend against them vigorously.

#### **Item 1A. Risk Factors**

*You should consider carefully the following information about the risks described below, together with the other information contained in this Quarterly Report and in our other public filings before making any investment decisions regarding our stock. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline, and you may lose all or part of the money you paid to buy our common stock.*

*The risk factors set forth below with an asterisk (\*) next to the title are new risk factors or risk factors containing changes, including any material changes, from the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2010, as filed with the SEC on March 4, 2011.*

#### **Risks Related to the Proposed Merger**

***\*If a sufficient number of shares are not tendered pursuant to the pending tender offer, the merger may not be completed and our business could be impaired.***

If Roche, through its wholly owned subsidiary, acquires at least 90% of our issued and outstanding shares pursuant to the tender offer, the merger can be effected as a “short form merger” under Delaware law. A short form merger would enable Roche to complete the acquisition of Anadys without any action on the part of the other holders of our shares. If Roche satisfies the minimum condition for completion of the tender but does not acquire 90% of the issued and outstanding shares pursuant to the tender offer (including through the exercise of a top-up option and any subsequent offering period), we will be required to hold a stockholders’ meeting in order to obtain the approval of our stockholders to consummate the merger. Although this would not prevent the merger from occurring because Roche would control a sufficient number of our shares to approve the merger, it would delay the completion of the merger and could create uncertainty for Anadys and our business could be adversely affected. If less than the required minimum number of shares are tendered, then neither the tender offer nor the merger may be completed and this could also cause significant uncertainty for Anadys and our business could be severely and adversely affected.

***\*Our executive officers and directors may have interests that are different from, or in addition to, those of our stockholders generally.***

Our executive officers and directors may have interests in the merger that are different from, or are in addition to, those of Anadys stockholders generally. These interests include direct or indirect ownership of Anadys common stock and stock options and the potential receipt of change in control payments by certain Anadys executive officers in connection with the proposed merger with Roche.

***\*If Anadys and Roche are not able to complete the pending tender offer and merger, we will likely need to pursue a different near term strategic path of conducting studies of setrobuvir in combination with other agents, which may require raising additional capital, which may not be available on acceptable terms, or at all.***

Neither we nor Roche can assure you that we will successfully complete the pending tender offer and close the merger in a timely manner, or at all. The Merger Agreement is subject to customary closing conditions and is contingent upon the tender of a sufficient number of shares held by our current stockholders pursuant to the cash tender offer. If Roche and we do not close the pending tender offer and merger, our Board of Directors will likely need to pursue a different strategic path in the near-term prior to pursuing any alternative strategic transaction, such as conducting studies of setrobuvir in combination with other agents, which may require raising additional capital. There is no guarantee that capital will be available on acceptable terms, or at all, and there is no guarantee that we will be able to arrange combination studies with third parties or that such studies, if conducted, will have outcomes favorable enough to lead to any strategic transaction. Furthermore, attempting to complete a different strategic transaction once we have additional data could prove to be costly and time consuming, and we cannot make any assurances that any future strategic transaction will occur on commercially reasonable terms or at all.

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***\*Failure to complete the pending tender offer and merger could adversely affect our stock price and our future business and operations.***

The merger with Roche is subject to customary closing conditions and is contingent upon the tender of a sufficient number of shares held by our current stockholders pursuant to the cash tender offer. Neither we nor Roche can assure you that the merger will occur. In the event that the merger is not consummated, we will be subject to significant costs, including legal, accounting and advisory fees related to the merger, which must be paid even if the merger is not completed, and the payment of an \$8 million termination fee under certain circumstances. If the merger is not consummated, the market price of our common stock may decline to the extent that the current market price of our common stock reflects a positive market assumption that the merger will be completed. In addition, if the merger is not completed, we may fail to retain key employees who have sought and obtained different employment in anticipation of the merger being completed.

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

***Any significant set-back regarding, or the failure of, setrobuvir will have a large negative impact on our business and stock price.***

Currently, we are focusing most of our resources on the development of setrobuvir. As a result, our development portfolio entails a highly concentrated risk of failure. If the timing or results of clinical trials and non-clinical studies of setrobuvir do not meet our, your, analysts' or others' expectations, the market price of our common stock could decline significantly. Any significant set-back regarding, or the failure of, setrobuvir will have a significant negative impact on us and our stock price.

***\*We may be unable to enter into future strategic or collaborative transactions, and in particular transactions around setrobuvir or ANA773, on terms acceptable to us, or at all.***

If the merger with Roche is not completed, our near and long-term viability will depend in part on our ability to successfully establish transactions with pharmaceutical and biotechnology companies. Since we do not currently possess the resources necessary to advance setrobuvir or ANA773 fully through later stage development, we either will need to develop or acquire these resources on our own, which will require substantial funding, time and effort, or will need to enter into collaborative agreements to assist in the development of these programs. If we fail to establish collaborations or licensing arrangements on acceptable terms, we may need to forego the future development of one or both of our programs. Even if we successfully establish new collaborations, these relationships may never result in the successful development or commercialization of any product candidates or the generation of milestone, sales or royalty revenue.

***\*In the event that the merger with Roche is not completed we will need to raise additional funds in order to advance setrobuvir through, and ANA773 into, later stage development, and we may not be able to obtain such funds.***

In order to advance setrobuvir through and ANA773 into later stage development, we will need to obtain additional funds. However, we may not be successful in obtaining such funds. Potential sources of additional funds include a new strategic alliance or other transaction, the sale of equity securities, project financing or debt financing. We cannot be sure that additional funding will be available or that such funding will be obtained on terms favorable to us or our stockholders.

***\*In the event that the merger with Roche is not completed and we are unable to raise capital when needed, we may be required to delay, reduce or eliminate our development programs.***

Our September 30, 2011 cash, cash equivalents and marketable securities balance was \$19.2 million. If we are unable to secure additional funding in the near-term, we have identified certain cash saving measures that, if implemented, would not be expected to impair our on-going conduct of the Phase IIb study of setrobuvir and would allow us to meet our working capital requirements with our existing cash, cash equivalents and securities available-for-sale through June 30, 2012.



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In addition, we will need to raise additional capital if we choose to conduct certain activities, including:

- fund our development programs;
- acquire rights to products or product candidates, technologies or businesses;
- establish and maintain manufacturing, sales and marketing operations; and
- commercialize our product candidates, if any, that receive regulatory approval.

Our future funding requirements will depend on, and could increase significantly as a result of many factors, including:

- the progress of our clinical trials;
- the progress of our nonclinical development activities;
- our ability to establish and maintain strategic alliances;
- the costs involved in enforcing or defending patent claims and other intellectual property rights;
- the pace and timing of development activities conducted under joint development arrangements we may establish;
- the cost and timing of regulatory approvals;
- the costs of establishing or expanding manufacturing, sales and distribution capabilities;
- the costs related to development and manufacture of pre-clinical, clinical and validation lots for regulatory and commercialization of drug supply;
- the commercialization of setrobuvir, ANA773 and any additional products; and
- the extent to which we acquire or invest in other products technologies and businesses.

We do not anticipate that we will generate significant revenues from operations for at least several years, if ever. Until we can generate significant revenues from operations, we expect to satisfy our future cash needs through public or private equity offerings, debt financings, strategic alliances or other transactions, project financing and grant funding, as well as through interest income earned on cash balances. We cannot be certain that additional funding will be available to us on acceptable terms, or at all. If funds are not available, we may be required to delay, reduce the scope of or eliminate one or both of our development programs or our commercialization efforts.

***Raising additional funds by issuing securities or through debt or project financing or strategic alliances and licensing arrangements may cause dilution to existing stockholders, restrict our operations or require us to relinquish proprietary rights.***

We may seek to raise additional funds through public or private equity offerings, debt financings, project financings or strategic alliances and licensing arrangements. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional capital by issuing equity securities, our stockholders' ownership will be diluted. Other financing activities may also have an equity component, which also may lead to dilution. Any debt or project financing we enter into may involve covenants that restrict our operations. These restrictive covenants may include limitations on borrowing, specific restrictions on the use of our assets as well as prohibitions on our ability to create liens, pay dividends, redeem capital stocks or make investments. In addition, if we raise additional funds through strategic alliances and licensing arrangements, it may be necessary to relinquish potentially valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. For example, we might be forced to relinquish all or a portion of our sales and marketing rights with respect to potential products or license intellectual property that enables licensees to develop competing products.

***We are at an early stage of development, and we may never attain product sales.***

Our existing organizational structure was formed in May 2000. Since then, most of our resources have been dedicated to the development of our proprietary drug discovery technologies, research and development and preclinical and early-stage clinical testing of compounds. Our current product candidates are at only the early-to-mid stages of clinical trials. Setrobuvir, ANA773 and any other

compounds that we may develop, may never be approved for commercial sales. These compounds will require extensive and costly development, preclinical testing and clinical trials prior to seeking regulatory approval for commercial sales. The time required to attain product sales and profitability is lengthy and highly uncertain, and we cannot assure you that we will be able to achieve or maintain product sales.

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***\*We expect our net losses to continue for at least several years, and we are unable to predict the extent of future losses and when we will become profitable in our business operations, if ever.***

We have incurred net losses since our incorporation in 1992, and through September 30, 2011 we have an accumulated deficit of \$322.9 million. Our losses are attributable in large part to the significant research and development costs required to identify and validate potential product candidates and conduct preclinical studies and clinical trials. To date, we have generated limited revenues, consisting of one-time or limited payments associated with past collaborations or grants, and we do not anticipate generating product revenues for at least several years, if ever. We will need to increase our operating expenses over at least the next several years in order to fund the development costs of our product candidates and further our development activities. As a result we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with our research and product development efforts, we are unable to predict the extent of any future losses or when we will become profitable in our business operations, if ever. Even if we do achieve profitability in our business operations, we may not be able to sustain or increase such profitability on an ongoing basis.

***The technologies on which we rely are unproven and may not result in the development of commercially viable products.***

Our current product candidates, setrobuvir and ANA773, were selected based on the presumption that intervention at their respective targets, HCV polymerase and Toll-Like Receptor-7, or TLR7, offers a therapeutic benefit. There can be no assurance that intervention at either target will offer sufficient benefit and acceptable toxicity to warrant continued development and approval. ANA773 relies on the biology of a specific receptor, or protein, named TLR7. However, the interaction between small molecules and TLR7 represents a relatively new mechanism of action for the treatment of disease, including HCV, and there is no guarantee that an acceptable balance between therapeutic benefit and risk will be achieved with TLR7 agonists in HCV infected patients. For example, in June 2006 we suspended dosing of ANA975, a TLR7 agonist prodrug, in our then on-going ANA975 clinical trial due to information from 13-week toxicology studies in animals that showed intense immune stimulation. We subsequently conducted additional pre-clinical studies and were unable to identify an acceptable balance between therapeutic benefit and risk using a daily dosing schedule over 13-weeks. Accordingly, we subsequently discontinued the development of ANA975 as a therapy for HCV infection. The science underlying setrobuvir is also new and unproven, as no products acting at the HCV polymerase have been approved for marketing. Setrobuvir and ANA773 are at only the early stage to mid stage of clinical investigation. The process of successfully discovering product candidates is expensive, time-consuming and unpredictable, and the historical rate of failure for drug candidates is extremely high. If our approaches to drug discovery and development are not successful, we will not be able to establish or maintain a clinical development portfolio or generate product revenue.

***\*Because the results of preclinical studies and early clinical trials are not necessarily predictive of future results, we can provide no assurances that setrobuvir or ANA773 will have favorable results in on-going or future clinical trials, or receive regulatory approval.***

Positive results from preclinical studies or early clinical trials should not be relied upon as evidence that later or larger-scale clinical trials will succeed. There is typically an extremely high rate of attrition from the failure of drug candidates proceeding through clinical trials. There is no guarantee that viral load declines or durability of response seen in early patient trials will be replicated in future trials of longer duration and/or larger patient populations. For example, the favorable 12 week viral response data from our setrobuvir Phase II studies may not translate into long-term benefit due to the potential emergence of resistant variants or other factors, such as low ribavirin levels in patients. Similarly, there is no guarantee that favorable safety and tolerability seen in short term studies will be replicated in studies of longer duration and/or in larger subject populations. Furthermore, if future toxicology studies have unexpected results, the clinical development of the compound at issue could be suspended, delayed and/or terminated. If setrobuvir or ANA773 fails to demonstrate sufficient safety and efficacy in any clinical trial or shows unexpected findings in future toxicology studies, we would experience potentially significant delays in, or be required to abandon, development of setrobuvir or ANA773. If we delay or abandon our development efforts related to setrobuvir or ANA773, we may not be able to generate sufficient revenues to become profitable, and our reputation in the industry and in the investment community would likely be significantly damaged, each of which would cause our stock price to decrease significantly.



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***We intend to develop setrobuvir and ANA773 as components of combination treatments, which presents additional challenges to the drug development process.***

We are developing setrobuvir and ANA773 as potential components of future combination treatments. We may face additional challenges with this approach, as opposed to developing product candidates for monotherapy. For example, any negative properties of our product candidates may be exacerbated when combined with other agents and/or have unexpected effects in humans. Furthermore, the optimal development of our product candidates may entail explorations of combinations with other agents, which, except for approved drugs, would require us to establish agreements or alliances with other companies or third parties. There is no guarantee that we will be able to enter into such alliances or agreements on terms that we view as favorable, or at all. An important element of our development strategy for setrobuvir is to test the agent in combination with one or more other direct-acting antivirals (DAAs). In order for us to pursue this development strategy, we will need to utilize approved DAAs if available or engage the interest of other biopharmaceutical or pharmaceutical companies, since we do not have another direct antiviral to combine with setrobuvir. Our ability to engage this interest from other companies that have direct antivirals in development will be impacted by such companies' internal HCV portfolio dynamics, with such dynamics influencing the companies' perceived attractiveness of combining with an agent such as setrobuvir. For those companies that have a desire to combine with an agent such as setrobuvir, we will be dependent on their perception of the profile of setrobuvir. If they do not view the profile of setrobuvir as favorably as we do, or if they establish other criteria for combination that we have not yet satisfied with setrobuvir, we could experience difficulties or delays in pursuing such combination trials. For example, within the HCV community to date there has been an emphasis on the genetic barrier to resistance of antiviral agents (leading to a potential conclusion that the administration of non-nucleosides is more likely to result in resistance than the administration of nucleosides due to the lower genetic barrier of resistance of nucleosides). Only more recently has there been an appreciation of the importance of a pharmacological barrier to resistance, which setrobuvir exhibited in the Phase IIa combination study. Depending on other companies' perception of this issue, we could experience less enthusiasm for setrobuvir as a combination partner. If we are unable to optimize the development of setrobuvir, our business prospects could be harmed, causing our stock price to suffer.

***There is no guarantee that in studies of setrobuvir in which setrobuvir will be dosed for longer duration in combination with other agents that we will be able to identify safe and tolerable doses that result in clinical benefit, as measured by clearance of virus and durability of that clearance.***

We are currently conducting a Phase IIb study in which setrobuvir will be dosed for up to 48 weeks in combination with pegylated interferon and ribavirin. In prior studies, the longest period that setrobuvir has been dosed for is 12 weeks. There is no guarantee that we will be able to identify safe and tolerable doses that result in clinical benefit, as measured by clearance of virus and durability of that clearance, when setrobuvir is dosed for longer durations. In addition, although we have presented in vitro data showing that combinations of setrobuvir with interferon and ribavirin and with certain direct antiviral agents appear to be synergistic, these results may not be replicated in clinical trials. Also, it is possible that setrobuvir will not be additive or synergistic with other potential components of future treatment regimens. Furthermore, it is possible that tolerability will be worse over longer durations of treatment than was seen for the same dose at a shorter duration of treatment. For example, in a 14 day healthy volunteer study conducted in 2009, three of the 24 subjects who received setrobuvir discontinued from the study due to the onset of a skin rash characterized as mild to moderate with itching during the study, at comparable dose levels that were well tolerated over three days in patients. Similarly, if the tolerability of doses of setrobuvir required for long-term treatment as part of future combinations is unacceptable or unfavorable relative to competitive product candidates, then the prospects for developing setrobuvir as a treatment for chronic hepatitis C will be diminished, causing our stock price to decrease significantly.

***\*If the merger with Roche is not completed, there is no guarantee that we will be able to resume our development plans for ANA773 without incurring additional expense, added delay or unforeseen additional regulatory requirements.***

Our near term development plans for ANA773 have been put on hold pending completion of our proposed merger with Roche. If the merger with Roche is not completed, there is no guarantee that we will be able to resume our development plans for ANA773 without incurring additional expense, added delay or unforeseen additional regulatory requirements.

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***The U.S. Food and Drug Administration (FDA) could impose additional requirements on the development of setrobuvir which could result in unexpected cost increases and/or delays to our development timelines.***

The development of setrobuvir in the United States is subject to ongoing regulation by the FDA. There is no guarantee that the FDA will not impose additional requirements on our development program for setrobuvir, including requirements associated with patient enrollment, manufacturing processes of our clinical trials materials or other development activities related to setrobuvir, which could result in increased costs to us or a delay in our desired timelines.

***Fast track designation does not guarantee approval, or expedited approval, of setrobuvir and there is no guarantee that setrobuvir will maintain fast track designation.***

In December 2008, we announced that the FDA granted fast track designation to setrobuvir for the treatment of chronic HCV infection. Under the FDA Modernization Act of 1997, fast track designation is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions. Compounds selected must demonstrate the potential to address an unmet medical need for such a condition. Mechanisms intended to facilitate development include opportunities for frequent dialogue with FDA reviewers and for timely review of submitted protocols. However, the designation does not guarantee approval or expedited approval of any application for the product. Furthermore, the FDA may revoke fast track designation from a product candidate at any time if it determines that the criteria are no longer met.

***\*In 2010 we decided to resume clinical investigation of ANA773 for HCV and conduct an exploratory Phase IIa study.***

Last year we decided to resume clinical investigation of ANA773 in HCV. We have plans to conduct a Phase IIa 28 day combination study of ANA773 where initial cohorts will be dosed with ANA773 and ribavirin and subsequent cohorts will test ANA773 as a triple combination with ribavirin and a direct-acting antiviral, to parallel the likely future use of interferon. We plan to conduct this trial in Europe and potentially countries outside of Europe; although initiation of this trial is currently on hold due to our proposed merger with Roche. If ANA773 does not achieve viral load reduction at levels comparable to injectable interferon but with a cleaner side effect profile, the prospects for developing ANA773 as a competitive HCV product will be diminished. Furthermore, prior clinical development of ANA773 for HCV was conducted in the Netherlands and not under a U.S. Investigational New Drug Application (IND). If, in the future, we want to proceed with the development of ANA773 for HCV in the United States, approval from the FDA under an IND will be required. There is no assurance that the FDA will agree that ANA773 should be tested as an investigational treatment for HCV. Currently, there is no evidence that a TLR7 agonist can confer long-term benefit as a therapy for HCV at an acceptable safety risk, and there is no assurance that the FDA will view the data from our ex-U.S. studies as sufficiently compelling to allow clinical investigation. If the FDA does not view the data from our ex-U.S. studies as sufficiently compelling, it may not allow studies under a U.S. IND, in which case development and commercialization of ANA773 for HCV in the United States would be precluded.

***In 2007 we terminated our ANA975 development program due to challenges seen in animal toxicology studies. To the extent that the ANA975 toxicology observations are mechanism related, our ANA773 program could be negatively impacted, causing our stock price to decline.***

ANA975 is an oral prodrug of isatoribine, a TLR7 agonist. In 2007 we discontinued the development of ANA975 as a treatment for HCV infection due to intense immune stimulation in animals. To the extent that any of the ANA975 toxicology observations are mechanism related, rather than compound specific, we, or a potential future collaborator, will need to determine whether the level of immune stimulation induced by TLR7 agonists can be modulated to achieve a potential therapeutic benefit with an acceptable safety profile. Although results from our ANA773 13-week animal toxicology study indicated that with every-other-day dosing of ANA773, immune stimulation of a magnitude believed to confer therapeutic potential can be achieved without adverse toxicology findings, there is no guarantee that this favorable toxicology profile will persist in future toxicology studies of longer duration, or that we will not see adverse safety findings in humans. If we are unable to modulate the immunomodulatory effect with a dose and schedule that provides therapeutic benefit without causing unacceptable adverse events, then the future development of ANA773 may not be viable, or attractive to a potential licensee, which could materially and adversely affect our business and cause our stock price to decline.

***Delays in the commencement of clinical testing of our current and potential product candidates could result in increased costs to us and delay our ability to generate revenues.***

Our potential drug products will require additional nonclinical testing and extensive clinical trials prior to submission of any regulatory application for commercial sales. Previously, we have conducted only early-stage clinical trials on our own. As a result, we have very limited experience conducting clinical trials. In part because of this limited experience, we cannot be certain that planned clinical trials will begin or be completed on time, if at all. Delays in the commencement of clinical testing could significantly increase our product development costs and delay product commercialization. In addition, many of the factors that may cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to denial of regulatory approval of a product candidate.

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The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organizations and trial sites;
- manufacturing sufficient quantities or producing drug meeting our quality standards for a product candidate;
- obtaining approval of an IND application or proposed trial design from the FDA; and
- obtaining institutional review board approval to conduct a clinical trial at a prospective site.

In addition, the commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size and nature of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease, the number of other products under development competing for the same patients in trials and the eligibility criteria for the clinical trial.

***Delays in the completion of, or the termination of, clinical testing of our current and potential product candidates could result in increased costs to us and delay or prevent us from generating revenues.***

Once a clinical trial has begun, it may be delayed, suspended or terminated by us, potential future collaborators, the FDA, or other regulatory authorities due to a number of factors, including:

- ongoing discussions with the FDA or other regulatory authorities regarding the scope or design of our clinical trials;
- failure to conduct clinical trials in accordance with regulatory requirements;
- lower than anticipated enrollment or retention rate of patients in clinical trials;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- lack of adequate funding to continue clinical trials;
- negative results of clinical trials;
- negative or potentially problematic results of ongoing and concurrent non-clinical toxicology studies;
- requests by the FDA for supplemental information on, or clarification of, the results of clinical trials conducted in other countries;
- insufficient supply or deficient quality of drug candidates or other materials necessary for the conduct of our clinical trials; or
- serious adverse events or other undesirable drug-related side effects experienced by participants.

Many of the factors that may lead to a delay, suspension or termination of clinical testing of a current or potential product candidate may also ultimately lead to denial of regulatory approval of a current or potential product candidate. If we experience delays in the completion of, or termination of, clinical testing, our financial results and the commercial prospects for our product candidates may be harmed, and our ability to generate product revenues will be delayed.

***Even if we successfully complete clinical trials of setrobuvir, ANA773 or any future product candidate, there are no assurances that we will be able to submit, or obtain FDA approval of, a new drug application.***

There can be no assurance that if our clinical trials of setrobuvir, ANA773 or any other potential product candidate are successfully completed, we will be able to submit a new drug application, or NDA, to the FDA or that any NDA we submit will be approved by the FDA in a timely manner, if at all. If we are unable to submit a NDA with respect to setrobuvir, ANA773 or any future product candidate, or if any NDA we submit is not approved by the FDA, we will be unable to commercialize that product in the United States. The FDA can and does reject NDAs and may require additional clinical trials, even when drug candidates performed well or achieved favorable results in large-scale Phase III clinical trials. If we fail to commercialize setrobuvir, ANA773 or any future product



candidate, we may be unable to generate sufficient revenues to attain profitability, and our reputation in the industry and in the investment community would likely be damaged, each of which would cause our stock price to decrease.

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***If we successfully develop products but those products do not achieve and maintain market acceptance, our business will not be profitable.***

Even if setrobuvir, ANA773 or any future product candidates are approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved product candidate by physicians, healthcare professionals and third-party payors and our profitability and growth will depend on a number of factors, including:

- our ability to provide acceptable evidence of safety and efficacy;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- availability of alternative treatments;
- pricing and cost effectiveness;
- effectiveness of our or our collaborators' sales and marketing strategy;
- our ability to obtain sufficient third-party insurance coverage or reimbursement; and
- our ability to establish or maintain an attractive price for setrobuvir when used in combination with other agents.

If setrobuvir, ANA773 or any future product candidate does not provide additional clinical benefit when included within a treatment regimen, that product likely will not be accepted favorably by the market. If any products we or our collaborators may develop do not achieve market acceptance, then we will not generate sufficient revenue to achieve or maintain profitability.

In addition, even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if:

- new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete; or
- complications, such as long-term toxicities and viral resistance, arise with respect to use of our products.

***We depend on outside parties to conduct our clinical trials, which may result in costs and delays that prevent us from obtaining regulatory approval or successfully commercializing product candidates.***

We engage clinical investigators and medical institutions to enroll patients in planned clinical trials and contract research organizations to perform data collection and analysis and other aspects of our preclinical studies and clinical trials. As a result, we depend on these clinical investigators, medical institutions and contract research organizations to properly perform the studies and trials. If these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our clinical trials may be extended, delayed or terminated. We may not be able to enter into replacement arrangements without undue delays or excessive expenditures. If there are delays in testing or regulatory approvals as a result of the failure to perform by third-parties, our drug development costs will increase and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. In addition, we may not be able to maintain any of these existing relationships, or establish new ones on acceptable terms, if at all.

***We do not have internal manufacturing capabilities, and if we fail to develop and maintain supply relationships with future collaborators or other outside manufacturers, we may be unable to develop or commercialize any of our products.***

Our ability to develop and commercialize products will depend in part on our ability to manufacture, or arrange for collaborators or other parties to manufacture, our products at a competitive cost, in accordance with regulatory requirements and in sufficient quantities for clinical testing and eventual commercialization. Our current manufacturing agreements reflect a much smaller scale than would be required for commercialization. If we are unable to enter into or maintain commercial-scale manufacturing agreements with future collaborators or capable contract manufacturers on acceptable terms the development and commercialization of our products could be delayed, which would adversely affect our ability to generate revenues and would increase our expenses.



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***If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any products we may develop, we may not be able to generate product revenue.***

We do not currently have the capabilities for the sales, marketing and distribution of pharmaceutical products. In order to commercialize any products, we would have to build our sales, marketing, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. The establishment and development of our own sales force to market any products we may develop in the United States will be expensive and time-consuming and could delay any product launch, and we cannot be certain that we would be able to successfully develop this capacity. If we are unable to establish our sales and marketing capability or any other non-technical capabilities necessary to commercialize any product we may develop, we will need to contract with third parties to market and sell any products we may develop in the United States. We will also need to develop a plan to market and sell any products we may develop outside the United States. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable.

***\*If we are unable to retain key management and scientific staff, we may be unable to successfully develop or commercialize our product candidates.***

We are a small company and have approximately 25 employees. Our success depends on our continued ability to retain and motivate highly qualified management and scientific personnel. In particular, our programs depend on our ability to retain highly skilled clinical and preclinical personnel in the field of HCV.

We may not be able to retain qualified management and scientific personnel in the future due to the intense competition for qualified personnel among biotechnology and pharmaceutical businesses, particularly in the San Diego, California area and also due to the recent announcement of our pending merger with Roche. If we are not able to retain the necessary personnel to accomplish our business objectives, we may experience constraints that will impede significantly the achievement of our development objectives. In addition, all of our employees are “at will” employees, which means that any employee may quit at any time and we may terminate any employee at any time. Currently we do not have employment agreements with any employees or members of senior management that provide any guarantee of continued employment by us. We do not currently carry “key person” insurance covering members of senior management other than Steve Worland, Ph.D., our President and Chief Executive Officer. The insurance covering Dr. Worland is in the amount of \$1.5 million. If we lose the services of Dr. Worland, or James L. Freddo, M.D., our Senior Vice President, Drug Development and Chief Medical Officer, or other members of our senior management team or key personnel, we may not be able to find suitable replacements, and our business may be harmed as a result.

***\*We are subject to litigation initiated in connection with the tender offer and proposed merger with Roche, which could be time consuming and divert our resources and the attention of our management.***

Between October 20 and October 25, 2011, three putative class action lawsuits (entitled (1) *Hammad v. Anadys Pharmaceuticals, Inc.*, Case No. 37-2011-00099789-CU-BT-CTL, (2) *Maestro v. Anadys Pharmaceuticals, Inc.*, Case No. 37-2011-00099895-CU-BT-CTL, and (3) *Shabtai v. Anadys Pharmaceuticals, Inc.*, Case No. 37-2011-00099995-CU-BT-CTL) were filed in San Diego Superior Court against the Company, members of the Anadys board of directors, Hoffmann-La Roche, Inc. (“Roche”), Bryce Acquisition Corporation (“Bryce”), and Roche Holdings, Inc. (“RHI”), arising out of the proposed acquisition of Anadys by Roche (“Proposed Transaction”). These lawsuits generally allege that the Anadys board of directors breached their fiduciary duties of care, loyalty, good faith, and independence to Anadys’ stockholders by entering into the merger agreement because the directors, among other things, (i) failed to maximize stockholder value; (ii) used a process that was unfair and inadequate and tailored to better their own interests at the expense of Anadys’ stockholders; (iii) failed to properly value Anadys; (iv) and agreed to preclusive deal-protection terms. The lawsuits also allege that Anadys, Roche, Bryce, and RHI aided and abetted the Anadys board of directors in breaching their fiduciary duties. Plaintiffs seek to stop or delay the acquisition of Anadys, or rescission of the merger in the event it is consummated, and seek monetary damages in an unspecified amount to be determined at trial. On October 25, 2011, the *Hammad* and *Maestro* lawsuits were consolidated as *In re Anadys Pharmaceuticals Shareholder Litigation*, Lead Case No. 37-2011-00099789-CU-BT-CTL. Defendants believe plaintiffs’ allegations in these actions are without merit and intend to defend against them vigorously. The outcome of this litigation

cannot be predicted at this time and any outcome in favor of the plaintiffs could have a significant adverse effect on the Proposed Transaction, our financial condition, and our results of operations.

***Earthquake or wildfire damage to our facilities could delay our research and development efforts and adversely affect our business.***

Our headquarters and research and development facilities in San Diego, California, are located in a seismic zone, and there is the possibility of an earthquake, which could be disruptive to our operations and result in delays in our research and development efforts. In addition, San Diego has experienced several severe wildfires during the past several years which have destroyed or damaged many businesses and residences in the San Diego area. In the event of an earthquake or a severe wildfire, if our facilities or the equipment in our facilities are significantly damaged or destroyed for any reason, or we are otherwise required to shut down our operations, we may not be able to rebuild or relocate our facility or replace any damaged equipment, or otherwise recommence our business operations, in a timely manner and our business, financial condition and results of operations could be materially and adversely affected.

***Our securities available-for-sale held in the form of marketable securities are subject to market, interest and credit risk that may reduce their value.***

A portion of our securities available-for-sale is invested in marketable securities. Our cash position may be adversely affected by changes in the value of these securities. In particular, the value of these holdings may be adversely affected by increases in interest rates, downgrades by rating agencies on the issuers of corporate bonds included in the portfolio and by other factors which may result in other than temporary declines in value of the investments. Each of these events may cause us to record charges to reduce the carrying value of our investment portfolio and may adversely affect our cash position.

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### **Risks Related to Our Industry**

*Because our product candidates and development and collaboration efforts depend on our intellectual property rights, adverse events affecting our intellectual property rights will harm our ability to commercialize products.*

Our commercial success depends on obtaining and maintaining patent protection and trade secret protection of our product candidates, proprietary technologies and their uses, as well as successfully defending these patents against third-party challenges. We will only be able to protect our product candidates, proprietary technologies and their uses from unauthorized use by third parties to the extent that valid and enforceable patents or effectively-protected trade secrets cover them.

Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, our ability to obtain and enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any issued patents may not provide us with sufficient protection for setrobuvir or ANA773 or provide sufficient protection to afford us a commercial advantage against competitive products or processes. In addition, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us.

Even with respect to patents that have issued or will issue, we cannot guarantee that the claims of these patents are, or will be valid, enforceable or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us. For example:

we might not have been the first to make, conceive, or reduce to practice the inventions covered by all or any of our pending patent applications and issued patents;

we might not have been the first to file patent applications for these inventions;

others may independently develop similar or alternative technologies or duplicate any of our technologies;

it is possible that none of our pending patent applications will result in issued patents;

our issued or acquired patents may not provide a basis for commercially viable products, may not provide us with any competitive advantages, or may be challenged by third parties;

our issued patents may not be valid or enforceable;

we may not develop additional proprietary technologies that are patentable; or

the patents of others may have an adverse effect on our business.

Patent applications in the United States are maintained in confidence for up to 18 months or longer after their filing. Consequently, we cannot be certain that we were the first to invent or the first to file patent applications on our product candidates. In the event that a third party has also filed a U.S. patent application relating to our product candidates or a similar invention, we may have to participate in interference proceedings declared by the U.S. Patent Office to determine priority of invention in the United States. The costs of these proceedings could be substantial and it is possible that our efforts would be unsuccessful, resulting in a material adverse effect on our U.S. patent position. Furthermore, we may not have identified all U.S. and foreign patents or published applications that affect our business either by blocking our ability to commercialize our drugs or by covering similar technologies that affect our drug market.

In addition, some countries, including many in Europe, do not grant patent claims directed to methods of treating humans, and in these countries patent protection may not be available at all to protect our drug candidates. Even if patents issue, we cannot guarantee that the claims of those patents will be valid and enforceable or provide us with any significant protection against competitive products, or otherwise be commercially valuable to us. We may be particularly affected by this because we expect that setrobuvir, if approved, will be marketed in foreign countries with high incidences of HCV infection.

Other companies may obtain patents and/or regulatory approvals to use the same drugs to treat diseases other than HCV. As a result, we may not be able to enforce our patents effectively because we may not be able to prevent healthcare providers from prescribing, administering or using another company's product that contains the same active substance as our products when treating patients infected with HCV.

If we fail to obtain and maintain patent protection and trade secret protection of setrobuvir or ANA773, proprietary technologies and their uses, the competition we face would increase, reducing our potential revenues and adversely affecting our ability to attain or maintain profitability.

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***If we are sued for infringing intellectual property rights of others, it will be costly and time-consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.***

Our commercial success also depends upon our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. We may be exposed to future litigation by third parties based on claims that our product candidates, technologies or activities infringe the intellectual property rights of others. Numerous U.S. and foreign issued patents and pending patent applications owned by others exist in HCV. These could materially affect our ability to develop our drug candidates or sell our products. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates or technologies may infringe. There also may be existing patents, of which we are not aware, that our product candidates or technologies may inadvertently infringe. Further, there may be issued patents and pending patent applications in fields relevant to our business, of which we may become aware from time to time, that we believe we do not infringe or that we believe are invalid or relate to immaterial portions of our overall drug discovery and development efforts. We cannot assure you that third parties holding any of these patents or patent applications will not assert infringement claims against us for damages or seeking to enjoin our activities. We also cannot assure you that, in the event of litigation, we will be able to successfully assert any belief we may have as to non-infringement, invalidity or immateriality, or that any infringement claims will be resolved in our favor.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. Any litigation or claims against us, with or without merit, may cause us to incur substantial costs, could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. In addition, intellectual property litigation or claims could result in substantial damages and force us to do one or more of the following if a court decides that we infringe on another party's patent or other intellectual property rights:

- cease selling, incorporating or using any of our product candidates or technologies that incorporate the challenged intellectual property;
- obtain a license from the holder of the infringed intellectual property right, which license may be costly or may not be available on reasonable terms, it at all; or
- redesign our processes or technologies so that they do not infringe, which could be costly and time consuming and may not be possible.

If we find during clinical evaluation that our drug candidates for the treatment of HCV should be used in combination with a product covered by a patent held by another company or institution, and that a labeling instruction is required in product packaging recommending that combination, we could be accused of, or held liable for, inducing infringement of the third-party patents covering the product recommended for co-administration with our product. In that case, we may be required to obtain a license from the other company or institution to use the required or desired package labeling, which may not be available on reasonable terms, or at all.

If we fail to obtain any required licenses or make any necessary changes to our technologies, we may be unable to develop or commercialize some or all of our product candidates.

***We may be involved in lawsuits or proceedings to protect or enforce our patent rights, trade secrets or know-how, which could be expensive and time-consuming.***

The defense and prosecution of intellectual property suits and related legal and administrative proceedings can be both costly and time-consuming. Litigation and interference proceedings could result in substantial expense to us and significant diversion of effort by our technical and management personnel. Further, the outcome of patent litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of the adverse party. This is especially true in biotechnology related patent cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree and which may be difficult to comprehend by a judge or jury. An adverse determination in an interference proceeding or litigation with respect to setrobuvir or ANA773, to which we may become a party could subject us to significant liabilities to third parties or require us to seek licenses from third parties. If required, the necessary licenses may not be available on acceptable terms, or



at all. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from commercializing setrobuvir or ANA773, which could have a material and adverse effect on our results of operations.

Furthermore, because of the substantial amount of pre-trial document and witness discovery required in connection with intellectual property litigation, there is risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the trading price of our common stock.

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***Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information and may not adequately protect our intellectual property.***

We also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. In order to protect our proprietary technology and processes, we also rely in part on confidentiality and intellectual property assignment agreements with our corporate partners, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information nor result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information or other breaches of the agreements. In addition, others may independently discover our trade secrets and proprietary information, and in such case we could not assert any trade secret rights against such party. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to seek to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

***Many competitors have significantly more resources and experience, which may harm our commercial opportunity.***

The biotechnology and pharmaceutical industries are subject to intense competition and rapid and significant technological change. We have many potential competitors, including major drug and chemical companies, specialized biotechnology firms, academic institutions, government agencies and private and public research institutions. Many of our competitors have significantly greater financial resources, experience and expertise in:

- research and development;
- preclinical testing;
- clinical trials;
- regulatory approvals;
- manufacturing; and
- sales and marketing of approved products.

Smaller or early-stage companies and research institutions may also prove to be significant competitors, particularly through collaborative arrangements with large and established pharmaceutical or other companies. We will also face competition from these parties in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, and acquiring and in-licensing technologies and products complementary to our programs or potentially advantageous to our business. If any of our competitors succeed in obtaining approval from the FDA or other regulatory authorities for their products sooner than we do or for products that are more effective or less costly than ours, our commercial opportunity could be significantly reduced.

***If our competitors develop treatments for HCV that are approved faster, marketed better or demonstrated to be more effective than setrobuvir, ANA773, or any other products that we may develop, our commercial opportunity will be reduced or eliminated.***

We believe that a significant number of drugs are currently under development and may become available in the future for the treatment of HCV. Potential competitors may develop treatments for HCV that are more effective or less costly than our product candidates or that would make our product candidates obsolete or non-competitive. Some of these products may use therapeutic approaches that compete directly with setrobuvir or ANA773. In addition, less expensive generic forms of currently marketed drugs could lead to additional competition upon patent expiration or invalidations.

Setrobuvir, a non-nucleoside polymerase inhibitor, was selected as a development candidate for the treatment of chronic hepatitis C virus infection in June 2007. If approved, setrobuvir would likely be used in combination with pegylated interferon and ribavirin and/or other DAAs such as protease inhibitors, NS5A inhibitors, and/or polymerase inhibitors. Setrobuvir may also be used in combination

with cyclophilin inhibitors which target a host (human) enzyme. Any product currently approved or approved in the future for the treatment of HCV infection could decrease or eliminate the commercial opportunity of setrobuvir. Other non-nucleoside inhibitors would likely be the most direct competitors for setrobuvir. To our knowledge, non-nucleoside polymerase inhibitor programs are currently under clinical evaluation by Pfizer, Gilead, Tibotec/Johnson & Johnson (Janssen), Abbott, Boehringer Ingelheim, Bristol-Myers Squibb, Idenix and Vertex. Further, a number of companies have non-nucleoside polymerase inhibitor research and pre-clinical development programs.

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Other potential competitors are products currently approved for the treatment of HCV infection: the pegylated interferon-alfa-based products PegIntron (pegylated interferon-alfa-2b) and Intron (interferon-alfa-2b), both of which are marketed by Merck, and Pegasys (pegylated interferon-alfa-2a) and Roferon- A (interferon-alfa-2a), both of which are marketed by Roche; the ribavirin-based products Copegus marketed by Roche, Rebetol marketed by Merck and generic ribavirin distributed by multiple companies; and two protease inhibitors recently approved by the FDA for the treatment of HCV: Incivek (telaprevir) which has been developed by Vertex Pharmaceuticals, Tibotec (Janssen Pharmaceutica / Johnson & Johnson) and Mitsubishi Tanabe Pharma, and Victrelis (boceprevir), developed by Merck, which has recently been approved by the FDA and the EMEA.

Setrobutvir may also face competition from DAAs currently in later stage clinical development for the treatment of HCV including the other protease inhibitors (TMC-435350, in development by Tibotec (Janssen Pharmaceutica/Johnson & Johnson) and Medivir; BMS-650032 in development by Bristol-Myers Squibb; BI-201335, in development by Boehringer Ingelheim; and danoprevir, in development by Roche), the nucleoside polymerase inhibitors (RG7128, in development by Roche; and PSI-7977, in development by Pharmasset), the NS5A inhibitor (BMS-790052, in development by Bristol-Myers Squibb), and the non-nucleoside polymerase inhibitors (GS-9190, in development by Gilead; VX-222, in development by Vertex; ABT-072 and ABT-333, in development by Abbott; BMS-791325, in development by BMS, IDX375 by Idenix, BI-207127 by Boehringer Ingelheim, TMC-647055 by Tibotec (Janssen Pharmaceutica/Johnson & Johnson); and filibuvir, in development by Pfizer). Cyclophilin inhibitors, such as DEB-025, in development by Novartis may also be competitive with setrobutvir.

***If we cannot establish pricing of our product candidates acceptable to the government, insurance companies, managed care organizations and other payors, any product sales will be severely hindered.***

The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care costs to contain or reduce costs of health care may adversely affect:

- our ability to set a price we believe is fair for any products we or our collaborators may develop;
- our ability to generate adequate revenues and gross margins; and
- the availability of capital.

In certain foreign markets, the pricing of prescription pharmaceuticals is subject to government control. In the United States, comprehensive health care reform legislation was recently enacted by the Federal government and we expect that there will continue to be a number of federal and state proposals to implement government control over the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. The trend toward managed health care in the United States will continue to put pressure on the rate of adoption and pricing of prescription pharmaceuticals, which may result in lower prices for our product candidates. We are currently unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect the recently enacted federal health care reform legislation or any such additional legislation or regulation would have on our business.

***If we cannot arrange for reimbursement policies favorable to our product candidates, their sales will be severely hindered.***

Our ability to commercialize setrobutvir or any other product candidate successfully will depend in part on the extent to which governmental authorities, private health insurers and other organizations establish appropriate reimbursement levels for the cost of setrobutvir or any other product and related treatments. Third party payors are increasingly challenging the prices charged for medical products and services, including treatments for HCV. Also, the trend toward managed health care in the United States as well as the comprehensive health care reform legislation recently enacted by the Federal government could result in exclusion of our product candidates from reimbursement programs such as Medicare and Medicaid. The cost containment measures that health care payors and providers are instituting and the effect of the comprehensive health care reform legislation recently enacted by the Federal government could materially and adversely affect our ability to earn product revenue and generate significant profits and could impact our ability to raise capital.

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***Product liability claims may damage our reputation and, if insurance proves inadequate, the product liability claims may harm our results of operations.***

We face an inherent risk of product liability exposure for claimed injuries related to the testing of our product candidates in human clinical trials, and will face an even greater risk if we or our potential future collaborators sell our product candidates commercially. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- the inability to establish new collaborations with potential collaborators;
- substantial costs of related litigation;
- substantial monetary awards to patients; and
- the inability to commercialize our product candidates.

We currently have product liability insurance that covers our clinical trials and plan to increase and expand this coverage as we commence larger scale trials. We also intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for any of our product candidates. However, insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

***Any claims relating to our improper handling, storage or disposal of biological, hazardous and radioactive materials could be time-consuming and costly.***

Our research and development involves the controlled use of hazardous materials, including chemicals that cause cancer, volatile solvents, including ethylacetate and acetonitrile, radioactive materials and biological materials including plasma from patients infected with HCV or other infectious diseases that have the potential to transmit disease. Our operations also produce hazardous waste products. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and waste products. If we fail to comply with these laws and regulations or with the conditions attached to our operating licenses, the licenses could be revoked, and we could be subjected to criminal sanctions and substantial liability or required to suspend or modify our operations. Although we believe that our safety procedures for handling and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources, and our clinical trials could be suspended. In addition, we may have to incur significant costs to comply with future environmental laws and regulations.

***Our business and operations would suffer in the event of system failures.***

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our development programs. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability as a result, our development programs may be adversely affected and the further development of our product candidates may be delayed. In addition, we may incur additional costs to remedy the damages caused by these disruptions or security breaches.

## **Risks Related to Our Common Stock**

***Future sales of our common stock may cause our stock price to decline.***

Our current stockholders hold a substantial number of shares of our common stock that they are able to sell in the public market. Significant portions of these shares are held by a small number of stockholders. Sales by our current stockholders of a substantial number of shares or the expectation that such sale may occur, could significantly reduce the market price of our common stock.

***\*Our stock price may be volatile.***

The market price of our common stock may fluctuate significantly in response to a number of factors, most of which we cannot control, including:

risks related to our pending tender offer and merger with Roche;

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changes in the regulatory status of our product candidates, including the status and results of our clinical trials of setrobuvir and ANA773;

significant contracts, new technologies, acquisitions, commercial relationships, joint ventures or capital commitments;

disputes or other developments relating to proprietary rights, including patents, trade secrets, litigation matters, and our ability to patent or otherwise protect our product candidates and technologies;

conditions or trends in the pharmaceutical and biotechnology industries;

fluctuations in stock market prices and trading volumes of similar companies, of our competitors or of the markets generally;

variations in our quarterly operating results;

changes in securities analysts' estimates of our financial performance;

failure to meet or exceed securities analysts' or investors' expectations of our quarterly financial results, clinical results or our achievement of milestones;

sales of large blocks of our common stock, or the expectation that such sales may occur, including sales by our executive officers, directors and significant stockholders;

additions or departures of key personnel;

discussion of our business, products, financial performance, prospects or our stock price by the financial and scientific press and online investor communities such as chat rooms;

regulatory developments in the United States and foreign countries;

economic and political factors, including wars, terrorism and political unrest; and

technological advances by our competitors.

### ***Our quarterly results may fluctuate significantly, resulting in fluctuations in our stock price.***

We expect our results of operations to be subject to quarterly fluctuations. The level of our revenues, if any, and results of operations at any given time, will be based primarily on the following factors:

the status of development of setrobuvir, ANA773 and our other product candidates, including results of preclinical studies and clinical trials and changes in regulatory status;

our execution of collaborative, licensing or other arrangements and the timing and accounting treatment of payments we make or receive under these arrangements;

whether or not we achieve specified research or commercialization milestones under any agreement that we enter into with collaborators and the timely payment by commercial collaborators of any amounts payable to us;

variations in the level of expenses related to our product candidates or potential product candidates during any given period; and

the effect of competing technological and market developments.

These factors, some of which are not within our control, may cause the price of our stock to fluctuate substantially. In particular, if our quarterly operating results fail to meet or exceed the expectations of securities analysts or investors, our stock price could drop suddenly and significantly. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

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### ***Our largest stockholders may take actions that are contrary to your interests, including selling their stock.***

A small number of our stockholders hold a significant amount of our outstanding stock. These stockholders may support competing transactions and have interests that are different from yours. In addition, the average number of shares of our stock that trade each day is generally low. As a result, sales of a large number of shares of our stock by these large stockholders or other stockholders within a short period of time could adversely affect our stock price.

### ***Anti-takeover provisions in our organizational documents and Delaware law may discourage or prevent a change in control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.***

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may delay or prevent a change in control, discourage bids at a premium over the market price of our common stock and adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. These provisions include:

- dividing our board of directors into three classes serving staggered three-year terms;
- prohibiting our stockholders from calling a special meeting of stockholders;
- permitting the issuance of additional shares of our common stock or preferred stock without stockholder approval;
- prohibiting our stockholders from making certain changes to our amended and restated certificate of incorporation or amended and restated bylaws except with 66 2/3% stockholder approval; and
- requiring advance notice for raising matters of business or making nominations at stockholders' meetings.

We are also subject to provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for three years unless the holder's acquisition of our stock was approved in advance by our board of directors. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, 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, which is responsible for appointing the members of our management.

### ***We have never paid cash dividends on our capital stock and we do not anticipate paying dividends in the foreseeable future.***

We have paid no cash dividends on any of our classes of capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of any future debt or credit facility may preclude us from paying any dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of potential gain for the foreseeable future.



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### Item 6. Exhibit Index

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference or Attached Hereto</u>
2.1	Agreement and Plan of Merger, dated October 16, 2011, by and among Anadys Pharmaceuticals, Inc., Hoffmann-La Roche Inc., Bryce Acquisition Corporation and, solely for the purposes set forth therein, Roche Holdings, Inc.	Incorporated by reference to the Registrant' s Current Report on Form 8-K (SEC File No. 000-50632) filed on October 19, 2011.
2.2	Form of Tender and Support Agreement, dated October 16, 2011, by and among Hoffmann-La Roche Inc., Bryce Acquisition Corporation and certain stockholders of Anadys Pharmaceuticals, Inc.	Incorporated by reference to the Registrant' s Current Report on Form 8-K (SEC File No. 000-50632) filed on October 19, 2011.
3.1	Form of Amended and Restated Certificate of Incorporation of the Registrant	Incorporated by reference to the Registrant' s Quarterly Report on Form 10-Q (SEC File No. 000-50632) filed on May 14, 2004.
3.2	Amended and Restated Bylaws of the Registrant	Incorporated by reference to the Registrant' s Current Report on Form 8-K (SEC File No. 000-50632) filed on December 5, 2007.
4.1	Form of Specimen Common Stock Certificate	Incorporated by reference to the Registrant' s Registration Statement on Form S-1 (SEC File No. 333-110528) filed on March 18, 2004.
4.2	Form of Warrant	Incorporated by reference to the Registrant' s Current Report on Form 8-K (SEC File No. 000-50632) filed on June 4, 2009.
10.25#	Form of Amended and Restated Severance and Change in Control Agreement effective as of August 25, 2011, by and between the Registrant and each executive officer party thereto	Incorporated by reference to the Registrant' s Schedule 14D-9 (SEC File No. 000-50632) filed on October 25, 2011.
31.1	Certification of President and Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Act of 1934, as amended	Attached Hereto.
31.2	Certification of Vice President, Finance and Operations pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Act of 1934, as amended	Attached Hereto.
32.1	Certifications of President and Chief Executive Officer and Vice President, Finance and Operations pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Attached Hereto.
101*	The following materials from the Registrant' s Quarterly Report on Form 10-Q for the quarter ended September 30, 2011, formatted in Extensible Business Reporting Language (XBRL) includes (i) Condensed Consolidated Balance Sheets at September 30, 2011 and December 31,	Attached Hereto.

2010, (ii) Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2011 and 2010, (iii) Condensed Consolidated Cash Flow Statements for the Nine Months Ended September 30, 2011 and 2010, and (iv) Notes to Condensed Consolidated Financial Statements.

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- \* XBRL information is furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Exchange Act of 1933, as amended, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.
- # Indicates management contract or compensatory plan.

**SIGNATURES**

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: November 7, 2011

ANADYS PHARMACEUTICALS, INC.

By: /s/ Stephen T. Worland, Ph.D.

Stephen T. Worland, Ph.D.

President and Chief Executive Officer

By: /s/ Peter T. Slover

Peter T. Slover

Vice President, Finance and Operations

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- # Indicates management contract or compensatory plan.

**CERTIFICATION OF PRESIDENT AND CHIEF EXECUTIVE OFFICER  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Stephen T. Worland, Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Anadys 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: November 7, 2011

/s/ Stephen T. Worland, Ph.D.

Stephen T. Worland, Ph.D.

President and Chief Executive Officer

**CERTIFICATION OF VICE PRESIDENT, FINANCE AND OPERATIONS  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Peter T. Slover, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Anadys 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: November 7, 2011

/s/ Peter T. Slover

Peter T. Slover

Vice President, Finance and Operations

**CERTIFICATION OF PRESIDENT AND CHIEF EXECUTIVE OFFICER AND VICE PRESIDENT, FINANCE AND OPERATIONS PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. Section 1350, as adopted), Stephen T. Worland, Ph.D., as President and Chief Executive Officer of the Company, and Peter T. Slover, as Vice President, Finance and Operations of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the three and nine months ended September 30, 2011, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Quarterly Report and results of operations of the Company for the periods covered by the Quarterly Report.

/s/ Stephen T. Worland, Ph.D.

\_\_\_\_\_  
Stephen T. Worland, Ph.D.

President and Chief Executive Officer

Date: November 7, 2011

/s/ Peter T. Slover

\_\_\_\_\_  
Peter T. Slover

Vice President, Finance and Operations

Date: November 7, 2011



**Condensed Cosolidated  
Balance Sheets  
(Parenthetical) (USD \$)**

**Sep. 30, 2011 Dec. 31, 2010**

**Stockholders' equity:**

<u>Preferred stock, par value</u>	\$ 0.001	\$ 0.001
<u>Preferred stock, shares authorized</u>	10,000,000	10,000,000
<u>Preferred stock, shares issued</u>		
<u>Preferred stock, shares outstanding</u>		
<u>Common stock, par value</u>	\$ 0.001	\$ 0.001
<u>Common stock, shares authorized</u>	90,000,000	90,000,000
<u>Common stock, shares issued</u>	57,176,285	57,141,223
<u>Common stock, shares outstanding</u>	57,176,285	57,141,223

Condensed Consolidated Statements of Operations (Unaudited) (USD \$) In Thousands, except Per Share data	3 Months Ended		9 Months Ended	
	Sep. 30,	Sep. 30,	Sep. 30,	Sep. 30,
	2011	2010	2011	2010
<b>Operating Expenses:</b>				
<u>Research and development</u>	\$ 7,991	\$ 2,488	\$ 19,999	\$ 9,273
<u>General and administrative</u>	1,670	1,510	4,739	4,752
<u>Total operating expenses</u>	9,661	3,998	24,738	14,025
<b>Other Income (Expense):</b>				
<u>Interest income and other, net</u>	26	22	106	115
<u>Gain (loss) from valuation of common stock warrant liability</u>	497	(767)	1,421	(13)
<u>Total other income (expense), net</u>	523	(745)	1,527	102
<u>Net loss</u>	\$ (9,138)	\$ (4,743)	\$ (23,211)	\$ (13,923)
<u>Net loss per share, basic and diluted</u>	\$ (0.16)	\$ (0.11)	\$ (0.41)	\$ (0.35)
<u>Shares used in calculating net loss per share, basic and diluted</u>	57,176	43,214	57,159	39,970

**Document and Entity  
Information (USD \$)**

**9 Months Ended**

**Sep. 30, 2011**

**Oct. 28,  
2011**

**Jun. 30,  
2010**

**Document and Entity Information**

**[Abstract]**

Entity Registrant Name

ANADYS PHARMACEUTICALS  
INC

Entity Central Index Key

0001128495

Document Type

10-Q

Document Period End Date

Sep. 30, 2011

Amendment Flag

false

Document Fiscal Year Focus

2011

Document Fiscal Period Focus

Q3

Current Fiscal Year End Date

--12-31

Entity Well-known Seasoned Issuer

No

Entity Voluntary Filers

No

Entity Current Reporting Status

Yes

Entity Filer Category

Accelerated Filer

Entity Public Float

\$ 60,521,084

Entity Common Stock, Shares Outstanding

57,438,114

## Subsequent Events

**9 Months Ended  
Sep. 30, 2011**

[Subsequent Events](#)

[\[Abstract\]](#)

[Subsequent Events](#)

### 7. Subsequent Events

On October 16, 2011, the Company entered into a Merger Agreement with Roche, pursuant to which, and on the terms and subject to the conditions thereof, among other things, Roche agreed to commence a cash tender offer (the Offer), which was initiated on October 25, 2011, to acquire all of the outstanding shares of common stock of the Company, par value \$0.001 per share (the Shares) at a price of \$3.70 per share (the Offer Price), net to the selling stockholder in cash, without interest and less any required withholding taxes. Following the completion of the tender offer and subject to the satisfaction or waiver of certain conditions set forth in the Merger Agreement, including, if required, receipt of approval by the stockholders of the Company, the Company will be a wholly owned subsidiary of Roche. If and when the Merger is effected, the shares not purchased pursuant to the Offer (other than shares held by the Company, Roche, any subsidiary of Roche or by stockholders of the Company who have perfected their statutory rights of appraisal under Delaware law) will be converted into the right to receive an amount in cash equal to the Offer Price, without interest, and less any required withholding taxes. In addition, each unexpired and unexercised option to purchase Shares then in effect, whether vested or unvested, will be cancelled, terminated and extinguished in exchange for the right to receive the excess, if any, of the Offer Price over the exercise price of such Option immediately prior to the effective time of the Merger.

Roche's obligation to accept for payment and pay for Shares tendered in the Offer is subject to certain conditions, including, among other things, (i) that the number of Shares validly tendered pursuant to the Offer (and not properly withdrawn prior to any then scheduled expiration date of the Offer), together with Shares then beneficially owned by Roche, represents at least a majority of (a) all Shares then outstanding plus (b) all Shares issuable upon the exercise, conversion or exchange of any options, warrants or other rights to acquire Shares then outstanding (other than options, warrants or other rights that have a per share exercise price that is equal to or greater than the Offer Price) regardless of whether or not then vested, (ii) the expiration or termination of any applicable waiting period under any applicable antitrust law, including the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and (iii) that the other conditions set forth in Annex I to the Merger Agreement have been satisfied or waived.

## Comprehensive Loss

9 Months Ended  
Sep. 30, 2011

[Comprehensive Loss](#)

[\[Abstract\]](#)

[Comprehensive Loss](#)

### 3. Comprehensive Loss

Comprehensive loss is comprised of net loss adjusted for changes in market values in securities available-for-sale. Below is a reconciliation of net loss to comprehensive loss for the periods presented (in thousands):

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2011</u>	<u>2010</u>	<u>2011</u>	<u>2010</u>
Net loss	\$ (9,138 )	\$ (4,743 )	\$ (23,211 )	\$ (13,923 )
Unrealized gain (loss)				
on securities				
available-for-sale	(2 )	(5 )	13	(38 )
Comprehensive loss	<u>\$ (9,140 )</u>	<u>\$ (4,748 )</u>	<u>\$ (23,198 )</u>	<u>\$ (13,961 )</u>

## Organization and Basis of Presentation

9 Months Ended  
Sep. 30, 2011

### [Organization and Basis of Presentation \[Abstract\]](#)

### [Organization and Basis of Presentation](#)

#### 1. Organization and Basis of Presentation

##### *Organization and Business*

The accompanying unaudited condensed consolidated financial statements of Anadys Pharmaceuticals, Inc. (together with its wholly owned subsidiaries, Anadys Pharmaceuticals Europe GmbH and Anadys Development Limited, the Company) should be read in conjunction with the audited consolidated financial statements and related disclosures included in the Company's 2010 Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) on March 4, 2011. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP) for interim financial information, in accordance with the instructions to Form 10-Q and the guidance in Article 10 of Regulation S-X. Accordingly, since they are interim financial statements, the accompanying unaudited condensed consolidated financial statements do not include all of the information and disclosures required by U.S. GAAP for complete financial statements. The accompanying unaudited condensed consolidated financial statements reflect all adjustments, consisting of normal recurring adjustments, that are, in the opinion of management, necessary for the fair statement of the results of operations for the interim periods presented. Interim results are not necessarily indicative of results to be expected for the year ended December 31, 2011 or for any other period(s).

On October 16, 2011, the Company entered into an Agreement and Plan of Merger (the Merger Agreement) with Hoffmann-La Roche Inc., a New Jersey corporation, Bryce Acquisition Corporation, a Delaware corporation and a wholly owned subsidiary of Hoffman-La Roche, Inc. and, solely for purposes of Section 9.13 therein, Roche Holdings, Inc., a Delaware corporation and the parent of Hoffman-La Roche, Inc. (collectively referred to as Roche), pursuant to which, and on the terms and subject to the conditions thereof, among other things, Roche initiated on October 25, 2011, a cash tender offer to acquire all of the outstanding shares of common stock of the Company, par value \$0.001 per share at a price of \$3.70 per share, net to the selling stockholder in cash, without interest and less any required withholding taxes. Following the completion of the tender offer and subject to the satisfaction or waiver of certain conditions set forth in the Merger Agreement, including, if required, receipt of approval by the stockholders of the Company, Bryce (Roche's acquisition subsidiary) will merge with and into the Company, with the Company surviving as a wholly owned subsidiary of Roche.

##### *Use of Estimates*

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect amounts reported in the financial statements and notes thereto. Actual results could differ materially from those estimates.

##### *Securities Available-for-Sale*

Investments with an original maturity of more than three months when purchased have been classified by management as securities available-for-sale. Such investments are carried at fair value, with unrealized gains and losses included as a component of accumulated other

comprehensive gain (loss) in stockholders' equity. Realized gains and losses and declines in value judged to be other-than-temporary (of which there have been none to date) on available-for-sale securities are included in interest income. The cost of securities sold is based on the specific-identification method. The Company views its available-for-sale securities as available for use in current operations. Accordingly, the Company has classified all investments as short-term, even though the stated maturity date may be one year or more beyond the current balance sheet date.

*Subsequent Events*

The Company evaluated all events or transactions that occurred after the balance sheet date of September 30, 2011 through the date it issued these financial statements. Subsequent to September 30, 2011 but prior to the issuance of these financial statements, the Company entered into an Agreement and Plan of Merger with Roche. See additional information related to the Merger Agreement at footnote 7 to these financial statements. No other subsequent events were identified during the Company's evaluation that require disclosure.

## Share-Based Compensation

9 Months Ended  
Sep. 30, 2011

### [Share-Based Compensation](#)

#### [\[Abstract\]](#)

### [Share-Based Compensation](#)

#### 4. Share-Based Compensation

Share-based compensation expense for stock options granted to employees and non-employee directors is estimated at the grant date based on the stock option's fair value as calculated by a Black-Scholes pricing model and the portion that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service period. The Company accounts for compensation expense for options granted to non-employees other than directors based on the fair value of the options issued using the Black-Scholes pricing model and these options are periodically re-measured as the underlying options vest.

A summary of the Company's stock options and related information as of September 30, 2011 is as follows:

	<u>Options Outstanding</u> (in thousands)	<u>Weighted Average Exercise Price</u>	<u>Weighted- Average Remaining Contractual Term in Years</u>	<u>Aggregate Intrinsic Value</u> (in thousands)
Balance at September 30, 2011	7,761	\$ 3.01	6.26	\$ 24
Exercisable at September 30, 2011	5,291	\$ 3.72	5.07	\$ —

The Company has reported the following amounts of share-based compensation expense in the unaudited condensed consolidated Statements of Operations (in thousands, except per share data):

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2011</u>	<u>2010</u>	<u>2011</u>	<u>2010</u>
Research and development expense	\$ 234	\$ 206	\$ 606	\$ 643
General and administrative expense	199	289	684	814
Total share-based compensation expense	\$ 433	\$ 495	\$ 1,290	\$ 1,457



Net share-based compensation expense, per common share basic and diluted	<u>\$ 0.01</u>	<u>\$ 0.01</u>	<u>\$ 0.02</u>	<u>\$ 0.04</u>
--	----------------	----------------	----------------	----------------

As of September 30, 2011, there was an additional \$1.6 million of total unrecognized compensation cost related to unvested stock options granted under the Company's stock option plans. This unrecognized compensation cost is expected to be recognized over a weighted-average period of 2.16 years.

The following assumptions were used to estimate the fair value of stock options granted during the three and nine months ended September 30, 2011 and 2010:

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>					
	<u>2011</u>	<u>2010</u>	<u>2011</u>	<u>2010</u>				
Stock options granted in each period	106,000	50,000	974,205	140,000				
<b>Assumptions:</b>								
Dividend yield	0.00	%	0.00	%	0.00	%	0.00	%
Expected volatility	84.70	%	84.56	%	84.70	%	84.56	%
Risk-free interest rate	2.11	%	2.42	%	2.11	%	2.42	%
Expected life of the option term (in years)	6.35		6.09		6.35		6.09	

Share-based compensation expense is based on awards ultimately expected to vest, and therefore is reduced by expected forfeitures. The Company estimates forfeitures based upon historical forfeiture rates, and will adjust its estimate of forfeitures in future periods if actual forfeitures differ, or are expected to differ, from such estimates. Changes in forfeiture estimates impact share-based compensation expense in the period in which the change in estimate occurs.

During the three months ended September 30, 2011, no stock options expired. During the nine months ended September 30, 2011, 151,461 stock options expired. There were no stock options that expired during the three and nine month periods ended September 30, 2010.

## Securities Available-for-Sale

9 Months Ended  
Sep. 30, 2011

### [Securities Available-for-Sale](#)

#### [\[Abstract\]](#)

### [Securities Available-for-Sale](#)

#### 5. Securities Available-for-Sale

Securities available-for-sale consisted of the following as of September 30, 2011 and December 31, 2010 (in thousands):

	September 30, 2011			
	Amortized	Unrealized		Market
	Cost	Gain	Loss	Value
Commercial paper	\$300	\$—	\$—	\$300
Municipal bonds	3,986	1	—	3,987
U.S. government sponsored enterprise securities	10,984	10	—	10,994
Corporate debt securities	2,801	2	(1 )	2,802
	<u>\$18,071</u>	<u>\$13</u>	<u>\$(1 )</u>	<u>\$18,083</u>

	December 31, 2010			
	Amortized	Unrealized		Market
	Cost	Gain	Loss	Value
Commercial paper	\$10,018	\$—	\$(1 )	\$10,017
Municipal bonds	1,654	—	—	1,654
U.S. government sponsored enterprise securities	15,983	7	(5 )	15,985
Corporate debt securities	2,713	—	(2 )	2,711
	<u>\$30,368</u>	<u>\$7</u>	<u>\$(8 )</u>	<u>\$30,367</u>

The amortized cost and estimated fair value of the Company's securities available-for-sale by contractual maturity as of September 30, 2011 and December 31, 2010 are shown below (in thousands):

	September 30, 2011			
	Amortized	Unrealized		Market
	Cost	Gain	Loss	Value
Within one year	\$17,809	\$11	\$(1 )	\$17,819
After one year	262	2	—	264
	<u>\$18,071</u>	<u>\$13</u>	<u>\$(1 )</u>	<u>\$18,083</u>

	December 31, 2010			
	Amortized	Unrealized		Market
	Cost	Gain	Loss	Value
Within one year	\$23,731	\$ 2	\$(5 )	\$23,728
After one year	6,637	5	(3 )	6,639

\$30,368   \$ 7   \$(8)   \$30,367

As of September 30, 2011, the Company performed a review of all of the securities in its portfolio with an unrealized loss position to determine if any other-than-temporary impairments were required to be recorded. Factors considered in the Company's assessment included but were not limited to the following: the Company's ability and intent to hold the security until maturity, the number of months until the security's maturity, the number of quarters that each security was in an unrealized loss position, ratings assigned to each security by independent rating agencies, the magnitude of the unrealized loss compared to the face value of the security and other market conditions. No other-than-temporary impairments were identified as of September 30, 2011 related to securities currently in the Company's portfolio. The Company also noted that none of the securities as of September 30, 2011 had been in an unrealized loss position for greater than one year.

## Fair Value Disclosures

9 Months Ended  
Sep. 30, 2011

[Fair Value Disclosures](#)

[\[Abstract\]](#)

[Fair Value Disclosures](#)

### 6. Fair Value Disclosures

As of September 30, 2011, the Company had \$19.2 million of cash equivalents and marketable securities consisting of money market funds, commercial paper, municipal bonds, U.S. government sponsored enterprise securities and corporate debt securities with maturities that range from one day to 18.3 months with an overall average time to maturity of 4.5 months. The Company has the ability to liquidate these investments without restriction or penalty. The Company determines fair value for marketable securities with Level 1 inputs through quoted market prices. The Company determines fair value for marketable securities with Level 2 inputs through broker or dealer quotations or alternative pricing sources with reasonable levels of price transparency. The Company's Level 2 marketable securities have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, typically utilizing third party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market based approaches and observable market inputs to determine value. These observable market inputs include reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, and other industry and economic events. The Company's Level 3 inputs are unobservable inputs based on the Company's assessment of what market participants would use in pricing the instruments.

On June 3, 2009, the Company sold warrants to purchase 2.9 million shares of common stock to institutional investors as part of an equity financing. The Company accounts for the common stock warrants which may potentially be settled with cash as a liability. The Company determines fair value for the common stock warrants with Level 3 inputs through a Black-Scholes pricing model.

There have been no transfers of assets or liabilities between the fair value measurement classifications.

The following table presents the Company's assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2011 (in thousands):

Description	Fair Value Measurements at Reporting Date Using			
	September 30, 2011	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds	\$ 857	\$ 857	\$ —	\$ —

Commercial paper	300	—	300	—
Municipal bonds	3,987	—	3,987	—
U.S. government sponsored enterprise securities	10,994	—	10,994	—
Corporate debt securities	2,802	—	2,802	—
<b>Total financial assets</b>	<b>\$ 18,940</b>	<b>\$ 857</b>	<b>\$ 18,083</b>	<b>\$ —</b>
Liabilities:				
Common stock warrants	\$ 460	\$ —	\$ —	\$ 460
<b>Total financial liabilities</b>	<b>\$ 460</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 460</b>

The Company reassesses the fair value of the common stock warrants at each reporting date utilizing a Black-Scholes pricing model. The following inputs were utilized in the Black-Scholes pricing model at September 30, 2011 and 2010:

	<u>September 30,</u>	
	<u>2011</u>	<u>2010</u>
Risk-free interest rate	0.43 %	0.96 %
Dividend yield	0.00 %	0.00 %
Expected volatility	79.43%	91.76%
Weighted-average expected life of warrant (in years)	2.7	3.7

As a result of the Company's reassessment of the fair value of the common stock warrants, the Company recorded a gain of \$0.5 million and a loss of \$0.8 million for the three months ended September 30, 2011 and 2010, respectively. As a result of the Company's reassessment of the fair value of the common stock warrants, the Company recorded a gain of \$1.4 million and a loss of \$0.01 million for the nine months ended September 30, 2011 and 2010, respectively. The gain (loss) is reflected in the Company's unaudited condensed consolidated statement of operations as a component of other income (expense), net.

The following table is a roll forward of the fair value of the common stock warrants, as to which fair value is determined by Level 3 inputs (in thousands):

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2011</u>	<u>2010</u>	<u>2011</u>	<u>2010</u>
Beginning balance	\$ 957	\$ 3,143	\$ 1,881	\$ 3,897
Purchases, issuances, and settlements	—	—	—	—
Realized gain (loss) included in net loss	497	(767)	1,421	(13)
<b>Ending balance</b>	<b>\$ 460</b>	<b>\$ 3,910</b>	<b>\$ 460</b>	<b>\$ 3,910</b>

**Condensed Consolidated  
Cash Flow Statements  
(Unaudited) (USD \$)  
In Thousands**

**9 Months Ended  
Sep. 30,      Sep. 30,  
2011            2010**

**Cash Flows from Operating Activities:**

Net loss \$ (23,211)    \$ (13,923)

**Adjustments to reconcile net loss to net cash used in operating activities:**

Depreciation 157            308

Share-based compensation expense 1,290          1,457

(Gain)loss on valuation of common stock warrant liability issued in connection with equity financing (1,421)        13

Gain from the sale of property and equipment                   (6)

Amortization of discount on securities available-for-sale 357            248

**Changes in operating assets and liabilities:**

Prepaid expenses and other current assets 417            (295)

Other assets                   60

Accounts payable and accrued expenses 3,928          (632)

Deferred rent 14

Other current and long-term liabilities (12)            (9)

Net cash used in operating activities (18,481)      (12,779)

**Cash Flows from Investing Activities:**

Purchases of securities available-for-sale (10,535)      (17,476)

Proceeds from the sale and maturity of securities available-for-sale 22,475        16,160

Purchases of property and equipment (30)            (7)

Proceeds from the sale of property and equipment                   6

Net cash provided by (used in) investing activities 11,910        (1,317)

**Cash Flows from Financing Activities:**

Proceeds from equity financing, net of issuance costs                   11,373

Proceeds from exercise of stock options and employee stock purchase plan 35              118

Net cash provided by financing activities 35              11,491

Net decrease in cash and cash equivalents (6,536)        (2,605)

Cash and cash equivalents at beginning of period 7,617          4,497

Cash and cash equivalents at end of period 1,081          1,892

**Supplemental Disclosure of Non-Cash Investing and Financing Activities:**

Unrealized loss on securities available-for-sale \$ 13            \$ (38)

## Net Loss Per Share

**9 Months Ended  
Sep. 30, 2011**

[Net Loss Per Share](#)

[\[Abstract\]](#)

[Net Loss Per Share](#)

### 2. Net Loss Per Share

Basic net loss per share was calculated by dividing the net loss for the period by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share was calculated by dividing the net loss for the period by the weighted-average number of common stock equivalents outstanding during the period determined using the treasury-stock method. For purposes of this calculation, options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted earnings per share when their effect is dilutive.

The Company has excluded the following outstanding options and warrants from the calculation of diluted net loss per share because the effect would be anti-dilutive for all periods presented (in thousands):

	<u>As of September 30,</u>	
	<u>2011</u>	<u>2010</u>
Options to purchase common stock	7,761	7,158
Common stock warrants	2,944	2,944
	<u>10,705</u>	<u>10,102</u>

**Condensed Consolidated  
Balance Sheets (USD \$)  
In Thousands**

**Sep. 30, Dec. 31,  
2011 2010**

**Current assets:**

<u>Cash and cash equivalents</u>	\$ 1,081	\$ 7,617
<u>Securities available-for-sale</u>	18,083	30,367
<u>Prepaid expenses and other current assets</u>	902	1,319
<u>Total current assets</u>	20,066	39,303
<u>Property and equipment, net</u>	107	234
<u>Total assets</u>	20,173	39,537

**Current liabilities:**

<u>Accounts payable and accrued expenses</u>	6,898	2,970
<u>Common stock warrant liability</u>	460	1,881
<u>Deferred rent</u>	14	0
<u>Total current liabilities</u>	7,372	4,851
<u>Other long-term liabilities</u>	1	13
<u>Commitments and contingencies</u>		

**Stockholders' equity:**

<u>Preferred stock, \$0.001 par value; 10,000,000 shares authorized at September 30, 2011 and December 31, 2010; no shares issued and outstanding at September 30, 2011 and December 31, 2010</u>		
<u>Common stock, \$0.001 par value; 90,000,000 shares authorized at September 30, 2011 and December 31, 2010; 57,176,285 and 57,141,223 shares issued and outstanding at September 30, 2011 and December 31, 2010, respectively</u>	57	57
<u>Additional paid-in capital</u>	335,623	334,298
<u>Accumulated other comprehensive gain (loss)</u>	12	(1)
<u>Accumulated deficit</u>	(322,892)	(299,681)
<u>Total stockholders' equity</u>	12,800	34,673
<u>Total liabilities and stockholders' equity</u>	\$ 20,173	\$ 39,537