INFINITY PHARMACEUTICALS, INC.
Form 10-Q
November 06, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2012

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 000-31141

INFINITY PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**33-0655706**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**

780 Memorial Drive, Cambridge, Massachusetts 02139

(Address of Principal Executive Offices) (Zip Code)

(617) 453-1000

(Registrant s Telephone Number, Including Area Code)

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 x 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 x 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 x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	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 x

Number of shares of the registrant s Common Stock, $0.001 par value, outstanding on September 30, 2012: 39,480,298

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INFINITY PHARMACEUTICALS, INC.

FORM 10-Q

FOR THE QUARTER ENDED SEPTEMBER 30, 2012

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PART I. FINANCIAL INFORMATION

Item 1. Unaudited Condensed Consolidated Financial Statements

INFINITY PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands, except share and per share amounts)

	September 30, 2012	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	$ 52,917	$ 24,197
Available-for-sale securities	135,853	91,081
Unbilled accounts receivable from Purdue entities		218
Prepaid expenses and other current assets	3,673	2,485
Total current assets	192,443	117,981
Property and equipment, net	3,871	4,582
Long-term available-for-sale securities	636	659
Restricted cash	1,127	1,125
Other assets	114	143
Total assets	$ 198,191	$ 124,490
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 4,892	$ 5,952
Accrued expenses	12,966	18,819
Deferred revenue from Purdue entities		4,215
Total current liabilities	17,858	28,986
Long-term debt due to Purdue entities, net of debt discount		37,553
Deferred revenue from Purdue entities, less current portion		42,147
Other liabilities	606	371
Total liabilities	18,464	109,057
Commitments and contingencies		
Stockholders equity :		
Preferred Stock, $.001 par value; 1,000,000 shares authorized; no shares issued and outstanding at September 30, 2012 and December 31, 2011		
Common Stock, $.001 par value; 100,000,000 shares authorized; 39,480,298 and 26,721,739 shares issued and outstanding at September 30, 2012 and December 31, 2011, respectively	39	27
Additional paid-in capital	455,610	284,436
Accumulated deficit	(276,031)	(269,052)
Accumulated other comprehensive income	109	22
Total stockholders equity	179,727	15,433

Total liabilities and stockholders equity	$ 198,191	$ 124,490

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

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INFINITY PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

(unaudited)

(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Collaborative research and development revenue from Purdue entities	$	$ 23,305	$ 47,114	$ 70,448
Operating expenses:				
Research and development	21,495	29,418	78,578	78,689
General and administrative	6,294	5,470	20,771	16,675
Total operating expenses	27,789	34,888	99,349	95,364
Gain on termination of Purdue entities alliance	46,555		46,555	
Income (loss) from operations	18,766	(11,583)	(5,680)	(24,916)
Other income (expense):				
Interest expense	(533)	(433)	(1,908)	(1,299)
Income from Massachusetts tax incentive award			193	
Interest and investment income	170	71	416	234
Total other expense	(363)	(362)	(1,299)	(1,065)
Net income (loss)	$ 18,403	$ (11,945)	$ (6,979)	$ (25,981)
Earnings (loss) per common share:				
Basic	$ 0.57	$ (0.45)	$ (0.24)	$ (0.98)
Diluted	$ 0.52	$ (0.45)	$ (0.24)	$ (0.98)
Weighted average number of common shares outstanding:				
Basic	32,039,866	26,666,332	28,638,512	26,590,597
Diluted	35,173,223	26,666,332	28,638,512	26,590,597
Other comprehensive income (loss):				
Net unrealized holding gains (losses) on available-for-sale securities arising during the period	$ 43	$ (26)	$ 87	$ (38)
Comprehensive income (loss)	$ 18,446	$ (11,971)	$ (6,892)	$ (26,019)

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

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INFINITY PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Cash Flows

(unaudited)

(in thousands)

	Nine Months Ended September 30,	
	2012	2011
Operating activities		
Net loss	$ (6,979)	$ (25,981)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,257	1,633
Stock-based compensation, including 401(k) match	5,082	4,151
Net amortization of available-for-sale securities	1,069	713
Impairment of property and equipment	121	
Non-cash interest expense on long-term debt due to Purdue entities	1,908	
Amortization of loan commitment asset from Purdue entities		1,299
Other, net	41	58
Changes in operating assets and liabilities:		
Unbilled accounts receivable	218	(716)
Prepaid expenses and other assets	(1,200)	(267)
Accounts payable, accrued expenses and other liabilities	(6,678)	(1,718)
Deferred revenue from Purdue entities	(38,887)	(3,727)
Net cash used in operating activities	(44,048)	(24,555)
Investing activities		
Purchases of property and equipment	(667)	(822)
Purchases of available-for-sale securities	(133,852)	(91,964)
Proceeds from sales of available-for-sale securities	6,281	1,289
Proceeds from maturities of available-for-sale securities	81,837	118,276
Net cash provided by (used in) investing activities	(46,401)	26,779
Financing activities		
Proceeds from issuance of common stock related to stock offering, net	82,800	
Proceeds from issuance of common stock to Purdue entities	27,500	
Proceeds from issuances of common stock related to stock incentive plans	8,869	455
Capital lease payments		(5)
Net cash provided by financing activities	119,169	450
Net increase in cash and cash equivalents	28,720	2,674
Cash and cash equivalents at beginning of period	24,197	20,417
Cash and cash equivalents at end of period	$ 52,917	$ 23,091
Supplemental schedule of noncash investing and financing activities		
Issuance of common stock to extinguish debt from Purdue entities	$ 51,277	$

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

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Infinity Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Organization

Infinity Pharmaceuticals, Inc. is an innovative drug discovery and development company seeking to discover, develop and deliver to patients best-in-class medicines designed to address diseases with significant unmet need. As used throughout these unaudited, condensed consolidated financial statements, the terms Infinity, we, us, and our refer to the business of Infinity Pharmaceuticals, Inc. and its wholly owned subsidiary.

2. Basis of Presentation

These condensed consolidated financial statements include the accounts of Infinity and its wholly owned subsidiary. We have eliminated all significant intercompany accounts and transactions in consolidation.

The accompanying condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring accruals and revisions of estimates, considered necessary for a fair presentation of the accompanying condensed consolidated financial statements have been included. Interim results for the three and nine months ended September 30, 2012 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2012.

The information presented in the condensed consolidated financial statements and related footnotes at September 30, 2012, and for the three and nine months ended September 30, 2012 and 2011, is unaudited, and the condensed consolidated balance sheet amounts and related footnotes at December 31, 2011 have been derived from our audited financial statements. For further information, please refer to the consolidated financial statements and accompanying footnotes included in our annual report on Form 10-K for the fiscal year ended December 31, 2011, which was filed with the U.S. Securities and Exchange Commission on March 13, 2012.

3. Significant Accounting Policies

Cash Equivalents and Available-For-Sale Securities

Cash equivalents and available-for-sale securities primarily consist of money market funds, U.S. government-sponsored enterprise obligations, corporate obligations, and mortgage-backed securities. Corporate obligations include obligations issued by corporations in countries other than the United States, including some issues that have not been guaranteed by governments and government agencies. We consider all highly liquid investments with maturities of three months or less at the time of purchase to be cash equivalents. Cash equivalents, which consist of money market funds, corporate obligations and a U.S. government-sponsored enterprise obligation, are stated at fair value. They are also readily convertible to known amounts of cash and have such short-term maturities that each presents insignificant risk of change in value due to changes in interest rates. Our classification of cash equivalents is consistent with prior periods.

We determine the appropriate classification of available-for-sale securities at the time of purchase and reevaluate such designation at each balance sheet date. We have classified all of our marketable securities at September 30, 2012 and December 31, 2011 as available-for-sale. We carry available-for-sale securities at fair value, with the unrealized gains and losses reported in accumulated other comprehensive income (loss), which is a separate component of stockholders equity.

We adjust the cost of available-for-sale debt securities for amortization of premiums and accretion of discounts to maturity. We include such amortization and accretion in interest and investment income. The cost of securities sold is based on the specific identification method. We include interest and dividends on securities classified as available-for-sale in interest and investment income.

We conduct periodic reviews to identify and evaluate each investment that is in an unrealized loss position in order to determine whether an other-than-temporary impairment exists. An unrealized loss exists when the current fair value of an individual security is less than its amortized cost basis. Unrealized losses on available-for-sale debt securities that are determined to be temporary, and not related to credit loss, are recorded, net of tax, in accumulated other comprehensive income (loss).

For available-for-sale debt securities in an unrealized loss position, we perform an analysis to assess whether we intend to sell or whether we would more likely than not be required to sell the security before the expected recovery of the amortized cost basis. Where we intend to sell a security or may be required to do so the security s decline in fair value is deemed to be other-than-temporary, and the full amount of the unrealized loss is recorded within earnings as an impairment loss.

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Regardless of our intent to sell a security, we perform additional analysis on all securities in an unrealized loss position to evaluate losses associated with the creditworthiness of the security. Credit losses are identified where we do not expect to receive cash flows sufficient to recover the amortized cost basis of a security and are recorded within earnings as an impairment loss.

Segment Information

We make operating decisions based upon performance of the enterprise as a whole and utilize our consolidated financial statements for decision making. We operate in one business segment, which focuses on drug discovery and development.

All of our revenues to date have been generated under research collaboration agreements. Revenue associated with the amortization of the deferred revenue associated with the grant of rights and licenses to, and reimbursed research and development services provided for, Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products L.P., or Purdue, accounted for all of our revenue for the three and nine months ended September 30, 2012 and 2011. Payments due from Mundipharma and Purdue represented our entire unbilled accounts receivable balance at December 31, 2011. We consider Mundipharma, Purdue and their respective associated entities to be related parties for financial reporting purposes because of their equity ownership (see note 7).

Basic and Diluted Earnings (Loss) per Common Share

Basic earnings or loss per share is based upon the weighted average number of common shares outstanding during the period. Diluted earnings or loss per share is based upon the weighted average number of common shares outstanding during the period, plus the effect of additional weighted average common equivalent shares outstanding during the period when the effect of adding such shares is dilutive. Common equivalent shares result from the assumed exercise of outstanding stock options (the proceeds of which are then assumed to have been used to repurchase outstanding stock using the treasury stock method) and the exercise of outstanding warrants. In addition, the assumed proceeds under the treasury stock method include the average unrecognized compensation expense of stock options that are in-the-money. This results in the assumed buyback of additional shares, thereby reducing the dilutive impact of stock options. Common equivalent shares have not been included in the net loss per share calculations for the three and nine months ended September 30, 2011 and the nine months ended September 30, 2012 because the effect of including them would have been anti-dilutive. Total potential gross common equivalent shares consisted of the following:

	At September 30,	
	2012	2011
Stock options	7,113,072	6,930,688
Warrants	136,655	3,246,629

Basic and diluted earnings (loss) per common share were determined as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
	(in thousands, except share and per share amounts)			
Basic				
Net income (loss)	$ 18,403	$ (11,945)	$ (6,979)	$ (25,981)
Weighted average common shares outstanding	32,039,866	26,666,332	28,638,512	26,590,597
Basic earnings (loss) per common share	$ 0.57	$ (0.45)	$ (0.24)	$ (0.98)
Diluted				
Net income (loss)	$ 18,403	$ (11,945)	$ (6,979)	$ (25,981)
Weighted average common shares outstanding	32,039,866	26,666,332	28,638,512	26,590,597
Effect of dilutive options	3,133,357			

Weighted average common shares outstanding assuming dilution	35,173,223	26,666,332	28,638,512	26,590,597
Diluted earnings (loss) per common share	$ 0.52	$ (0.45)	$ (0.24)	$ (0.98)

Stock-Based Compensation Expense

We measure stock-based compensation cost at the grant date based on the estimated fair value of the award, and recognize it as expense over the employee s requisite service period on a straight-line basis. We have no awards with market or performance conditions. We use the Black-Scholes valuation model in determining the fair value of equity awards.

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Revenue Recognition

To date, all of our revenue has been generated under research collaboration agreements. The terms of these research collaboration agreements may include payment to us of non-refundable, up-front license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved, and/or royalties on product sales. On January 1, 2011, we adopted on a prospective basis a newly issued accounting standard related to multiple-deliverable revenue arrangements. We apply this standard to new revenue arrangements or material modifications of existing revenue arrangements. This standard eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon our best estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item.

Under our strategic alliance with Mundipharma and Purdue, we recognized revenues from non-refundable, up-front license fees on a straight-line basis over the contracted or estimated period of performance, which was the research and development term. We regularly considered whether events warranted a change in the estimated period of performance under an agreement. Such a change would have caused us to modify the period of time over which we recognized revenue from the up-front license fee on a prospective basis and would, in turn, result in changes in our quarterly and annual results. We recognized research and development funding as earned over the period of effort as related research and development costs are incurred in proportion to our forecasted total expenses as compared to the total expected research and development funding for the year. We recognized the impact of any change in forecasted total expenses or expected research and development funding as a change in accounting estimate and recorded the impact of that change on a prospective basis. On July 17, 2012, we mutually agreed with Mundipharma and Purdue to terminate our strategic alliance agreements. Further information regarding the terms and conditions of this termination is described below under Note 7, Collaborations.

On January 1, 2011, we adopted on a prospective basis a newly issued accounting standard related to the milestone method of revenue recognition. We apply this standard to new revenue arrangements or material modifications to existing revenue arrangements. At the inception of each agreement that includes milestone payments, we evaluate whether each milestone is substantive on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether:

- the consideration is commensurate with either (1) our performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from our performance to achieve the milestone,
- the consideration relates solely to past performance, and
- the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement.

We evaluate factors such as the clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment. We recognize revenues related to substantive milestones in full in the period in which the substantive milestone is achieved. If a milestone payment is not considered substantive, we recognize the applicable milestone over the remaining period of performance. Our strategic alliance with Mundipharma and Purdue did not include potential milestone payments.

We will recognize royalty revenue, if any, based upon actual and estimated net sales by the licensee of licensed products in licensed territories in the period the sales occur. We have not recognized any royalty revenue to date.

Research and Development Expense

Research and development expense consists of expenses incurred in performing research and development activities, including salaries and benefits, overhead expenses including facilities expenses, materials and supplies, preclinical expenses, clinical trial and related clinical manufacturing expenses, stock-based compensation expense, depreciation of equipment, contract services, and other outside expenses. We also include as research and development expense up-front license payments related to acquired technologies which have not yet reached technological feasibility and have no alternative use. We expense research and development costs as they are incurred. We have been a party to collaboration agreements in which we are reimbursed for work performed on behalf of the collaborator, as well as one in which we reimbursed the collaborator for work it has performed. We record all appropriate expenses under our collaborations as research and development expense. If the arrangement provides for reimbursement of research and development expenses, as was the case with our alliance with Mundipharma and Purdue, we record the reimbursement as revenue. If the arrangement provides for us to reimburse the collaborator for research and development

expenses or achieving a development milestone for which a payment is due, as is the case with our agreement with Intellikine, Inc., or Intellikine, we record the reimbursement or the achievement of the development milestone as research and development expense. In January 2012, Intellikine was acquired by Takeda Pharmaceutical Company Limited, or Takeda, acting through its Millennium business unit. We refer to our phosphoinositide-3-kinase, or PI3K, program licensor as Millennium.

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Income Taxes

We use the liability method to account for income taxes. Deferred tax assets and liabilities are determined based on differences between financial reporting and income tax basis of assets and liabilities, as well as net operating loss carryforwards, and are measured using the enacted tax rates and laws that will be in effect when the differences reverse. Deferred tax assets are reduced by a valuation allowance to reflect the uncertainty associated with their ultimate realization. The effect on deferred taxes of a change in tax rate is recognized in income or loss in the period that includes the enactment date.

We use our judgment for the recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. We recognize any material interest and penalties related to unrecognized tax benefits in income tax expense.

Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, we have recorded a full valuation allowance against our otherwise recognizable net deferred tax assets as of September 30, 2012 and December 31, 2011.

Fair Value Measurements

We define fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. We determine fair value based on the assumptions market participants use when pricing the asset or liability. We also use the fair value hierarchy that prioritizes the information used to develop these assumptions.

We value our available-for-sale securities utilizing third party pricing services. The pricing services use many observable market inputs to determine value, including benchmark yields, reportable trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers, reference data, new issue data, monthly payment information and collateral performance. We validate the prices provided by our third party pricing services by understanding the models used, obtaining market values from other pricing sources, and confirming those securities trade in active markets.

Property and Equipment

Property and equipment are stated at cost. Depreciation is recorded using the straight-line method over the estimated useful lives of the applicable assets. Application development costs incurred for computer software developed or obtained for internal use are capitalized. Upon sale or retirement, the cost and related accumulated depreciation are eliminated from the respective account, and the resulting gain or loss, if any, is included in current operations. Amortization of leasehold improvements and capital leases is included in depreciation expense. Repairs and maintenance charges that do not increase the useful life of the assets are charged to operations as incurred. Property and equipment are depreciated over the following periods:

Laboratory equipment	5 years
Computer equipment and software	3 to 5 years
Leasehold improvements	Shorter of lease term or useful life of asset
Furniture and fixtures	7 years

4. Stock-Based Compensation

Total stock-based compensation expense, related to all equity awards, for the three and nine months ended September 30, 2012 and 2011 comprised the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
	(in thousands)			
Effect of stock-based compensation on net income (loss) by line item:				

Research and development	$ 772	$ 680	$ 2,371	$ 2,085
General and administrative	995	671	2,711	2,066

As of September 30, 2012, we had approximately $10.0 million of total unrecognized compensation cost, net of estimated forfeitures, related to unvested stock options, which are expected to be recognized over a weighted-average period of 2.8 years.

During the nine months ended September 30, 2012, 1,201,541 stock options were exercised, with a weighted-average exercise price of $7.38 per share.

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During the nine months ended September 30, 2012, we granted options to purchase 1,697,913 shares of our common stock at a weighted average fair value of $5.97 per share. During the nine months ended September 30, 2011, we granted options to purchase 1,159,501 shares of our common stock at a weighted average fair value of $3.45 per share. For the three and nine months ended September 30, 2012 and 2011, the fair values were estimated using the Black-Scholes valuation model using the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Risk-free interest rate	0.8%	1.7%	1.1%	2.3%
Expected annual dividend yield				
Expected stock price volatility	62.6%	57.6%	63.3%	58.0%
Expected term of options	6.2 years	6.1 years	6.1 years	5.9 years

5. Cash, Cash Equivalents and Available-for-Sale Securities

The following is a summary of cash, cash equivalents and available-for-sale securities:

	September 30, 2012			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
		(in thousands)		
Cash and cash equivalents due in 90 days or less	$ 52,917	$	$	$ 52,917
Available-for-sale securities:				
Corporate obligations due in one year or less	104,953	77	(46)	104,984
Corporate obligations due in one to five years	12,346	3	(6)	12,343
Mortgage-backed securities due after ten years	561	75		636
U.S. government-sponsored enterprise obligations due in one year or less	1,519	1		1,520
U.S. government-sponsored enterprise obligations due in one to five years	17,001	5		17,006
Total available-for-sale securities	136,380	161	(52)	136,489
Total cash, cash equivalents and available-for-sale securities	$ 189,297	$ 161	$ (52)	$ 189,406

	December 31, 2011			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
		(in thousands)		
Cash and cash equivalents due in 90 days or less	$ 24,197	$	$	$ 24,197
Available-for-sale securities:				
Corporate obligations due in one year or less	60,593	29	(50)	60,572
Corporate obligations due in one to five years	5,937	8	(3)	5,942
Mortgage-backed securities due after ten years	603	56		659
U.S. government-sponsored enterprise obligations due in one year or less	335			335
U.S. government-sponsored enterprise obligations due in one to five years	24,250	2	(20)	24,232

Total available-for-sale securities	91,718	95	(73)	91,740
Total cash, cash equivalents and available-for-sale securities	$ 115,915	$ 95	$ (73)	$ 115,937

We held 16 debt securities at September 30, 2012 that had been in an unrealized loss position for less than 12 months. The fair value on these securities was $44.9 million. We evaluated our securities for other-than-temporary impairments based on quantitative and qualitative factors. We considered the decline in market value for these 16 securities to be primarily attributable to current economic and market conditions. It is not more likely than not that we will be required to sell these securities, and we do not intend to sell these securities before the recovery of their amortized cost bases. Based on our analysis, we do not consider these investments to be other-than-temporarily impaired as of September 30, 2012.

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As of September 30, 2012, we held 15 financial institution and other corporate debt securities located in Switzerland, Australia, the Netherlands and Japan with a fair value of $57.5 million. Six of these securities had gross unrealized losses totaling $14 thousand as of September 30, 2012. These securities are short-term in nature and are scheduled to mature within 12 months. Based on our analysis, we do not consider these investments to be other-than-temporarily impaired as of September 30, 2012.

There were no other-than-temporary impairments recognized for the three and nine months ended September 30, 2012 and 2011. Realized gains on our available-for-sale securities were immaterial for the three and nine months ended September 30, 2012 and 2011.

6. Fair Value

We use a valuation hierarchy for disclosure of the inputs used to measure fair value. This hierarchy prioritizes the inputs into three broad levels. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value. The classification of a financial asset or liability within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement. For our fixed income securities, we reference pricing data supplied by our custodial agent and nationally known pricing vendors, using a variety of daily data sources, largely readily-available market data and broker quotes. We validate the prices provided by our third party pricing services by reviewing their pricing methods and obtaining market values from other pricing sources. After completing our validation procedures, we did not adjust or override any fair value measurements provided by our pricing services as of September 30, 2012 and December 31, 2011.

The following table provides the assets carried at fair value measured on a recurring basis as of September 30, 2012:

	Level 1	Level 2
	(in thousands)	
Cash and cash equivalents	$ 37,661	$ 15,256
Corporate obligations (including commercial paper)		117,327
Mortgage-backed securities		636
U.S. government-sponsored enterprise obligations		18,526
Total	$ 37,661	$ 151,745

The fair value of the available-for-sale securities and cash and cash equivalents (including asset types listed below with maturities of three months or less at the time of purchase) is based on the following inputs:

Corporate Obligations:

Commercial paper: calculations by custodian based on three month Treasury bill published on last business day of the month.

Other: benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data.

Mortgage-backed securities: benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data, new issue data, monthly payment information and collateral performance.

U.S. government-sponsored enterprise obligations: benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data.

There have been no changes to the valuation methods during the nine months ended September 30, 2012. We evaluate transfers between levels at the end of each reporting period. There were no transfers of assets or liabilities between Level 1 and Level 2 during the nine months ended September 30, 2012. We had no available-for-sale securities that were classified as Level 3 at any point during the nine months ended September 30, 2012 or during the year ended December 31, 2011.

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7. Collaborations

Strategic Alliance Termination Agreements

On July 17, 2012, we terminated our strategic alliance with Mundipharma and Purdue and entered into termination and revised relationship agreements (2012 termination agreements) with each of those entities. The alliance was previously governed by strategic alliance agreements that we entered into with each of Mundipharma and Purdue in November 2008. The strategic alliance agreement with Purdue was focused on the development and commercialization in the United States of products targeting fatty acid amide hydrolase, or FAAH. The strategic alliance agreement with Mundipharma was focused on the development and commercialization outside of the United States of all products and product candidates that inhibit or target the Hedgehog pathway, FAAH, phosphoinositide-3-kinase, or PI3K, and product candidates arising out of our early discovery projects in all disease fields. Our heat shock protein 90, or Hsp90, program was expressly excluded from the alliance.

Under the terms of the 2012 termination agreements:

- All intellectual property rights that we had previously licensed to Mundipharma and Purdue to develop and commercialize products under the previous strategic alliance agreements terminated, with the result that we have worldwide rights to all product candidates that had previously been covered by the strategic alliance.

- We have no further obligation to provide research and development services to Mundipharma and Purdue as of July 17, 2012.

- Mundipharma and Purdue have no further obligation to provide research and development funding to us. Under the alliance, Mundipharma was obligated to reimburse us for research and development expenses we incurred, up to an annual aggregate cap for each alliance program other than FAAH. During the nine months ended September 30, 2012, we received $55 million in research and development funding. We recognized revenue for reimbursed research and development services we performed for Mundipharma and Purdue. We recognized $0 and $45 million in such revenue in the three and nine months ended September 30, 2012, respectively. We recognized $22.3 million and $67.3 million in such revenue, which included $0.5 million and $3.3 million, respectively, in revenue related to reimbursed research and development services for the transition of the FAAH program, in the three and nine months ended September 30, 2011, respectively. We did not record a liability for amounts previously funded by Purdue and Mundipharma as this relationship was not considered a financing arrangement.

- We are obligated to pay Mundipharma and Purdue a 4% royalty in the aggregate (subject to reduction as described in the discussion of the securities purchase agreement below), on worldwide net sales of products that were covered by the alliance until such time as they have recovered approximately $260 million, representing the research and development funding paid to us for research and development services performed by us through the termination of the strategic alliance. After this cost recovery, our royalty obligations to Mundipharma and Purdue will be reduced to a 1% royalty on net sales in the United States of products that were previously subject to the strategic alliance. All payments are contingent upon the successful commercialization of products subject to the alliance that are subject to significant further development. As such, there is significant uncertainty about whether any such products will ever be approved or commercialized. If no products are commercialized, no payments will be due by us to Mundipharma and Purdue; therefore, no amounts have been accrued.

Royalties are payable under these agreements until the later to occur of the last-to-expire of specified patent rights and the expiration of non-patent regulatory exclusivities in a country, provided that if royalties are payable solely on the basis of non-patent regulatory exclusivity, each of the royalty rates is reduced by 50%. In addition, royalties payable under these agreements after Mundipharma and Purdue have recovered all research and development expenses paid to us are subject to reduction on account of third party royalty payments or patent litigation damages or settlements which might be required to be paid by us if litigation were to arise, with any such reductions capped at 50% of the amounts otherwise payable during the applicable royalty payment period.

As a result of the 2012 termination agreements, we have no further research and development service performance obligations to Mundipharma or Purdue. We recognized $0 and $2.1 million in revenue from the upfront license fee in the three and nine months ended September 30, 2012, respectively. We recognized $1.0 million and $3.1 million in such revenue in the three and nine months ended September 30, 2011, respectively.

The 2012 termination agreements resulted in a gain on termination of Purdue entities alliance and a positive net income impact of $46.6 million, or $1.45 in basic earnings per share and $1.32 in fully diluted earnings per share for the three months ended September 30, 2012. For the nine months ended September 30, 2012, the 2012 termination agreements resulted in a positive net income impact of $46.6 million, or $1.63 in basic and diluted earnings per share.

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Line of Credit Agreement

In connection with the previous strategic alliance with Mundipharma and Purdue, we also entered into a line of credit agreement with Purdue and its independent associated company, Purdue Pharma L.P., or PPLP, that provided for the borrowing by us of one or more unsecured loans up to an aggregate maximum principal amount of $50 million. In March 2009, Purdue assigned its interest under the line of credit agreement to PPLP. The extension of the line of credit at an interest rate below our incremental borrowing rate represented the transfer of additional value to us in the arrangement. As such, we recorded the fair value of the line of credit of $17.3 million as a loan commitment asset on our balance sheet in 2008. The fair value of the loan commitment asset was determined using a discounted cash flow model of the differential between the terms and rates of the line of credit and market rates. We amortized the loan commitment asset to interest expense until we drew down the line of credit in November 2011. We recorded approximately $0.4 million and $1.3 million of related amortization expense in the three and nine months ended September 30, 2011, respectively.

In November 2011, we borrowed $50 million under this line of credit, which we recorded as long-term debt. The loan would have matured and was payable in full, including principal and any accrued interest, on April 1, 2019, which we referred to as the maturity date, and would have been subordinate to any senior indebtedness that we may have incurred. The loan bore interest at a fluctuating rate set at the prime rate on the business day prior to the funding of the loan and reset on the last business day of each month ending thereafter. At the time of the borrowing, the prime rate was 3.25%. Interest was compounded on each successive three-month anniversary following the date of borrowing. Upon drawing down the $50 million under the line of credit agreement, we reclassified the loan commitment asset as a debt discount which reduced the debt on our balance sheet. The unamortized balance of the loan commitment asset was $12.7 million as of the date of borrowing. We recorded interest expense on the net amount borrowed using the effective interest method. We recorded $0.5 million and $1.9 million of related interest expense in the three and nine months ended September 30, 2012, respectively, using an effective interest rate of 7.29%.

On September 7, 2012, upon completion of the sale and issuance of common stock to PPLP under the 2012 securities purchase agreement (described below), the line of credit agreement with PPLP terminated in its entirety.

2008 Securities Purchase Agreement

In connection with the previous strategic alliance with Mundipharma and Purdue, we also entered into a securities purchase agreement with Purdue and PPLP. Under the securities purchase agreement, we issued and sold in two separate closings an aggregate of 6,000,000 shares of our common stock and warrants to purchase up to an aggregate of 6,000,000 shares of our common stock, for an aggregate purchase price of $75 million. An equal number of securities were sold to each purchaser. As of September 30, 2012, all warrants that were issued in connection with the strategic alliance expired without having been exercised.

We recorded an aggregate of $59.3 million in deferred revenue associated with the grant of rights and licenses to Mundipharma and Purdue, which consisted of the excess of the amount paid for the purchased shares over the closing market price on the day before the equity closings and the value of the loan commitment asset. We determined that the rights and licenses did not have stand-alone value, and we considered all of the obligations under the arrangement to be a single unit of accounting. There was no obligation for us to repay the $59.3 million, and we had been recognizing the deferred revenue ratably over 14 years, which was our estimated period of performance under the arrangement through July 17, 2012.

2012 Securities Purchase Agreement

On July 17, 2012, in connection with the termination of the strategic alliance with Mundipharma and Purdue, we executed a securities purchase agreement with PPLP, which we refer to as the 2012 securities purchase agreement, under which we agreed to sell and issue 5,416,565 shares of our common stock to PPLP and two entities associated with PPLP, which we collectively refer to as the BRP entities, at a price of $14.50 per share for an aggregate consideration of approximately $78.5 million. The consideration was composed of: (i) extinguishment of approximately $51.0 million in principal and interest due and owing to PPLP under the line of credit agreement, and (ii) $27.5 million in cash. We completed the sale and issuance on September 7, 2012 at which time the line of credit agreement with PPLP terminated in its entirety.

The 2012 securities purchase agreement also provides that, at any time during the period beginning January 1, 2013 and ending December 31, 2018, in the event we propose to make an underwritten offering of our common stock, subject to certain limitations, the Purdue entities will have piggyback registration rights, which require us, at the election of the Purdue entities, to use our reasonable best efforts to cause to be included in such underwritten offering, common stock then held by the Purdue entities representing up to 20% of the total estimated maximum dollar amount of our common stock proposed to be sold in such underwritten offering.

In addition, the BRP entities have agreed to enter into a lockup agreement if requested by us and/or the managing underwriters, placement agents or initial purchasers for any offering of our stock prior to December 31, 2013, pursuant to which the BRP entities will agree not to, among other things, offer, sell or otherwise transfer or dispose of, directly or indirectly, any common stock held by the BRP entities or to enter into any agreement that transfers, in whole or in part, any of the economic consequences of ownership of any common stock held by the BRP entities, for a specified period of time requested by us, the managing underwriters, the placement agents or the initial purchasers.

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The 2012 securities purchase agreement also terminated, as of July 17, 2012, all attendance rights to meetings of our board of directors held by the Purdue entities.

The BRP entities and each associated company holding shares of our common stock have agreed to be present at each regular or special meeting of our stockholders held through September 6, 2017 and to vote all of their shares as recommended by our board of directors in the proxy materials mailed to our stockholders in connection with such meeting, except that with respect to any proposal to amend our corporate charter or approve certain extraordinary transactions, all shares of our common stock that are owned by those entities that were not issued pursuant to the 2012 securities purchase agreement will be voted in proportion to the manner in which all of our stockholders (other than those entities) vote in respect of such proposal, regardless of the recommendation of our board of directors.

Accounting Impact of Alliance Termination, Debt Extinguishment and Sale and Issuance of Common Stock

We recorded the following during the three months ended September 30, 2012:

Gain on termination of Purdue entities strategic alliance of $46.6 million

Additional equity on our balance sheet of $74.4 million

Extinguished $39.5 million of debt on balance sheet

Eliminated $54.0 million of deferred revenue on balance sheet

Received cash of $27.5 million

We considered the fact that certain elements of the arrangement discussed above close before others, despite the fact that all of the elements were negotiated and signed concurrently in contemplation of one another. In particular, the strategic alliance with Mundipharma and Purdue was terminated on July 17, 2012, and therefore, there are no further deliverables required under those agreements. However, the equity offering and debt extinguishment did not close at that time because certain regulatory events outside of our control had to occur prior to the closing. As a result, we evaluated the termination of the strategic alliance separately from the financing transaction, including the extinguishment of debt and sale and issuance of stock. We recorded the gain on termination of the Mundipharma and Purdue strategic alliance for $46.6 million which represented our past performance under the 2008 collaboration because we have no further obligation to provide research and development, and the financial risk associated with the research and development has been transferred to the Purdue entities. In particular, any payment of royalties to Mundipharma and Purdue are conditional on the future commercialization of our products.

To establish the financial impact of the stock issuance and debt extinguishment, we determined both the fair value of the common stock we sold and issued and the debt and accrued interest extinguished. We consider Mundipharma and Purdue to be related parties for financial reporting purposes because of their equity ownership. Therefore, we recorded the difference between extinguishing the fair value of the debt and accrued interest, the sale and issuance of our common stock and receiving $27.5 million in cash in additional paid-in capital.

Millennium

In July 2010, we entered into a development and license agreement with Intellikine, Inc., or Intellikine, under which we obtained rights to discover, develop and commercialize pharmaceutical products targeting the delta and/or gamma isoforms of PI3K, including IPI-145. We paid Intellikine a $13.5 million up-front license fee. The entirety of this fee was included as research and development expense in the year ended December 31, 2010, although $8.5 million of this fee was paid in January 2011. During the second half of 2011, we paid Intellikine $4.0 million in milestone payments associated with the initiation of two Phase 1 studies of IPI-145, which we recorded as research and development expense. In January 2012, Intellikine was acquired by Takeda Pharmaceutical Company Limited, or Takeda, acting through its Millennium business unit. We refer to our PI3K program licensor as Millennium. In addition to developing IPI-145, we are seeking to identify additional novel delta, gamma and dual delta/gamma-specific inhibitors of PI3K for future development. We are obligated to pay up to an additional $21 million in success-based milestones for the development of two distinct product candidates, and up to $450 million in success-based milestones for the

approval and commercialization of two distinct products. In addition, we are obligated to pay Millennium tiered royalties on net sales ranging from single digits to low double digits upon successful commercialization of products licensed to us, which are payable until the later to occur of the expiration of specified patent rights and the expiration of non-patent regulatory exclusivities in a country, subject to reduction in certain circumstances.

Under the agreement, we obtained rights to direct all development and commercialization activities worldwide for products arising from the agreement for all therapeutic indications. For a product in which the first Phase 2 clinical trial, as defined in the agreement, conducted is in an oncology indication, which we refer to as an oncology product, Millennium will have the option, prior to the initiation of the first pivotal clinical study and upon payment of an option fee, to convert its royalty interest in U.S. sales and its right to receive certain milestone payments into the right to share in 50% of profits and losses on U.S. development and commercialization, and to participate in up to 30% of the detailing effort for these products in the United States.

Millennium may terminate its participation rights in any oncology product with 12 months prior written notice to us, after which Millennium s participation rights would revert back to the original milestone- and royalty-based payment structure, provided that Millennium would not be entitled to receive royalty payments for net sales occurring prior to the termination date and certain specified milestone payments.

Other than pursuant to the agreement, neither we nor Millennium may research, develop or commercialize products directed to the delta and/or gamma isoforms of PI3K which meet certain selectivity criteria, except that Millennium may research, develop or commercialize such products that it was researching, developing or commercializing on its own or with a third party prior to its acquisition of Intellikine.

The agreement expires when the parties have no further obligations to each other thereunder, unless earlier terminated. Either party may terminate the agreement on 75 days prior written notice if the other party materially breaches the agreement and fails to cure such breach within the applicable notice period, provided that the notice period is reduced to 30 days where the alleged breach is non-payment. Millennium may also terminate the agreement if we are not diligent in developing or commercializing the licensed products and do not, within three months after notice from Millennium, demonstrate to Millennium s reasonable satisfaction that we have not failed to be diligent. The foregoing periods are subject to extension in certain circumstances. Additionally, Millennium may terminate the agreement upon 30 days prior written notice if we or a related party bring an action challenging the validity of any of the licensed patents, provided that we have not withdrawn such action before the end of the 30-day notice period. We may terminate the agreement at any time upon 180 days prior written notice provided after the end of the research term that is currently set to expire in July 2013. The agreement also provides for customary reciprocal indemnification obligations of the parties.

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8. Accrued Expenses

Accrued expenses consisted of the following:

	September 30, 2012	December 31, 2011
	(in thousands)	
Accrued compensation and benefits	$ 6,346	$ 6,287
Accrued drug manufacturing costs	2,494	4,888
Accrued clinical studies	1,613	2,977
Accrued preclinical studies	200	1,232
Other	2,313	3,435
Total accrued expenses	$ 12,966	$ 18,819

9. Common Stock Offering

In August 2012, we completed an offering of 6,095,000 shares of common stock, which were sold at a price of $14.50 per share. This offering resulted in $82.8 million of net proceeds. Related legal and accounting fees were recorded as an offset to additional paid-in capital.

10. Income from Massachusetts Tax Incentive Award

During the nine months ended September 30, 2012, we recognized $0.2 million as other income. We were awarded a tax grant from the Commonwealth of Massachusetts of approximately $0.5 million for the year ended December 31, 2009, which is earned over a five year period based on headcount growth. We achieved the headcount growth through December 31, 2011 and therefore recognized a pro rata portion of the grant. As the amount received for the award is not related to our ordinary course of operations, we have recorded the amount as other income. If we do not achieve the headcount growth in future years, we may have to refund the Commonwealth of Massachusetts a portion of the grant.

11. Restructuring Activities

In June 2012, we voluntarily stopped all company-sponsored clinical trials of saridegib, our Hedgehog pathway inhibitor, after a planned futility analysis of interim data from our Phase 2, double-blind, randomized, placebo-controlled study evaluating saridegib in patients with metastatic or locally advanced, inoperable chondrosarcoma showed that treatment with saridegib was similar to placebo and, therefore, the trial would not meet its primary endpoint. Following this analysis, we accelerated our review of data from 12 evaluable patients enrolled in our exploratory Phase 2 clinical trial evaluating saridegib in patients with myelofibrosis, which showed that the level of clinical activity observed in these patients did not satisfy our pre-specified criteria for expansion of the trial. We will continue to incur costs associated with the discontinuation of company-sponsored development of saridegib, but we do not expect these costs to be significant beyond 2012. We reallocated remaining resources to other potential development programs and product portfolio efforts and reduced our work force. We incurred a restructuring expense of $0.1 million and $1.5 million related to this reduction in the three and nine months ended September 30, 2012, respectively and expect to incur an additional $13 thousand in remaining expenses through December 31, 2012. In July 2012, we agreed with Mundipharma and Purdue to terminate our strategic alliance agreements with the result that Mundipharma would have no further obligation to provide research and development funding to us (See Note 7, Collaborations, above), and therefore we undertook a subsequent workforce reduction. During the three months ended September 30, 2012, we incurred a restructuring expense of $1.1 million related to this reduction.

As a result of both of these work force reductions, we reduced our employee headcount by approximately 20% compared to our employee headcount as of December 31, 2011. The following table summarizes the impact of the work force reductions on operating expenses and payments for the nine months ended September 30, 2012 and the current liability remaining on the balance sheet as of September 30, 2012, in thousands:

	Charges Incurred	Amounts Paid	Amounts Accrued at

	During the Nine Months Ended September 30, 2012	Through September 30, 2012	September 30, 2012
Employee severance, benefits and related costs for work force reductions	$ 2,571	$ (1,210)	$ 1,361

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We have recorded all associated restructuring expenses associated with the work force reductions as research and development and general and administrative expenses on the statement of operations and comprehensive income (loss). We expect all payments to be complete by the third quarter of 2013.

During the nine months ended September 30, 2012, we recognized an impairment loss of approximately $0.1 million related to lab equipment as a result of the discontinuation of company-sponsored development of saridegib which is not recorded in the table above.

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

Forward-Looking Information

The following discussion of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and related notes included elsewhere in this report. Some of the information contained in this discussion and analysis and set forth elsewhere in this report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the section titled Risk Factors in Part II of this report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Business Overview

We are an innovative drug discovery and development company seeking to discover, develop and deliver to patients best-in-class medicines designed to address diseases with significant unmet need. We combine proven scientific expertise with a passion for developing novel small molecule drugs that target emerging disease pathways. Our programs focused on the inhibition of phosphoinositide-3-kinase, heat shock protein 90, and fatty acid amide hydrolase are evidence of our innovative approach to drug discovery and development. We have worldwide development and commercialization rights to all of our development candidates and early discovery programs, subject to certain obligations to our current and former development partners.

PI3K Inhibitor Program. The phosphoinositide-3-kinases, or PI3Ks, are a family of enzymes involved in key immune cell functions, including cell proliferation and survival, cell differentiation and cellular trafficking. PI3K-delta and PI3K-gamma, two of the four isoforms of PI3K, play key roles in inflammatory and autoimmune diseases. Additionally, in certain hematologic malignancies, PI3K-gamma and PI3K-delta contribute to the survival and proliferation of cancer cells. Therefore, inhibition of PI3K-delta and/or PI3K-gamma may have therapeutic potential across a broad range of inflammatory diseases and hematologic malignancies.

Our lead compound in this program is IPI-145, a potent, oral inhibitor of PI3K-delta and PI3K-gamma, which we are investigating in both inflammatory diseases and hematologic malignancies. We believe that IPI-145 is the first delta-gamma inhibitor in clinical development. We completed our Phase 1, randomized, double-blind, placebo-controlled trial of IPI-145 in healthy adult subjects designed to support the development of IPI-145 in inflammatory diseases. IPI-145 was well tolerated in this trial, with no clinically significant changes in clinical laboratory values or vital signs. Data from this study have been accepted for presentation on November 11, 2012 at the American College of Rheumatology, or ACR, Annual Meeting. In July 2012, we initiated a Phase 2a randomized, double-blind, placebo-controlled trial of IPI-145 in approximately 30 patients with mild asthma. The endpoints of this multi-dose, two-way cross-over study include safety, pharmacokinetics and forced expiratory volume, or FEV_1, a standard measure of lung function. We are also planning to initiate a Phase 2, randomized, placebo-controlled, global study to evaluate the safety and activity of multiple doses of IPI-145 in patients with moderate to severe rheumatoid arthritis.

We have also initiated a Phase 1, open-label, dose-escalation study designed to evaluate the safety, pharmacokinetics and clinical activity of IPI-145 in patients with advanced hematologic malignancies. In July 2012, we expanded the trial to enroll a cohort of approximately 30 patients with chronic lymphocytic leukemia, indolent non-Hodgkin s lymphoma or mantle cell lymphoma. This cohort expansion allows us to obtain further safety and pharmacokinetic data, as well as to assess activity of IPI-145 administered at 25 mg twice daily. There have been confirmed investigator assessments of clinical response at lower dose levels, including 15 mg twice daily and less. To date, IPI-145 has been generally well tolerated in this trial, and dose escalation remains ongoing. We are also planning for up to five additional cohort expansions in a range of hematologic malignancies once the maximum tolerated dose of IPI-145 is determined. The malignancies that may be evaluated in these cohort expansions include T-cell lymphomas, diffuse large B-cell lymphoma, acute lymphocytic leukemia and myeloproliferative malignancies. We expect to present data from this study at the American Society of Hematology, or ASH, Annual Meeting on December 10, 2012.

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We are also conducting discovery activities to identify additional PI3K-delta and/or PI3K-gamma inhibitors, which we believe has the potential to optimize the development of our portfolio of PI3K inhibitors across a broad range of indications. We expect to name our next development candidate in this program and begin IND-enabling studies by the end of 2012.

Hsp90 Inhibitor Program. Retaspimycin hydrochloride (HCl), also known as IPI-504, is a novel, potent and selective inhibitor of heat shock protein 90, or Hsp90. Cancer cells depend on Hsp90 to maintain in their properly folded functional state many proteins critical for cancer growth, proliferation and survival in a functional state. Certain anticancer therapies may enhance the dependency of cancer cells on Hsp90. Therefore, combining an Hsp90 inhibitor with another anticancer therapy may enhance cancer cell killing. We completed patient enrollment in a Phase 2, randomized, double-blind, placebo-controlled clinical trial evaluating retaspimycin HCl in combination with docetaxel, a chemotherapy, compared to placebo and docetaxel in approximately 200 patients with second- or third-line non-small cell lung cancer, or NSCLC, who are naive to docetaxel treatment and have a history of heavy smoking. We stratified patients in our Phase 2 trial by pathological subtype based on results from our Phase 1b trial in which we observed partial responses in patients with squamous cell carcinoma. In addition, we are prospectively evaluating a novel biomarker that we believe may be predictive of response. We expect to report data from this trial in the first half of 2013.

We are also enrolling patients in a Phase 1b/2 trial to explore the safety and efficacy of retaspimycin HCl in combination with everolimus, an inhibitor of the mammalian target of rapamycin, or mTOR, pathway, in NSCLC patients with a KRAS gene mutation. The objective of this Phase 1b/2 trial is to determine the recommended dose for the combination treatment and to evaluate the safety and clinical activity of retaspimycin HCl in combination with everolimus. We expect to provide topline data from this Phase 1b/2 trial in the first half of 2013.

FAAH Inhibitor Program. In July 2012, we reacquired from Purdue Pharmaceutical Products L.P., or Purdue, and Mundipharma International Corporation Limited, or Mundipharma, the global development and commercialization rights for products arising out of a program directed toward fatty acid amide hydrolase, or FAAH. It is believed that inhibition of FAAH may enable the body to bolster its own analgesic and anti-inflammatory response, and may have applicability in a broad range of painful or inflammatory conditions. The lead compound in our FAAH program is IPI-940, a novel, orally available inhibitor of FAAH with potential application for the treatment of a broad range of painful or inflammatory diseases. In October 2010, we reported top-line data from a Phase 1 randomized clinical trial of IPI-940 in 48 healthy adult volunteers demonstrating marked FAAH inhibition and increased anandamide levels. In addition, IPI-940 was well tolerated, with no observed dose-limiting toxicities or clinically significant changes in clinical laboratory values, vital signs or electrocardiogram parameters. We are currently seeking potential partnering opportunities for our FAAH program.

Hedgehog Pathway Inhibitor Program. In June 2012, we voluntarily stopped all company-sponsored clinical trials of saridegib, our lead Hedgehog pathway inhibitor, after a planned futility analysis of interim data from our Phase 2, double-blind, randomized, placebo-controlled study evaluating saridegib in patients with metastatic or locally advanced, inoperable chondrosarcoma showed that treatment with saridegib was similar to placebo and, therefore, the trial would not meet its primary endpoint. Following this analysis, we accelerated our review of data from 12 evaluable patients enrolled in our exploratory Phase 2 clinical trial evaluating saridegib in patients with myelofibrosis, which showed that the level of clinical activity observed in these patients did not satisfy our pre-specified criteria for expansion of the trial. Based on these analyses, we voluntarily stopped both trials and are conducting closeout activities. In both trials, saridegib was generally well tolerated. We expect to present the final data from these studies after all analyses are complete.

We are also currently in the process of obtaining and analyzing data from our discontinued randomized, double-blind, placebo-controlled Phase 2 clinical trial evaluating saridegib in combination with gemcitabine, a chemotherapy, in patients with previously untreated, metastatic, pancreatic cancer. The trial was discontinued in January 2012 following a preliminary analysis showing a difference in survival favoring the placebo plus gemcitabine treatment group due to a higher rate of progressive disease in the saridegib plus gemcitabine treatment group, and not a result of the safety profile of saridegib. We expect to present final data from this trial after our analyses are complete.

Collaboration Agreements

Millennium

In July 2010, we entered into a development and license agreement with Intellikine, Inc., or Intellikine, under which we obtained rights to discover, develop and commercialize pharmaceutical products targeting the delta and/or gamma isoforms of PI3K, including IPI-145. We paid Intellikine a $13.5 million up-front license fee. The entirety of this fee was included as research and development expense in the year ended December 31, 2010, although $8.5 million of this fee was paid in January 2011. During the second half of 2011, we paid Intellikine $4.0 million in milestone payments associated with the initiation of two Phase 1 studies of IPI-145, which we recorded as research and development expense. In January 2012, Intellikine was acquired by Takeda Pharmaceutical Company Limited, or Takeda, acting through its Millennium business unit. We refer to our PI3K program licensor as Millennium. In addition to developing IPI-145, we are seeking to identify additional novel delta, gamma and dual delta/gamma-specific inhibitors of PI3K for future development. We are obligated to pay up to an additional $21 million in

success-based milestones for the development of two distinct product candidates, and up to $450 million in success-based milestones for the approval and commercialization of two distinct products. In addition, we are obligated to pay Millennium

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tiered royalties on net sales ranging from single digits to low double digits upon successful commercialization of products licensed to us, which are payable until the later to occur of the expiration of specified patent rights and the expiration of non-patent regulatory exclusivities in a country, subject to reduction in certain circumstances.

Under the agreement, we obtained rights to direct all development and commercialization activities worldwide for products arising from the agreement for all therapeutic indications. For a product in which the first Phase 2 clinical trial, as defined in the agreement, conducted is in an oncology indication, which we refer to as an oncology product, Millennium will have the option, prior to the initiation of the first pivotal clinical study and upon payment of an option fee, to convert its royalty interest in U.S. sales and its right to receive certain milestone payments into the right to share in 50% of profits and losses on U.S. development and commercialization, and to participate in up to 30% of the detailing effort for these products in the United States.

Millennium may terminate its participation rights in any oncology product with 12 months prior written notice to us, after which Millennium s participation rights would revert back to the original milestone- and royalty-based payment structure, provided that Millennium would not be entitled to receive royalty payments for net sales occurring prior to the termination date and certain specified milestone payments.

Other than pursuant to the agreement, neither we nor Millennium may research, develop or commercialize products directed to the delta and/or gamma isoforms of PI3K which meet certain selectivity criteria, except that Millennium may research, develop or commercialize such products that it was researching, developing or commercializing on its own or with a third party prior to its acquisition of Intellikine.

The agreement expires when the parties have no further obligations to each other thereunder, unless earlier terminated. Either party may terminate the agreement on 75 days prior written notice if the other party materially breaches the agreement and fails to cure such breach within the applicable notice period, provided that the notice period is reduced to 30 days where the alleged breach is non-payment. Millennium may also terminate the agreement if we are not diligent in developing or commercializing the licensed products and do not, within three months after notice from Millennium, demonstrate to Millennium s reasonable satisfaction that we have not failed to be diligent. The foregoing periods are subject to extension in certain circumstances. Additionally, Millennium may terminate the agreement upon 30 days prior written notice if we or a related party bring an action challenging the validity of any of the licensed patents, provided that we have not withdrawn such action before the end of the 30-day notice period. We may terminate the agreement at any time upon 180 days prior written notice provided after the end of the research term that is currently set to expire in July 2013. The agreement also provides for customary reciprocal indemnification obligations of the parties.

Mundipharma and Purdue

On July 17, 2012, we terminated our strategic alliance with Mundipharma and Purdue and entered into termination and revised relationship agreements with each of those entities, which we refer to as the 2012 termination agreements. The alliance was previously governed by strategic alliance agreements that we entered into with each of Mundipharma and Purdue in November 2008. The strategic alliance agreement with Purdue was focused on the development and commercialization in the United States of products targeting FAAH. The 2008 agreement with Mundipharma was focused on the development and commercialization outside of the United States of all products and product candidates that inhibit or target the Hedgehog pathway, FAAH, PI3K, and product candidates arising out of our early discovery projects in all disease fields. Our Hsp90 program was expressly excluded from the alliance.

Under the terms of the 2012 termination agreements:

All intellectual property rights that we had previously licensed to Mundipharma and Purdue to develop and commercialize products under the previous strategic alliance agreements terminated, with the result that we have worldwide rights to all product candidates that had previously been covered by the strategic alliance.

We have no further obligation to provide research and development services to Mundipharma and Purdue as of July 17, 2012.

Mundipharma and Purdue have no further obligation to provide research and development funding to us. Under the alliance, Mundipharma was obligated to reimburse us for research and development expenses we incurred, up to an annual aggregate cap for each alliance program other than FAAH. During the nine months ended September 30, 2012, we received $55 million in research and

development funding. We recognized revenue for reimbursed research and development services we performed for Mundipharma and Purdue. We recognized $0 and $45 million in such revenue in the three and nine months ended September 30, 2012, respectively. We recognized $22.3 million and $67.3 million in such revenue, which included $0.5 million and $3.3 million, respectively, in revenue related to reimbursed research and development services for the transition of the FAAH program, in the three and nine months ended September 30, 2011, respectively. We did not record a liability for amounts previously funded by Purdue and Mundipharma as this relationship was not considered a financing arrangement.

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We are obligated to pay Mundipharma and Purdue a 4% royalty in the aggregate (subject to reduction as below), on worldwide net sales of products that were covered by the alliance until such time as they have recovered approximately $260 million, representing the research and development funding paid to us for research and development services performed by us through the termination of the strategic alliance. After this cost recovery, our royalty obligations to Mundipharma and Purdue will be reduced to a 1% royalty on net sales in the United States of products that were previously subject to the strategic alliance. All payments are contingent upon the successful commercialization of products subject to the alliance that are subject to significant further development. As such, there is significant uncertainty about whether any such products will ever be approved or commercialized. If no products are commercialized, no payments will be due by us to Mundipharma and Purdue; therefore, no amounts have been accrued.

Royalties are payable under these agreements until the later to occur of the last-to-expire of specified patent rights and the expiration of non-patent regulatory exclusivities in a country, provided that if royalties are payable solely on the basis of non-patent regulatory exclusivity, each of the royalty rates is reduced by 50%. In addition, royalties payable under these agreements after Mundipharma and Purdue have recovered all research and development expenses paid to us are subject to reduction on account of third party royalty payments or patent litigation damages or settlements which might be required to be paid by us if litigation were to arise, with any such reductions capped at 50% of the amounts otherwise payable during the applicable royalty payment period.

As a result of the 2012 termination agreements, we have no further research and development service performance obligations to Mundipharma or Purdue. We recognized $0 and $2.1 million in revenue from the upfront license fee in the three and nine months ended September 30, 2012, respectively. We recognized $1.0 million and $3.1 million in such revenue in the three and nine months ended September 30, 2011, respectively.

Line of Credit Agreement

In connection with the previous strategic alliance with Mundipharma and Purdue, we also entered into a line of credit agreement with Purdue and its independent associated company, Purdue Pharma L.P., or PPLP, that provided for the borrowing by us of one or more unsecured loans up to an aggregate maximum principal amount of $50 million. In March 2009, Purdue assigned its interest under the line of credit agreement to PPLP. The extension of the line of credit at an interest rate below our incremental borrowing rate represented the transfer of additional value to us in the arrangement. As such, we recorded the fair value of the line of credit of $17.3 million as a loan commitment asset on our balance sheet in 2008. The fair value of the loan commitment asset was determined using a discounted cash flow model of the differential between the terms and rates of the line of credit and market rates. We amortized the loan commitment asset to interest expense until we drew down the line of credit in November 2011. We recorded approximately $0.4 million and $1.3 million of related amortization expense in the three and nine months ended September 30, 2011, respectively.

In November 2011, we borrowed $50 million under this line of credit, which we recorded as long-term debt. The loan would have matured and was payable in full, including principal and any accrued interest, on April 1, 2019, which we referred to as the maturity date, and would have been subordinate to any senior indebtedness that we may have incurred. The loan bore interest at a fluctuating rate set at the prime rate on the business day prior to the funding of the loan and reset on the last business day of each month ending thereafter. At the time of the borrowing, the prime rate was 3.25%. Interest was compounded on each successive three-month anniversary following the date of borrowing. Upon drawing down the $50 million under the line of credit agreement, we reclassified the loan commitment asset as a debt discount which reduced the debt on our balance sheet. The unamortized balance of the loan commitment asset was $12.7 million as of the date of borrowing. We recorded interest expense on the net amount borrowed using the effective interest method. We recorded $0.5 million and $1.9 million of related interest expense in the three and nine months ended September 30, 2012, respectively, using an effective interest rate of 7.29%.

On September 7, 2012, upon completion of the sale and issuance of common stock to PPLP under the 2012 securities purchase agreement (described below), the line of credit agreement with PPLP terminated in its entirety.

2008 Securities Purchase Agreement

In connection with the previous strategic alliance with Mundipharma and Purdue, we also entered into a securities purchase agreement with Purdue and PPLP. Under the securities purchase agreement, we issued and sold in two separate closings an aggregate of 6,000,000 shares of our common stock and warrants to purchase up to an aggregate of 6,000,000 shares of our common stock, for an aggregate purchase price of $75 million. An equal number of securities were sold to each purchaser. As of September 30, 2012, all warrants that were issued in connection with the strategic alliance expired without having been exercised.

We recorded an aggregate of $59.3 million in deferred revenue associated with the grant of rights and licenses to Mundipharma and Purdue, which consisted of the excess of the amount paid for the purchased shares over the closing market price on the day before the equity closings and the value of the loan commitment asset. We determined that the rights and licenses did not have stand-alone

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value, and we considered all of the obligations under the arrangement to be a single unit of accounting. There was no obligation for us to repay the $59.3 million, and we had been recognizing the deferred revenue ratably over 14 years, which was our estimated period of performance under the arrangement through July 17, 2012.

2012 Securities Purchase Agreement

On July 17, 2012, in connection with the termination of the strategic alliance with Mundipharma and Purdue, we executed a securities purchase agreement with PPLP, which we refer to as the 2012 securities purchase agreement, under which we agreed to sell and issue 5,416,565 shares of our common stock to PPLP and two entities associated with PPLP, which we collectively refer to as the BRP entities, at a price of $14.50 per share for an aggregate consideration of approximately $78.5 million. The consideration was composed of: (i) extinguishment of approximately $51.0 million in principal and interest due and owing to PPLP under the line of credit agreement, and (ii) $27.5 million in cash. We completed the sale and issuance on September 7, 2012 at which time the line of credit agreement with PPLP terminated in its entirety.

The 2012 securities purchase agreement also provides that, at any time during the period beginning January 1, 2013 and ending December 31, 2018, in the event we propose to make an underwritten offering of our common stock, subject to certain limitations, the Purdue entities will have piggyback registration rights, which require us, at the election of the Purdue entities, to use our reasonable best efforts to cause to be included in such underwritten offering, common stock then held by the Purdue entities representing up to 20% of the total estimated maximum dollar amount of our common stock proposed to be sold in such underwritten offering.

In addition, the BRP entities have agreed to enter into a lockup agreement if requested by us and/or the managing underwriters, placement agents or initial purchasers for any offering of our stock prior to December 31, 2013, pursuant to which the BRP entities will agree not to, among other things, offer, sell or otherwise transfer or dispose of, directly or indirectly, any common stock held by the BRP entities or to enter into any agreement that transfers, in whole or in part, any of the economic consequences of ownership of any common stock held by the BRP entities, for a specified period of time requested by us, the managing underwriters, the placement agents or the initial purchasers.

The 2012 securities purchase agreement also terminated, as of July 17, 2012, all attendance rights to meetings of our board of directors held by the Purdue entities.

The BRP entities and each associated company holding shares of our common stock have agreed to be present at each regular or special meeting of our stockholders held through September 6, 2017, and to vote all of their shares as recommended by our board of directors in the proxy materials mailed to our stockholders in connection with such meeting, except that with respect to any proposal to amend our corporate charter or approve certain extraordinary transactions, all shares of our common stock that are owned by those entities that are were not issued pursuant to the 2012 securities purchase agreement will be voted in proportion to the manner in which all of our stockholders (other than those entities) vote in respect of such proposal, regardless of the recommendation of our board of directors.

Accounting Impact of Alliance Termination, Debt Extinguishment and Sale and Issuance of Common Stock

We recorded the following during the three months ended September 30, 2012:

- Gain on termination of Purdue entities strategic alliance of $46.6 million
- Additional equity on our balance sheet of $74.4 million
- Extinguished $39.5 million of debt on balance sheet
- Eliminated $54.0 million of deferred revenue on balance sheet
- Received cash of $27.5 million

We considered the fact that certain elements of the arrangement discussed above close before others, despite the fact that all of the elements were negotiated and signed concurrently in contemplation of one another. In particular, the strategic alliance with Mundipharma and Purdue was terminated on July 17, 2012, and therefore, there are no further deliverables required under those agreements. However, the equity offering and debt extinguishment did not close at that time because certain regulatory events outside of our control had to occur prior to the closing. As a result, we evaluated the termination of the strategic alliance separately from the financing transaction, including the extinguishment of debt and sale and issuance of stock. We recorded the gain on termination of the Mundipharma and Purdue strategic alliance for $46.6 million which represented our past performance under the 2008 collaboration because we have no further obligation to provide research and development, and the financial risk associated with the research and development has been transferred to the Purdue entities. In particular, any payment of royalties to Mundipharma and Purdue are conditional on the future commercialization of our products.

To establish the financial impact of the stock issuance and debt extinguishment, we determined both the fair value of the common stock we sold and issued and the debt and accrued interest extinguished. We consider Mundipharma and Purdue to be related parties for financial reporting purposes because of their equity ownership. Therefore, we recorded the difference between extinguishing the fair value of the debt and accrued interest, the sale and issuance of our common stock and receiving $27.5 million in cash in additional paid-in capital.

Financial Overview

Revenue

All of our revenue to date has been derived from license fees, the reimbursement of research and development costs, contract service revenue and milestone payments received from our collaboration partners. License fees were recognized as revenue ratably over the expected research and development period under our arrangement with Mundipharma and Purdue. Because our agreements with Mundipharma and Purdue also provided for funding for our research and development efforts, we recognized this cost reimbursement as revenue in the period earned in proportion to our forecasted total expenses as compared to the total research funding budget for the year. In the future, we may generate revenue from a combination of product sales, research and development support services and milestone payments in connection with strategic relationships, and royalties resulting from the sales of products developed under licenses of our intellectual property. We expect that any revenue we generate will fluctuate from year to year as a result of the timing and amount of license fees, research and development reimbursement, milestone and other payments earned under our collaborative or strategic relationships, and the amount and timing of payments that we earn upon the sale of our products, to the extent any are successfully commercialized. If we fail to complete the development of our drug candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenue, and our financial statements, would be materially adversely affected.

Research and Development Expense

We are a drug discovery and development company. Our research and development expense primarily consists of the following:

compensation of personnel associated with research activities;

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clinical testing costs, including payments made to contract research organizations;

costs of purchasing laboratory supplies and materials;

costs of manufacturing drug candidates for preclinical testing and clinical studies;

costs associated with the licensing of research and development programs;

preclinical testing costs, including costs of toxicology studies;

fees paid to external consultants;

fees paid to professional service providers for independent monitoring and analysis of our clinical trials;

costs for collaboration partners to perform research activities, including development milestones for which a payment is due when achieved;

depreciation of equipment; and

allocated costs of facilities.

General and Administrative Expense

General and administrative expense primarily consists of compensation of personnel in executive, finance, accounting, legal, information technology infrastructure, corporate communications, corporate development, human resources and commercial functions. Other costs include facilities costs not otherwise included in research and development expense, and professional fees for legal and accounting services. General and administrative expense also consists of the costs of maintaining our intellectual property portfolio.

Other Income and Expense

Interest and investment income typically consists of interest earned on cash, cash equivalents and available-for-sale securities, net of interest expense, and amortization of warrants. Interest expense included amortization of the loan commitment asset from Purdue entities, net, from April 2009 through November 2011 when we drew down the full $50 million loan available under the line of credit agreement. Interest expense also included accrued interest on the long-term debt, including amortization of the debt discount, through September 7, 2012 when the debt was extinguished.

Income from Massachusetts tax incentive award represents the pro-rata amount earned for an award we received for headcount growth.

Critical Accounting Policies and Significant Judgments and Estimates

The discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make judgments, estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, accrued expenses, assumptions in the valuation of stock-based compensation and income taxes. We base our estimates on historical experience and on various

other assumptions that we believe to be reasonable under the circumstances. Actual results could differ from those estimates.

There have been no material changes to our critical accounting policies during the nine months ended September 30, 2012. Please refer to Part II, Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations of our annual report on Form 10-K for the fiscal year ended December 31, 2011 for a discussion of our critical accounting policies and significant judgments and estimates.

Results of Operations

The following tables summarize our results of operations for each of the three and nine months ended September 30, 2012 and 2011, together with the change in these items in dollars and as a percentage:

	Three Months Ended September 30,			
	2012	2011	$ Change	% Change
		(in thousands)		
Revenue	$	$ 23,305	$ (23,305)	(100)%
Research and development expense	(21,495)	(29,418)	7,923	(27)%
General and administrative expense	(6,294)	(5,470)	(824)	15%
Gain on termination of Purdue entities alliance	46,555		46,555	
Interest expense	(533)	(433)	(100)	23%
Interest and investment income	170	71	99	139%

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	Nine Months Ended September 30,			
	2012	2011	$ Change	% Change
	(in thousands)			
Revenue	$ 47,114	$ 70,448	$ (23,334)	(33)%
Research and development expense	(78,578)	(78,689)	111	0%
General and administrative expense	(20,771)	(16,675)	(4,096)	25%
Gain on termination of Purdue entities alliance	46,555		46,555	
Interest expense	(1,908)	(1,299)	(609)	47%
Income from Massachusetts incentive tax award	193		193	
Interest and investment income	416	234	182	78%

Revenue

Our revenue during the three and nine months ended September 30, 2012 consisted of approximately $0 and $45 million, respectively, for reimbursed research and development services we performed under our strategic alliance with Mundipharma and Purdue, and $0 million and $2.1 million, respectively, from the amortization of the deferred revenue associated with the grant of rights and licenses under this alliance. Our revenue during the three and nine months ended September 30, 2011 consisted of approximately $22.3 million and $67.3 million, respectively, for reimbursed research and development services, including $0.5 million and $3.3 million, respectively, in revenue related to reimbursed research and development services for the transition of the FAAH program, and $1.0 million and $3.1 million, respectively, from the amortization of the deferred revenue associated with the grant of rights and licenses under our alliance with Mundipharma and Purdue. The decrease in reimbursed research and development services revenue for the three and nine months ended September 30, 2012 was due to the 2012 termination agreements with Mundipharma and Purdue. We do not expect to recognize any research and development service revenue in future periods from Mundipharma and Purdue.

Research and Development Expense

Research and development expense represented approximately 77% and 84% of our total operating expenses for the three months ended September 30, 2012 and 2011, respectively. Research and development expense represented approximately 79% and 83% of our total operating expenses for the nine months ended September 30, 2012 and 2011, respectively. The $7.9 million decrease in research and development expense for the three months ended September 30, 2012 as compared to the three months ended September 30, 2011 was primarily attributable a decrease of $5.0 million in pharmaceutical development and clinical expenses related to the discontinuation of company-sponsored development of saridegib and $3.0 million of expense related to the achievement of a milestone in our PI3K inhibitor program during 2011. Research and development expense was approximately flat when comparing the nine months ended September 30, 2012 to the nine months ended September 30, 2011. Further information regarding restructuring activities is described below under the heading Liquidity and Capital Resources Organizational Restructuring.

We began to track and accumulate costs by major program starting on January 1, 2006. These expenses primarily relate to payroll and related expenses for personnel working on the programs, process development and manufacturing, preclinical toxicology studies, clinical trial costs and allocated costs of facilities. During the three and nine months ended September 30, 2012 and 2011, and from January 1, 2006 through September 30, 2012, we estimate that we incurred the following expenses by program:

Program	Three Months Ended September 30, 2012	Three Months Ended September 30, 2011	Nine months ended September 30, 2012	Nine months ended September 30, 2011	January 1, 2006 to September 30, 2012
			(in millions)		
Hedgehog pathway inhibitor	$ 4.9	$ 12.6	$ 33.0	$ 35.6	$ 161.7
Hsp90 inhibitor	5.3	3.7	16.1	9.9	118.8
FAAH inhibitor		0.2		2.7	31.1
PI3K inhibitor	7.7	8.5	17.8	16.5	59.3

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We expect expenses related to our Hedgehog pathway inhibitor program to decrease significantly as a result of the discontinuation of company-sponsored development. We do not believe that the historical costs associated with our lead drug development programs are indicative of the future costs associated with these programs nor represent what any other future drug development program we initiate may cost. Due to the variability in the length of time and scope of activities necessary to develop a drug candidate and uncertainties related to cost estimates and our ability to obtain marketing approval for our drug candidates, accurate and meaningful estimates of the total costs required to bring our product candidates to market are not available.

Because of the risks inherent in drug discovery and development, we cannot reasonably estimate or know:

- the nature, timing and costs of the efforts necessary to complete the development of our programs;
- the completion dates of these programs; or
- the period in which material net cash inflows are expected to commence, if at all, from the programs described above and any potential future product candidates.

There is significant uncertainty regarding our ability to successfully develop any drug candidates. These risks include the uncertainty of:

- the scope, rate of progress and cost of our clinical trials that we are currently running or may commence in the future;
- the scope and rate of progress of our preclinical studies and other research and development activities;
- clinical trial results;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights relating to our programs under development;
- the terms and timing of any strategic alliance, licensing and other arrangements that we have or may establish in the future relating to our programs under development;
- the cost and timing of regulatory approvals;
- the cost of establishing clinical supplies of any product candidates; and
- the effect of competing technological and market developments.

General and Administrative Expense

The increase in general and administrative expense for the three months ended September 30, 2012 as compared to the three months ended September 30, 2011 is primarily attributable to an increase of $0.6 million in salaries and benefits expenses, primarily related to a charge taken in connection with restructuring activities. The increase in general and administrative expense for the nine months ended September 30, 2012 as compared to the nine months end September 30, 2011 is primarily attributable to an increase of $2.1 million in salaries and benefits expenses,

which includes a charge taken in connection with restructuring activities, an increase of $1.3 million in new product planning and other consulting expenses, and an increase of $0.8 million in corporate legal expenses primarily related to the 2012 termination agreements with Purdue and Mundipharma.

Gain on Termination of Purdue Entities Alliance

The gain on termination of Purdue entities alliance is due to the 2012 termination agreements. We do not expect to recognize any more gains on termination of Purdue entities alliance in future periods.

Interest Expense

Interest expense increased in the three and nine months ended September 30, 2012 as compared to the three and nine months ended September 30, 2011 due to our drawdown of the entire amount available under the $50 million line of credit from Purdue during November 2011. The long-term debt to the Purdue entities was extinguished on September 7, 2012.

Interest and Investment Income

Interest and investment income increased in the three and nine months ended September 30, 2012 as compared to the three and nine months ended September 30, 2011 primarily due to a higher average balance of our cash equivalents and available-for-sale securities.

Income from Massachusetts Tax Incentive Award

During the nine months ended September 30, 2012, we recognized $0.2 million as other income. We were awarded a tax grant from the Commonwealth of Massachusetts for approximately $0.5 million for the year ended December 31, 2009, which is earned over a five year period based on headcount growth. We achieved the headcount growth through December 31, 2011 and therefore recognized a pro rata portion of the grant. As the amount received for the award is not related to our ordinary course of operations, we have recorded the amount as other income. If we do not achieve the headcount growth in future years, we may have to refund the Commonwealth of Massachusetts a portion of the grant.

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Liquidity and Capital Resources

We have not generated any revenue from the sale of drugs to date, and we do not expect to generate any such revenue for the next several years, if at all. We have instead relied on the proceeds from sales of equity securities, interest on investments, license fees, expense reimbursement under our collaborations, milestone payments, contract service payments and debt to fund our operations. Our available-for-sale debt securities primarily trade in liquid markets, and the average days to maturity of our portfolio, as of September 30, 2012, is less than six months. Because our product candidates are in various stages of clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability.

Our significant capital resources are as follows:

	September 30, 2012	December 31, 2011
	(in thousands)	
Cash, cash equivalents and available-for-sale securities	$ 189,406	$ 115,937
Working capital	174,585	88,995

	Nine months ended September 30,	
	2012	2011
	(in thousands)	
Cash provided by (used in):		
Operating activities	$ (44,048)	$ (24,555)
Investing activities	(46,401)	26,779
Capital expenditures (included in investing activities above)	(667)	(822)
Financing activities	119,169	450

Cash Flows

The principal use of cash in operating activities in all periods presented was our net spending on our research and development programs: that is, investments in research and development that were not reimbursed by our strategic alliance partners. On July 17, 2012, we mutually agreed with Mundipharma and Purdue to terminate the strategic alliance agreements, and as a result, the total research and development funding for 2012 was $55 million. We will not receive any more research and development funding from Mundipharma and Purdue. During the nine months ended September 30, 2011, spending on all of our research and development programs other than our Hsp90 program was reimbursed by Purdue and Mundipharma up to contractually specified annual caps. We exceeded the contractually budgeted amount for research and development funding from Mundipharma for the year ended December 31, 2011. We expect to continue our investments in 2012 and beyond in the PI3K program, the Hsp90 program and discovery programs. Our cash flow used in operating activities for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 increased primarily due to a decrease in research and development funding from Purdue entities as a result of the termination of the strategic alliance. Cash flows from operations in future periods can vary significantly due to various factors, including changes in accounts payable and accrued expenses, as well as future collaboration arrangements. However, we expect cash used in operating activities to increase without the research and development funding from Mundipharma.

Net cash used in investing activities for the nine months ended September 30, 2012 included $133.9 million in purchases of available-for-sale securities and proceeds of $81.8 million from maturities of available-for-sale securities. Capital expenditures in the nine months ended September 30, 2012 primarily consisted of laboratory equipment.

Net cash from financing activities for the nine months ended September 30, 2012 included $82.8 million of net proceeds from a public stock offering, $27.5 million of proceeds from issuance of common stock to PPLP as a result of termination of strategic agreements with Mundipharma and Purdue and $8.9 million of proceeds from issuances of common stock from stock option exercises related to stock incentive plans.

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Liquidity

We will need substantial additional funds to support our planned operations. In the absence of additional funding or business development activities and based on our current operating plans, we expect that our current cash and investments are sufficient to fund our planned operations into 2014. We may, however, seek to raise additional funds before that date for other reasons, including if:

- our drug candidates require more extensive clinical or preclinical testing than we currently expect;
- we advance more of our drug candidates than expected into costly later stage clinical trials;
- we advance more preclinical drug candidates than expected into early stage clinical trials;
- the cost of acquiring raw materials for, and of manufacturing, our drug candidates is higher than anticipated;
- we are required, or consider it advisable, to acquire or license intellectual property rights from one or more third parties; or
- we experience a loss in our investments due to general market conditions or other reasons.

Historically, we have relied on our strategic alliance with Mundipharma and Purdue for a significant portion of our research and development funding needs. Mundipharma and Purdue provided us approximately $260 million in research and development funding during the term of our strategic alliance. Following the termination of the strategic alliance agreements with Mundipharma and Purdue on July 17, 2012, we will no longer be receiving funding from Mundipharma or Purdue and will have to use other resources available to us to help fund our research and development expenses. Our efforts to raise sufficient capital to replace the funding we previously received under the terminated strategic alliance agreements may not be successful.

During the three months ended September 30, 2012, we received $82.8 million of net proceeds from our public stock offering. We may continue to seek additional funding through public or private financings of equity or debt securities, but such financing may not be available on acceptable terms, or at all, particularly in light of current market conditions. In addition, the terms of our financings may be dilutive to, or otherwise adversely affect, holders of our common stock, and such terms may impact our ability to make capital expenditures or incur additional debt. We may also seek additional funds through arrangements with collaborators or other third parties, or through project financing. These arrangements would generally require us to relinquish or encumber rights to some of our technologies or product candidates, and we may not be able to enter into such agreements on acceptable terms, if at all. If we are unable to obtain additional funding on a timely basis, we may be required to curtail or terminate some or all of our product development programs or to scale back, suspend or terminate our business operations.

Organizational Restructuring

In June 2012, we voluntarily stopped all company-sponsored clinical trials of saridegib, and in July 2012, we restructured our strategic alliance agreements with Mundipharma and Purdue such that we are no longer entitled to research and development funding. As a result, we implemented work force reductions totaling 20% of our employee headcount as of December 31, 2011. Our work force reductions resulted in restructuring charges totaling $2.6 million related to severance, benefits and related costs for employees and was recorded in research and development expenses and general and administrative expenses in the nine months ended September 30, 2012. We expect to realize cost savings from this restructuring activity during 2013.

Contractual Obligations and Off-Balance Sheet Arrangements

Since inception, we have not engaged in any off-balance sheet financing activities, including the use of structured finance, special purpose entities or variable interest entities.

During the nine months ended September 30, 2012, we extinguished our long-term debt due to Purdue entities by issuing shares of our common stock. Please see note 7 of our condensed consolidated financial statements. There have been no other material changes to our contractual obligations and off-balance sheet arrangements during the nine months ended September 30, 2012. Please refer to Part II, Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations of our annual report on Form 10-K for the fiscal year ended December 31, 2011 for a discussion of our contractual obligations.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our interest income is sensitive to changes in the general level of U.S. interest rates, particularly since a significant portion of our investments are in money market funds, corporate obligations, and U.S. government-sponsored enterprise obligations. We do not enter into investments for trading or speculative purposes. Our cash is deposited in and invested through highly rated financial institutions in North America. Our marketable securities are subject to interest rate risk and will fall in value if market interest rates increase.

A hypothetical 100 basis point increase in interest rates would result in an approximate $1.0 million decrease in the fair value of our investments as of September 30, 2012, as compared to an approximate $0.8 million decrease as of December 31, 2011. We have the ability to hold our fixed income investments until maturity and, therefore, we do not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments.

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Item 4. Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2012. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2012, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal quarter ended September 30, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1A. Risk Factors

You should carefully consider the following risk factors, in addition to other information included in this quarterly report on Form 10-Q, in evaluating Infinity and our business. If any of the following risks occur, our business, financial condition and operating results could be materially adversely affected. These risk factors restate and supersede the risk factors set forth under the heading Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2011.

Risks Related to Our Stage of Development as a Company

Our results to date do not guarantee that any of our product candidates will be safe or effective, or receive regulatory approval.

The risk of failure of our current drug candidates is high. To date, the data supporting our clinical development strategy for our drug candidates are derived solely from laboratory and preclinical studies and limited early-to-mid-stage clinical trials. Later clinical trials may not yield data consistent with earlier clinical trials, as was the case with our randomized Phase 2 clinical trial of saridegib in patients with pancreatic cancer, which we elected to discontinue in January 2012 following a preliminary analysis of data that did not confirm what was observed in the single-arm, Phase 1b portion of the study. Similarly, clinical responses seen in patients enrolled at early stages of a clinical trial may not be replicated in patients enrolled in that trial at a later time. In addition, adverse events observed in a small number of patients in early clinical trials may be seen in a greater number of patients in later studies and have greater statistical significance than previously anticipated. In the event that our clinical trials do not yield data consistent with earlier experience, it may be necessary for us to change our development strategy or abandon development of that drug candidate, either of which could result in delays, additional costs and a decrease in our stock price. It is impossible to predict when or if any of our drug candidates will prove safe or effective in humans or receive regulatory approval. These drug candidates may not demonstrate in patients the chemical and pharmacological properties ascribed to them in laboratory studies or early-stage clinical trials, and they may interact with human biological systems or other drugs in unforeseen, ineffective or harmful ways. If we are unable to discover or successfully develop drugs that are safe and effective in humans, we will not have a viable business.

We have a history of operating losses, expect to incur significant and increasing operating losses in the future, and may never be consistently profitable.

We have a limited operating history for you to evaluate our business. We have no approved products and have generated no product revenue from sales. We have primarily incurred operating losses. As of September 30, 2012, we had an accumulated deficit of $276.0 million. We expect to continue to spend significant resources to fund the research and development of IPI-145, retaspimycin HCl, and our other drug candidates. While we may have net income in future periods as the result of non-recurring collaboration revenue, we expect to incur substantial operating losses over the next several years as our clinical trial and drug manufacturing activities increase. As a result, we expect that our accumulated deficit will also increase significantly.

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Our drug candidates are in varying stages of preclinical and clinical development and may never be approved for sale or generate any revenue. We will not be able to generate product revenue unless and until one of our drug candidates successfully completes clinical trials and receives regulatory approval. Since even our most advanced drug candidate requires substantial additional clinical development, we do not expect to receive revenue from our drug candidates for several years, if at all. Even if we eventually generate revenues, we may never be profitable, and if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

We may be unable to raise the substantial additional capital that we will need to sustain our operations.

We will need substantial additional funds to support our planned operations. In the absence of additional funding or business development activities and based on our current operating plans, we expect that our current cash and investments are sufficient to fund our planned operations into 2014. In the absence of changes to our current operating plans, we will need to raise additional funds by that date. Our need to raise additional funds may be accelerated if our research and development expenses exceed our current expectation, if we acquire a third party or if we acquire or license rights to additional drug candidates or new technologies from one or more third parties. Our need to raise additional funds may also be accelerated for other reasons, including if:

- our drug candidates require more extensive clinical or preclinical testing than we currently expect;
- we advance more of our drug candidates than expected into costly later stage clinical trials;
- we advance more preclinical drug candidates than expected into early stage clinical trials;
- we acquire additional business, technologies, products or product candidates;
- the cost of acquiring raw materials for, and of manufacturing, our drug candidates is higher than anticipated;
- we are required, or consider it advisable, to acquire or license intellectual property rights from one or more third parties; or
- we experience a loss in our investments due to general market conditions or other reasons.

Historically, we relied on our strategic alliance with Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products L.P., or Purdue, for a significant portion of our research and development funding needs. Mundipharma and Purdue provided us approximately $260 million in research and development funding during the term of our strategic alliance. Following the termination of the strategic alliance agreements with Mundipharma and Purdue on July 17, 2012, we will no longer be receiving funding from Mundipharma or Purdue and will have to use other resources available to us to help fund our research and development expenses. Our efforts to raise sufficient capital to replace the funding we previously received under the terminated strategic alliance agreements may not be successful.

We may seek additional funding through public or private financings of equity or debt securities, but such financing may not be available on acceptable terms, or at all, particularly in light of current market conditions. In addition, the terms of such financings may result in, among other things, dilution for stockholders or the incurrence of indebtedness that may impact our ability to make capital expenditures or incur additional debt. We may also seek additional funds through arrangements with collaborators or other third parties, or through project financing. These arrangements would generally require us to relinquish or encumber rights to some of our technologies or drug candidates, and we may not be able to enter into such arrangements on acceptable terms, if at all. If we are unable to obtain additional funding on a timely basis, we may be required to curtail or terminate some or all of our product development programs or to scale back, suspend or terminate our business operations.

If we are not able to attract and retain key personnel and advisors, we may not be able to operate our business successfully.

We are highly dependent on our management team, particularly Adelene Perkins and Julian Adams, and the other members of our executive leadership team. All of these individuals are employees-at-will, which means that neither Infinity nor the employee is obligated to a fixed term of service and that the employment relationship may be terminated by either Infinity or the employee at any time, without notice, and whether or not cause or good reason exists for such termination. The loss of the services of any of these individuals might impede the achievement of our research, development and commercialization objectives. We do not maintain key person insurance on any of our employees.

Recruiting and retaining qualified scientific and business personnel is also critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. This competition is particularly intense near our headquarters in Cambridge, Massachusetts. We also experience competition for the hiring of scientific personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development strategy. Our consultants and advisors may be employed by other entities, have commitments under consulting or advisory contracts with third parties that limit their availability to us, or both.

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We may not be able to execute our business strategy if we are unable to enter into alliances with other companies that can provide capabilities or funding for the development and commercialization of our drug candidates.

As part of our business strategy, we have historically entered, and expect to enter in the future, alliances with major biotechnology or pharmaceutical companies to jointly develop specific drug candidates and to jointly commercialize them if they are approved. In these alliances, we would expect our alliance partner to provide substantial funding, as well as significant capabilities in development, marketing and sales. We may not be successful in entering into any such alliances on favorable terms, if at all. Even if we do succeed in securing such alliances, we may not be able to maintain them if, for example, development or approval of a drug candidate is delayed or sales of an approved drug are disappointing. Furthermore, any delay in entering into alliances could delay the development and commercialization of our drug candidates and reduce their competitiveness, even if they reach the market. Any such delay related to our alliances could adversely affect our business.

If an alliance partner terminates or fails to perform its obligations under agreements with us, the development and commercialization of our drug candidates could be delayed or terminated.

If any future alliance partner does not devote sufficient time and resources to its alliance arrangements with us, we may not realize the potential commercial benefits of the arrangement, and our results of operations may be adversely affected. In addition, if any alliance partner were to breach or terminate its arrangements with us, the development and commercialization of the affected drug candidate could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue development and commercialization of the drug candidate on its own, and we may find it difficult to attract a new alliance partner for such drug candidate.

Much of the potential revenue from any alliance we may enter into in the future will likely consist of contingent payments, such as royalties payable on sales of any successfully developed drugs. Any such contingent revenue will depend upon our, and our alliance partner s, ability to successfully develop, introduce, market and sell new products. In some cases, we will not be involved in these processes, and we will depend entirely on our alliance partners. Any of our future alliance partners may fail to develop or effectively commercialize these products because it:

- decides not to devote the necessary resources because of internal constraints, such as limited personnel with the requisite scientific expertise, limited cash resources or specialized equipment limitations, or the belief that other drug development programs may have a higher likelihood of obtaining regulatory approval or may potentially generate a greater return on investment;

- does not have sufficient resources necessary to carry the drug candidate through clinical development, regulatory approval and commercialization; or

- cannot obtain the necessary regulatory approvals. In addition, we entered into a development and license agreement with Intellikine, Inc., or Intellikine, in 2010 under which we obtained rights to discover, develop and commercialize pharmaceutical products targeting the delta and/or gamma isoforms of PI3K, including IPI-145. In January 2012, Intellikine was acquired by Takeda Pharmaceutical Company Limited, or Takeda, acting through its Millennium business unit. We refer to our PI3K program licensor as Millennium. While our agreement with Millennium precludes Millennium from developing or commercializing products directed to the PI3K delta and/or gamma isoforms that meet certain selectivity criteria, Millennium may research, develop and commercialize such products that it was researching, developing or commercializing on its own or with a third party prior to its acquisition of Intellikine. Additionally, Millennium or other potential competitors may develop products directed to other isoforms of PI3K that could be competitive with our PI3K program.

If any future alliance partner fails to develop or effectively commercialize our drug candidates, we may not be able to develop and commercialize that drug independently, and our financial condition and operations would be negatively impacted.

We may encounter difficulties in managing organizational change, which could adversely affect our operations.

Our ability to manage changes to our organization effectively depends upon the continual improvement of our processes and procedures, and the preservation of our corporate culture. We may not be able to implement improvements in an efficient or timely manner, or maintain our corporate culture through organizational change. If we do not meet these challenges, we may be unable to take advantage of market opportunities, execute our business strategies or respond to competitive pressures, which in turn may give rise to inefficiencies that would increase our losses or delay our programs.

We may undertake strategic acquisitions in the future and any difficulties from integrating acquired businesses, technologies, products and product candidates could adversely affect our business and our stock price.

We may acquire additional businesses, technologies, products or product candidates that complement or augment our existing business. We may not be able to integrate any acquired business, technology, product or product candidate successfully or operate any

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acquired business profitably. Integrating any newly acquired business, technology, product or product candidate could be expensive and time-consuming. Integration efforts often place a significant strain on managerial, operational and financial resources and could prove to be more difficult or expensive than we expect. The diversion of the attention of our management to, and any delay or difficulties encountered in connection with, any future acquisitions we may consummate could result in the disruption of our ongoing business or inconsistencies in standards, controls, procedures and policies that could adversely affect our ability to maintain relationships with customers, suppliers, collaborators, employees and others with whom we have business dealings. We may need to raise additional funds through public or private debt or equity financings to acquire any businesses, technologies, products or product candidates, which may result in, among other things, dilution for stockholders or the incurrence of indebtedness.

As part of our efforts to acquire businesses, technologies, products and product candidates or to enter into other significant transactions, we conduct business, legal and financial due diligence in an effort to identify and evaluate material risks involved in the transaction. We will also need to make certain assumptions regarding acquired product candidates, including, among other things, development costs, the likelihood of receiving regulatory approval and the market for such product candidates. If we are unsuccessful in identifying or evaluating all such risks or our assumptions prove to be incorrect, we might not realize some or all of the intended benefits of the transaction. If we fail to realize intended benefits from acquisitions we may consummate in the future, our business, and financial results could be adversely affected.

In addition, we will likely incur significant expenses in connection with our efforts, if any, to consummate acquisitions. These expenses may include fees and expenses for investment bankers, attorneys, accountants and other advisers in connection with our efforts, and could be incurred whether or not an acquisition is consummated. Even if we consummate a particular acquisition, we may incur as part of such acquisition substantial closure costs associated with, among other things, elimination of duplicate operations and facilities. In such case, the incurrence of these costs could adversely affect our financial results for particular quarterly or annual periods.

Our investments are subject to risks that may cause losses and affect the liquidity of these investments.

As of September 30, 2012, we had approximately $189.4 million in cash, cash equivalents and available-for-sale securities. We historically have invested these amounts in money market funds, corporate obligations, U.S. government-sponsored enterprise obligations, U.S. Treasury securities and mortgage-backed securities meeting the criteria of our investment policy, which is focused on the preservation of our capital. Corporate obligations may include obligations issued by corporations in countries other than the Unites States, including some issues that have not been guaranteed by governments and government agencies. Our investments are subject to general credit, liquidity, market and interest rate risks and instability in the global financial markets. We may realize losses in the fair value of these investments or a complete loss of these investments. In addition, should our investments cease paying or reduce the amount of interest paid to us, our interest income would suffer. These market risks associated with our investment portfolio may have a material adverse effect on our financial results and the availability of cash to fund our operations.

The estimates and judgments we make, or the assumptions on which we rely, in preparing our condensed consolidated financial statements could prove inaccurate.

Our condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses. Such estimates and judgments include those related to revenue recognition, accrued expenses, assumptions in the valuation of stock-based compensation and income taxes. We base our estimates and judgments on historical experience, facts and circumstances known to us and on various assumptions that we believe to be reasonable under the circumstances. These estimates and judgments, or the assumptions underlying them, may change over time or prove inaccurate. If this is the case, we may be required to restate our financial statements as we did in 2011, which could in turn subject us to securities class action litigation. Defending against such potential litigation relating to a restatement of our financial statements would be expensive and would require significant attention and resources of our management. Moreover, our insurance to cover our obligations with respect to the ultimate resolution of any such litigation may be inadequate. As a result of these factors, any such potential litigation could have a material adverse effect on our financial results and cause our stock price to decline.

Under our strategic alliance termination agreements, Mundipharma and Purdue continue to have the right to audit research and development expenses incurred by us during the term of our former strategic alliance, in order to verify the research and development funding amounts previously paid by Mundipharma and Purdue. Mundipharma has requested such an audit in the context of discussions regarding renegotiation of our strategic alliance agreements. If, as a result of any audit, it is determined that Mundipharma and Purdue have overpaid research and development expenses, we will be required to refund the amount of such overpayment, plus interest, and if such amount is material we may be required to restate prior period revenue.

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If we are not able to maintain effective internal controls under Section 404 of the Sarbanes-Oxley Act, our business and stock price could be adversely affected.

Section 404 of the Sarbanes-Oxley Act of 2002 requires us, on an annual basis, to review and evaluate our internal controls, and requires our independent auditors to attest to the effectiveness of our internal controls. Any failure by us to maintain the effectiveness of our internal controls in accordance with the requirements of Section 404 of the Sarbanes-Oxley Act, as such requirements exist today or may be modified, supplemented or amended in the future, could have a material adverse effect on our business, operating results and stock price.

Risks Related to the Development and Commercialization of Our Drug Candidates

All of our drug candidates remain subject to clinical testing and regulatory approval. This process is highly uncertain and we may never be able to obtain marketing approval for any of our drug candidates.

To date, we have not obtained approval from the FDA or any foreign regulatory authority to market or sell any of our drug candidates. Our drug candidates are subject to extensive governmental regulations relating to development, clinical trials, manufacturing and commercialization. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process are required in the United States and in many foreign jurisdictions prior to the commercial sale of medicinal products like our drug candidates. For example, retaspimycin HCl, is being evaluated in Phase 2 clinical trials, which are intended to evaluate the safety and effectiveness of the drug candidate in a particular disease indication. In addition, we are conducting a Phase 2 and a Phase 1 clinical trial to evaluate IPI-145, the lead compound in our PI3K inhibitor program, and we intend to commence a second Phase 2 trial of IPI-145 in late 2012. If any of these trials are successful, we will need to conduct further clinical trials and apply for regulatory approval before we may market or sell any of our drug products. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that none of the drug candidates we are developing, or may in the future develop, either alone or in collaboration with strategic alliance partners, will obtain marketing approval. In connection with the clinical trials of our current and future drug candidates, we face, among other risks, risks that:

- the drug candidate may not prove to be safe or effective;
- the results of later trials may not confirm positive results from earlier preclinical studies or clinical trials; and
- the results may not meet the level of statistical significance required by the FDA or other regulatory authorities.

For example, in June 2012 we voluntarily stopped our Phase 2, double-blind, randomized, placebo-controlled study evaluating saridegib in patients with metastatic or locally advanced, inoperable chondrosarcoma and our exploratory Phase 2 clinical trial evaluating saridegib in patients with myelofibrosis after the studies showed that treatment with saridegib was similar to placebo or did not satisfy our pre-specified criteria for trial expansion. As a result, we terminated our development of saridegib.

We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA and comparable foreign regulatory agencies. The time required to complete clinical trials and for regulatory review by the FDA and other countries regulatory agencies is uncertain and typically takes many years. Some of our drug candidates may be eligible for the FDA s programs that are designed to facilitate the development and expedite the review of certain drugs, but we cannot provide any assurance that any of our drug candidates will qualify for one or more of these programs. Even if a drug candidate qualifies for one or more of these programs, the FDA may later decide that the drug candidate no longer meets the conditions for qualification.

Our analysis of data obtained from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unanticipated delays or increased costs due to changes in government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review.

Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability to generate revenues from the particular drug candidate. Furthermore, the uses for which any regulatory authority may grant approval to market a product may be limited, thus placing limitations on the manner in which we may market the product and limiting its market potential.

Our drug candidates must undergo rigorous clinical trials prior to receipt of regulatory approval. Any problems in these clinical trials could delay or prevent commercialization of our drug candidates.

We cannot predict whether we will encounter problems with any of our ongoing or planned clinical trials that will cause us or regulatory authorities to delay or suspend clinical trials or to delay the analysis of data from ongoing clinical trials. Any of the following could delay the clinical development of our drug candidates:

- unexpected or unfavorable results of discussions with the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;

- delays in receiving, or the inability to obtain, required approvals from institutional review boards or other reviewing entities at clinical sites selected for participation in our clinical trials;

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- delays in enrolling patients into clinical trials;
- a lower than anticipated retention rate of patients in clinical trials;
- the need to repeat clinical trials as a result of inconclusive or negative results or unforeseen complications in testing;
- inadequate supply, delays in distribution or deficient quality of, or inability to purchase drug product or other materials necessary to conduct our clinical trials;
- unfavorable FDA inspection and review of a clinical trial site or records of any clinical or preclinical investigation;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials, which may occur even if they were not observed in earlier trials or only observed in a limited number of participants;
- a finding that the trial participants are being exposed to unacceptable health risks;
- the placement by the FDA of a clinical hold on a trial; or
- any restrictions on, or post-approval commitments with regard to, any regulatory approval we ultimately obtain that render the drug candidate not commercially viable.

We may suspend, or the FDA or other applicable regulatory authorities may require us to suspend, clinical trials of a drug candidate at any time if we or they believe the patients participating in such clinical trials, or in independent third party clinical trials for drugs based on similar technologies, are being exposed to unacceptable health risks or for other reasons.

The delay, suspension or discontinuation of any of our clinical trials, or a delay in the analysis of clinical data for our drug candidates, for any of the foregoing reasons, could adversely affect our efforts to obtain regulatory approval for and to commercialize our drug candidates, increase our operating expenses, and have a material adverse effect on our financial results.

Our inability to enroll sufficient numbers of patients in our clinical trials, or any delays in patient enrollment, can result in increased costs and longer development periods for our drug candidates.

Clinical trials require sufficient patient enrollment, which is a function of many factors, including:

- the size of the patient population;
- the nature of the trial protocol;
- the number of clinical trial sites and the proximity of patients to those sites;

- the availability of effective treatments for the relevant disease;
- the eligibility criteria for the trial;
- the commitment of clinical investigators to identify eligible patients; and
- competing studies or trials.

Our failure to enroll patients in a clinical trial could delay the initiation or completion of the clinical trial beyond current expectations. In addition, the FDA could require us to conduct clinical trials with a larger number of subjects than has been projected for any of our drug candidates. As a result of these factors, we may not be able to enroll a sufficient number of patients in a timely or cost-effective manner.

Furthermore, enrolled patients may drop out of a clinical trial, which could impair the validity or statistical significance of the clinical trial. A number of factors can influence the patient discontinuation rate, including, but not limited to:

- the inclusion of a placebo arm in a trial;
- possible inactivity or low activity of the drug candidate being tested at one or more of the dose levels being tested;
- the occurrence of adverse side effects, whether or not related to the drug candidate; and
- the availability of numerous alternative treatment options, including clinical trials evaluating competing drug candidates, that may induce patients to discontinue their participation in the trial.

A delay in our clinical trial activities could adversely affect our efforts to obtain regulatory approval for and to commercialize our drug candidates, increase our operating expenses, and have a material adverse effect on our financial results.

If we are unable to successfully develop companion diagnostics for our drug candidates, or experience significant delays in doing so, we may not realize the full commercial potential of our drug candidates.

An important component of our business strategy is to develop companion diagnostics for each of our drug candidates. For example, we are prospectively evaluating a molecular subpopulation of patients in our clinical trial evaluating retaspimycin HCl plus

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docetaxel in smokers with non-small cell lung cancer, for which development of an appropriate diagnostic test may be an important component of our future development and commercial strategy. There has been limited success to date industry wide in developing companion diagnostics. To be successful, we will need to address a number of scientific, technical and logistical challenges. Companion diagnostics are subject to regulation by the FDA and similar regulatory authorities outside the United States as medical devices and require separate regulatory approval prior to commercialization. We have limited experience in the development of diagnostics and may not be successful in developing appropriate diagnostics to pair with any of our drug candidates that receive marketing approval. Given our limited experience in developing diagnostics, we expect to rely, in part, on third parties for their design and manufacture. If we, or any third parties that we engage to assist us, are unable to successfully develop companion diagnostics for our drug candidates, or experience delays in doing so, the development of our drug candidates may be adversely affected, our drug candidates may not receive marketing approval and we may not realize the full commercial potential of any drug candidates that receive marketing approval.

We rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily.

We rely on third parties such as contract research organizations, medical institutions and external investigators to enroll qualified patients, conduct our clinical trials and provide services in connection with such clinical trials, and we intend to rely on these and other similar entities in the future. Our reliance on these third parties for clinical development activities reduces our control over these activities. Accordingly, these third party contractors may not complete activities on schedule, or may not conduct our clinical trials in accordance with regulatory requirements or the trial design. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be required to replace them. Replacing a third party contractor may result in a delay of the affected trial and unplanned costs. If this were to occur, our efforts to obtain regulatory approval for and to commercialize our drug candidates may be delayed.

In addition, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocol for the trial. The FDA requires us to comply with certain standards, referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. If any of our trial investigators or third party contractors does not comply with good clinical practices, we may not be able to use the data and reported results from the trial. If this were to occur, our efforts to obtain regulatory approval for and to commercialize our drug candidates may be delayed.

Manufacturing difficulties could delay or preclude commercialization of our drug candidates and substantially increase our expenses.

Our drug candidates require precise, high quality manufacturing. The third party manufacturers on which we rely may not be able to comply with the FDA s current good manufacturing practices, or cGMPs, and other applicable government regulations and corresponding foreign standards. These regulations govern manufacturing processes and procedures and the implementation and operation of systems to control and assure the quality of products. The FDA and foreign regulatory authorities may, at any time, audit or inspect a manufacturing facility to ensure compliance with cGMPs and other quality standards. Any failure by our contract manufacturers to achieve and maintain high manufacturing and quality control standards could result in the inability of our drug candidates to be released for use in one or more countries. In addition, such a failure could result in, among other things, patient injury or death, product liability claims, penalties or other monetary sanctions, the failure of regulatory authorities to grant marketing approval of our drug candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of drug candidates or products, operating restrictions and/or criminal prosecution, any of which could significantly and adversely affect supply of our drug candidates and seriously hurt our business.

Contract manufacturers may also encounter difficulties involving production yields or delays in performing their services. We do not have control over third party manufacturers performance and compliance with applicable regulations and standards. If, for any reason, our manufacturers cannot perform as agreed, we may be unable to replace such third party manufacturers in a timely manner and the production of our drug candidates would be interrupted, resulting in delays in clinical trials and additional costs. Switching manufacturers may be difficult because the number of potential manufacturers is limited and, depending on the type of material manufactured at the contract facility, the change in contract manufacturer must be submitted to and/or approved by the FDA and comparable regulatory authorities outside of the United States. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our drug candidates after receipt of regulatory approval. It may be difficult or impossible for us to find a replacement manufacturer on acceptable terms quickly, or at all.

To date, our drug candidates have been manufactured for preclinical testing and clinical trials primarily by third party manufacturers. If the FDA or other regulatory agencies approve any of our drug candidates for commercial sale, we expect that we would continue to rely, at least initially, on third party manufacturers to produce commercial quantities of our approved drug candidates. These manufacturers may not be able to successfully increase the manufacturing capacity for any approved drug candidates in a timely or economical manner, or at all. Significant scale-up of manufacturing might entail changes in the

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manufacturing process that have to be submitted to or approved by the FDA or other regulatory agencies. If contract manufacturers engaged by us are unable to successfully increase the manufacturing capacity for a drug candidate, or we are unable to establish our own manufacturing capabilities, the commercial launch of any approved products may be delayed or there may be a shortage in supply.

We have commercialization rights to all product candidates in our portfolio, but we currently have limited marketing, sales and distribution experience and capabilities.

We currently have global commercialization rights for products arising out of our all of our development programs. In order to successfully commercialize our drug candidates, we will need to, and we intend to, establish adequate marketing, sales and distribution capabilities for commercialization in the United States, and to seek a qualified partner with these capabilities for commercialization outside the United States. We may not successfully establish these capabilities or have sufficient resources to do so. If we do not establish adequate marketing, sales and distribution capabilities or engage a qualified partner, our ability to successfully commercialize any drug candidates that we successfully develop will be adversely affected, as will our financial results. Even if we do develop such capabilities, we will compete with other companies that have more experienced and well-funded marketing, sales and distribution operations, and we will incur additional expenses.

If physicians and patients do not accept our future drugs, we may not be able to generate significant revenues from product sales.

Even if any of our drug candidates obtains regulatory approval, that product may not gain market acceptance among physicians, patients and the medical community for a variety of reasons including:

- timing of our receipt of any marketing approvals, the terms of any such approvals and the countries in which any such approvals are obtained;
- timing of market introduction of competitive drugs;
- lower demonstrated clinical safety and efficacy compared to other drugs;
- lack of cost-effectiveness;
- lack of reimbursement from managed care plans and other third-party payors;
- inconvenient or difficult administration;
- prevalence and severity of side effects;
- potential advantages of alternative treatment methods;
- safety concerns with similar drugs marketed by others;
- the reluctance of the target population to try new therapies and of physicians to prescribe those therapies;

the success of our physician education programs; and

ineffective sales, marketing and distribution support.

If any of our approved drugs fails to achieve market acceptance, we would not be able to generate significant revenue from those drugs, which may adversely impact our ability to become profitable.

Even if we receive regulatory approvals for marketing our drug candidates, we could lose our regulatory approvals and our business would be adversely affected if we, our strategic alliance partners, or our contract manufacturers fail to comply with continuing regulatory requirements.

The FDA continues to review products even after they receive initial approval. If we receive approval to commercialize any of our drug candidates, the manufacturing, marketing and sale of these drugs will be subject to continuing regulation, including compliance with quality systems regulations, GMPs, adverse event requirements, and prohibitions on promoting a product for unapproved uses. Enforcement actions resulting from our failure to comply with government and regulatory requirements could result in fines, suspension of approvals, withdrawal of approvals, product recalls, product seizures, mandatory operating restrictions, criminal prosecution, civil penalties and other actions that could impair the manufacturing, marketing and sale of our drug candidates and our ability to conduct our business.

If our drug candidates exhibit harmful side effects after approval, our regulatory approvals could be revoked or otherwise negatively impacted, and we could become subject to costly and damaging product liability claims.

Even if we receive regulatory approval for any of our drug candidates, we will have tested them in only a small number of patients during our clinical trials. If our applications for marketing are approved and more patients begin to use our products, new risks and side effects associated with our products may be discovered or previously observed risks and side effects may become more prevalent and/or clinically significant. In addition, supplemental clinical trials that may be conducted on a drug following its initial approval may produce findings that are inconsistent with the trial results previously submitted to regulatory authorities. As a result,

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regulatory authorities may revoke their approvals, or we may be required to conduct additional clinical trials, make changes in labeling of our product, reformulate our product or make changes and obtain new approvals for our and our suppliers manufacturing facilities. We also might have to withdraw or recall our products from the marketplace. Any safety concerns with respect to a product may also result in a significant drop in the potential sales of that product, damage to our reputation in the marketplace, or result in us becoming subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales of our approved product or substantially increase the costs and expenses of commercializing and marketing our product.

We are subject to uncertainty relating to reimbursement policies that could hinder or prevent the commercial success of our drug candidates.

Our ability to commercialize our product candidates successfully will depend in part on the coverage and reimbursement levels set by governmental authorities, private health insurers and other third-party payors. As a threshold for coverage and reimbursement, third-party payors generally require that drug products have been approved for marketing by the FDA. Third-party payors also are increasingly challenging the effectiveness of and prices charged for medical products and services. We may not obtain adequate third-party coverage or reimbursement for our drug candidates or we may be required to sell our drug candidates at prices that are below our expectations.

We expect that private insurers will consider the efficacy, cost effectiveness and safety of our drug candidates in determining whether, and at what level, to approve reimbursement for our drug candidates. Obtaining these approvals can be a time consuming and expensive process. Our business would be materially adversely affected if we do not receive approval for reimbursement of our drug candidates from private insurers on a timely or satisfactory basis. Our business could also be adversely affected if private insurers, including managed care organizations, the Medicare and Medicaid programs or other reimbursing bodies or payors limit the indications for which our drug candidates will be reimbursed to a smaller set than we believe our drug candidates are effective in treating.

In some foreign countries, particularly Canada and the countries of Europe, the pricing of prescription pharmaceuticals is subject to strict governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory approval and product launch. To obtain favorable reimbursement for the indications sought or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our drug candidates to other available therapies. If reimbursement for our products is unavailable in any country in which reimbursement is sought, limited in scope or amount, or if pricing is set at unsatisfactory levels, our business would be materially harmed.

We expect to experience pricing pressures in connection with the sale of our drug candidates and our future products due to the potential healthcare reforms discussed below, as well as the trend toward programs aimed at reducing health care costs, the increasing influence of health maintenance organizations and additional legislative proposals.

Healthcare reform measures could hinder or prevent our product candidates commercial success.

The U.S. government and other governments have shown significant interest in pursuing healthcare reform, as evidenced by the passing of the Patient Protection and Affordable Healthcare Act and the Health Care and Education Reconciliation Act. This healthcare reform law increases the number of individuals who receive health insurance coverage and closes a gap in drug coverage under Medicare Part D as established under the Medicare Prescription Drug Improvement Act of 2003; each of these reforms could potentially increase our future revenue from any of our drug candidates that are approved for sale. The law, however, also implements cost containment measures that could adversely affect our future revenue. These measures include increased drug rebates under Medicaid for brand name prescription drugs and extension of these rebates to Medicaid managed care. The legislation also extends 340B discounted pricing on outpatient drugs to children s hospitals, critical access hospitals, and rural health centers; this expansion reduces the amount of reimbursement received for drugs purchased by these new 340B-covered entities.

Additional provisions of the health care reform law may negatively affect our future revenue and prospects for profitability. Along with other pharmaceutical manufacturers and importers of brand name prescription drugs, we would be assessed a fee based on our proportionate share of sales of brand name prescription drugs to certain government programs, including Medicare and Medicaid. As part of the health care reform law s provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program (commonly known as the donut hole), we will also be required to provide a 50% discount on brand name prescription drugs sold to beneficiaries who fall within the donut hole.

In the aftermath of the healthcare reform law, private health insurers and managed care plans are likely to continue challenging the prices charged for medical products and services. These cost-control initiatives could decrease the price we might establish for any of our drug candidates, which would result in lower product revenue or royalties payable to us.

In addition, in some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. These proposed reforms could result in reduced reimbursement rates for any of our drug candidates, which would adversely affect our business strategy, operations and financial results.

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Our business could be harmed if we are unable to comply with applicable fraud and abuse and other laws and regulations where our drug candidates may ultimately be sold.

As our pipeline of drug candidates matures, we are becoming increasingly subject to extensive and complex laws and regulations, including but not limited to healthcare fraud and abuse and patient privacy laws and regulations by both the federal government and the states in which we conduct our business. These laws and regulations include:

- the federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers;

- the federal Health Insurance Portability and Accountability Act of 1996, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- the Federal Food, Drug, and Cosmetic Act, which, among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our financial results. We are developing and implementing a corporate compliance program designed to ensure that we will market and sell any drug candidates that we successfully develop in compliance with all applicable laws and regulations, but we cannot guarantee that this program will protect us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Risks Related to Our Field

Our competitors and potential competitors may develop products that make ours less attractive or obsolete.

In building our product development pipeline, we have intentionally pursued targets with applicability across multiple therapeutic areas and indications. This approach gives us several product opportunities in oncology, inflammatory disease and pain, which are highly competitive and rapidly changing segments of the pharmaceutical industry. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations are pursuing the development of novel drugs that target various diseases in these segments. We currently face, and expect to continue to face, intense and increasing competition as new products enter the market and advanced technologies become available. Moreover, there are a number of large pharmaceutical companies currently marketing and selling products in these segments including Bristol-Myers Squibb Company, the Roche Group and its subsidiary Genentech, Novartis AG and Pfizer, Inc. In addition to currently approved drugs, there are a significant number of drugs that are currently under development and may become available in the future for the treatment of various forms of cancer, inflammatory diseases and pain. We are also aware of a number of

companies seeking to develop drug candidates directed to the same biological targets that our own drug candidates are designed to inhibit. Specifically, we believe the following companies are developing compounds that target Hsp90, which is the target of retaspimycin HCl: Synta Pharmaceuticals Corp., Novartis AG, Astex Pharmaceuticals, Inc., Daiichi Sankyo, Inc., Debiopharm Group, Exelixis, Inc., and Kyowa Hakko Kirin Co. Ltd. Also, we believe that Gilead Sciences, Inc., Amgen Inc. and GlaxoSmithKline are developing drugs that target the delta and/or gamma isoforms of PI3K. In addition, many companies are developing product candidates directed to disease targets such as Bruton s Tyrosine Kinase, or BTK, Janus Kinase, or JAK, and Spleen Tyrosine Kinase, or Syk, in the fields of hematology-oncology and inflammation, including in the specific diseases for which we are currently developing IPI-145, or for which we may develop IPI-145 or other PI3K inhibitors in the future.

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Many of our competitors have:

- significantly greater financial, technical and human resources than us, and may be better equipped to discover, develop, manufacture and commercialize drug candidates;
- more extensive experience in preclinical testing and clinical trials, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products; and/or
- drug candidates that have been approved or are in later-stage clinical development than our own drug candidates.

Our competitors may commence and complete clinical testing of their product candidates, obtain regulatory approvals, and begin commercialization of their products sooner than we and/or our strategic alliance partners may for our own drug candidates. These competitive products may have superior safety or efficacy, have more attractive pharmacologic properties, or may be manufactured less expensively than our drug candidates. If we are unable to compete effectively against these companies on the basis of safety, efficacy or cost, then we may not be able to commercialize our drug candidates or achieve a competitive position in the market. This would adversely affect our ability to generate revenues.

We may have significant product liability exposure that may harm our business and our reputation.

We face exposure to significant product liability or other claims if any of our drug candidates is alleged to have caused harm. These risks are inherent in the testing, manufacturing and marketing of human medicinal products. Although we do not currently commercialize any products, claims could be made against us based on the use of our drug candidates in clinical trials. We currently have clinical trial insurance and will seek to obtain product liability insurance prior to the commercial launch of any of our drug candidates. Our insurance may not, however, provide adequate coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain current amounts of insurance coverage or obtain additional or sufficient insurance at a reasonable cost. If we are sued for any injury caused by our products or product candidates, our liability could exceed our insurance coverage and our total assets, and we would need to divert management attention to our defense. Claims against us, regardless of their merit or potential outcome, may also generate negative publicity or hurt our ability to recruit investigators and patients to our clinical trials, obtain physician acceptance of our products, or expand our business.

We work with hazardous materials that may expose us to liability.

Our activities involve the controlled storage, use and disposal of hazardous materials, including infectious agents, corrosive, explosive and flammable chemicals, and various radioactive compounds. We are subject to certain federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. We incur significant costs to comply with these laws and regulations. In addition, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, regulatory authorities may curtail our use of these materials, and we could be liable for any civil damages that result. These damages may exceed our financial resources or insurance coverage, and may seriously harm our business. Additionally, an accident could damage, or force us to shut down, our operations.

Security breaches may disrupt our operations and harm our operating results.

Our network security and data recovery measures may not be adequate to protect against computer viruses, break-ins, and similar disruptions from unauthorized tampering with our computer systems. The misappropriation, theft, sabotage or any other type of security breach with respect to any of our proprietary and confidential information that is electronically stored, including research or clinical data, could have a material adverse impact on our business, operating results and financial condition. Additionally, any break-in or trespass of our facilities that results in the misappropriation, theft, sabotage or any other type of security breach with respect to our proprietary and confidential information, including research or clinical data, or that results in damage to our research and development equipment and assets, could have a material adverse impact on our business, operating results and financial condition.

Risks Related to Intellectual Property

Our success depends substantially upon our ability to obtain and maintain intellectual property protection for our drug candidates.

We own or hold exclusive licenses to a number of U.S. and foreign patents and patent applications directed to our drug candidates. Our success depends on our ability to obtain patent protection both in the United States and in other countries for our drug candidates, their methods of manufacture and methods of their use. Our ability to protect our drug candidates from unauthorized or infringing use by third parties depends substantially on our ability to obtain and enforce our patents.

Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and molecular diagnostics and the claim scope of these patents, our ability to obtain and enforce patents that may issue from any pending or future patent applications is uncertain and involves complex legal, scientific and factual questions. The standards

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that the United States Patent and Trademark Office, or PTO, and its foreign counterparts use to grant patents are not always applied predictably or uniformly and are subject to change. To date, no consistent policy has emerged regarding the breadth of claims allowed in pharmaceutical or molecular diagnostics patents. Thus, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us. Even if patents do issue, we cannot guarantee that the claims of these patents will be held valid or enforceable by a court of law, will provide us with any significant protection against competitive products, or will afford us a commercial advantage over competitive products.

The U.S. Congress passed the Leahy-Smith America Invents Act, or the America Invents Act, which will become effective in March 2013. The America Invents Act reforms United States patent law in part by changing the standard for patent approval for certain patents from a first to invent standard to a first to file standard and developing a post-grant review system. This new law changes United States patent law in a way that may severely weaken our ability to obtain patent protection in the United States. Additionally, recent judicial decisions establishing new case law and a reinterpretation of past case law, as well as regulatory initiatives, may make it more difficult for us to protect our intellectual property.

If we do not obtain adequate intellectual property protection for our products in the United States, competitors could duplicate them without repeating the extensive testing that we had been required to undertake to obtain approval of the products by the FDA. Regardless of any patent protection, under the current statutory framework the FDA is prohibited by law from approving any generic version of any of our products for up to five years after it has approved our product. Upon the expiration of that period, or if that time period is altered, the FDA could approve a generic version of our product unless we have patent protection sufficient for us to block that generic version. Without sufficient patent protection, the applicant for a generic version of our product would only be required to conduct a relatively inexpensive study to show that its product is bioequivalent to our product, and would not have to repeat the studies that we conducted to demonstrate that the product is safe and effective. In the absence of adequate patent protection in other countries, competitors may similarly be able to obtain regulatory approval in those countries of products that duplicate our products. The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States. Many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. Some of our development efforts are performed in China, India, and other countries outside of the United States through third party contractors. We may not be able to monitor and assess intellectual property developed by these contractors effectively; therefore, we may not be able to appropriately protect this intellectual property and could thus lose valuable intellectual property rights. In addition, the legal protection afforded to inventors and owners of intellectual property in countries outside of the United States may not be as protective of intellectual property rights as in the United States, and we may, therefore, be unable to acquire and protect intellectual property developed by these contractors to the same extent as if these development activities were being conducted in the United States. If we encounter difficulties in protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

In addition, we rely on intellectual property assignment agreements with our strategic alliance partners, vendors, employees, consultants, scientific advisors and other collaborators to grant us ownership of new intellectual property that is developed by them. These agreements may not result in the effective assignment to us of that intellectual property. As a result, our ownership of key intellectual property could be compromised.

Patent interference, opposition or similar proceedings relating to our intellectual property portfolio are costly, and an unfavorable outcome could prevent us from commercializing our drug candidates.

Patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the PTO for the entire time prior to issuance as a U.S. patent. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Consequently, we cannot be certain that we were the first to invent, or the first to file patent applications on, our drug candidates or their therapeutic use. In the event that a third party has also filed a U.S. patent application relating to our drug candidates or a similar invention, we may have to participate in interference proceedings declared by the PTO or the third party to determine priority of invention in the United States. An adverse decision in an interference proceeding may result in the loss of rights under a patent or patent application. In addition, the cost of interference proceedings could be substantial.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which non-compliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we fail to comply with these requirements, competitors might be able to enter the market earlier than would otherwise have been the case, which could decrease our revenue from that product.

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Claims by third parties of intellectual property infringement are costly and distracting, and could deprive us of valuable rights we need to develop or commercialize our drug candidates.

Our commercial success will depend on whether there are third party patents or other intellectual property relevant to our potential products that may block or hinder our ability to develop and commercialize our drug candidates. We may not have identified all U.S. and foreign patents or published applications that may adversely affect our business either by blocking our ability to manufacture or commercialize our drugs or by covering similar technologies that adversely affect the applicable market. In addition, we may undertake research and development with respect to potential products, even when we are aware of third party patents that may be relevant to such potential products, on the basis that we may challenge or license such patents. For example, in our Hsp90 inhibitor program, we are conducting clinical trials evaluating the administration of retaspimycin HCl in combination with docetaxel and everolimus. We are aware of issued patents and published applications directed to combinations of Hsp90 inhibitors with a variety of therapeutic agents. We are also aware of patents and patent applications directed to methods of treating various disorders using a variety of Hsp90 inhibitors. We are in the process of evaluating the scope and validity of these patents and applications to determine whether we need to obtain one or more licenses. There are no assurances that such licenses will be available on commercially reasonable terms, or at all. If such licenses are not available, we may become subject to patent litigation and, while we cannot predict the outcome of any of litigation, it may be expensive and time consuming. If we are unsuccessful in litigation concerning patents owned by third parties, we may be precluded from selling our products.

While we are not currently aware of any litigation or third party claims of intellectual property infringement related to our drug candidates, the biopharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents and claim that the use of our technologies infringes these patents or that we are employing their proprietary technology without authorization. We could incur substantial costs and diversion of management and technical personnel in defending against any claims that the manufacture and sale of our potential products or use of our technologies infringes any patents, or defending against any claim that we are employing any proprietary technology without authorization. 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, especially in pharmaceutical patent cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. In the event of a successful claim of infringement against us, we may be required to:

- pay substantial damages;
- stop developing, manufacturing and/or commercializing the infringing drug candidates or approved products;
- develop non-infringing products, technologies and methods; and
- obtain one or more licenses from other parties, which could result in our paying substantial royalties or the granting of cross-licenses to our technologies.

If any of the foregoing were to occur, we may be unable to commercialize the affected products, or we may elect to cease certain of our business operations, either of which could severely harm our business.

We may undertake infringement or other legal proceedings against third parties, causing us to spend substantial resources on litigation and exposing our own intellectual property portfolio to challenge.

Competitors may infringe our patents. To prevent infringement or unauthorized use, we may need to file infringement suits, which are expensive and time-consuming. In an infringement proceeding, a court may decide that one or more of our patents is invalid, unenforceable, or both. Even if the validity of our patents is upheld, a court may refuse to stop the other party from using the technology at issue on the ground that the other party s activities are not covered by our patents. In this case, third parties may be able to use our patented technology without paying licensing fees or royalties. Policing unauthorized use of our intellectual property is difficult, and we may not be able to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States. In addition, third parties may affirmatively challenge our rights to, or the scope or validity of, our patent rights.

Confidentiality agreements may not adequately prevent disclosure of trade secrets and other proprietary information.

In order to protect our proprietary technology, we rely in part on confidentiality agreements with our vendors, strategic alliance partners, employees, consultants, scientific advisors, clinical investigators and other collaborators. We generally require each of these individuals and entities to execute a confidentiality agreement at the commencement of a relationship with us. These agreements may not effectively prevent disclosure of confidential information, and may not provide an adequate remedy in the event of unauthorized disclosure or misuse of confidential information or other breaches of the agreements.

In addition, we may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. Trade secrets are, however, difficult to protect. 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

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illegally obtained and is using our trade secrets is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside of 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 could result in a diversion of management s attention, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

If we fail to obtain necessary or useful licenses to intellectual property, we could encounter substantial delays in the research, development and commercialization of our drug candidates.

We may decide to license third party technology that we deem necessary or useful for our business. We may not be able to obtain these licenses at a reasonable cost, or at all. If we do not obtain necessary licenses, we could encounter substantial delays in developing and commercializing our drug candidates while we attempt to develop alternative technologies, methods and drug candidates, which we may not be able to accomplish. Furthermore, if we fail to comply with our obligations under our third party license agreements, we could lose license rights that are important to our business. For example, if we fail to use diligent efforts to develop and commercialize compounds and products licensed under our development and license agreement with Millennium, we could lose our license rights under that agreement, including rights to IPI-145.

Risks Associated with Our Common Stock

Our common stock may have a volatile trading price and low trading volume.

The market price of our common stock has been and could continue to be subject to significant fluctuations. Some of the factors that may cause the market price of our common stock to fluctuate include:

- the results of our current and any future clinical trials of our drug candidates;
- the results of preclinical studies and planned clinical trials of our discovery-stage programs;
- product portfolio decisions resulting in the delay or termination of our product development programs;
- future sales of, and the trading volume in, our common stock, including the sale by entities associated with Purdue of the shares of our common stock that they currently own;
- our entry into key agreements, including those related to the acquisition or in-licensing of new programs, or the termination of key agreements, including our development and license agreement with Millennium;
- the results and timing of regulatory reviews relating to the approval of our drug candidates;
- the initiation of, material developments in, or conclusion of litigation to enforce or defend any of our intellectual property rights;
- the initiation of, material developments in, or conclusion of litigation to defend product liability claims;
- the failure of any of our drug candidates, if approved, to achieve commercial success;

the results of clinical trials conducted by others on drugs that would compete with our drug candidates;

issues in manufacturing our drug candidates or any approved products;

the loss of key employees;

changes in estimates or recommendations, or publication of inaccurate or unfavorable research about our business, by securities analysts who cover our common stock;

future financings through the issuance of equity or debt securities or otherwise;

changes in the structure of healthcare payment systems;

our cash position and period-to-period fluctuations in our financial results; and

general and industry-specific economic conditions.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock.

In the past, when the market price of a stock has been volatile, as our stock price may be, holders of that stock have occasionally brought securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit is without merit, negative publicity could be generated and we could incur substantial costs defending the lawsuit. A stockholder lawsuit could also divert the time and attention of our management.

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We do not anticipate paying cash dividends, so you must rely on stock price appreciation for any return on your investment.

We anticipate retaining any future earnings for reinvestment in our research and development programs. Therefore, we do not anticipate paying cash dividends in the future. As a result, only appreciation of the price of our common stock will provide a return to stockholders. Investors seeking cash dividends should not invest in our common stock.

Our stockholder rights plan, anti-takeover provisions in our organizational documents, and Delaware law may make an acquisition of us difficult.

We are a party to a stockholder rights plan, also referred to as a poison pill, which is intended to deter a hostile takeover by making any unsolicited proposed acquisition of us more expensive and less desirable to the potential acquirer.

In addition, we are incorporated in Delaware. Anti-takeover provisions of Delaware law and our organizational documents may make a change in control more difficult. Also, under Delaware law, our board of directors may adopt additional anti-takeover measures. For example, our charter authorizes our board of directors to issue up to 1,000,000 shares of undesignated preferred stock, of which only 99,000 shares have been designated to date, and to determine the terms of those shares of stock without any further action by our stockholders. If our board of directors exercises this power, it could be more difficult for a third party to acquire a majority of our outstanding voting stock. Our charter and by-laws also contain provisions limiting the ability of stockholders to call special meetings of stockholders.

Our stock incentive plan generally permits our board of directors to provide for acceleration of vesting of options granted under that plan in the event of certain transactions that result in a change of control. If our board of directors uses its authority to accelerate vesting of options, this action could make an acquisition more costly, and it could prevent an acquisition from going forward.

Under Section 203 of the Delaware General Corporation Law, a corporation may not engage in a business combination with any holder of 15% or more of its capital stock until the holder has held the stock for three years unless, among other possibilities, the board of directors approves the transaction. Our board of directors could use this provision to vote against any such transaction. The existence of the foregoing provisions could limit the price that investors might be willing to pay in the future for shares of our common stock.

Our executive officers, directors and major shareholders may be able to exert significant control over the company, which may make an acquisition of us difficult.

Our executive officers, directors, their respective affiliates and entities associated with Purdue currently control approximately 34% of our outstanding common stock. These stockholders have the ability to influence our company through this ownership position. For example, as a result of this concentration of ownership, these stockholders, if acting together, may have the ability to affect the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger or similar transaction. This concentration of ownership may, therefore, harm the market price of our common stock by:

delaying, deferring or preventing a change in control of Infinity;

impeding a merger, consolidation, takeover or other business combination involving Infinity; or

discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of Infinity.

Item 6. Exhibits

(a) Exhibits.

The exhibits listed in the Exhibit Index are included in this report.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

INFINITY PHARMACEUTICALS, INC.

Date: November 6, 2012

By: /s/ ADELENE Q. PERKINS
Adelene Q. Perkins
President and Chief Executive Officer
(Principal Executive Officer)

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EXHIBIT INDEX

Exhibit	Description
3.1	Restated Certificate of Incorporation of the Registrant. Previously filed as Exhibit 3.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (File No. 000-31141) and incorporated herein by reference.
3.2	Amended and Restated Bylaws of the Registrant. Previously filed as Exhibit 3.1 to the Registrant s Current Report on Form 8-K filed on March 17, 2009 (File No. 000-31141) and incorporated herein by reference.
4.1	Form of Common Stock Certificate. Previously filed as Exhibit 4.1 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2007 (File No. 000-31141) and incorporated herein by reference.
4.2	Rights Agreement between the Registrant and American Stock Transfer & Trust Company dated February 13, 2003, which includes the form of Certificate of Designation for the Series A junior participating preferred stock as Exhibit A, the form of Rights Certificate as Exhibit B and the Summary of Rights to Purchase Series A junior participating preferred stock as Exhibit C. Previously filed as Exhibit 4.2 to the Registrant s Current Report on Form 8-K filed on February 24, 2003 (File No. 000-31141) and incorporated herein by reference.
4.3	First Amendment to the Rights Agreement between the Registrant and American Stock Transfer & Trust Company dated April 11, 2006. Previously filed as Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed on April 12, 2006 (File No. 000-31141) and incorporated herein by reference.
4.4	Second Amendment to the Rights Agreement between the Registrant and American Stock Transfer & Trust Company, LLC dated November 19, 2008. Previously filed as Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed on November 20, 2008 (File No. 000-31141) and incorporated herein by reference.
10.1	Offer Letter between the Registrant and Lawrence E. Bloch, M.D., J.D. dated May 15, 2012. Previously filed as Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed on July 23, 2012 (File No. 000-31141) and incorporated herein by reference.
10.2	Sixth Amendment to Lease dated July 8, 2012 between the Registrant and ARE-770/784/790 Memorial Drive LLC. Previously filed as Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q filed on August 7, 2012 (File No. 000-31141) and incorporated herein by reference.
10.3	Securities Purchase Agreement, dated as of July 17, 2012, between the Registrant, Purdue Pharma L.P., Beacon Company and Rosebay Medical Company L.P. Previously filed as Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed on July 19, 2012 (File No. 000-31141) and incorporated herein by reference.
10.4	Termination and Revised Relationship Agreement, dated as of July 17, 2012, between the Registrant and Mundipharma International Corporation Limited. Previously filed as Exhibit 10.2 to the Registrant s Current Report on Form 8-K filed on July 19, 2012 (File No. 000-31141) and incorporated herein by reference.
10.5	Termination and Revised Relationship Agreement, dated as of July 17, 2012, between the Registrant and Purdue Pharmaceutical Products L.P. Previously filed as Exhibit 10.3 to the Registrant s Current Report on Form 8-K filed on July 19, 2012 (File No. 000-31141) and incorporated herein by reference.
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended. Filed herewith.
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended. Filed herewith.
32.1	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Filed herewith.
32.2	Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Filed herewith.
101*	The following materials from the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2012, formatted in XBRL (eXtensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Cash Flows, and (iv) Notes to Condensed Consolidated Financial Statements.

* Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed as part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.