

INFINITY PHARMACEUTICALS, INC.

Form 10-Q

May 06, 2010

[Table of Contents](#)

**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 March 31, 2010

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)

Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)  
**33-0655706**  
(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 ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

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

Large accelerated filer ☐ Accelerated filer ☒  
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 ☒

Number of shares of the registrant's Common Stock, \$0.001 par value, outstanding on March 31, 2010: 26,266,968

---

**Table of Contents**

**INFINITY PHARMACEUTICALS, INC.**

**FORM 10-Q**

**FOR THE QUARTER ENDED MARCH 31, 2010**

**TABLE OF CONTENTS**

	<b>Page No.</b>
<b>PART I</b>	
<b><u>FINANCIAL INFORMATION</u></b>	<b>1</b>
<b>Item 1.</b>	
<b><u>Unaudited Condensed Consolidated Financial Statements</u></b>	<b>1</b>
<u>Condensed Consolidated Balance Sheets as of March 31, 2010 and December 31, 2009</u>	1
<u>Condensed Consolidated Statements of Operations for the Three Months Ended March 31, 2010 and 2009</u>	2
<u>Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2010 and 2009</u>	3
<u>Notes to Condensed Consolidated Financial Statements</u>	4
<b>Item 2.</b>	
<b><u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>	<b>11</b>
<b>Item 3.</b>	
<b><u>Quantitative and Qualitative Disclosures About Market Risk</u></b>	<b>20</b>
<b>Item 4.</b>	
<b><u>Controls and Procedures</u></b>	<b>20</b>
<b>PART II</b>	
<b><u>OTHER INFORMATION</u></b>	<b>21</b>
<b>Item 1A.</b>	
<b><u>Risk Factors</u></b>	<b>21</b>
<b>Item 6.</b>	
<b><u>Exhibits</u></b>	<b>35</b>
<b><u>Signatures</u></b>	<b>36</b>

**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Condensed Consolidated Financial Statements**  
**INFINITY PHARMACEUTICALS, INC.****Condensed Consolidated Balance Sheets****(unaudited)**

	<b>March 31, 2010</b>	<b>December 31, 2009</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 16,648,271	\$ 16,287,229
Available-for-sale securities	109,015,719	113,758,778
Notes receivable from employees	51,656	55,059
Prepaid expenses and other current assets	3,125,025	3,511,968
Total current assets	128,840,671	133,613,034
Property and equipment, net	5,839,841	5,694,150
Loan commitment asset from Purdue entities, net	15,587,100	16,020,075
Long-term available-for-sale securities	683,839	690,506
Notes receivable from employees	29,901	38,036
Restricted cash	1,147,092	1,146,788
Other assets	107,510	115,244
Total assets	\$ 152,235,954	\$ 157,317,833
<b>Liabilities and stockholders equity</b>		
Current liabilities:		
Accounts payable	\$ 2,559,974	\$ 1,441,231
Accrued expenses	8,843,103	8,542,923
Deferred revenue from Purdue entities	3,991,004	2,987,512
Current portion of capital leases	5,840	6,459
Total current liabilities	15,399,921	12,978,125
Deferred revenue from Purdue entities, less current portion	35,108,475	35,855,463
Other liabilities	2,093,221	2,219,224
Capital leases, less current portion	4,927	5,489
Total liabilities	52,606,544	51,058,301
Commitments and contingencies		
Stockholders equity:		
Preferred Stock, \$0.001 par value; 1,000,000 shares authorized, no shares issued and outstanding at March 31, 2010 and December 31, 2009		
Common Stock, \$0.001 par value; 100,000,000 shares authorized, and 26,266,968 and 26,238,954 shares issued and outstanding, at March 31, 2010 and December 31, 2009, respectively	26,267	26,239
Additional paid-in capital	289,446,474	287,593,176
Accumulated deficit	(189,758,607)	(181,397,174)
Accumulated other comprehensive income (loss)	(84,724)	37,291
Total stockholders equity	99,629,410	106,259,532

Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

Total liabilities and stockholders' equity	\$ 152,235,954	\$ 157,317,833
--	----------------	----------------

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

**Table of Contents**

**INFINITY PHARMACEUTICALS, INC.**  
**Condensed Consolidated Statements of Operations**  
**(unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
Collaborative research and development revenue from Purdue entities	\$ 15,993,496	\$ 9,429,158
Operating expenses:		
Research and development	19,377,805	21,241,526
General and administrative	4,749,001	5,330,208
Total operating expenses	24,126,806	26,571,734
Loss from operations	(8,133,310)	(17,142,576)
Other income (expense):		
Interest expense	(433,057)	(369)
Income from residual funding after reacquisition of Hsp90 program		12,450,000
Interest and investment income	204,934	742,493
Total other income (expense)	(228,123)	13,192,124
Net loss	\$ (8,361,433)	\$ (3,950,452)
Basic and diluted loss per common share	\$ (0.32)	\$ (0.15)
Basic and diluted weighted average number of common shares outstanding	26,244,297	25,910,687

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

**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Condensed Consolidated Statements of Cash Flows****(unaudited)**

	<b>Three Months Ended March 31, 2010</b>	<b>Three Months Ended March 31, 2009</b>
<b>Operating activities</b>		
Net loss	\$ (8,361,433)	\$ (3,950,452)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	556,285	495,044
Stock-based compensation, including 401(k) match	1,830,548	1,795,178
Gain on sale of property and equipment		(34,519)
Net amortization (accretion) of available-for-sale securities	424,885	(345,311)
Amortization of loan commitment asset from Purdue	432,975	
Other, net	18,845	11,626
Changes in operating assets and liabilities:		
Accounts receivable and unbilled accounts receivable		1,189,570
Prepaid expenses and other current assets	386,943	(220,721)
Accounts payable, accrued expenses and other liabilities	1,304,301	(2,020,790)
Deferred revenue from Purdue entities	256,504	18,506,532
Net cash provided by (used in) operating activities	(3,150,147)	15,426,157
<b>Investing activities</b>		
Purchases of property and equipment	(701,976)	(942,388)
Proceeds from sale of property and equipment		34,519
Purchases of available-for-sale securities	(58,294,393)	(67,379,551)
Proceeds from sales of available-for-sale securities	7,239,262	
Proceeds from maturities of available-for-sale securities	55,258,080	38,437,844
Net cash provided by (used in) investing activities	3,500,973	(29,849,576)
<b>Financing activities</b>		
Proceeds from issuances of common stock	11,397	121,410
Proceeds from issuance of common stock and warrants to Purdue entities		11,830,000
Capital lease payments	(1,181)	(1,445)
Net cash provided by financing activities	10,216	11,949,965
Net increase (decrease) in cash and cash equivalents	361,042	(2,473,454)
Cash and cash equivalents at beginning of period	16,287,229	16,574,549
Cash and cash equivalents at end of period	\$ 16,648,271	\$ 14,101,095

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

**Table of Contents**

**Infinity Pharmaceuticals, Inc.**

**Notes to Condensed Consolidated Financial Statements**

**(Unaudited)**

**1. Organization**

Infinity Pharmaceuticals, Inc. is a drug discovery and development company that is utilizing its strength in small molecule drug technologies to discover and develop medicines for difficult to treat diseases. 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 months ended March 31, 2010 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2010.

The information presented in the condensed consolidated financial statements and related footnotes at March 31, 2010, and for the three months ended March 31, 2010 and 2009, is unaudited, and the condensed consolidated balance sheet amounts and related footnotes at December 31, 2009 have been derived from our audited financial statements. For further information, 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, 2009, which was filed with the U.S. Securities and Exchange Commission ( SEC ) on March 12, 2010.

**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, U.S. Treasury obligations and mortgage-backed securities. 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 consists of a money market fund in the presented periods, and corporate obligations and U.S. government-sponsored enterprise obligations in past periods, are stated at market value and are both readily convertible to known amounts of cash and close enough to maturity 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 March 31, 2010 and December 31, 2009 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. Realized gains on our available-for-sale securities for the three months ended March 31, 2010 were immaterial. There were no realized gains for the three months ended March 31, 2009. We include interest and dividends on securities classified as available-for-sale in interest and investment income.

Other-than-temporary impairments must be recognized through earnings if we have the intent to sell the debt security or if it is more likely than not that we will be required to sell the debt security before recovery of our amortized cost basis. Even if we do not expect to sell a debt security, we must also evaluate expected cash flows to be received and determine if a credit loss has occurred. In the event of a credit loss, only the amount associated with the credit loss is recognized through earnings. The amount of loss relating to other factors is recorded in accumulated



other comprehensive income (loss).

**Table of Contents****Infinity Pharmaceuticals, Inc.****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)*****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 licenses to, and reimbursed research and development services provided for, Mundipharma International Corporation Limited ( Mundipharma ) and Purdue Pharmaceutical Products L.P. ( Purdue ) accounted for all of our revenue for the three months ended March 31, 2010 and 2009. We consider Mundipharma, Purdue and associated entities to be related parties for financial reporting purposes because of their equity ownership (see Note 8).

***Basic and Diluted Loss per Common Share***

Basic loss per share is based upon the weighted average number of common shares outstanding during the period, excluding restricted shares of common stock that has been issued but is not yet vested. Diluted 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 vesting of restricted shares of common stock. 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 loss per share calculations for the periods presented because the effect of including them would have been anti-dilutive. Total potential gross common equivalent shares consisted of the following:

	<b>At March 31,</b>	
	<b>2010</b>	<b>2009</b>
Stock options	6,025,042	5,029,159
Warrants	6,246,629	6,246,629
Unvested restricted shares of common stock	11,347	39,339

***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.

***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. We divide agreements containing multiple elements into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the collaborative partner and whether there is objective and reliable evidence of fair value of the undelivered obligation(s). For these agreements, we allocate the consideration we receive among the separate units based on their respective fair values or, in some cases, the residual method, and we apply the applicable revenue recognition criteria to each of the separate units.

## Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

We recognize revenues from non-refundable, up-front license fees on a straight-line basis over the contracted or estimated period of performance, which is typically the research or development term. We recognize research and development funding as earned over the period of effort as related research costs are incurred. We regularly consider whether events warrant a change in the estimated period of performance under an agreement. Such a change would cause us to modify the period of time over which we recognize revenue on a prospective basis from the up-front license fees paid to us under that agreement and would, in turn, result in changes in our quarterly and annual results.

We recognize milestone payments as revenue upon achievement of the milestone only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (4) the milestone is at risk for both parties. If any of these conditions is not met, we defer the recognition of revenue underlying the milestone payment and recognize it over the remaining estimated period of performance under the contract as we complete our performance obligations.

**Table of Contents**

**Infinity Pharmaceuticals, Inc.**

**Notes to Condensed Consolidated Financial Statements (Continued)**

**(Unaudited)**

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

***Research and Development Expense***

Research and development expense consists of expenses incurred in performing research and development activities, including salaries and benefits, facilities expenses, overhead expenses, materials and supplies, preclinical expenses, clinical trial and related clinical manufacturing expenses, stock-based compensation expense, contract services, and other outside expenses. We expense research and development costs as they are incurred. We have entered into certain collaboration agreements in which expenses are shared with the collaborator, and others in which we are reimbursed for work performed on behalf of the collaborator. We record all of our expenses as research and development expense. If the arrangement is a cost-sharing arrangement and there is a period during which we receive payments from the collaborator, we record payments from the collaborator for its share of the development effort as a reduction of research and development expense. If the arrangement is a cost-sharing arrangement and there is a period during which we make payments to the collaborator, we record our payments to the collaborator for its share of the development effort as additional research and development expense. If the arrangement provides for reimbursement of research and development expenses, we record the reimbursement as revenue. Our alliance with Mundipharma and Purdue provides for the reimbursement of research and development expenses.

***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 March 31, 2010 and December 31, 2009.

***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.

The carrying amounts reflected in the condensed consolidated balance sheets for notes receivable from employees, prepaid expenses and other current assets, accounts payable and accrued expenses approximate fair value due to their short term maturities.

***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 are included in depreciation expense. Repairs and

## Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

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 life of lease or useful life of asset
Furniture and fixtures	7 years

**Table of Contents****Infinity Pharmaceuticals, Inc.****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)****4. Stock-Based Compensation**

Total stock-based compensation expense, related to all equity awards, for the three months ended March 31, 2010 and 2009 comprised the following:

	Three Months Ended March 31, 2010	Three Months Ended March 31, 2009
<i>Effect of stock-based compensation on net loss by line item:</i>		
Research and development	\$ 959,364	\$ 863,037
General and administrative	871,184	932,141

As of March 31, 2010, there was approximately \$10.4 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 2.2 years.

During the three months ended March 31, 2010, we granted options to purchase 1,132,530 shares of our common stock at a weighted average fair value of \$3.51. During the three months ended March 31, 2009, we granted options to purchase 359,010 shares of our common stock at a weighted average fair value of \$3.92. The fair values were estimated using the Black-Scholes valuation model using the following weighted-average assumptions:

	For the Three Months Ended March 31, 2010	For the Three Months Ended March 31, 2009
Risk-free interest rate	2.89%	1.90%
Expected annual dividend yield		
Expected stock price volatility	59.68%	56.56%
Expected term of options	5.70 years	5.38 years

**5. Comprehensive Loss**

Comprehensive loss is comprised of net loss and other comprehensive income (loss). Other comprehensive income (loss) includes unrealized holding gains and losses arising during the period on available-for-sale securities that are not other-than-temporarily impaired. For the three months ended March 31, 2010 and 2009, comprehensive loss was as follows:

	Three Months Ended March 31, 2010	2009
Net loss	\$ (8,361,433)	\$ (3,950,452)
Net unrealized holding gains (losses) on available-for-sale securities arising during the period	(122,015)	112,976
<b>Total comprehensive loss</b>	<b>\$ (8,483,448)</b>	<b>\$ (3,837,476)</b>

Accumulated other comprehensive income (loss) consists of unrealized net gains (losses) on available-for-sale securities.

**6. Cash, Cash Equivalents and Available-for-Sale Securities**

# Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

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

		March 31, 2010		
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash and cash equivalents due in 90 days or less	\$ 16,648,271	\$	\$	\$ 16,648,271
Available-for-sale securities				
Corporate obligations due in one year or less	14,564,195	1,392	(11,166)	14,554,421
U.S. Treasury securities due in one year or less	2,257,419	1,626		2,259,045
Mortgage-backed securities due after ten years	691,295		(7,456)	683,839
U.S. government-sponsored enterprise obligations due in one year or less	72,582,532	18,396	(1,155)	72,599,773
U.S. government-sponsored enterprise obligations due in one to five years	19,688,841		(86,361)	19,602,480
Total available-for-sale securities	109,784,282	21,414	(106,138)	109,699,558
Total cash, cash equivalents and available-for-sale securities	\$ 126,432,553	\$ 21,414	\$ (106,138)	\$ 126,347,829

**Table of Contents****Infinity Pharmaceuticals, Inc.****Notes to Condensed Consolidated Financial Statements (Continued)****(Unaudited)**

		<b>December 31, 2009</b>		
	<b>Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Estimated Fair Value</b>
Cash and cash equivalents due in 90 days or less	\$ 16,287,229	\$	\$	\$ 16,287,229
Available-for-sale securities				
Corporate obligations due in one year or less	31,505,149	13,461	(205)	31,518,405
U.S. Treasury securities due in one year or less	2,268,546	3,684		2,272,230
Mortgage-backed securities due after ten years	699,376		(8,870)	690,506
U.S. government-sponsored enterprise obligations due in one year or less	64,841,354	71,583	(494)	64,912,443
U.S. government-sponsored enterprise obligations due in one to five years	15,097,568		(41,868)	15,055,700
Total available-for-sale securities	114,411,993	88,728	(51,437)	114,449,284
Total cash, cash equivalents and available-for-sale securities	\$ 130,699,222	\$ 88,728	\$ (51,437)	\$ 130,736,513

There were 14 debt securities that had been in an unrealized loss position for less than 12 months at March 31, 2010. The aggregate unrealized loss on these securities was \$106,138 and the fair value was \$45,314,543. To determine whether an other-than-temporary impairment exists, we consider whether we have the ability and intent to hold these investments until a market price recovery, and considered whether evidence indicating the recoverability of the cost of the investments outweighed evidence to the contrary. Since the decline in market value was primarily attributable to current economic conditions and we believe that we have the ability to hold these investments until a recovery of fair value, we do not consider these investments to be other-than-temporarily impaired at March 31, 2010.

There were no other-than-temporary impairments recognized for the three months ended March 31, 2010 and 2009.

**7. 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.

The following table provides the assets carried at fair value measured on a recurring basis as of March 31, 2010:

	<b>Level 1</b>	<b>Level 2</b>
Cash and cash equivalents	\$ 16,648,271	\$
Corporate obligations (including commercial paper)		14,554,421
Mortgage-backed securities		683,839
U.S. Treasury securities		2,259,045
U.S. government-sponsored enterprise obligations		92,202,253



Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

Total	\$ 16,648,271	\$ 109,699,558
-------	---------------	----------------

**Table of Contents**

**Infinity Pharmaceuticals, Inc.**

**Notes to Condensed Consolidated Financial Statements (Continued)**

**(Unaudited)**

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. Treasury securities:* benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data and vendor trading platform data.

*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.

We did not change these valuation methods during the three months ended March 31, 2010.

**8. Collaborations**

***Purdue and Mundipharma***

In November 2008, we entered into strategic alliance agreements with each of Purdue and Mundipharma to develop and commercialize pharmaceutical products. The alliance includes product candidates that inhibit or target the Hedgehog pathway and fatty acid amide hydrolase, or FAAH, and product candidates arising out of all our discovery projects in all disease fields that achieve development candidate status on or before December 31, 2011 (with Mundipharma having the right, through the exercise of two consecutive one-year options, to extend such period through December 31, 2013). We refer to such three to five year period as the funded discovery period. Our heat shock protein 90, or Hsp90, and Bcl-2 programs are expressly excluded from the alliance. The agreement with Purdue is focused on the development and U.S. commercialization of products targeting FAAH. The agreement with Mundipharma is focused on the development and commercialization outside of the United States of all products and product candidates covered by the alliance, including those targeting FAAH.

Under the strategic alliance agreements, we have responsibility and decision-making authority for the performance of early discovery projects and the development of all product candidates on a worldwide basis. There are no joint steering or similar committees for the alliance.

Mundipharma is obligated to pay 100% of our contractually budgeted amounts for research and development expenses incurred by us for early discovery projects and product candidates included in the alliance until the later of December 31, 2013 and the commencement of the first Phase 3 clinical trial of such product candidate, which we refer to as the transition date. The contractually budgeted amount for the period between November 19, 2008 and December 31, 2009 was \$50 million and the contractually budgeted amounts for the years ending December 31, 2010

## Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

and 2011 are \$65 million and \$85 million, respectively. After the transition date for each product candidate other than those arising out of the FAAH project, we will share with Mundipharma all research and development costs for such product candidate equally. Mundipharma has the right to opt out of any early discovery project or any preclinical or clinical development program on an annual basis in November of each year. In the event of an opt-out decision, Mundipharma, together with Purdue with respect to the FAAH project, will continue to provide funding for, in the aggregate, 100% of our contractually budgeted research and development expenses for the applicable project or program for one year after the date of such opt out. Purdue has a comparable opt out right with respect to the FAAH project. In addition to the annual opt-out right, Mundipharma and Purdue will each have the right to opt out of participation in the FAAH project following completion of the first Phase 1 clinical trial of IPI-940. We expect completion of this clinical trial in 2010. If Mundipharma and Purdue were to exercise this right, there is no residual funding obligation for the FAAH project, but we may redeploy contractually-budgeted amounts that had been allocated to the FAAH project to any other project that is the subject of the alliance. In addition, we and Mundipharma each have the right to opt out of continued development of a product candidate after it has reached the transition date, with a one year tail funding obligation for its 50% of post-transition date research and development expenses. If a party exercises its right to opt out of the development of a product or product candidate after the transition date, the other party may elect to continue the development and assume responsibility for the worldwide commercialization of such product or product candidate, subject to the payment of a royalty. We are recording revenue for reimbursed research and development services we perform for Mundipharma and Purdue. We recorded \$15.3 million and \$8.7 million in such revenue in the periods ended March 31, 2010 and 2009, respectively. In the first month of each quarter, Purdue and Mundipharma each prepay an estimated quarterly research and development service amount, which we record as deferred revenue and recognize as revenue as expenses are incurred over the period of effort.

## **Table of Contents**

### **Infinity Pharmaceuticals, Inc.**

#### **Notes to Condensed Consolidated Financial Statements (Continued)**

#### **(Unaudited)**

In connection with the entry into the strategic alliance agreements in November 2008, we also entered into a securities purchase agreement and line of credit agreement with Purdue and its independent associated company, Purdue Pharma L.P. ( PPLP ). In March 2009, Purdue assigned its interest under the line of credit agreement to PPLP. Under the securities purchase agreement we issued and sold in a first equity closing in November 2008 an aggregate of four million shares of our common stock at a purchase price of \$11.25 per share, for an aggregate purchase price of \$45 million. Of such shares, two million shares of our common stock were purchased by each purchaser. In January 2009, we conducted a second equity closing where we issued and sold an aggregate of two million shares of our common stock and warrants to purchase up to an aggregate of six million shares of our common stock, for an aggregate purchase price of \$30 million. An equal number of shares and warrants were purchased by each purchaser.

These warrants are currently exercisable for:

1,000,000 shares of our common stock at any time up to July 1, 2010, at an exercise price of \$20.00 per share;

2,000,000 shares of our common stock at any time up to July 1, 2011, with an initial exercise price of \$20.00 per share, with such exercise price increasing over time depending on when such warrants are exercised, up to a maximum exercise price of \$30.00 per share; and

3,000,000 shares of our common stock at any time up to July 2, 2012, with an initial exercise price of \$30.00 per share, with such exercise price increasing over time depending on when such warrants are exercised, up to a maximum exercise price of \$40.00 per share.

The fair value of these warrants was estimated as of November 2008 using a binomial valuation model assuming no expected dividends, a volatility of 58%, contractual lives ranging from 1.6 years to 3.6 years and risk-free interest rates ranging from 1.0% to 1.5%. The aggregate fair value of these warrants of approximately \$1.3 million was recorded as additional paid-in capital in the three months ended March 31, 2009.

In November 2008, for financial statement purposes we recorded \$23.8 million as deferred revenue associated with the grant of licenses to Mundipharma and Purdue. This amount represented the excess of the amount paid by Purdue and PPLP for the four million shares of our common stock (\$11.25 per share) over the closing market price on the day before the first equity closing (\$5.29 per share). In 2008, we considered our obligation, absent material adverse changes, to issue Purdue and PPLP the second closing securities as a forward contract with immaterial intrinsic value, which was recorded in stockholders' equity. This forward contract closed in January 2009 upon the issuance of the second closing securities. In January 2009, for financial statement purposes, we recorded \$18.2 million as deferred revenue associated with the grant of licenses to Mundipharma and Purdue representing the excess of the \$30 million paid by Purdue and PPLP for the second closing securities over the fair market value of these securities (\$5.29 per share for the common stock and approximately \$1.3 million for the warrants) as of the day before the first equity closing.

All deferred revenue related to this strategic alliance is currently recognized as revenue ratably over 14 years, which is our estimated period of performance under the alliance agreements. We periodically review this estimate and make adjustments as facts and circumstances dictate. We recognized \$0.7 million in such revenue in the periods ended March 31, 2010 and 2009.

The line of credit agreement provides for the borrowing by us of one or more unsecured loans up to an aggregate maximum principal amount of \$50 million. The loans may be drawn by us through March 31, 2012. The loans, which may be used by us for any proper corporate purpose, mature on April 1, 2019 and will be subordinate to any senior indebtedness that we may incur. Borrowings made under the line of credit agreement will bear interest, payable on the maturity date, at a fluctuating rate set at the prime rate on the business day prior to the funding of each loan and will be reset on the last business day of each month ending thereafter. Interest will be compounded on each successive

## Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

three-month anniversary of the funding of each loan. Outstanding loans may be prepaid without penalty or premium prior to the maturity date. Amounts borrowed under the credit agreement, once borrowed, may not be borrowed again. We have certain rights to repay outstanding amounts under the line of credit agreement in shares of our common stock.

### ***MedImmune/AZ***

In August 2006, we entered into a product development and commercialization agreement with MedImmune, Inc., an affiliate of AstraZeneca plc ( MedImmune/AZ ), to jointly develop and commercialize cancer drugs targeting Hsp90 and the Hedgehog pathway. Under the terms of this agreement, we shared equally with MedImmune/AZ all development costs, as

**Table of Contents**

**Infinity Pharmaceuticals, Inc.**

**Notes to Condensed Consolidated Financial Statements (Continued)**

**(Unaudited)**

well as potential profits and losses, from any future marketed products. In November 2007, we regained from MedImmune/AZ worldwide development and commercialization rights under our Hedgehog pathway program on a royalty-free basis. In December 2008, we regained from MedImmune/AZ worldwide development and commercialization rights under our Hsp90 chaperone inhibitor program, subject to the payment of single-digit royalties on worldwide net sales, if any, of each of IPI-504 and IPI-493. In January 2009, we reached an agreement with MedImmune/AZ to settle the residual funding obligation remaining for 2009 through lump-sum payments totaling \$12.5 million, which were recorded as income from residual funding after reacquisition of Hsp90 program (a component of other income) in the three months ended March 31, 2009. We received \$6.2 million in cash from MedImmune/AZ in the three months ended March 31, 2009 and recorded an unbilled receivable for remaining amounts due from MedImmune/AZ, which was subsequently received in the following quarter.

**9. Loan Commitment Asset**

In connection with the strategic alliance with Purdue and Mundipharma, we also entered into a line of credit agreement with Purdue and 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 this additional value as a loan commitment asset at its fair value of \$17.3 million 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. The loan commitment asset is measured at fair value on a nonrecurring basis and will only be re-measured at fair value for nonrecurring events such as an impairment loss. Because Purdue and its associated companies became related parties for financial reporting purposes as a result of their equity ownership, we recorded the offset to this asset as additional paid-in capital in 2008.

We are amortizing this asset to interest expense over the life of the loan arrangement, or 10 years commencing on April 1, 2009, the date we could begin drawing on the line. We recorded approximately \$0.4 million of related amortization expense in the period ended March 31, 2010. As of March 31, 2010, no amounts have been borrowed under this line of credit.

**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 a drug discovery and development company that is utilizing our strength in small molecule drug technologies to discover and develop medicines for difficult to treat diseases. Our discovery program has generated four clinical stage drug candidates spanning programs in the inhibition of heat shock protein 90, or Hsp90, chaperone system, the Hedgehog signaling pathway and fatty acid amide hydrolase, or FAAH.

We are developing two drug candidates in our Hsp90 inhibitor program including IPI-504 (retaspimycin hydrochloride), an intravenously-administered small molecule, and orally administered IPI-493. Hsp90 is a central component of the cellular chaperone system a system that supports and stabilizes cancer-causing proteins such as EGFR and HER2, enabling multiple forms of cancer to thrive. Inhibition of the Hsp90 chaperone knocks out this critical source of support for cancer cells, leading to tumor growth inhibition and cancer cell death. Thus, Hsp90 chaperone inhibition may represent a significant yet currently unaddressed strategy for treating patients with cancer.



## **Table of Contents**

We are evaluating IPI-504 in a Phase 2 trial in combination with Herceptin® (trastuzumab) in patients with HER2-positive metastatic breast cancer and in a Phase 1b trial in combination with Taxotere® (docetaxel) focused on patients with non-small cell lung cancer, or NSCLC. We anticipate presenting preliminary data from the breast cancer study in the second half of 2010. In addition, we have completed enrollment in a single-agent trial of IPI-504 in patients with advanced NSCLC, and based on preliminary data showing a response rate in patients with wild-type EGFR expression, we undertook an effort to better understand the molecular characteristics of the responding patients. We anticipate that data from this research, along with final data from this clinical trial, will be presented during the American Society for Clinical Oncology Annual Meeting in June 2010. In the near future, we expect to evaluate data from our ongoing clinical trial of IPI-504 in patients with metastatic breast cancer and, following this evaluation, we intend to make a portfolio decision regarding further near-term investment in IPI-504.

We are evaluating IPI-493 in a Phase 1 clinical trial in patients with advanced solid tumors. This trial is designed to assess the safety and tolerability of IPI-493 and to identify a dose and schedule for subsequent studies. We anticipate the commencement of active enrollment in a Phase 1 study of IPI-493 in patients with advanced hematologic malignancies in the near term, and reporting data from our Phase 1 program in 2010.

We have worldwide development and commercialization rights for our Hsp90 chaperone inhibitor program, which includes IPI-504 and IPI-493, subject to the payment to our former partner, MedImmune, Inc., an affiliate of AstraZeneca plc, of a single-digit royalty on net sales of IPI-504 and IPI-493. We refer to MedImmune, Inc. in this report as MedImmune/AZ.

The lead candidate in our Hedgehog signaling pathway, or Hedgehog pathway, program is IPI-926, a novel, orally-available inhibitor of the Hedgehog pathway. The Hedgehog pathway is normally active during embryonic development and regulates tissue and organ formation. Malignant activation of the Hedgehog pathway is believed to play a central role in allowing the proliferation and survival of cancer cells, including in pancreatic, prostate, small cell lung, breast, blood cancers, as well as certain skin and brain cancers. IPI-926 has demonstrated anti-tumor activity in numerous preclinical models.

We recently initiated a randomized Phase 1b/2 clinical trial evaluating IPI-926 in combination with gemcitabine in patients with pancreatic cancer. The Phase 1b portion of the study is a dose-escalation evaluating once-daily oral administration of IPI-926 and weekly intravenous administration of gemcitabine. The Phase 2 portion of this trial is set to commence once the recommended Phase 2 doses for IPI-926 and gemcitabine have been established. The Phase 2 portion of the trial is an international, multi-center, randomized, double-blind trial evaluating approximately 120 patients with pancreatic cancer. The primary endpoint of the Phase 2 portion of the trial is overall survival. Secondary endpoints include progression free survival, time to progression, and overall response rate. We continue to enroll patients in a Phase 1 clinical trial evaluating IPI-926 in patients with advanced and/or metastatic solid tumors. The primary objectives of this trial are to evaluate the safety and tolerability of IPI-926 and to identify a dose and schedule for subsequent studies. We intend to report data from this study in 2010. We are pursuing our Hedgehog pathway program in collaboration with Mundipharma International Corporation Limited, or Mundipharma.

We also have a program directed to FAAH, an emerging target for neuropathic pain. The enzyme FAAH degrades anandamide, which is a neurotransmitter that produces a pain relieving effect in response to pain and nerve injury. FAAH inhibition is believed to increase the duration of anandamide's effect, prolonging pain relief at the site of release. We recently initiated a Phase 1 clinical trial of IPI-940, our novel, orally available inhibitor of FAAH, and anticipate completing this trial in 2010. The objectives of this trial are to evaluate the safety, tolerability, and pharmacokinetic and pharmacodynamic properties of IPI-940. We are pursuing our FAAH program in collaboration with Mundipharma and its independent associated company, Purdue Pharmaceutical Products L.P., or Purdue.

We have spent, and expect to continue to spend, significant resources to fund the research and development of IPI-504, IPI-493, IPI-926, IPI-940 and our other drug candidates. While we may have net income in future periods as the result of non-recurring collaboration income, we expect to incur substantial operating losses over the next several years as our clinical trial and drug manufacturing activities increase.

### ***Collaboration Agreements***

***Purdue and Mundipharma.*** In November 2008, we entered into strategic alliance agreements with each of Purdue and Mundipharma to develop and commercialize pharmaceutical products. The alliance includes product candidates that inhibit or target the Hedgehog pathway and FAAH, and product candidates arising out of all our discovery projects in all disease



## **Table of Contents**

fields that achieve development candidate status on or before December 31, 2011 (with Mundipharma having the right, through the exercise of two consecutive one-year options, to extend such period through December 31, 2013). We refer to such three to five year period as the funded discovery period. Our Hsp90 and Bcl-2 programs are expressly excluded from the alliance. The agreement with Purdue is focused on the development and U.S. commercialization of products targeting FAAH. The agreement with Mundipharma is focused on the development and commercialization outside of the United States of all products and product candidates covered by the alliance, including those targeting FAAH.

Under the strategic alliance agreements, we have responsibility and decision-making authority for the performance of early discovery projects and the development of all product candidates on a worldwide basis. There are no joint steering or similar committees for the alliance. Mundipharma is obligated to pay 100% of our contractually budgeted amounts for research and development expenses incurred by us for early discovery projects and product candidates included in the alliance until the later of December 31, 2013 and the commencement of the first Phase 3 clinical trial of such product candidate, which we refer to as the transition date. The contractually budgeted amount for the period between November 19, 2008 and December 31, 2009 was \$50 million and the contractually budgeted amounts for the years ended December 31, 2010 and 2011 are \$65 million and \$85 million, respectively. After the transition date for each product candidate other than those arising out of the FAAH project, we will share with Mundipharma all research and development costs for such product candidate equally. We are recording revenue for reimbursed research and development services we perform for Mundipharma and Purdue. We recorded \$15.3 million and \$8.7 million in such revenue in the three months ended March 31, 2010 and 2009, respectively.

Mundipharma has the right to opt out of any early discovery project or any preclinical or clinical development program on an annual basis in November of each year. In the event of an opt-out decision, Mundipharma, together with Purdue with respect to the FAAH project, will continue to provide funding for, in the aggregate, 100% of our contractually budgeted research and development expenses for the applicable project or program for one year after the date of such opt out. Purdue has a comparable opt out right with respect to the FAAH project. In addition to the annual opt out right, Mundipharma and Purdue will each have the right to opt out of participation in the FAAH project following completion of the first Phase 1 clinical trial of IPI-940. We expect completion of this clinical trial in 2010. If Mundipharma and Purdue were to exercise this right, there is no residual funding obligation for the FAAH project, but we may redeploy contractually-budgeted amounts that had been allocated to the FAAH project to any other project that is the subject of the alliance. In addition, we and Mundipharma each have the right to opt out of continued development of a product candidate after it has reached the transition date, with a one year tail funding obligation for its 50% of post-transition date research and development expenses. If a party exercises its right to opt out of the development of a product or product candidate after the transition date, the other party may elect to continue the development and assume responsibility for the worldwide commercialization of such product or product candidate, subject to the payment of a royalty.

Except as set forth above with respect to FAAH products and opt-out products, we will have the right and responsibility to market and sell products arising from the research program in the United States and Mundipharma will have the right and responsibility to market and sell products arising from the research program outside of the United States. Other than pursuant to the strategic alliance agreements, neither we, Purdue nor Mundipharma may develop, manufacture or commercialize products that arise out of the research program or products that are directed to the same target or pathway as a product included in the research program, unless and until a party terminates its rights with respect to such products.

If we in-license any product or product candidate during the funded discovery period for which commercialization rights outside of the United States are available for grant by us to Mundipharma, Mundipharma will have the option to include such in-licensed product or product candidate in the alliance by paying us a prescribed percentage of the up-front license fee or other acquisition cost, which percentage could be up to 60% of such fee or cost, in order for Mundipharma to obtain commercialization rights for such in-licensed product or product candidate in all countries outside of the United States, and by funding research and development costs in the same manner as products or product candidates arising out of our internal discovery programs. The agreement with Mundipharma provides for the agreed-upon research and development budgets to be updated to reflect the inclusion of any in-licensed products or product candidates. There will be no royalties paid between the parties on in-licensed candidates.

Except with respect to products that have been in-licensed by us, for which no royalties will be payable between the parties, we are obligated to pay Mundipharma a 5% royalty on net sales of the commercialized products until such time as Mundipharma has recovered all research and development expenses paid to us under the research program prior to the applicable transition date. After such cost recovery, we are obligated to pay a tiered, 1% to 3% royalty on U.S. net sales of those products. For products in which Mundipharma has opted-out of development prior to the transition date, we are obligated to pay royalties of 1% to 5% of worldwide net sales as a function of the stage of development of the applicable product candidate at the time of opt-out. For products in which either party has opted-out of development following the

## **Table of Contents**

transition date, the commercializing party is obligated to pay the other party a 5% royalty on net sales. Mundipharma is obligated to pay us a tiered, 10% to 20% royalty on annual net sales outside of the United States of each product arising out of the alliance, and Purdue is obligated to pay us a tiered, 10% to 20% royalty on annual net sales of FAAH products in the United States. Royalties are payable 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 rates above is reduced by one-half. In addition, all royalties payable under the strategic alliance agreements, whether by us, Purdue or Mundipharma, are subject to reduction on account of third party royalty payments or patent litigation damages or settlements, with any such reductions capped at 50% of the amounts otherwise payable during the applicable royalty payment period.

Each of the strategic alliance agreements expire when the parties thereto have no further obligations to each other thereunder. Either party may terminate the strategic alliance agreement to which it is a party on 60 days prior written notice if the other party materially breaches the agreement and fails to cure such breach within the 60-day notice period. The agreements may also be terminated by Purdue or Mundipharma in the event of a change in control of Infinity or in the event that, during the funded research period, (i) Julian Adams is no longer a full-time executive of Infinity, or (ii) both Steven H. Holtzman and Adelene Q. Perkins are no longer full-time executives of Infinity. Upon termination of either strategic alliance agreement by us or either Purdue or Mundipharma, either party to the other strategic alliance agreement may terminate that agreement.

In connection with the entry into the strategic alliance agreements, we also entered into a securities purchase agreement and line of credit agreement with Purdue and its independent associated company, Purdue Pharma L.P., or PPLP. In March 2009, Purdue assigned its interest under the line of credit agreement to PPLP. Under the securities purchase agreement we issued and sold in a first equity closing in November 2008 an aggregate of four million shares of our common stock at a purchase price of \$11.25 per share, for an aggregate purchase price of \$45 million. Of such shares, two million shares of our common stock were purchased by each purchaser. In January 2009, we conducted a second equity closing where we issued and sold an aggregate of two million shares of our common stock, and warrants to purchase up to an aggregate of six million shares of our common stock, for an aggregate purchase price of \$30 million. Of the second closing securities, an equal number were purchased by each purchaser.

In 2008, we recorded \$23.8 million as deferred revenue associated with the grant of licenses to Mundipharma and Purdue. This amount represented the excess of the amount paid by Purdue and PPLP for our common stock (\$11.25 per share) over the closing market price on the day before the first equity closing (\$5.29 per share). In 2008, we considered our obligation, absent material adverse changes, to issue Purdue and PPLP the second closing securities to be a forward contract with immaterial intrinsic value, which was recorded in stockholders' equity. This forward contract closed in January 2009 upon the issuance of the second closing securities. In January 2009, we recorded \$18.2 million as deferred revenue associated with the grant of licenses to Mundipharma and Purdue, representing the excess of the \$30 million paid by Purdue and PPLP for the second closing securities over the fair market value of these securities (\$5.29 per share for the common stock and approximately \$1.3 million for the warrants) as of the day before the first equity closing. All deferred revenue related to the strategic alliance with Mundipharma and Purdue will be recognized as revenue ratably over 14 years, which is our estimated period of performance under the arrangement. We will periodically review this estimate and make adjustments as facts and circumstances dictate. We recognized \$0.7 million in such revenue in each of the periods ended March 31, 2010 and 2009.

The line of credit agreement provides for the borrowing by us of one or more unsecured loans up to an aggregate maximum principal amount of \$50 million. The loans may be drawn by us during the three-year period that began on April 1, 2009. The loans, which may be used by us for any proper corporate purpose, mature on April 1, 2019, which we refer to as the maturity date, and will be subordinate to any senior indebtedness that we may incur. Borrowings made under the line of credit agreement will bear interest, payable on the maturity date, at a fluctuating rate set at the prime rate on the business day prior to the funding of each loan and will be reset on the last business day of each month ending thereafter. Interest will be compounded on each successive three-month anniversary of the funding of each loan. Outstanding loans may be prepaid without penalty or premium prior to the maturity date. Amounts borrowed under the credit agreement, once borrowed, may not be borrowed again. We have certain rights to repay outstanding amounts under the line of credit agreement in shares of our common stock.

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. We began amortizing this asset to interest expense over the life of the loan arrangement, or 10 years, on April 1, 2009. We recorded approximately \$0.4 million of related amortization expense in the period ended March 31, 2010. Because Purdue and its associated companies became related parties as a result of their equity ownership, we recorded the offset to this asset as additional paid-in capital in 2008. As of March 31, 2010, no amounts have been borrowed under this line of credit.

## **Table of Contents**

**MedImmune/AZ.** In August 2006, we entered into a product development and commercialization agreement with MedImmune/AZ, to jointly develop and commercialize cancer drugs targeting Hsp90 and the Hedgehog pathway. Under the terms of this agreement, we shared equally with MedImmune/AZ all development costs, as well as potential profits and losses, from any future marketed products. In November 2007, we regained from MedImmune/AZ worldwide development and commercialization rights under our Hedgehog pathway program on a royalty-free basis. In December 2008, we regained from MedImmune/AZ worldwide development and commercialization rights under our Hsp90 chaperone inhibitor program. In January 2009, we reached an agreement with MedImmune/AZ to settle the residual funding obligation remaining for 2009 through lump-sum payments totaling \$12.5 million, which were recorded as income from residual funding after reacquisition of Hsp90 program (a component of other income) in the three months ended March 31, 2009. We received \$6.2 million in cash from MedImmune/AZ in the three months ended March 31, 2009 and recorded an unbilled receivable for remaining amounts due from MedImmune/AZ, which was subsequently received in the following quarter.

The profit and cost-sharing provisions of our arrangement with MedImmune/AZ are no longer applicable, and we have full control over all future development and commercialization activities under our Hsp90 and Hedgehog pathway programs, subject to the payment of single-digit royalties to MedImmune/AZ on worldwide net sales, if any, of each of IPI-504 and IPI-493. We do not have a royalty obligation to MedImmune/AZ on any future sales of IPI-926.

### ***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 milestones payments received from our collaboration partners. As the agreement with Mundipharma and Purdue provides for funding for our research and development efforts, we recognize this cost reimbursement as revenue in the period earned. 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 results of operations and financial position, would be materially adversely affected.

#### ***Research and Development Expense***

We are a drug discovery and development company that has focused its efforts in the field of cancer and related conditions. Our research and development expense primarily consists of the following:

compensation of personnel associated with research activities, including consultants;

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

laboratory supplies and materials;

manufacturing drug candidates for preclinical testing and clinical studies;

preclinical testing costs, including costs of toxicology studies;

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

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 and human resources functions. Other costs include facilities costs not otherwise included in research and development expense, professional fees for legal and accounting services and early commercial development costs. General and administrative expense also consists of the costs of maintaining our intellectual property portfolio.

## **Table of Contents**

### *Other Income and Expense*

Interest expense and other 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 includes amortization of the loan commitment asset from PPLP starting on April 1, 2009. Income from residual funding after reacquisition of Hsp90 program was recorded in the three months ended March 31, 2009.

### *Critical Accounting Policies and Significant Judgments and Estimates*

The following discussion and analysis of our financial condition and results of operations is based on our 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. We believe that the following accounting policies and estimates are most critical to aid you in understanding and evaluating our reported financial results.

### *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. We divide agreements containing multiple elements into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the collaborative partner and whether there is objective and reliable evidence of fair value of the undelivered obligation(s). For these agreements, we allocate the consideration we receive among the separate units based on their respective fair values or, in some cases, the residual method, and we apply the applicable revenue recognition criteria to each of the separate units.

We recognize revenues from non-refundable, up-front license fees on a straight-line basis over the contracted or estimated period of performance, which is typically the research or development term. We recognize research and development funding as earned over the period of effort as related research costs are incurred. We regularly consider whether events warrant a change in the estimated period of performance under an agreement. Such a change would cause us to modify the period of time over which we recognize revenue on a prospective basis from the up-front license fees paid to us under that agreement and would, in turn, result in changes in our quarterly and annual results.

We recognize milestone payments as revenue upon achievement of the milestone only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (4) the milestone is at risk for both parties. If any of these conditions is not met, we defer the recognition of revenue underlying the milestone payment and recognize it over the remaining estimated period of performance under the contract as we complete our performance obligations.

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

### *Research and Development Expense*

Research and development expense consists of expenses incurred in performing research and development activities. We expense research and development costs as they are incurred. We have entered into certain collaboration agreements in which expenses are shared with the collaborator, and others in which we are reimbursed for work performed on behalf of the collaborator. We record all of these expenses as research and development expense. If the arrangement is a cost-sharing arrangement and there is a period during which we receive payments from the collaborator, we record payments from the collaborator for its share of the development effort as a reduction of research and development expense. If the arrangement is a cost-sharing arrangement and there is a period during which we make payments to the collaborator, we record our payments to the collaborator for its share of the development effort as additional research and development expense. If the arrangement provides for reimbursement of research and development expenses, we record the reimbursement as revenue. Our alliance with Mundipharma and Purdue provides for the reimbursement of our research and development expenses.



**Table of Contents***Accrued Expenses*

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves identifying services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date. Examples of services for which we must estimate accrued expenses include contract service fees paid to contract manufacturers in conjunction with pharmaceutical development work and to contract research organizations in connection with clinical trials and preclinical studies. In connection with these service fees, our estimates are most affected by our understanding of the status and timing of services provided. The majority of our service providers invoice us in arrears for services performed. In the event that we do not identify certain costs that have been incurred by our service providers, or if we over- or under-estimate the level of services performed or the costs of such services in any given period, our reported expenses for such period would be too low or too high. We often rely on subjective judgments to determine the date on which certain services commence, the level of services performed on or before a given date, and the cost of such services. We make these judgments based upon the facts and circumstances known to us. Our estimates of expenses in future periods may be over- or under-accrued.

*Stock-Based Compensation*

We expense the fair value of employee stock options and other equity compensation. We use our judgment in determining the fair value of our equity instruments, including in selecting the inputs we use for the Black-Scholes valuation model. Equity instrument valuation models are by their nature highly subjective. Any significant changes in any of our judgments, including those used to select the inputs for the Black-Scholes valuation model, could have a significant impact on the fair value of the equity instruments granted and the associated compensation charge we record in our financial statements.

*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 will recognize any material interest and penalties related to unrecognized tax benefits in income tax expense.

*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.

*Results of Operations*

The following tables summarize our results of operations for each of the three months ended March 31, 2010 and 2009, in thousands, together with the change in these items in dollars and as a percentage:

	<b>Three Months Ended March 31,</b>		<b>\$ Change</b>	<b>% Change</b>
	<b>2010</b>	<b>2009</b>		
Revenue	\$ 15,993	\$ 9,429	\$ 6,564	70%
Research and development expense	(19,378)	(21,242)	1,864	(9)%
General and administrative expense	(4,749)	(5,330)	581	(11)%
Interest expense	(433)		(433)	NA
Income from residual funding after reacquisition of Hsp90 program		12,450	(12,450)	(100)%

## Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

Interest and investment income	205	742	(537)	(72)%
<i>Revenue</i>				

Our revenue during the three months ended March 31, 2010 consisted of approximately \$15.3 million for reimbursed research and development services and \$0.7 million from the amortization of the deferred revenue associated with the grant of licenses under our strategic alliance agreements with Mundipharma and Purdue. Our revenue during the three months ended March 31, 2009 consisted of approximately \$8.7 million for reimbursed research and development services and \$0.7 million from the amortization of the deferred revenue associated with the grant of licenses under our strategic alliances with Mundipharma and Purdue. The increase in reimbursed research and development services revenue is a result of increased internal effort and greater external expenses on our FAAH inhibitor, Hedgehog pathway inhibitor and early discovery programs.



## **Table of Contents**

### *Research and Development Expense*

Research and development expense represented approximately 80% of our total operating expenses for the three months ended March 31, 2010 and 2009. The decrease in research and development expense for the three months ended March 31, 2010 as compared to the three months ended March 31, 2009 was primarily attributable to:

a decrease of \$2.8 million in expenses for clinical trials, as a consequence of the closure of the phase 3 clinical trial of IPI-504 in patients with GIST in April 2009; and

a decrease of \$1.8 million in pharmaceutical development expenses, as a consequence of reduced IPI-504 manufacturing activity in the first quarter of 2010.

These decreases were partially offset by:

an increase of \$1.4 million in compensation and benefits, including stock-based compensation for our research and development personnel, which was driven by the hiring of new research and development personnel and annual base salary increase and an increase in amounts accrued under our contingent cash compensation program;

an increase of \$0.7 million in preclinical expenses as our FAAH program has advanced; and

an increase of \$0.6 million in expenses for consulting services.

During the three months ended March 31, 2010 and 2009, we estimate that we incurred the following expenses by program. 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.

<b>Program</b>	<b>Three Months Ended March 31, 2010</b>	<b>Three Months Ended March 31, 2009</b>
Hsp90 chaperone inhibitor	\$ 5.5 million	\$ 12.8 million
Hedgehog pathway inhibitor	5.5 million	3.9 million
FAAH inhibitor	4.8 million	1.9 million

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 or 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, 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.

We are conducting multiple studies of our Hsp90 chaperone inhibitors, IPI-504 and IPI-493. These studies are focused on establishing a dose and schedule of administration that optimizes safety and efficacy of these candidates, and identifying patient populations most likely to benefit from Hsp90 inhibition. In the near future, we expect to evaluate data from our ongoing clinical trial of IPI-504 in combination with Herceptin® (trastuzumab) in patients with HER2-positive metastatic breast cancer and, following this evaluation, we intend to make a portfolio decision regarding further near-term investment in IPI-504.

We expect expenses for our Hedgehog pathway inhibitor program to increase as we make progress in the clinical development of IPI-926. In addition, we expect expenses for our FAAH program to increase as we continue clinical development of IPI-940.

### *General and Administrative Expense*

## Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

The decrease in general and administrative expense for the three months ended March 31, 2010 as compared to the three months ended March 31, 2009 is primarily attributable to a decrease of \$0.7 million in consulting expenses, principally related to early commercial development.

### *Income from Residual Funding After Reacquisition of Hsp90 Program*

Following our reacquisition of the Hsp90 program in December 2008, MedImmune/AZ remained obligated to fund an amount equivalent to its share of the Hsp90 program costs for the ensuing six-month period. Reimbursable amounts from the date of reacquisition were recorded as income from residual funding after reacquisition of Hsp90 program. In January 2009, we agreed with MedImmune/AZ to settle the residual funding obligations through lump sum payments totaling \$12.5 million.

**Table of Contents***Interest and Investment Income*

Interest and investment income decreased in the three months ended March 31, 2010 as compared to the three months ended March 31, 2009 primarily as a result of the lower yields on our cash equivalents and available-for-sale securities. We expect interest and investment income to continue to be lower in 2010 as compared to 2009 due to lower expected yields and lower average balances.

*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 reimbursements under our collaborations, a milestone payment, contract service payments and debt to fund our operations. Our available-for-sale debt securities primarily trade in liquid markets, and the average number of days to maturity of our portfolio as of March 31, 2010 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:

	<b>March 31, 2010</b>	<b>December 31, 2009</b>
Cash, cash equivalents and available-for-sale securities	\$ 126,347,829	\$ 130,736,513
Working capital	113,440,750	120,634,909
	<b>Three Months Ended March 31, 2010</b>	<b>2009</b>
Cash provided by (used in):		
Operating activities	\$ (3,150,147)	\$ 15,426,157
Investing activities	3,500,973	(29,849,576)
Capital expenditures (included in investing activities above)	(701,976)	(942,388)
Financing activities	10,216	11,949,965

*Cash Flows*

The principal use of cash in operating activities in all of the periods presented was the funding of our research and development expenses, which increase as the pipeline advances. Cash flows from operations in future periods can vary significantly due to various factors, including changes in accounts payable, accrued expenses and deferred revenue. During January 2009, we issued to Purdue and PPLP an aggregate of two million shares of our common stock and warrants to purchase up to six million shares of our common stock for cash proceeds of \$30 million. The issuance of these securities was recorded for \$11.8 million in our cash flows from financing activities, which represents the fair market value (\$5.29 per share for the common stock and approximately \$1.3 million for the warrants) as of the day before the first equity closing, and \$18.2 million was accounted for as an up-front license fee in deferred revenue and recorded in our cash flows from operating activities.

Net cash from investing activities for the period ended March 31, 2010 included \$58.3 million in purchases of available-for-sale securities, proceeds of \$55.3 million from maturities of available-for-sale securities and proceeds of \$7.2 million from sales of available-for-sale securities. Capital expenditures in the three months ended March 31, 2010 primarily consisted of capitalized software costs and laboratory equipment.

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, together with research and development funding from Purdue and Mundipharma and the \$50.0 million line of credit that has been made available to us by PPLP, are sufficient to fund our planned operations into 2013. We may, however, need to raise additional funds before that date if our research and development expenses exceed our current expectations, if we do not receive the payments we expect to receive from Mundipharma and Purdue, or if we acquire a third party or license rights to additional drug candidates or new technologies from one or more third parties. We may need to raise additional funds for other reasons, including:

our drug candidates require more extensive clinical or preclinical testing than we currently expect;

## **Table of Contents**

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;

Mundipharma or Purdue elects to discontinue its participation in a partnered program; or

we experience a loss in our investments due to general market conditions or other reasons.

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 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 drug 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.

### ***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.

### **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, U.S. government-sponsored enterprise obligations, corporate obligations, U.S. Treasury securities and mortgage-backed securities. 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 \$456,000 decrease in the fair value of our investments as of March 31, 2010, as compared to an approximate \$446,000 decrease as of December 31, 2009. 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.

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

Our management, with the participation of our principal executive and financial officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2010. 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

## Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

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 March 31, 2010, our principal executive and financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended March 31, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

---

**Table of Contents**

**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, 2009.

***Risks Related to Our Stage of Development as a Company***

*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 March 31, 2010, we had an accumulated deficit of \$189.8 million. We have spent, and expect to continue to spend, significant resources to fund the research and development of IPI-504, IPI-493, IPI-926, IPI-940 and our other drug candidates. While we may have net income in future periods as the result of non-recurring collaboration income, 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.

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, together with research and development funding from Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products L.P., or Purdue, and the \$50 million line of credit that has been made available to us by Purdue Pharma L.P., are sufficient to fund our planned operations into 2013. We may, however, need to raise additional funds before that date if our research and development expenses exceed our current expectations, if we do not receive the payments we expect to receive from Mundipharma and Purdue, or if we acquire a third party or license rights to additional drug candidates or new technologies from one or more third parties. We may need to raise additional funds for other reasons, including:

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;

## Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

Mundipharma or Purdue elects to discontinue its participation in a partnered program; or

we experience a loss in our investments due to general market conditions or other reasons.

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 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 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.



## **Table of Contents**

*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 clinical candidates is high. To date, the data supporting our clinical development strategy for IPI-504, IPI-493, IPI-926, and IPI-940 are derived solely from laboratory and preclinical studies and, in the case of IPI-504, limited early-to-mid-stage clinical trials. Later clinical trials may not yield data consistent with earlier clinical trials, as was the case in our Phase 3 clinical trial of IPI-504 in patients with gastrointestinal stromal tumors, or GIST, which we elected to close in April 2009 when an early review of safety data showed a higher than anticipated mortality rate among patients enrolled in the treatment arm. In such a case, it may be necessary for us to change our development strategy or abandon development of that drug candidate, either of which would result in delays and additional costs. For example, in the near future, we expect to evaluate data from our ongoing clinical trial of IPI-504 in combination with Herceptin® (trastuzumab) in patients with HER2-positive metastatic breast cancer and, following this evaluation, we intend to make a portfolio decision regarding further near-term investment in IPI-504. It is impossible to predict when or if IPI-504, IPI-493, IPI-926, IPI-940 or any of our other 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.

*If our global strategic alliance with Mundipharma and Purdue, or any future alliance we may enter into, is unsuccessful, our operations may be negatively impacted.*

We have a global strategic alliance with Mundipharma to research, develop and jointly commercialize IPI-926, IPI-940 and product candidates arising out of our Hedgehog pathway, fatty acid amide hydrolase, or FAAH, and early discovery programs, and with Purdue to commercialize product candidates arising out of our FAAH program in the United States. Under the strategic alliance agreements, Mundipharma and Purdue have committed to provide substantial funding, significant capabilities in the field of pain and, in the case of Mundipharma, significant capabilities in marketing and sales outside of the United States. The success of this alliance is largely dependent on the resources, efforts, technology and skills brought to such alliance by Mundipharma and Purdue. Disputes and difficulties in these types of relationships are common, often due to conflicting priorities or conflicts of interest. Merger and acquisition activity may exacerbate these conflicts. The benefits of this alliance will be reduced or eliminated if Mundipharma and/or Purdue:

terminates either or both of the strategic alliance agreements;

fails to devote financial or other resources to the applicable alliance, thereby hindering or delaying development, manufacturing or commercialization activities;

fails to successfully develop or manufacture any products arising out of our FAAH program or to commercialize any drug candidate under the applicable alliance; or

fails to maintain the financial resources necessary to continue financing its portion of development, manufacturing, and commercialization costs or its own operations.

Under our agreements with Mundipharma and Purdue, each agreement may be terminated on 60 days prior written notice if we were to materially breach such agreement and fail to cure such breach within the 60-day notice period. In addition, each of these strategic alliance agreements may be terminated in the event we experience a change in control or in the event that, during the funded research period, either Julian Adams is no longer a full-time executive of Infinity or both Steven Holtzman and Adelene Perkins are no longer full-time executives of Infinity. In addition:

Mundipharma has the right to opt out of participation in the Hedgehog pathway and early discovery programs in November of each calendar year, subject to 12 months of continued funding; and

## Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

Purdue and Mundipharma have the right to opt out of participation in the FAAH program immediately following completion of the first Phase 1 clinical trial of IPI-940, which we expect to occur in 2010, and with no further program funding obligation.

If Mundipharma and/or Purdue were to exercise its right to opt out of a program or to terminate its respective agreement, we may not have sufficient financial resources or capabilities to continue development and commercialization of products from the affected program, and our ability to attract a new alliance partner would be made more difficult.

Much of the potential revenue from our alliance with Mundipharma and Purdue, and any alliances we may enter into in the future, will 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 partners', ability to successfully develop, introduce, market and sell new products. In some cases, we will not be involved in these processes and will depend entirely on our alliance

---

## **Table of Contents**

partners. For example, Mundipharma will be responsible for all of the commercialization efforts outside of the United States for any products that are successfully developed from our Hedgehog pathway program and our early stage development programs, and Purdue and Mundipharma will be jointly responsible for all development and commercialization activities for products arising out of the FAAH program following Phase 1 clinical trials. Any of our current or future alliance partners may fail to develop or effectively commercialize products using our products or technologies 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.

If any current or 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.

*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, Julian Adams and Steven Holtzman, 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. For example, Purdue and Mundipharma each have the right to terminate its strategic alliance with us if, during the funded research period, either Julian Adams is no longer a full-time executive of Infinity or both Steven Holtzman and Adelene Perkins are no longer full-time executives of Infinity. 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.

*We may encounter difficulties in managing our growth, which could adversely affect our operations.*

Our ability to manage our growth 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 slow our growth or give rise to inefficiencies that would increase our losses or delay our programs.

We may acquire additional technology and complementary businesses in the future. Acquisitions involve many risks, any one of which could materially harm our business, including the diversion of management's attention from core business concerns, failure to exploit acquired technologies, or the loss of key employees from either our business or the acquired business.

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

As of March 31, 2010, we had approximately \$126 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

## Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

securities and mortgage-backed securities meeting the criteria of our investment policy, which is focused on the preservation of our capital. These investments are subject to general credit, liquidity, market and interest rate risks. 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 condition and results of operations.

## **Table of Contents**

*The estimates 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 the accrual of research and development expenses and revenue recognition. 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 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 U.S. Food and Drug Administration, or FDA, or any foreign regulatory authority to market or sell any of our drug candidates. Our success depends primarily upon our, and our strategic alliance partners', ability to develop and commercialize our drug candidates successfully. Our two drug candidates in our Hsp90 program are IPI-504, which is currently in multiple early-to-mid-stage clinical trials, and IPI-493, which is being evaluated in a Phase 1 clinical trial. Our Hedgehog pathway inhibitor, IPI-926 is being evaluated in a Phase 1 clinical trial and in a Phase 1b/2 clinical trial. We also commenced our first clinical trial of IPI-940 in February 2010, and we have other drug candidates in various stages of preclinical development and discovery research.

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. 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 IPI-504, IPI-493, IPI-926, IPI-940 and any other drug candidate we may seek to develop in the future, 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, as was the case with our Phase 3 clinical trial of IPI-504 in GIST; and

the results may not meet the level of statistical significance required by the FDA or other regulatory authorities.

In the near future, we expect to evaluate data from our ongoing clinical trial of IPI-504 in combination with Herceptin® (trastuzumab) in patients with HER2-positive metastatic breast cancer and, following this evaluation, we intend to make a portfolio decision regarding further near-term investment in IPI-504.

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

## Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

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.

## **Table of Contents**

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. For example, the Food and Drug Administration Amendments Act of 2007, or FDAAA, may make it more difficult and costly for us to obtain regulatory approval of our drug candidates and to produce, market and distribute products after approval. The FDAAA granted a variety of new powers to the FDA, many of which are aimed at improving the safety of drug products before and after approval. In particular, it authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information, and require risk evaluation and mitigation strategies for certain drugs. In addition, it significantly expanded the federal government's clinical trial registry and results databank and creates new restrictions on the advertising and promotion of drug products. Under the FDAAA, companies that violate the new law are subject to substantial civil monetary penalties.

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, as was the case with our decision to close our Phase 3 clinical trial of IPI-504 in GIST, 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;

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 or deficient quality of 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;

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 results of operations and financial condition.



## **Table of Contents**

*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 our clinical trials could delay the 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 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 results of operations and financial condition.

*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

## Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

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

## **Table of Contents**

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 these 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 other 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 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.

A natural product is utilized in the production of IPI-926. This product is currently supplied from naturally available plant material. Our ability to acquire and process sufficient amounts of plant material to meet our manufacturing requirements is subject to a number of risks, including the receipt of permits from federal and state authorities, adverse weather conditions or natural disasters that may impact plant availability or our ability to harvest it. In addition, we may be unsuccessful in identifying other locations where this plant naturally occurs or establishing a sustainable method for growing this plant in a controlled environment. A material shortage of this plant could adversely impact or disrupt the manufacture of IPI-926, thus impacting our clinical trial activities and, if IPI-926 is successfully developed, our ability to satisfy commercial demand for the product, thus adversely affecting our financial position and results of operations.

*We have certain commercialization rights to our oncology product portfolio, but we currently have limited marketing and sales experience and capabilities.*

We currently have commercialization rights in the United States for products arising out of our all of our programs, except the FAAH program, and worldwide commercialization rights for our Hsp90 chaperone inhibitor program, including IPI-504 and IPI-493. In order to successfully commercialize our drug candidates, we will need to establish adequate marketing and sales capabilities. We may not successfully establish these capabilities or have sufficient resources to do so. If we do not establish adequate marketing and sales capabilities, our ability to successfully commercialize any drug candidates that we successfully develop will be adversely affected, as will our financial condition and results of operations. Even if we do develop such capabilities, we will compete with other companies that have experienced and well-funded marketing and sales 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;



**Table of Contents**

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 or achieve profitability.

*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 collaborators, 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, good manufacturing practices, 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. 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, 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

## Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

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 which 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 to approve reimbursement for our drug candidates and at what level. 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 program or other reimbursing bodies or payors limit the indications for which our drug candidates will be reimbursed to a smaller set than we believe it is effective in treating.

## **Table of Contents**

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 could 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. Any government-adopted reform measures could adversely impact the pricing of healthcare products and services in the U.S. or internationally and the amount of reimbursement available from governmental agencies or other third party payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce health care costs may adversely affect our ability to set prices for our products which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

In both the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory proposals and initiatives to change the health care system in ways that could affect our ability to sell our products profitably. Some of these proposed and implemented reforms could result in reduced reimbursement rates for our potential products, which would adversely affect our business strategy, operations and financial results. For example, in March 2010, President Obama signed into law a legislative overhaul of the U.S. healthcare system, known as the Patient Protection and Affordable Care Act of 2010, as amended by the Healthcare and Education Affordability Reconciliation Act of 2010. This law, which we refer to as the PPACA, may have far reaching consequences for biopharmaceutical companies like us. As a result of this new legislation, substantial changes could be made to the current system for paying for healthcare in the United States, including changes made in order to extend medical benefits to those who currently lack insurance coverage. Extending coverage to a large population could substantially change the structure of the health insurance system and the methodology for reimbursing medical services and drugs. These structural changes could entail modifications to the existing system of private payors and government programs, such as Medicare and Medicaid, creation of a government-sponsored healthcare insurance source, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the United States could impact the reimbursement for prescribed drugs, including our product candidates. If reimbursement for our approved product candidates, if any, is substantially less than we expect in the future, or rebate obligations associated with them are substantially increased, our business could be materially and adversely impacted.

In addition, the Medicare Prescription Drug Improvement and Modernization Act of 2003 reformed the way Medicare will cover and reimburse for pharmaceutical products. This legislation could also decrease the coverage and price that we may receive for our products. Other third-party payors are increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for us to go through the process of seeking reimbursement from Medicare and private payors. Our products may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a profitable basis.

Further federal and state proposals and health care reforms could limit the prices that can be charged for the product candidates that we develop and may further limit our commercial opportunity. Our results of operations could be materially adversely affected by the PPACA, by the Medicare prescription drug coverage legislation, by the possible effect of such current or future legislation on amounts that private insurers will pay and by other health care reforms that may be enacted or adopted in the future.

---

## **Table of Contents**

*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 health care 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 ability to operate our business and 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 U.S. 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.*

We seek to develop new drugs for cancer and related conditions. The cancer therapeutic segment of the pharmaceutical industry is highly competitive and rapidly changing. 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 forms of cancer. 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 to treat cancer, including Bristol-Myers Squibb Company, F. Hoffmann-La Roche Ltd. and its subsidiary Genentech, Inc., 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. 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 are aware of numerous companies that have



## Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

clinical development programs for compounds targeting Hsp90, which is the target of IPI-504 and IPI-493. These companies include, without limitation, Bristol Myers Squibb Company, Biogen Idec Inc., Synta Pharmaceuticals Corp., Vernalis plc (in collaboration with Novartis), Pfizer, Inc., Astex Therapeutics Limited, Exelixis, Inc., Myriad Pharmaceuticals, Inc., Kyowa Hakko Kirin Co. Ltd., and Abraxis Bioscience, Inc. In addition, Genentech, Inc. (through its collaboration with Curis, Inc.), Bristol Myers Squibb Company (through its collaboration with Exelixis, Inc.), Novartis AG and Pfizer, Inc. are developing drugs targeting the Hedgehog pathway, which is also being targeted by IPI-926. Finally, we believe that each of Pfizer, Inc., Ironwood Pharmaceuticals, Inc. and sanofi-aventis are developing inhibitors of FAAH.

## **Table of Contents**

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, various radioactive compounds, and compounds known to cause birth defects. 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***

## Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

*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. Our lead oral Hsp90 candidate, IPI-493, contains an active pharmaceutical ingredient for which we believe composition of matter

## **Table of Contents**

protection is unavailable. Consequently, we have filed patent applications directed to IPI-493 and other novel formulations of this active pharmaceutical ingredient, as well as methods of their use, which may not provide the same level of protection as composition of matter patent protection on the active pharmaceutical ingredient itself.

Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions 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 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 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. In addition, the U.S. Congress has considered, and may consider in the future, legislation that could change United States law regarding, among other things, post-grant review of issued patents and the calculation of damages once patent infringement has been determined by a court of law. If enacted into law, these provisions could severely weaken patent protection in the United States.

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 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. For example, we are aware of third parties who are actively researching ansamycin analogs that are similar to IPI-504. These third parties have pending applications related to these analogs, but we have the first published application covering IPI-504. Notwithstanding the fact that we filed the first patent application related to these analogs, it is possible that an interference proceeding could be declared between our application covering IPI-504 and one or more of these third party applications, even the one of those applications for which we have secured a license. 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.



## **Table of Contents**

*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 noncompliance 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. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

*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 affect our business either by blocking our ability to manufacture or commercialize our drugs or by covering similar technologies that 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 chaperone inhibitor program, we have initiated clinical trials evaluating the administration of IPI-504 in combination with each of trastuzumab and docetaxel, and we may conduct additional trials with IPI-504 in combination with other therapeutic agents. We are aware of issued patents and published applications directed to combinations of Hsp90 chaperone inhibitors with a variety of other therapeutic agents. We are also aware of patents and patent applications directed to methods of treating various disorders using a variety of Hsp90 chaperone 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.

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 this 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

## Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

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.

## **Table of Contents**

*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 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 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.

## ***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 could 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 IPI-504, IPI-493, IPI-926, IPI-940 and our other drug candidates;

the results of preclinical studies and planned clinical trials of our other 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;

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 strategic alliance agreements with Purdue and Mundipharma;

the results and timing of regulatory reviews relating to the approval of our drug candidates;



## Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

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 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 health care 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.

## **Table of Contents**

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.

*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 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 901,000 shares of currently undesignated preferred stock 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 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, certain affiliates and other major shareholders control approximately 40% of our outstanding common stock and have the ability to influence the 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 determine 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.

**Table of Contents**

**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: May 6, 2010

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

**Table of Contents**

**EXHIBIT INDEX**

<b>Exhibit</b>	<b>Description</b>
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.
31.1	Certification of principal executive and 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 and 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.