

INFINITY PHARMACEUTICALS, INC.

Form 10-Q

May 07, 2013

[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended March 31, 2013

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, 2013: 47,828,899

**Table of Contents**

**INFINITY PHARMACEUTICALS, INC.**

**FORM 10-Q**

**FOR THE QUARTER ENDED MARCH 31, 2013**

**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, 2013 and December 31, 2012</u>	1
<u>Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three Months Ended March 31, 2013 and 2012</u>	2
<u>Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2013 and 2012</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>13</b>
<b>Item 3.</b>	
<b><u>Quantitative and Qualitative Disclosures About Market Risk</u></b>	<b>21</b>
<b>Item 4.</b>	
<b><u>Controls and Procedures</u></b>	<b>21</b>
<b>PART II</b>	
<b><u>OTHER INFORMATION</u></b>	<b>22</b>
<b>Item 1A.</b>	
<b><u>Risk Factors</u></b>	<b>22</b>
<b>Item 6.</b>	
<b><u>Exhibits</u></b>	<b>36</b>
<b><u>Signatures</u></b>	<b>37</b>

**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Unaudited Condensed Consolidated Financial Statements****INFINITY PHARMACEUTICALS, INC.****Condensed Consolidated Balance Sheets****(unaudited)****(in thousands, except share and per share amounts)**

	March 31, 2013	December 31, 2012
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 101,142	\$ 175,742
Available-for-sale securities	201,426	150,276
Prepaid expenses and other current assets	5,267	3,731
Total current assets	307,835	329,749
Property and equipment, net	3,925	4,079
Long-term available-for-sale securities	580	617
Restricted cash	1,128	1,128
Other assets	25	87
Total assets	\$ 313,493	\$ 335,660
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 2,940	\$ 2,148
Accrued expenses	7,839	10,059
Due to Millennium, current	6,508	6,456
Total current liabilities	17,287	18,663
Due to Millennium, less current portion	6,302	6,252
Other liabilities	539	540
Total liabilities	24,128	25,455
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, \$0.001 par value; 1,000,000 shares authorized, no shares issued and outstanding at March 31, 2013 and December 31, 2012		
Common Stock, \$0.001 par value; 100,000,000 shares authorized, and 47,828,899 and 47,499,257 shares issued and outstanding, at March 31, 2013 and December 31, 2012, respectively	48	48
Additional paid-in capital	639,508	633,039
Accumulated deficit	(350,342)	(323,016)
Accumulated other comprehensive income	151	134
Total stockholders' equity	289,365	310,205
Total liabilities and stockholders' equity	\$ 313,493	\$ 335,660

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

*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 and Comprehensive Loss****(unaudited)****(in thousands, except share and per share amounts)**

	<b>Three Months Ended March 31,</b>	
	<b>2013</b>	<b>2012</b>
Collaborative research and development revenue from Purdue entities	\$	\$ 25,202
Operating expenses:		
Research and development	20,231	28,551
General and administrative	7,430	6,812
Total operating expenses	27,661	35,363
Loss from operations	(27,661)	(10,161)
Other income (expense):		
Interest expense		(681)
Investment and other income	335	120
Total other income (expense)	335	(561)
Net loss	\$ (27,326)	\$ (10,722)
Basic and diluted loss per common share	\$ (0.57)	\$ (0.40)
Basic and diluted weighted average number of common shares outstanding	47,620,147	26,776,856
Other comprehensive income:		
Net unrealized holding gains on available-for-sale securities arising during the period	17	54
Comprehensive loss	\$ (27,309)	\$ (10,668)

*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)****(in thousands)**

	<b>Three Months Ended March 31,</b>	
	<b>2013</b>	<b>2012</b>
<b>Operating activities</b>		
Net loss	\$ (27,326)	\$ (10,722)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	442	446
Stock-based compensation, including 401(k) match	3,992	1,504
Net amortization of available-for-sale securities	393	292
Non-cash interest expense on long-term debt due to Purdue entities		681
Other, net	102	16
Changes in operating assets and liabilities:		
Unbilled accounts receivable		(19)
Prepaid expenses and other assets	(1,474)	(1,636)
Accounts payable, accrued expenses and other liabilities	(1,429)	(4,093)
Deferred revenue from Purdue entities		2,316
Net cash used in operating activities	(25,300)	(11,215)
<b>Investing activities</b>		
Purchases of property and equipment	(287)	(236)
Purchases of available-for-sale securities	(91,829)	(11,807)
Proceeds from maturities of available-for-sale securities	40,340	21,829
Net cash provided by (used in) investing activities	(51,776)	9,786
<b>Financing activities</b>		
Proceeds from issuances of common stock related to stock incentive plans	2,476	694
Net cash provided by financing activities	2,476	694
Net decrease in cash and cash equivalents	(74,600)	(735)
Cash and cash equivalents at beginning of period	175,742	24,197
Cash and cash equivalents at end of period	\$ 101,142	\$ 23,462

*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 an innovative drug discovery and development company seeking to discover, develop and deliver to patients best-in-class medicines designed to address diseases with significant unmet needs. 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, 2013 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2013.

The information presented in the condensed consolidated financial statements and related footnotes at March 31, 2013, and for the three months ended March 31, 2013 and 2012, is unaudited, and the condensed consolidated balance sheet amounts and related footnotes at December 31, 2012 have been derived from our audited financial statements. For further information, please refer to the consolidated financial statements and accompanying footnotes included in our annual report on Form 10-K for the fiscal year ended December 31, 2012, which was filed with the U.S. Securities and Exchange Commission, on March 5, 2013.

Certain amounts in the prior years condensed consolidated financial statements have been reclassified to conform with the current-year presentation. These reclassifications have no impact on previously reported net loss or cash flows.

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

We determine the appropriate classification of marketable 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, 2013 and December 31, 2012 as available-for-sale. We carry available-for-sale securities at fair value, with the unrealized gains and losses reported in accumulated other comprehensive income (loss), which is a separate component of stockholders' equity.

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



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

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

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

**Table of Contents**

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

**Segment Information**

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

All of our revenues to date have been generated under research collaboration agreements. Revenue associated with the amortization of the deferred revenue associated with the grant of rights and licenses to, and reimbursed research and development services provided for, Mundipharma International Corporation Limited (Mundipharma), and Purdue Pharmaceutical Products L.P. (Purdue), accounted for all of our revenue for the three months ended March 31, 2012. We considered Mundipharma, Purdue and their respective associated entities to be related parties for financial reporting purposes because of their equity ownership prior to April 2013 (see note 7).

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

Basic net loss per share is based upon the weighted average number of common shares outstanding during the period. Diluted net 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). In addition, the assumed proceeds under the treasury stock method include the average unrecognized compensation expense of stock options that are in-the-money. This results in the assumed buyback of additional shares, thereby reducing the dilutive impact of stock options. Common equivalent shares have not been included in the net loss per share calculations for the periods presented because the effect of including them would have been anti-dilutive. Total potential gross common equivalent shares consisted of the following:

	At March 31,	
	2013	2012
Stock options	6,241,841	7,992,966
Warrants		3,220,655

**Comprehensive Loss**

Comprehensive loss is comprised of net loss and other comprehensive income (loss). Other comprehensive income (loss) is comprised of unrealized holding gains and losses arising during the period on available-for-sale securities that are not other-than-temporarily impaired. During the three months ended March 31, 2013, there were no reclassifications out of accumulated other comprehensive income (loss).

**Stock-Based Compensation Expense**

For awards granted to employees and directors, 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 requisite service period on a straight-line basis. We record the expense of services rendered by non-employees based on the estimated fair value of the stock option as of the respective vesting date. We use the Black-Scholes valuation model in determining the fair value of all equity awards. We have no awards with market or performance conditions.

**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 recognize revenue based upon our best estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item.

Under our previous strategic alliance with Mundipharma and Purdue, we recognized revenues from non-refundable, up-front license fees on a straight-line basis over the contracted or estimated period of performance, which was the research and development term. We regularly considered whether events warranted a change in the estimated period of performance under an agreement. Such a change would have caused us

to modify the period of time over which we recognized revenue from the up-front license fee on a prospective

---

**Table of Contents**

basis and would have, in turn, resulted in changes in our quarterly and annual results. We recognized research and development funding as earned over the period of effort as related research and development costs were incurred in proportion to our forecasted total expenses as compared to the total expected research and development funding for the year. We recognized the impact of any change in forecasted total expenses or expected research and development funding as a change in accounting estimate and recorded the impact of that change on a prospective basis. On July 17, 2012, we mutually agreed with Mundipharma and Purdue to terminate our strategic alliance agreements. Further information regarding the terms and conditions of this termination is described below under note 7.

At the inception of each agreement that includes milestone payments, we evaluate whether each milestone is substantive on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether:

the consideration is commensurate with either (1) our performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from our performance to achieve the milestone,

the consideration relates solely to past performance, and

the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement.

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

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

***Research and Development Expense***

Research and development expense consists of expenses incurred in performing research and development activities, including salaries and benefits, overhead expenses including facilities expenses, materials and supplies, preclinical expenses, clinical trial and related clinical manufacturing expenses, stock-based compensation expense, depreciation of equipment, contract services, and other outside expenses. We also include as research and development expense up-front license payments related to acquired technologies which have not yet reached technological feasibility and have no alternative use. We expense research and development costs as they are incurred. We have been a party to collaboration agreements in which we were reimbursed for work performed on behalf of the collaborator, as well as one in which we reimbursed the collaborator for work it had performed. We record all appropriate expenses under our collaborations as research and development expense. If the arrangement provides for reimbursement of research and development expenses, as was the case with our alliance with Mundipharma and Purdue, we record the reimbursement as revenue. If the arrangement provides for us to reimburse the collaborator for research and development expenses or achieving a development milestone for which a payment is due, as was the case with our agreement with Intellikine, Inc. (Intellikine) we record the reimbursement or the achievement of the development milestone as research and development expense. In January 2012, Intellikine was acquired by Takeda Pharmaceutical Company Limited (Takeda) acting through its Millennium business unit.

***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 and tax credit 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 of a change in tax rate on deferred taxes is recognized in income or loss in the period that includes the enactment date.

We use our judgment 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.

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

Due to the uncertainty surrounding the realization of the net deferred tax assets in future periods, we have recorded a full valuation allowance against our otherwise recognizable net deferred tax assets as of March 31, 2013 and December 31, 2012.

### ***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.

**Table of Contents**

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

**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 maintenance charges that do not increase the useful life of the assets are charged to operations as incurred. Property and equipment are depreciated over the following periods:

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

**4. Stock-Based Compensation**

Total stock-based compensation expense, related to all equity awards, for the three months ended March 31, 2013 and 2012 comprised the following:

	Three Months Ended March 31, 2013	Three Months Ended March 31, 2012 (in thousands)
<i>Effect of stock-based compensation on net loss by line item:</i>		
Research and development	\$ 1,542	\$ 791
General and administrative	2,450	713

As of March 31, 2013, we had approximately \$25.2 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 3.1 years.

During the three months ended March 31, 2013, we granted options to purchase 986,094 shares of our common stock at a weighted average fair value of \$20.44 with a weighted average exercise price of \$37.33. During the three months ended March 31, 2012, we granted options to purchase 1,195,813 shares of our common stock at a weighted average fair value of \$4.66 with a weighted average exercise price of \$8.00. For the three months ended March 31, 2013 and 2012, the fair values were estimated using the Black-Scholes valuation model using the following weighted-average assumptions:

	Three Months Ended March 31, 2013	Three Months Ended March 31, 2012
Risk-free interest rate	0.8%	1.2%
Expected annual dividend yield		
Expected stock price volatility	60.4%	63.6%
Expected term of options	5.0 years	6.1 years



**Table of Contents****5. Cash, Cash Equivalents and Available-for-Sale Securities**

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

	Cost	March 31, 2013		Estimated Fair Value
		Gross Unrealized Gains	Gross Unrealized Losses	
		(in thousands)		
Cash and cash equivalents due in 90 days or less	\$ 101,142	\$	\$	\$ 101,142
Available-for-sale securities:				
Corporate obligations due in one year or less	115,813	65	(20)	115,858
Corporate obligations due in one to five years	4,042	1		4,043
U.S. Treasury obligations	9,577			9,577
Mortgage-backed securities due after ten years	509	71		580
U.S. government-sponsored enterprise obligations due in one year or less	67,413	35	(1)	67,447
U.S. government-sponsored enterprise obligations due in one to five years	4,501			4,501
<b>Total available-for-sale securities</b>	<b>201,855</b>	<b>172</b>	<b>(21)</b>	<b>202,006</b>
<b>Total cash, cash equivalents and available-for-sale securities</b>	<b>\$ 302,997</b>	<b>\$ 172</b>	<b>\$ (21)</b>	<b>\$ 303,148</b>

	Cost	December 31, 2012		Estimated Fair Value
		Gross Unrealized Gains	Gross Unrealized Losses	
		(in thousands)		
Cash and cash equivalents due in 90 days or less	\$ 175,742	\$	\$	\$ 175,742
Available-for-sale securities:				
Corporate obligations due in one year or less	88,644	53	(13)	88,684
Corporate obligations due in one to five years	16,291	8	(9)	16,290
Mortgage-backed securities due after ten years	547	70		617
U.S. government-sponsored enterprise obligations due in one year or less	38,779	22		38,801
U.S. government-sponsored enterprise obligations due in one to five years	6,498	3		6,501
<b>Total available-for-sale securities</b>	<b>150,759</b>	<b>156</b>	<b>(22)</b>	<b>150,893</b>
<b>Total cash, cash equivalents and available-for-sale securities</b>	<b>\$ 326,501</b>	<b>\$ 156</b>	<b>\$ (22)</b>	<b>\$ 326,635</b>

We held 18 debt securities at March 31, 2013 that had been in an unrealized loss position for less than 12 months. The fair value on these securities was \$43.8 million. We evaluated our securities for other-than-temporary impairments based on quantitative and qualitative factors. We considered the decline in market value for these 18 securities to be primarily attributable to current economic and market conditions. It is not more likely than not that we will be required to sell these securities, and we do not intend to sell these securities before the recovery of their amortized cost bases, which recovery is expected within the next 12 months. Based on our analysis, we do not consider these investments to be other-than-temporarily impaired as of March 31, 2013.



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

As of March 31, 2013, we held 23 financial institution debt securities and other corporate debt securities located in Japan, Switzerland, Australia, the United Kingdom, the Netherlands, and Canada with a fair value of \$104.1 million. Nine of these securities, which were issued by Switzerland, Australia and Canada, had gross unrealized losses of \$7 thousand and a fair value of \$17.4 million. These securities are short term in nature and are scheduled to mature within 12 months. Based on our analysis, we do not consider these investments to be other-than-temporarily impaired as of March 31, 2013.

We had no material realized gains or losses on our available-for-sale securities for the three months ended March 31, 2013 and 2012. There were no other-than-temporary impairments recognized for the three months ended March 31, 2013 and 2012.

**Table of Contents****6. Fair Value**

We use a valuation hierarchy for disclosure of the inputs used to measure fair value. This hierarchy prioritizes the inputs into three broad levels. Level 1 inputs, which we consider the highest level 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. For our fixed income securities, we reference pricing data supplied by our custodial agent and nationally known pricing vendors, using a variety of daily data sources, largely readily-available market data and broker quotes. We validate the prices provided by our third party pricing services by reviewing their pricing methods and obtaining market values from other pricing sources. After completing our validation procedures, we did not adjust or override any fair value measurements provided by our pricing services as of March 31, 2013 and December 31, 2012.

The following table provides the assets carried at fair value measured on a recurring basis as of March 31, 2013:

	Level 1	Level 2
	(in thousands)	
<i>Assets:</i>		
Cash and cash equivalents	\$ 25,049	\$ 76,093
Corporate obligations (including commercial paper)		119,901
U.S. Treasury obligations		9,577
Mortgage-backed securities		580
U.S. government-sponsored enterprise obligations		71,948
<b>Total</b>	<b>\$ 25,049</b>	<b>\$ 278,099</b>

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.

The amount due to Millennium is recorded at its carrying value at March 31, 2013. The fair value of the amount due to Millennium, a Level 2 measurement, was approximately \$12.9 million as of March 31, 2013 and was determined using a discounted cash flow model and based on an

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

interest rate we would be charged for a similar loan as of March 31, 2013 (see note 7).

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

There have been no changes to the valuation methods during the three months ended March 31, 2013. We evaluate transfers between levels at the end of each reporting period. There were no transfers of assets or liabilities between Level 1 and Level 2 during the three months ended March 31, 2013. We had no available-for-sale securities that were classified as Level 3 at any point during the three months ended March 31, 2013 or during the year ended December 31, 2012.

---

**Table of Contents****7. Collaborations*****Millennium***

In July 2010, we entered into a development and license agreement with Intellikine, Inc. (Intellikine) under which we obtained rights to discover, develop and commercialize pharmaceutical products targeting the delta and/or gamma isoforms of PI3K, including IPI-145, and paid Intellikine a \$13.5 million up-front license fee. In January 2012, Intellikine was acquired by Takeda Pharmaceutical Company Limited (Takeda) acting through its Millennium business unit. We refer to our PI3K program licensor as Millennium. In December 2012, we amended and restated our development and license agreement with Millennium.

Under the terms of the amended and restated agreement, we retained our worldwide development and commercialization rights for products arising from the agreement for all therapeutic indications. We and Millennium no longer conduct the collaborative research program, and the restrictions on each party's ability to research, develop and commercialize products directed to the delta and/or gamma isoforms of PI3K that meet certain selectivity criteria have terminated, subject, in the case of Millennium, to the exclusive licenses granted to us under the amended and restated agreement.

Additionally, under the amended and restated agreement, Millennium waived the option it had under the original agreement to convert, upon payment of an option fee, its royalty interest in U.S. sales of PI3K products and its right to receive certain milestone payments with respect to such products into the right to share in 50% of profits and losses on U.S. development and commercialization of those PI3K products for which the first Phase 2 clinical trial, as defined in the original agreement, was conducted in an oncology indication, and to participate in up to 30% of the detailing effort for these products in the United States. In consideration of such waiver, we agreed to pay to Millennium \$15 million, payable in installments. During the year ended December 31, 2012, we paid \$1.7 million of the \$15 million, and we recorded the \$15 million release payment at its fair value of \$14.4 million in research and development expenses. The remaining amount is payable in two equal payments, which we expect to pay in 2013 and 2014, and which we recorded as short-term and long-term liabilities due to Millennium on our balance sheet.

In addition to developing IPI-145, we announced our second potent, oral PI3K-delta,gamma inhibitor, IPI-443, and we are seeking to identify additional novel inhibitors of PI3K-delta and/or PI3K-gamma for future development. We are obligated to pay to Millennium up to \$15 million in remaining success-based milestones for the development of two distinct product candidates, and up to \$450 million in success-based milestones for the approval and commercialization of two distinct products. As a result of the amendment, such products may include products we license in from a third party. In addition, we are obligated to pay Millennium tiered royalties on worldwide net sales ranging from seven percent to 11 percent, which are the same royalty levels as those specified under the original agreement, upon successful commercialization of products described in the agreement. Such royalties are payable until the later to occur of the expiration of specified patent rights and the expiration of non-patent regulatory exclusivities in a country, subject to reduction, and limits on the number of products, in certain circumstances.

The amended and restated agreement expires on the later of the expiration of certain patents and the expiration of the royalty payment terms for the products, unless earlier terminated. Either party may terminate the agreement on 75 days' prior written notice if the other party materially breaches the agreement and fails to cure such breach within the applicable notice period, provided that the notice period is reduced to 30 days where the alleged breach is non-payment. Millennium may also terminate the agreement if we are not diligent in developing or commercializing the licensed products and do not, within three months after notice from Millennium, demonstrate to Millennium's reasonable satisfaction that we have not failed to be diligent. The foregoing periods are subject to extension in certain circumstances. Additionally, Millennium may terminate the agreement upon 30 days' prior written notice if we or a related party bring an action challenging the validity of any of the licensed patents, provided that we have not withdrawn such action before the end of the 30-day notice period. We may terminate the agreement at any time upon 180 days' prior written notice. The agreement also provides for customary reciprocal indemnification obligations of the parties.

***Mundipharma and Purdue******Strategic Alliance Termination Agreements***

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



---

**Table of Contents**

Under the terms of the 2012 termination agreements:

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

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

Mundipharma and Purdue have no further obligation to provide research and development funding to us. Under the alliance, Mundipharma was obligated to reimburse us for research and development expenses we incurred, up to an annual aggregate cap for each alliance program other than FAAH. We recorded \$25.2 million in collaborative research and development revenue for the three months ended March 31, 2012. We did not record a liability for amounts previously funded by Purdue and Mundipharma as this relationship was not considered a financing arrangement.

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

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

*Line of Credit Agreement*

In connection with the previous strategic alliance with Mundipharma and Purdue, we also entered into a line of credit agreement with Purdue and its independent associated company, Purdue Pharma L.P. (PPLP) that provided for the borrowing by us of one or more unsecured loans up to an aggregate maximum principal amount of \$50 million. We recorded interest expense on the net amount borrowed using the effective interest method. We recorded \$0.7 million of related interest expense in the three months ended March 31, 2012 using an effective interest rate of 7.29%.

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

*2012 Securities Purchase Agreement*

On July 17, 2012, in connection with the termination of the strategic alliance with Mundipharma and Purdue, we executed a securities purchase agreement with PPLP, which we refer to as the 2012 securities purchase agreement, under which we agreed to sell and issue 5,416,565 shares of our common stock to PPLP and two entities associated with PPLP, which we collectively refer to as the BRP entities, at a price of \$14.50 per share for an aggregate consideration of approximately \$78.5 million. The consideration was composed of extinguishment of approximately \$51.0 million in principal and interest owed to PPLP under a line of credit agreement and \$27.5 million in cash. We completed the sale and issuance on September 7, 2012 at which time the line of credit agreement with PPLP terminated in its entirety. As of March 31, 2013, the BRP entities held approximately 11.4 million shares of our outstanding common stock. Immediately following the closing on April 16, 2013 of the

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

April 2013 offering described below, the BRP entities no longer owned any shares of our common stock. On April 11, 2013, we entered into a letter agreement with the BRP entities described below, pursuant to which the 2012 securities purchase agreement terminated effective as of April 16, 2013.

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

**Table of Contents**

In addition, the BRP entities had agreed that during the period between July 17, 2012 and December 31, 2013, if requested by us and/or the managing underwriters, placement agents or initial purchasers for any offering of our stock proposed by us during such period, not to, among other things, offer, sell or otherwise transfer or dispose of, directly or indirectly, any common stock held by the BRP entities or to enter into any agreement that transfers, in whole or in part, any of the economic consequences of ownership of any common stock held by the BRP entities, during such period as may have been requested by such managing underwriters, the placement agents or the initial purchasers, and to execute a lock-up agreement reflecting such restrictions, provided that all of our officers, directors and affiliates entered into similar agreements with equivalent terms.

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

Pursuant to the 2012 securities purchase agreement, the BRP entities and each associated company holding shares of our common stock also agreed to be present at each regular or special meeting of our stockholders held through September 6, 2017 and to vote all of their shares as recommended by our board of directors in the proxy materials mailed to our stockholders in connection with such meeting, subject to limitations specified in the 2012 securities purchase agreement.

*Subsequent Event - April 2013 Offering and 2013 Termination Agreement*

On April 9, 2013, we entered into a letter agreement with the BRP Entities, referred to herein as the April 9 letter agreement, pursuant to which the parties agreed that effective upon the public announcement of the public offering described below and contingent upon the sale of shares by the selling stockholders in the public offering: (i) we waived the existing lock-up restrictions set forth in the 2012 securities purchase agreement, but only with respect to the shares of our common stock sold by the selling stockholders in the public offering; (ii) with respect to any shares that were held by the selling stockholders and PPLP after the public offering, which we refer to as the remaining shares, the selling stockholders and PPLP agreed they would not exercise, in connection with our next offering of capital stock, the piggyback registration rights described above; and (iii) any such remaining shares would be subject to a lock-up between us and the selling stockholders and PPLP through the six-month anniversary of the execution of the underwriting agreement in connection with the public offering and the selling stockholders and PPLP agreed, if so requested, pursuant to the 2012 securities purchase agreement to execute a lock-up agreement with the underwriters, placement agents or other initial purchasers in any offering of our capital stock that commenced on or before December 31, 2013.

On April 10, 2013, we executed an underwriting agreement with Morgan Stanley & Co. LLC and J.P. Morgan Securities LLC as underwriters, certain of the BRP entities as selling stockholders, and PPLP, relating to an underwritten public offering of up to 11,416,565 shares of our common stock held by the BRP entities, referred to herein as the public offering.

On April 11, 2013, we entered into a letter agreement with the BRP entities, pursuant to which the 2012 securities purchase agreement, as amended by the April 9 letter agreement, terminated upon the sale of all of the shares of our common stock held by the BRP entities in the public offering on April 16, 2013. The termination of the 2012 securities purchase agreement resulted in, among other things, the elimination of (i) the piggyback registration rights of the BRP entities, (ii) the lock-up arrangements in effect with respect to the shares of our common stock held by the BRP entities, and (iii) except with respect to our 2013 annual meeting of stockholders (to the extent the shares of our common stock sold in the public offering were held by the BRP entities on or before the record date set for the our 2013 annual meeting of stockholders), the BRP entities' agreement to vote their respective shares as provided in the 2012 securities purchase agreement.

The BRP entities, through two selling stockholders, sold 11,416,565 shares in the public offering at a price of \$40 per share, representing their entire holdings in our common stock. The public offering closed on April 16, 2013, and, as a result, the BRP entities no longer owned any shares of our common stock at such time.

**8. Accrued Expenses**

Accrued expenses consisted of the following:

	March 31, 2013	December 31, 2012
	(in thousands)	
Accrued compensation and benefits	\$ 2,945	\$ 5,555
Accrued drug manufacturing costs	1,313	1,288



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

Accrued clinical studies	1,331	1,234
Other	2,250	1,982
Total accrued expenses	\$ 7,839	\$ 10,059

**Table of Contents****9. Restructuring Activities**

In June 2012, we voluntarily stopped all company-sponsored clinical trials of saridegib, our Hedgehog pathway inhibitor. We reallocated remaining resources to other potential development programs and product portfolio efforts and reduced our work force. In July 2012, we agreed with Mundipharma and Purdue to terminate our strategic alliance agreements with the result that Mundipharma would have no further obligation to provide research and development funding to us (see note 7), and therefore we undertook a subsequent workforce reduction.

The associated restructuring expenses were recorded as research and development and general and administrative expenses in the year ended December 31, 2012. The following table summarizes the impact of the payments for the three months ended March 31, 2013 and the current liability remaining on the balance sheet as of March 31, 2013, in thousands:

	Amounts Accrued at December 31, 2012	Amounts Paid Through March 31, 2013	Amounts Accrued at March 31, 2013
Employee severance, benefits and related costs for work force reductions	\$ 392	\$ (279)	\$ 113

**10. Subsequent Event**

In April 2013, the BRP entities, through two selling stockholders, sold in an underwritten public offering 11,416,565 shares of our common stock at a price of \$40 per share, representing their entire holdings in our common stock. We did not sell any shares or receive any proceeds from the offering, and the total number of shares of our outstanding common stock did not change as a result of the offering. See note 7 above under the heading *Subsequent Event - April 2013 Offering and 2013 Termination Agreement* for further description of the offering and related agreements.

**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**  
**Forward-Looking Information**

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

**Business Overview**

We are an innovative drug discovery and development company seeking to discover, develop and deliver to patients best-in-class medicines designed to address diseases with significant unmet need. We combine proven scientific expertise with a passion for developing novel small molecule drugs that target emerging disease pathways. Our programs focused on the inhibition of phosphoinositide-3-kinase (PI3K), and heat shock protein 90 (Hsp90), are evidence of our innovative approach to drug discovery and development. We have worldwide development and commercialization rights to all of our product candidates and early discovery programs, subject to certain financial obligations to our current licensor and former development partners.

**Research and Development Programs****PI3 Kinase Inhibitor Program**

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

IPI-145, our lead product candidate, is a potent, oral inhibitor of Class I PI3K-delta and PI3K-gamma, which we are investigating in both hematologic malignancies and inflammatory diseases. We believe that IPI-145 is the first PI3K-delta,gamma inhibitor in clinical development. We are conducting a Phase 1, open-label, dose-escalation study designed to evaluate the safety, pharmacokinetics and clinical activity of IPI-145 in patients with advanced hematologic malignancies. Additionally, we are enrolling patients in five additional expansion cohorts in the Phase 1 study to further evaluate the safety, pharmacokinetics and activity of IPI-145 in patients with the following hematologic malignancies:

Chronic lymphocytic leukemia, indolent non-Hodgkin lymphoma and mantle cell lymphoma,

T-cell lymphomas,

---

## **Table of Contents**

Aggressive B-cell lymphomas,

Myeloid neoplasms, and

T-cell or B-cell acute lymphoblastic leukemia/lymphoma.

We intend to provide updated data from this study at two medical meetings in June 2013, including at the American Society of Clinical Oncology (ASCO) 2013 Annual Meeting and the 12<sup>th</sup> International Conference on Malignant Lymphoma. We are planning to initiate at least two additional trials of IPI-145 in patients with hematologic malignancies in 2013. Additionally, the U.S. Food and Drug Administration (FDA), and the European Medicines Agency have granted orphan drug designation to IPI-145 for the potential treatment of chronic lymphocytic leukemia and small lymphocytic lymphoma.

In addition to exploring hematologic malignancies, we are investigating IPI-145 for potential applications in inflammatory diseases in two Phase 2 trials. The first is a Phase 2a randomized, double-blind, placebo-controlled trial of IPI-145 in approximately 30 patients with mild, allergic asthma. Endpoints of this multi-dose, two-way crossover study include safety, pharmacokinetics and FEV<sub>1</sub>, a measure of lung function. We expect to provide an update on this trial in the second half of 2013. The second trial, which we refer to as the ASPIRA trial, is a Phase 2, randomized, double-blind, placebo-controlled study designed to evaluate the efficacy, safety and pharmacokinetics of IPI-145 in patients with rheumatoid arthritis (RA). The study is expected to enroll approximately 316 adults with moderate-to-severe RA and is designed to examine three dose levels of IPI-145 given twice daily for 12 weeks in combination with methotrexate compared to treatment with methotrexate alone. The primary efficacy endpoint of the study is the American College of Rheumatology (ACR)<sub>20</sub> response rate, which is defined as the proportion of people who achieve at least a 20 percent improvement in ACR response criteria.

In January 2013, we announced our second potent, oral PI3K-delta,gamma inhibitor, IPI-443. We expect to complete in the second half of 2013 nonclinical studies designed to enable the initiation of Phase 1 clinical development.

### ***Retaspimycin Hydrochloride***

Our second clinical candidate, retaspimycin hydrochloride (HCl), is a novel, potent and selective inhibitor of heat shock protein 90 (Hsp90). We completed patient enrollment in a Phase 2, randomized, double-blind, placebo-controlled clinical trial evaluating retaspimycin HCl in combination with docetaxel, a chemotherapy, compared to placebo and docetaxel in 226 patients with second or third-line non-small cell lung cancer (NSCLC), who are naive to docetaxel treatment and have a history of heavy smoking. We stratified patients in our Phase 2 trial by squamous cell carcinoma and adenocarcinoma based on results from our Phase 1b trial in which we observed partial responses in patients with squamous cell carcinoma. In addition, we are prospectively evaluating a novel biomarker that we believe may be predictive of response. Due to the anticipated timing of planned correlative studies and biomarker analyses, we now expect to report topline overall survival data from this trial in the second half of 2013.

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

### ***Other Programs***

In addition to our clinical stage programs, we have multiple innovative projects in earlier stages of development. Through our internal discovery efforts, we also discovered IPI-940, a novel, orally available inhibitor of fatty acid amide hydrolase (FAAH). It is believed that inhibition of FAAH may enable the body to bolster its own analgesic and anti-inflammatory response, and may have applicability in a broad range of painful or inflammatory conditions. We are currently seeking potential partnering opportunities for our FAAH program. In June 2012, we voluntarily stopped all company-sponsored clinical trials of saridegib, our lead Hedgehog pathway inhibitor.

### ***Strategic Alliances***

#### ***Millennium***

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

In July 2010, we entered into a development and license agreement with Intellikine, Inc. (Intellikine) under which we obtained rights to discover, develop and commercialize pharmaceutical products targeting the delta and/or gamma isoforms of PI3K, including IPI-145. We paid Intellikine a \$13.5 million up-front license fee. In January 2012, Intellikine was acquired by Takeda Pharmaceutical Company Limited (Takeda) acting through its Millennium business unit. We refer to our PI3K program licensor as Millennium. In December 2012, we amended and restated our development and license agreement with Millennium.

Under the terms of the amended and restated agreement, we retained our worldwide development and commercialization rights for products arising from the agreement for all therapeutic indications. We and Millennium no longer conduct the collaborative

---

## **Table of Contents**

research program, and the restrictions on each party's ability to research, develop and commercialize products directed to the delta and/or gamma isoforms of PI3K that meet certain selectivity criteria have terminated, subject, in the case of Millennium, to the exclusive licenses granted to us under the amended and restated agreement.

Additionally, under the amended and restated agreement, Millennium waived the option it had under the original agreement to convert, upon payment of an option fee, its royalty interest in U.S. sales of PI3K products and its right to receive certain milestone payments with respect to such products into the right to share in 50% of profits and losses on U.S. development and commercialization of those PI3K products for which the first Phase 2 clinical trial, as defined in the original agreement was conducted in an oncology indication, and to participate in up to 30% of the detailing effort for these products in the United States. In consideration of such waiver, we agreed to pay to Millennium \$15 million, payable in installments. During the year ended December 31, 2012, we paid \$1.7 million of the \$15 million, and we recorded the \$15 million release payment at its fair value of \$14.4 million in research and development expenses. The remaining amount is payable in two equal payments, which we expect to pay in 2013 and 2014, and which we recorded as short-term and long-term liabilities due to Millennium on our balance sheet.

In addition to developing IPI-145, we announced our second potent, oral PI3K-delta,gamma inhibitor, IPI-443, and we are seeking to identify additional novel inhibitors of PI3K-delta and/or PI3K-gamma for future development. We are obligated to pay to Millennium up to \$15 million in remaining success-based milestones for the development of two distinct product candidates, and up to \$450 million in success-based milestones for the approval and commercialization of two distinct products. As a result of the amendment, such products may include products we license in from a third party. In addition, we are obligated to pay Millennium tiered royalties on worldwide net sales ranging from seven percent to 11 percent, which are the same royalty levels as those specified under the original agreement, upon successful commercialization of products described in the agreement. Such royalties are payable until the later to occur of the expiration of specified patent rights and the expiration of non-patent regulatory exclusivities in a country, subject to reduction, and limits on the number of products, in certain circumstances.

The amended and restated agreement expires on the later of the expiration of certain patents and the expiration of the royalty payment terms for the products, unless earlier terminated. Either party may terminate the agreement on 75 days' prior written notice if the other party materially breaches the agreement and fails to cure such breach within the applicable notice period, provided that the notice period is reduced to 30 days where the alleged breach is non-payment. Millennium may also terminate the agreement if we are not diligent in developing or commercializing the licensed products and do not, within three months after notice from Millennium, demonstrate to Millennium's reasonable satisfaction that we have not failed to be diligent. The foregoing periods are subject to extension in certain circumstances. Additionally, Millennium may terminate the agreement upon 30 days' prior written notice if we or a related party bring an action challenging the validity of any of the licensed patents, provided that we have not withdrawn such action before the end of the 30-day notice period. We may terminate the agreement at any time upon 180 days' prior written notice. The agreement also provides for customary reciprocal indemnification obligations of the parties.

### ***Mundipharma and Purdue***

#### ***Strategic Alliance Termination Agreements***

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

Under the terms of the 2012 termination agreements:

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

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

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

Mundipharma and Purdue have no further obligation to provide research and development funding to us. Under the alliance, Mundipharma was obligated to reimburse us for research and development expenses we incurred, up to an annual aggregate cap for each alliance program other than FAAH. We recorded \$25.2 million in collaborative research and development revenue for the three months ended March 31, 2012. We did not record a liability for amounts previously funded by Purdue and Mundipharma as this relationship was not considered a financing arrangement.

---

**Table of Contents**

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

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

*Line of Credit Agreement*

In connection with the previous strategic alliance with Mundipharma and Purdue, we also entered into a line of credit agreement with Purdue and its independent associated company, Purdue Pharma L.P. (PPLP), that provided for the borrowing by us of one or more unsecured loans up to an aggregate maximum principal amount of \$50 million. We recorded interest expense on the net amount borrowed using the effective interest method. We recorded \$0.7 million of related interest expense in the three months ended March 31, 2012 using an effective interest rate of 7.29%.

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

*2012 Securities Purchase Agreement*

On July 17, 2012, in connection with the termination of the strategic alliance with Mundipharma and Purdue, we executed a securities purchase agreement with PPLP, which we refer to as the 2012 securities purchase agreement, under which we agreed to sell and issue 5,416,565 shares of our common stock to PPLP and two entities associated with PPLP, which we collectively refer to as the BRP entities, at a price of \$14.50 per share for an aggregate consideration of approximately \$78.5 million. The consideration was composed of extinguishment of approximately \$51.0 million in principal and interest owed to PPLP under a line of credit agreement and \$27.5 million in cash. We completed the sale and issuance on September 7, 2012 at which time the line of credit agreement with PPLP terminated in its entirety. As described below, on April 11, 2013, we entered into a letter agreement with the BRP entities, pursuant to which the 2012 securities purchase agreement terminated effective as of April 16, 2013.

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

In addition, the BRP entities had agreed that during the period between July 17, 2012 and December 31, 2013, if requested by us and/or the managing underwriters, placement agents or initial purchasers for any offering of our stock proposed by us during such period, not to, among other things, offer, sell or otherwise transfer or dispose of, directly or indirectly, any common stock held by the BRP entities or to enter into any agreement that transfers, in whole or in part, any of the economic consequences of ownership of any common stock held by the BRP entities, during such period as may have been requested by such managing underwriters, the placement agents or the initial purchasers, and to execute a lock-up agreement reflecting such restrictions, provided that all of our officers, directors and affiliates entered into similar agreements with equivalent terms.

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



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

Pursuant to the 2012 securities purchase agreement, the BRP entities and each associated company holding shares of our common stock also agreed to be present at each regular or special meeting of our stockholders held through September 6, 2017 and to vote all of their shares as recommended by our board of directors in the proxy materials mailed to our stockholders in connection with such meeting, subject to limitations specified in the 2012 securities purchase agreement.

---

## **Table of Contents**

### *April 2013 Offering and 2013 Termination Agreement*

On April 9, 2013, we entered into a letter agreement with the BRP Entities, referred to herein as the April 9 letter agreement, pursuant to which the parties agreed that effective upon the public announcement of the public offering described below and contingent upon the sale of shares by the selling stockholders in the public offering: (i) we waived the existing lock-up restrictions set forth in the 2012 securities purchase agreement, but only with respect to the shares of our common stock sold by the selling stockholders in the public offering; (ii) with respect to any shares that were held by the selling stockholders and PPLP after the public offering, which we refer to as the remaining shares, the selling stockholders and PPLP agreed they would not exercise, in connection with our next offering of capital stock, the piggyback registration rights described above; and (iii) any such remaining shares would be subject to a lock-up between us and the selling stockholders and PPLP through the six-month anniversary of the execution of the underwriting agreement in connection with the public offering and the selling stockholders and PPLP agreed, if so requested, pursuant to the 2012 securities purchase agreement to execute a lock-up agreement with the underwriters, placement agents or other initial purchasers in any offering of our capital stock that commenced on or before December 31, 2013.

On April 10, 2013, we executed an underwriting agreement with Morgan Stanley & Co. LLC and J.P. Morgan Securities LLC as underwriters, certain of the BRP entities as selling stockholders, and PPLP, relating to an underwritten public offering of up to 11,416,565 shares of our common stock held by the BRP entities, referred to herein as the public offering.

On April 11, 2013, we entered into a letter agreement with the BRP entities, pursuant to which the 2012 securities purchase agreement, as amended by the April 9 letter agreement, terminated upon the sale of all of the shares of our common stock held by the BRP entities in the public offering on April 16, 2013. The termination of the 2012 securities purchase agreement resulted in, among other things, the elimination of (i) the piggyback registration rights of the BRP entities, (ii) the lock-up arrangements in effect with respect to the shares of our common stock held by the BRP entities, and (iii) except with respect to our 2013 annual meeting of stockholders (to the extent the shares of our common stock sold in the public offering were held by the BRP entities on or before the record date set for the our 2013 annual meeting of stockholders), the BRP entities' agreement to vote their respective shares as provided in the 2012 securities purchase agreement.

The BRP entities, through two selling stockholders, sold 11,416,565 shares in the public offering at a price of \$40 per share, representing their entire holdings in our common stock. The public offering closed on April 16, 2013, and, as a result, the BRP entities no longer owned any shares of our common stock at such time.

### ***Financial Overview***

#### ***Revenue***

All of our revenue to date has been derived from license fees, the reimbursement of research and development costs, contract service revenue and milestone payments received from our collaboration partners. License fees were recognized as revenue ratably over the expected research and development period under our arrangement with Mundipharma and Purdue. Because our agreements with Mundipharma and Purdue also provided for funding for our research and development efforts, we recognized this cost reimbursement as revenue in the period earned in proportion to our forecasted total expenses as compared to the total research funding budget for the year. In the future, we may generate revenue from a combination of product sales, research and development support services and milestone payments in connection with strategic relationships and royalties resulting from the sales of products developed under licenses of our intellectual property. We expect that any potential future 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.

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

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

compensation of personnel associated with research activities;

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

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

costs of purchasing laboratory supplies and materials;

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

costs associated with the licensing of research and development programs;

preclinical testing costs, including costs of toxicology studies;

fees paid to external consultants;

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

**Table of Contents**

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

depreciation of equipment; and

allocated costs of facilities.

**General and Administrative Expense**

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

**Other Income and Expense**

Investment and other income typically consists of interest earned on cash, cash equivalents and available-for-sale securities. Interest expense included accrued interest on the long-term debt, including amortization of the debt discount.

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

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

There have been no material changes to our critical accounting policies during the three months ended March 31, 2013. Please refer to Part II, Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations of our annual report on Form 10-K for the fiscal year ended December 31, 2012 for a discussion of our critical accounting policies and significant judgments and estimates.

**Results of Operations**

The following tables summarize our results of operations for each of the three months ended March 31, 2013 and 2012, together with the change in these items in dollars and as a percentage:

	Three Months Ended March 31,		\$ Change	% Change
	2013	2012		
	(in thousands)			
Revenue	\$	\$ 25,202	\$ (25,202)	(100)%
Research and development expense	(20,231)	(28,551)	8,320	(29)%
General and administrative expense	(7,430)	(6,812)	(618)	9%
Interest expense		(681)	(681)	(100)%
Investment and other income	335	120	215	179%

**Revenue**

We recorded no revenue during the three months ended March 31, 2013 as we terminated our strategic alliance agreements with Mundipharma and Purdue in July 2012. Our revenue during the three months ended March 31, 2012 consisted of approximately \$24.2 million for reimbursed research and development services we performed under our strategic alliance with Mundipharma and Purdue, and \$1.0 million from the amortization of the deferred revenue associated with the grant of rights and licenses under this alliance.



**Table of Contents***Research and Development Expense*

The \$8.3 million decrease in research and development expense for the three months ended March 31, 2013 as compared to the three months ended March 31, 2012 was primarily due to \$3.1 million in lower clinical manufacturing expenses and \$2.9 million in lower clinical expenses largely attributable to the discontinuation of company-sponsored development of saridegib, our Hedgehog pathway inhibitor.

We began to track and accumulate expenses by major program starting on January 1, 2006. During the three months ended March 31, 2013 and 2012, and from January 1, 2006 through March 31, 2013, we estimate that we incurred the following expenses by program:

Program	Three Months Ended		January 1, 2006 to March 31, 2013
	March 31, 2013	Three Months Ended March 31, 2012 (in millions)	
PI3K inhibitors	\$ 13.0	\$ 4.7	\$ 103.3
Hsp90 inhibitor	4.8	5.2	128.8
Hedgehog pathway inhibitor	0.6	14.2	163.3

We expect expenses related to our PI3K programs to increase as we continue clinical development of IPI-145 and preclinical development of IPI-443. We expect to incur minimal expenses related to our Hedgehog pathway inhibitor program as a result of the discontinuation of company-sponsored development. We do not believe that the historical costs associated with our lead drug development programs are indicative of the future costs associated with these programs nor represent what any other future drug development program we initiate may cost. Due to the variability in the length of time and scope of activities necessary to develop a product candidate and uncertainties related to our cost estimates and our ability to obtain marketing approval for our product candidates, accurate and meaningful estimates of the total costs required to bring our product candidates to market are not available.

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

the nature, timing and estimated costs of the efforts necessary to complete the development of our programs;

the completion dates of these programs; or

the period in which material net cash inflows are expected to commence, if at all, from the programs described above and any potential future product candidates.

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

the scope, rate of progress and cost of our clinical trials that we are currently running or may commence in the future;

the scope and rate of progress of our preclinical studies and other research and development activities;

clinical trial results;

the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights relating to our programs under development;

the terms and timing of any strategic alliance, licensing and other arrangements that we have or may establish in the future relating to our programs under development;

the cost and timing of regulatory approvals;

the cost of establishing clinical supplies of any product candidates; and

the effect of competing technological and market developments.

*General and Administrative Expense*

The increase in general and administrative expense for the three months ended March 31, 2013 as compared to the three months ended March 31, 2012 is primarily attributable to higher stock-based compensation expense, including \$1.3 million for non-employee stock options.

*Interest Expense*

Interest expense decreased in the three months ended March 31, 2013 as compared to the three months ended March 31, 2012 due to the extinguishment on September 7, 2012 of the long-term debt due to the Purdue entities. We do not expect to record interest expense during the year ended December 31, 2013.

**Table of Contents***Investment and Other Income*

Investment and other income increased in the three months ended March 31, 2013 as compared to the three months ended March 31, 2012 primarily due to a non-recurring cash distribution received from one of our insurance carriers.

*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, debt, interest on investments, up-front license fees, expense reimbursement, milestones and cost sharing under our collaborations to fund our operations. Our available-for-sale debt securities primarily trade in liquid markets, and the average days to maturity of our portfolio, as of March 31, 2013, 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:

	March 31, 2013	December 31, 2012
	(in thousands)	
Cash, cash equivalents and available-for-sale securities	\$ 303,148	\$ 326,635
Working capital	290,548	311,086
	<b>Three Months Ended March 31,</b>	
	<b>2013</b>	<b>2012</b>
	(in thousands)	
Cash provided by (used in):		
Operating activities	\$ (25,300)	\$ (11,215)
Investing activities	(51,776)	9,786
Capital expenditures (included in investing activities above)	(287)	(236)
Financing activities	2,476	694

*Cash Flows*

The principal use of cash in operating activities in all periods presented was related to our research and development programs. Our cash flow used in operating activities for the three months ended March 31, 2013 compared to the three months ended March 31, 2012 increased primarily due to the discontinuation of all research and development funding following the termination of our strategic alliance with Purdue and Mundipharma in July 2012. During the three months ended March 31, 2012, we received research and development funding from Mundipharma totaling \$27.5 million. However, our cash flow used in operating activities in future periods may vary significantly due to various factors, including potential cash inflows from future collaboration agreements and potential cash outflows for licensing new programs from third parties.

Net cash from investing activities for the period ended March 31, 2013 included \$91.9 million in purchases of available-for-sale securities and proceeds of \$40.3 million from maturities of available-for-sale securities. Capital expenditures in the three months ended March 31, 2013 primarily consisted of laboratory equipment, computer equipment and software.

We will need substantial additional funds to support our planned operations. In the absence of additional funding or business development activities and based on our current operating plans, we expect that our current cash and investments are sufficient to fund our planned operations into 2015. We may need to raise additional funds for other reasons, including if:

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

we advance more of our drug candidates than expected into costly later stage clinical trials;



we advance more preclinical drug candidates than expected into early stage clinical trials;

the cost of acquiring raw materials for, and of manufacturing, our drug candidates is higher than anticipated;

we are required, or consider it advisable, to acquire or license intellectual property rights from one or more third parties; or

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

---

## **Table of Contents**

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

We have received \$244.8 million of net proceeds from our public stock offerings since the termination of the strategic alliance agreements with Mundipharma and Purdue. We may continue to seek additional funding through public or private financings of equity or debt securities, but such financing may not be available on acceptable terms, if at all. In addition, the terms of our financings may be dilutive to, or otherwise adversely affect, holders of our common stock, and such terms may impact our ability to make capital expenditures or incur additional debt. We may also seek additional funds through arrangements with collaborators or other third parties, or through project financing. These arrangements would generally require us to relinquish or encumber rights to some of our technologies or product candidates, and we may not be able to enter into such agreements on acceptable terms, if at all. If we are unable to obtain additional funding on a timely basis, we may be required to curtail or terminate some or all of our development programs or to scale back, suspend or terminate our business operations.

### ***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.

There have been no material changes to our contractual obligations and off-balance sheet arrangements during the three months ended March 31, 2013.

We are obligated to pay to Millennium up to \$15 million in remaining success-based milestones for the development of two distinct product candidates, and up to \$450 million in success-based milestones for the approval and commercialization of two distinct products. Because the achievement of these milestones had not occurred as of March 31, 2013, such contingencies have not been recorded in our financial statements.

Please refer to Part II, Item 7 *Management's Discussion and Analysis of Financial Condition and Results of Operations* of our annual report on Form 10-K for the fiscal year ended December 31, 2012 for a discussion of our judgments and estimates.

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

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

A hypothetical 100 basis point increase in interest rates would result in an approximate \$1.1 million decrease in the fair value of our investments as of March 31, 2013, as compared to an approximate \$1.0 million decrease as of December 31, 2012. 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 officers, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2013. 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, (Exchange Act) means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management

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

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, 2013, our principal executive and financial officers concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

---

## **Table of Contents**

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal quarter ended March 31, 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

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

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

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

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

*We have a history of operating losses, expect to incur significant and increasing operating losses in the future, may never become profitable, or if we become profitable we may not remain 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, 2013, we had an accumulated deficit of \$350.3 million. We expect to continue to spend significant resources to fund the research and development of IPI-145, retaspimycin HCl, and our other product candidates. While we may have net income in future periods as the result of non-recurring collaboration revenue, we expect to incur substantial operating losses over the next several years as our clinical trial and drug manufacturing activities increase. As a result, we expect that our accumulated deficit will also increase significantly.

Our product 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 product candidates successfully completes clinical trials and receives regulatory approval. Since even our most advanced product candidate requires substantial additional clinical development, we do not expect to receive revenue from our product candidates for several years, if ever. Even if we eventually generate revenues, we may never be profitable, and if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

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

We will need substantial additional funds to support our planned operations. In the absence of additional funding or business development activities and based on our current operating plans, we expect that our current cash and investments are sufficient to fund our current operating plans into 2015. In the absence of changes to our current operating plans, we will need to raise additional funds by that date. Our need to raise additional funds may be accelerated if our research and development expenses exceed our current expectation, if we acquire a third party or if we acquire or license rights to additional product candidates or new technologies from one or more third parties. Our need to raise additional funds may also be accelerated for other reasons, including if:

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

we advance our product candidates into clinical trials for more indications than we currently expect;

we advance more of our product candidates than expected into costly later stage clinical trials;

we advance more preclinical product candidates than expected into early stage clinical trials;

we acquire additional business, technologies, products or product candidates;

---

**Table of Contents**

the cost of acquiring raw materials for, and of manufacturing, our product candidates is higher than anticipated;

we are required, or consider it advisable, to acquire or license intellectual property rights from one or more third parties; or

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

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

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

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

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

Recruiting and retaining qualified scientific and business personnel is also critical to our success. We may not be able to attract or 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 not be able to execute our business strategy if we are unable to enter into alliances with other companies that can provide capabilities or funding for the development and commercialization of our product candidates.***

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

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

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



---

## **Table of Contents**

Much of the potential revenue from any alliance we may enter into in the future will likely consist of contingent payments, such as royalties payable on sales of any successfully developed drugs. Any such contingent revenue will depend upon our, and our alliance partner's, ability to successfully develop, introduce, market and sell new drugs. In some cases, we will not be involved in some or all of these processes, and we will depend entirely on our alliance partners. Any of our future alliance partners may fail to develop or effectively commercialize these drugs 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 product candidates 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 product candidate through clinical development, regulatory approval and commercialization; or

cannot obtain the necessary regulatory approvals.

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

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

Our ability to effectively manage changes to our organization 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 during periods of organizational change. If we do not meet these challenges, we may be unable to take advantage of market opportunities, execute our business strategies or respond to competitive pressures, which in turn may give rise to inefficiencies that would increase our losses or delay our programs.

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

We may acquire additional businesses, products, product candidates, or technologies that complement or augment our existing business. We may not be able to integrate any acquired business, product, product candidate or technology successfully or operate any acquired business profitably. Integrating any newly acquired business, product, product candidate, or technology could be expensive and time-consuming. Integration efforts often place a significant strain on managerial, operational and financial resources and could prove to be more difficult or expensive than we expect. The diversion of the attention of our management to, and any delay or difficulties encountered in connection with, any future acquisitions we may consummate could result in the disruption of our ongoing business or inconsistencies in standards, controls, procedures and policies that could adversely affect our ability to maintain relationships with customers, suppliers, collaborators, employees and others with whom we have business dealings. We may need to raise additional funds through public or private debt or equity financings to acquire any businesses, products, product candidates, or technologies which may result in, among other things, dilution for stockholders or the incurrence of indebtedness.

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

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



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

As of March 31, 2013, we had approximately \$303.1 million in cash, cash equivalents and available-for-sale securities. We historically have invested these amounts in money market funds, corporate obligations, U.S. government-sponsored enterprise obligations, U.S. Treasury securities and mortgage-backed securities meeting the criteria of our investment policy, which prioritizes the preservation of our capital. Corporate obligations may include obligations issued by corporations in countries other than the United States, including some issues that have not been guaranteed by governments and government agencies. Our investments are subject to

---

## **Table of Contents**

general credit, liquidity, market and interest rate risks and instability in the global financial markets. We may realize losses in the fair value of these investments or a complete loss of these investments. In addition, should our investments cease paying or reduce the amount of interest paid to us, our interest income would suffer. These market risks associated with our investment portfolio may have a material adverse effect on our financial results and the availability of cash to fund our operations.

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

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

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

*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 Product Candidates**

*All of our product 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 product candidates.*

To date, we have not obtained approval from the FDA or any foreign regulatory authority to market or sell any of our product candidates. Our product 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 product candidates. For example, we are evaluating retaspimycin HCl, in Phase 2 and Phase 1b/2 clinical trials. In addition, we are conducting a Phase 1 and two Phase 2 clinical trials to evaluate IPI-145, the lead compound in our PI3K inhibitor program. We intend to commence additional trials of IPI-145, subject to receiving applicable regulatory clearances to commence these trials. If any of these trials are successful, we will need to conduct further clinical trials and apply for regulatory approval before we may market or sell any of our future products. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that none of the product candidates we are developing, or may in the future develop, either alone or in collaboration with strategic alliance partners, will obtain marketing approval. 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 product candidates may be eligible for the FDA's programs that are designed to facilitate the development and expedite the review of certain drugs, but we cannot provide any assurance that any of our product candidates will qualify for one or more of these programs. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product candidate no longer meets the conditions for qualification.

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

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 and other regulatory policy during the period of product candidate development, clinical trials and FDA and other regulatory review.

## **Table of Contents**

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

***Our product 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 product 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, suspend, or discontinue clinical trials or to delay the analysis of data from ongoing clinical trials. Any of the following could delay or disrupt the clinical development of our product candidates:

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 or discontinue clinical trials as a result of inconclusive or negative results or unforeseen complications in testing or because the results of later trials may not confirm positive results from earlier preclinical studies or clinical trials;

inadequate supply, delays in distribution or deficient quality of, or inability to purchase or manufacture drug product or other materials necessary to conduct our clinical trials;

unfavorable FDA or other foreign regulatory inspection and review of a clinical trial site or records of any clinical or preclinical investigation;

serious and unexpected drug-related side effects experienced by participants in our clinical trials, which may occur even if they were not observed in earlier trials or only observed in a limited number of participants;

a finding that the trial participants are being exposed to unacceptable health risks;

the placement by the FDA or a foreign regulatory authority 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 product candidate not commercially viable.

We may suspend, or the FDA or other applicable regulatory authorities may require us to suspend, clinical trials of a product 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.

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

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

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

***Our inability to enroll sufficient numbers of patients in our clinical trials, or any delays in patient enrollment, can result in increased costs and longer development periods for our product 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, including eligibility criteria for the trial;

the number of clinical trial sites and the proximity of patients to those sites;

the availability of safe and effective treatments for the relevant disease;

## **Table of Contents**

the commitment of clinical investigators to identify eligible patients; and

competing studies or trials.

Our failure to enroll patients in a clinical trial could delay the initiation or completion of the clinical trial beyond current expectations. In addition, the FDA or other foreign regulatory authority could require us to conduct clinical trials with a larger number of patients than has been projected for any of our product 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 product 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 product candidate; and

the availability of numerous alternative treatment options, including clinical trials evaluating competing product candidates, that may induce patients to discontinue their participation in the trial.

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

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

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

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

We rely on third parties such as contract research organizations, medical institutions and external investigators to enroll qualified patients, conduct our clinical trials and provide services in connection with such clinical trials, and we intend to rely on these and other similar entities in the future. Our reliance on these third parties for clinical development activities reduces our control over these activities. Accordingly, these third party contractors may not complete activities on schedule, or may not conduct our clinical trials in accordance with regulatory requirements or the trial design. If these third parties do not successfully carry out their contractual obligations 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 product candidates may be delayed.

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

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 product candidates may be delayed.

---

## **Table of Contents**

### ***Manufacturing difficulties could delay or preclude commercialization of our product candidates and substantially increase our expenses.***

Our product 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 (cGMPs) and other applicable government regulations and corresponding foreign standards. These regulations govern manufacturing processes and procedures and the implementation and operation of systems to control and assure the quality of products. The FDA and foreign regulatory authorities may, at any time, audit or inspect a manufacturing facility to ensure compliance with cGMPs and other quality standards. Any failure by our contract manufacturers to achieve and maintain high manufacturing and quality control standards could result in the inability of our product 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 product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and/or criminal prosecution, any of which could significantly and adversely affect supply of our product candidates and seriously hurt our business.

Contract manufacturers may also encounter difficulties involving production yields or delays in performing their services. We do not have control over third party manufacturers' performance and compliance with applicable regulations and standards. If, for any reason, our manufacturers cannot perform as agreed, we may be unable to replace such third party manufacturers in a timely manner, and the production of our product 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 product 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 product 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 product 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 product candidates. These manufacturers may not be able to successfully increase the manufacturing capacity for any approved product 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 product candidate, or we are unable to establish our own manufacturing capabilities, the commercial launch of any approved products may be delayed or there may be a shortage in supply.

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

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

### ***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 product candidates obtains regulatory approval, that product may not gain market acceptance among physicians, patients and the medical community for a variety of reasons including:

timing of our receipt of any marketing approvals, the terms of any such approvals and the countries in which any such approvals are obtained;

timing of market introduction of competitive products;



lower demonstrated clinical safety and efficacy compared to other products;

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;

## **Table of Contents**

safety concerns with similar products marketed by others;

the reluctance of the target population to try new therapies and of physicians to prescribe those therapies;

the success of our physician education programs; and

ineffective sales, marketing and distribution support.

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

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

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

***If our product 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 product candidates, we will have tested them in only a small number of patients and over a limited period of time during our clinical trials. If our applications for marketing are approved and more patients begin to use our products, or patients use our products for a longer period of time, new risks and side effects associated with our products may be discovered or previously observed risks and side effects may become more prevalent and/or clinically significant. In addition, supplemental clinical trials that may be conducted on a drug following its initial approval may produce findings that are inconsistent with the trial results previously submitted to regulatory authorities. As a result, regulatory authorities may revoke their approvals, or we may be required to conduct additional clinical trials, make changes in labeling of our product, reformulate our product or make changes and obtain new approvals for our and our suppliers manufacturing facilities. We also might have to withdraw or recall our products from the marketplace. Any safety concerns with respect to a product may also result in a significant drop in the potential sales of that product, damage to our reputation in the marketplace, or result in us becoming subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales of our approved product or substantially increase the costs and expenses of commercializing and marketing our product.

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

Our ability to commercialize any future products 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 in the U.S. generally require that product candidates 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 future products or we may be required to sell our future products at prices that are below our expectations.

We expect that private insurers will consider the efficacy, cost effectiveness and safety of our future products in determining whether, and at what level, to approve reimbursement for our future products. 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 future products from private insurers on a timely or satisfactory basis. Our business could also be adversely affected if private insurers, including managed care organizations, the Medicare and Medicaid programs or other reimbursing bodies or payors limit the indications for which our future products will be reimbursed to a smaller set than we believe our future products are effective in treating.

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

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 products to other available therapies. If reimbursement for our products is unavailable in any country in which reimbursement is sought or is limited in scope or amount, or if pricing is set at unsatisfactory levels, our business would be materially harmed.

---

## **Table of Contents**

We expect to experience pricing pressures in connection with the sale of our future products, if any, 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 future products' commercial success.***

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

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

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

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

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

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

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

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

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

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

the Federal Food, Drug, and Cosmetic Act, which, among other things, strictly regulates drug marketing, prohibits manufacturers from marketing drugs 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.

**Table of Contents**

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

**Risks Related to Our Field**

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

In building our product development pipeline, we have intentionally pursued targets with applicability across multiple therapeutic areas and indications. This approach gives us several product opportunities in oncology and inflammatory diseases, which are highly competitive and rapidly changing segments of the pharmaceutical industry. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations are pursuing the development of novel drugs that target various diseases in these segments. We currently face, and expect to continue to face, intense and increasing competition as new products enter the market and advanced technologies become available. Moreover, there are a number of large pharmaceutical companies currently marketing and selling products in these segments including Bristol-Myers Squibb Company, the Roche Group and its subsidiary Genentech, Novartis AG and Pfizer, Inc. In addition to currently approved drugs, there are a significant number of drugs that are currently under development and may become available in the future for the treatment of various forms of cancer and inflammatory diseases. We are also aware of a number of companies seeking to develop product candidates directed to the same biological targets that our own product candidates are designed to inhibit. Specifically, we believe the following companies are developing compounds that target Hsp90, which is the target of retaspimycin HCl: Synta Pharmaceuticals Corp., Novartis AG, Astex Pharmaceuticals, Inc., Daiichi Sankyo, Inc., Debiopharm Group, Exelixis, Inc., Esanex, Inc., and Kyowa Hakko Kirin Co. Ltd. Also, we believe that Gilead Sciences, Inc., Amgen Inc., GlaxoSmithKline, and TG Therapeutics, Inc. are developing drugs that target the delta and/or gamma isoforms of PI3K, which is the target of IPI-145. In addition, many companies are developing product candidates directed to disease targets such as Bruton's Tyrosine Kinase (BTK), Janus Kinase (JAK), Spleen Tyrosine Kinase (Syk), and B-cell lymphoma 2 (Bcl-2) in the fields of hematology-oncology and inflammation, including in the specific diseases for which we are currently developing IPI-145, or for which we may develop IPI-145, IPI-443 or other PI3K inhibitors in the future. Such companies include Pharmacyclics, Inc., Incyte Corporation, Astra Zeneca PLC, and AbbVie, Inc.

Many of our competitors have:

significantly greater financial, technical and human resources than we have, and may be better equipped to discover, develop, manufacture and commercialize product candidates than we are;

more extensive experience in preclinical testing and clinical trials, obtaining regulatory approvals and manufacturing and marketing products than we do; and/or

product candidates that have been approved or are in later-stage clinical development than our own product 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 product candidates. These competitive products may have superior safety or efficacy, have more attractive pharmacologic properties, or may be manufactured less expensively than our future products. 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 future products 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.*

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

We face exposure to significant product liability or other claims if any of our product 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 product 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 product 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 product candidates or future products, our liability could exceed our insurance coverage and our total assets, and we would need to

---

## **Table of Contents**

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 future products, or expand our business.

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

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

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

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

## **Risks Related to Intellectual Property**

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

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

Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and molecular diagnostics and the claim scope of these patents, our ability to obtain and enforce patents that may issue from any pending or future patent applications is uncertain and involves complex legal, scientific and factual questions. The standards that the United States Patent and Trademark Office (PTO), and its foreign counterparts use to grant patents are not always applied predictably or uniformly and are subject to change. To date, no consistent policy has emerged regarding the breadth of claims allowed in pharmaceutical or molecular diagnostics patents. Thus, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us. Even if patents do issue, we cannot guarantee that the claims of these patents will be held valid or enforceable by a court of law, will provide us with any significant protection against competitive products, or will afford us a commercial advantage over competitive products.

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

If we do not obtain adequate intellectual property protection for our products in the United States, competitors could duplicate them without repeating the extensive testing that we will have been required to undertake to obtain approval 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



for products that duplicate our products.

---

**Table of Contents**

The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States. Many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. Some of our development efforts are performed in China, India, and other countries outside of the United States through third party contractors. We may not be able to monitor and assess intellectual property developed by these contractors effectively; therefore, we may not be able to appropriately protect this intellectual property and could thus lose valuable intellectual property rights. In addition, the legal protection afforded to inventors and owners of intellectual property in countries outside of the United States may not be as protective of intellectual property rights as in the United States, and we may, therefore, be unable to acquire and protect intellectual property developed by these contractors to the same extent as if these development activities were being conducted in the United States. If we encounter difficulties in protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

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

***Patent interference, opposition or similar proceedings relating to our intellectual property portfolio are costly, and an unfavorable outcome could prevent us from commercializing our product 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 product candidates or their therapeutic use. In the event that a third party has also filed a U.S. patent application relating to our product candidates or a similar invention, we may have to participate in interference proceedings declared by the PTO or the third party to determine priority of invention in the United States. An adverse decision in an interference proceeding may result in the loss of rights under a patent or patent application. In addition, the cost of interference proceedings could be substantial.

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

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

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

While we are not currently aware of any litigation or third party claims of intellectual property infringement related to our product 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

---

## **Table of Contents**

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 product candidates or approved products;

develop non-infringing product candidates, technologies and methods; and

obtain one or more licenses from other parties, which could result in our paying substantial royalties or the granting of cross-licenses to our technologies.

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

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

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

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

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

In addition, we may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. Trade secrets are, however, difficult to protect. Others may independently discover our trade secrets and proprietary information, and in such case we could not assert any trade secret rights against such party. Enforcing a claim that a party 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 product 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 product candidates while we attempt to develop alternative technologies, methods and product candidates, which we may not be able to accomplish. Furthermore, if we fail to comply with our obligations under our third party license agreements, we could lose license rights that are

important to our business. For example, if we fail to use diligent efforts to develop and commercialize products licensed under our amended and restated development and license agreement with Millennium, we could lose our license rights under that agreement, including rights to IPI-145.

**Risks Associated with Our Common Stock**

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

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

the results of our current and any future clinical trials of our product candidates;

**Table of Contents**

the results of preclinical studies and planned clinical trials of our discovery-stage programs;

product portfolio decisions resulting in the delay or termination of our product development programs;

future sales of, and the trading volume in, our common stock;

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 amended and restated development and license agreement with Millennium;

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

the initiation of, material developments in, or conclusion of litigation to enforce or defend any of our intellectual property rights;

the initiation of, material developments in, or conclusion of litigation to defend product liability claims;

the failure of any of our product candidates, if approved, to achieve commercial success;

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

issues in manufacturing our product candidates or any approved products;

the loss of key employees;

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

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

changes in the structure of healthcare payment systems;

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

general and industry-specific economic and/or capital market 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.

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

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.

***Anti-takeover provisions in our organizational documents and Delaware law may make an acquisition of us difficult.***

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

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

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

**Table of Contents**

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

To our knowledge, as of April 17, 2013, our executive officers, directors, their respective affiliates, and stockholders holding 5% or more of our common stock, owned in the aggregate approximately 46% of our common stock. These stockholders have the ability to influence our company through this ownership position. For example, as a result of this concentration of ownership, these stockholders, if acting together, may have the ability to affect the outcome of matters submitted to our stockholders for approval, including the election and removal of directors, changes to our equity compensation plans, 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 7, 2013

By: */s/* LAWRENCE E. BLOCH, M.D., J.D.  
**Lawrence E. Bloch, M.D., J.D.**  
**Executive Vice President, Chief Financial Officer and Chief  
Business Officer  
(Principal Financial Officer &  
Principal Accounting 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.
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.
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended. Filed herewith.
32.1	Certification of principal executive 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.
32.2	Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Filed herewith.
101*	The following materials from the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, formatted in XBRL (eXtensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations and Comprehensive Loss, (iii) the Condensed Consolidated Statements of Cash Flows, and (iv) Notes to Condensed Consolidated Financial Statements.

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