

INFINITY PHARMACEUTICALS, INC.

Form 10-Q

August 11, 2014

[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 June 30, 2014**

**OR**

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

**For the transition period from                      to                      .**

**Commission file number 000-31141**

**INFINITY PHARMACEUTICALS, INC.**

**(Exact Name of Registrant as Specified in its Charter)**

**Delaware** **33-0655706**  
**(State or Other Jurisdiction of** **(I.R.S. Employer**  
**Incorporation or Organization)** **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.

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 June 30, 2014: 48,586,344

**Table of Contents**

**INFINITY PHARMACEUTICALS, INC.**  
**FORM 10-Q**  
**FOR THE QUARTER ENDED JUNE 30, 2014**  
**TABLE OF CONTENTS**

	<b>Page No.</b>
<b>PART I</b>	
<b><u>FINANCIAL INFORMATION</u></b>	1
<b>Item 1.</b>	
<b><u>Unaudited Condensed Consolidated Financial Statements</u></b>	1
<u>Condensed Consolidated Balance Sheets as of June 30, 2014 and December 31, 2013</u>	1
<u>Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three and Six Months Ended June 30, 2014 and 2013</u>	2
<u>Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2014 and 2013</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>	14
<b>Item 3.</b>	
<b><u>Quantitative and Qualitative Disclosures About Market Risk</u></b>	23
<b>Item 4.</b>	
<b><u>Controls and Procedures</u></b>	23
<b>PART II</b>	
<b><u>OTHER INFORMATION</u></b>	24
<b>Item 1A.</b>	
<b><u>Risk Factors</u></b>	24
<b>Item 6.</b>	
<b><u>Exhibits</u></b>	39
<b><u>Signatures</u></b>	40

**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)**

	<b>June 30, 2014</b>	<b>December 31, 2013</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 85,516	\$ 68,114
Available-for-sale securities	55,642	145,772
Loan commitment asset, net (note 8)	7,719	
Prepaid expenses and other current assets	11,310	11,055
<b>Total current assets</b>	<b>160,187</b>	<b>224,941</b>
Property and equipment, net	3,361	4,010
Long-term available-for-sale securities	545	582
Restricted cash	1,131	1,130
Other assets	361	47
<b>Total assets</b>	<b>\$ 165,585</b>	<b>\$ 230,710</b>
<b>Liabilities and stockholders equity</b>		
Current liabilities:		
Accounts payable	\$ 3,923	\$ 6,375
Accrued expenses	16,022	9,164
Due to Millennium, current	6,561	6,667
<b>Total current liabilities</b>	<b>26,506</b>	<b>22,206</b>
Due to Millennium, less current portion		6,456
Other liabilities	594	773
<b>Total liabilities</b>	<b>27,100</b>	<b>29,435</b>
Commitments and contingencies		
Stockholders equity:		
Preferred Stock, \$0.001 par value; 1,000,000 shares authorized, no shares issued and outstanding at June 30, 2014 and December 31, 2013		
Common Stock, \$0.001 par value; 100,000,000 shares authorized, and 48,586,344 and 48,227,838 shares issued and outstanding, at June 30, 2014 and December 31, 2013, respectively	48	48

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

Additional paid-in capital	668,361	650,867
Accumulated deficit	(530,086)	(449,796)
Accumulated other comprehensive income	162	156
<b>Total stockholders' equity</b>	<b>138,485</b>	<b>201,275</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 165,585</b>	<b>\$ 230,710</b>

*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 June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
<b>Operating expenses:</b>				
Research and development	\$ 28,165	\$ 26,080	\$ 62,656	\$ 46,311
General and administrative	7,057	6,675	13,861	14,105
Total operating expenses	35,222	32,755	76,517	60,416
Loss from operations	(35,222)	(32,755)	(76,517)	(60,416)
<b>Other income (expense):</b>				
Interest expense	(2,938)		(4,077)	
Investment and other income	136	164	304	499
Total other income (expense)	(2,802)	164	(3,773)	499
Net loss	\$ (38,024)	\$ (32,591)	\$ (80,290)	\$ (59,917)
Basic and diluted loss per common share	\$ (0.78)	\$ (0.68)	\$ (1.66)	\$ (1.25)
Basic and diluted weighted average number of common shares outstanding	48,543,853	47,915,726	48,446,849	47,785,620
<b>Other comprehensive loss:</b>				
Net unrealized holding gains (losses) on available-for-sale securities arising during the period	7	(104)	6	(87)
Comprehensive loss	\$ (38,017)	\$ (32,695)	\$ (80,284)	\$ (60,004)

*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>Six Months Ended June 30,</b>	
	<b>2014</b>	<b>2013</b>
<b>Operating activities</b>		
Net loss	\$ (80,290)	\$ (59,917)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	920	871
Stock-based compensation, including 401(k) match	6,691	6,076
Net amortization of premium/discount on available-for-sale securities	963	921
Non-cash interest expense on amount Due to Millennium	105	206
Amortization of loan commitment asset	4,077	
Other, net	(1)	
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(569)	(1,360)
Accounts payable, accrued expenses and other liabilities	1,227	2,156
Due to Millennium	(6,667)	
Net cash used in operating activities	(73,544)	(51,047)
<b>Investing activities</b>		
Purchases of property and equipment	(271)	(971)
Purchases of available-for-sale securities	(12,536)	(180,865)
Proceeds from sales of available-for-sale securities		1,031
Proceeds from maturities of available-for-sale securities	101,746	107,730
Net cash provided by (used in) investing activities	88,939	(73,075)
<b>Financing activities</b>		
Proceeds from issuances of common stock related to stock incentive plans	2,060	3,628
Proceeds from issuances of common stock related to employee stock purchase plan	393	
Deferred transaction costs	(446)	
Net cash provided by financing activities	2,007	3,628
Net increase (decrease) in cash and cash equivalents	17,402	(120,494)
Cash and cash equivalents at beginning of period	68,114	175,742
Cash and cash equivalents at end of period	\$ 85,516	\$ 55,248
<b>Supplemental schedule of noncash investing and financing activities</b>		
Loan commitment asset	\$ 11,350	\$

Facility fee	\$	3,000	\$
Warrants issued	\$	8,350	\$

*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 biopharmaceutical company dedicated to discovering, developing and delivering best-in-class medicines to patients with difficult-to-treat diseases. As used throughout these unaudited, condensed consolidated financial statements, the terms Infinity, we, us, and our refer to the business of Infinity Pharmaceuticals, Inc. and its wholly owned subsidiaries.

**2. Basis of Presentation**

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

The accompanying condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring accruals and revisions of estimates, considered necessary for a fair presentation of the accompanying condensed consolidated financial statements have been included. Interim results for the three and six months ended June 30, 2014 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2014.

The information presented in the condensed consolidated financial statements and related footnotes at June 30, 2014, and for the three and six months ended June 30, 2014 and 2013, is unaudited, and the condensed consolidated balance sheet amounts and related footnotes at December 31, 2013 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, 2013, which was filed with the U.S. Securities and Exchange Commission on February 25, 2014.

**3. Significant Accounting Policies**

***Cash Equivalents and Available-For-Sale Securities***

Cash equivalents and available-for-sale securities primarily consist of money market funds, U.S. government-sponsored enterprise obligations, corporate obligations and mortgage-backed securities. Corporate obligations include obligations issued by corporations in countries other than the United States, including some obligations that have not been guaranteed by governments or 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, 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 June 30, 2014 and December 31, 2013 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, 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 investment and other income. The cost of securities sold is based on the specific identification method. We include in investment and other income interest and dividends on securities classified as available-for-sale.

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.

**Table of Contents**

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 decline in fair value of the security is deemed to be other-than-temporary, and the full amount of the unrealized loss is recorded within earnings as an impairment loss.

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

All of our revenues to date have been generated under research collaboration agreements.

***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 and the exercise of outstanding warrants (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:

	<b>At June 30,</b>	
	<b>2014</b>	<b>2013</b>
Stock options	6,821,697	6,194,337
Warrants	1,000,000	

***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 six months ended June 30, 2014, there were no reclassifications out of accumulated other comprehensive income (loss).

***Stock-Based Compensation Expense***

For awards granted to employees and directors, including our Employee Stock Purchase Plan, or ESPP, 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. For awards with performance conditions, we estimate the likelihood of satisfaction of the performance conditions, which affects the period over which the expense is recognized, and recognize the expense over the requisite service period on a straight-line basis. We have no awards with market 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.

## **Table of Contents**

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.

In making this assessment, 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. 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.

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, comparator drug 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 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., or Intellikine, we record the reimbursement or the achievement of the development milestone as research and development expense. In January 2012, Intellikine was acquired by Takeda Pharmaceutical Company Limited, or Takeda, acting through its Millennium business unit. We refer to our PI3K program licensor as Millennium.

### ***Income Taxes***

We use the liability method to account for income taxes. Deferred tax assets and liabilities are determined based on temporary 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.

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 June 30, 2014 and December 31, 2013.

### ***Fair Value Measurements***

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

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

**Table of Contents*****Property and Equipment***

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

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

**4. Stock-Based Compensation**

Total stock-based compensation expense, related to all equity awards, for the three and six months ended June 30, 2014 and 2013 comprised the following:

	<b>Three Months Ended</b>		<b>Six Months</b>	
	<b>June 30,</b>		<b>Ended</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
	<b>(in thousands)</b>			
<i>Effect of stock-based compensation on net loss by line item:</i>				
Research and development	\$ 1,771	\$ 1,477	\$ 3,976	\$ 3,019
General and administrative	1,176	607	2,715	3,057

During the three months ended June 30, 2013, we recorded a benefit to general and administrative expense of \$0.7 million for the effects of reducing the fair value of non-employee grants caused by changes in the stock price during the quarter for unvested shares.

As of June 30, 2014, we had approximately \$21.6 million of total unrecognized compensation cost, net of estimated forfeitures, related to unvested stock options and awards under our ESPP, which are expected to be recognized over a weighted-average period of 2.5 years.

During the six months ended June 30, 2014, two members of our board of directors retired and were granted the right to exercise their vested stock options for an additional six-month period. In addition, one employee whose employment terminated received an accelerated vesting of his unvested options. In connection with these modifications, we recognized an additional \$0.4 million in stock-based compensation expense during the six months ended June 30, 2014

***Stock Options***

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

During the six months ended June 30, 2014, we granted options to purchase 1,382,684 shares of our common stock at a weighted-average fair value of \$7.53 and a weighted-average exercise price of \$12.73. During the six months ended June 30, 2013, we granted options to purchase 1,176,944 shares of our common stock at a weighted-average fair value of \$19.31 and a weighted-average exercise price of \$35.16. For the three and six months ended June 30, 2014 and 2013, the fair values were estimated using the Black-Scholes valuation model using the following weighted-average assumptions:

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
Risk-free interest rate	1.7%	0.6%	1.7%	0.8%
Expected annual dividend yield				
Expected stock price volatility	70.7%	69.3%	71.0%	61.8%
Expected term of options	5.0 years	4.7 years	5.1 years	5.0 years



**Table of Contents**

During the six months ended June 30, 2014, options to purchase 297,815 shares of common stock were exercised, with a weighted-average exercise price of \$6.92.

*Employee Stock Purchase Plan*

The weighted-average fair value of each purchase right granted during the six months ended June 30, 2014 was \$6.33. For the six months ended June 30, 2014, the fair values were estimated using the Black-Scholes valuation model using the following weighted-average assumptions:

	<b>Six Months Ended June 30, 2014</b>
Risk-free interest rate	0.2%
Expected annual dividend yield	
Expected stock price volatility	75.21%
Expected term of options	1.2 years

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

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

	<b>Cost</b>	<b>June 30, 2014 Gross Unrealized Gains (in thousands)</b>	<b>Gross Unrealized Losses</b>	<b>Estimated Fair Value</b>
Cash and cash equivalents due in 90 days or less	\$ 85,516	\$	\$	\$ 85,516
Available-for-sale securities:				
Corporate obligations due in one year or less	39,929	40	(2)	39,967
Mortgage-backed securities due after ten years	435	110		545
U.S. government-sponsored enterprise obligations due in one year or less	15,661	14		15,675
Total available-for-sale securities	56,025	164	(2)	56,187
Total cash, cash equivalents and available-for-sale securities	\$ 141,541	\$ 164	\$ (2)	\$ 141,703

	<b>Cost</b>	<b>December 31, 2013 Gross Unrealized Gains (in thousands)</b>	<b>Gross Unrealized Losses</b>	<b>Estimated Fair Value</b>
Cash and cash equivalents due in 90 days or less	\$ 68,114	\$	\$	\$ 68,114

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

Available-for-sale securities:

Corporate obligations due in one year or less	103,889	18	(16)	103,891
Corporate obligations due in one to five years	13,513	32		13,545
Mortgage-backed securities due after ten years	478	104		582
U.S. government-sponsored enterprise obligations due in one year or less	24,144	13		24,157
U.S. government-sponsored enterprise obligations due in one to five years	4,174	5		4,179
Total available-for-sale securities	146,198	172	(16)	146,354
Total cash, cash equivalents and available-for-sale securities	\$ 214,312	\$ 172	\$ (16)	\$ 214,468

We held two debt securities at June 30, 2014 that had been in an unrealized loss position for less than 12 months and no debt securities that had been in an unrealized loss position for 12 months or greater. The fair value on these securities was \$4 million.

**Table of Contents**

We evaluated our securities for other-than-temporary impairments based on quantitative and qualitative factors. We considered the decline in market value for these two securities to be primarily attributable to current economic and market conditions. It is not more likely than not that we will be required to sell these securities, and we do not intend to sell these securities before the recovery of their amortized cost bases. Based on our analysis, we do not consider these investments to be other-than-temporarily impaired as of June 30, 2014.

As of June 30, 2014, we held eight debt securities from financial institutions and other companies located in Japan, Switzerland, the Netherlands, the United Kingdom and France with a fair value of \$20.6 million. Two of these securities, which were issued by Japan and the Netherlands, had gross unrealized losses of \$2,000 and a fair value of \$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 June 30, 2014.

We had no material realized gains or losses on our available-for-sale securities for the three and six months ended June 30, 2014 and 2013. There were no other-than-temporary impairments recognized for the three and six months ended June 30, 2014 and 2013.

**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. The classification of a financial asset or liability within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement. For our fixed income securities, we reference pricing data supplied by our custodial agent and nationally known pricing vendors, using a variety of daily data sources, largely readily-available market data and broker quotes. We validate the prices provided by our third party pricing services by reviewing their pricing methods and obtaining market values from other pricing sources. After completing our validation procedures, we did not adjust or override any fair value measurements provided by our pricing services as of June 30, 2014 and December 31, 2013.

The following table provides the assets carried at fair value measured on a recurring basis as of June 30, 2014:

	<b>Level 1</b>	<b>Level 2</b>
	<b>(in thousands)</b>	
Cash and cash equivalents	\$ 85,516	\$
Corporate obligations (including commercial paper)		39,967
Mortgage-backed securities		545
U.S. government-sponsored enterprise obligations		15,675
<b>Total</b>	<b>\$ 85,516</b>	<b>\$ 56,187</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 the three month Treasury bill published on the last business day of the month.

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

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

*U.S. Government-Sponsored Enterprise Obligations:* benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data.

The amount due to Millennium is recorded at its carrying value at June 30, 2014. The fair value of the amount due to Millennium, a Level 2 measurement, was approximately \$6.6 million as of June 30, 2014 and was determined using a discounted cash flow model and based on an interest rate we would be charged for a similar loan as of June 30, 2014 (see note 7).

## **Table of Contents**

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

There have been no changes to the valuation methods during the six months ended June 30, 2014. 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 six months ended June 30, 2014. We had no available-for-sale securities that were classified as Level 3 at any point during the six months ended June 30, 2014 or during the year ended December 31, 2013.

## **7. Collaborations**

### ***Millennium***

In July 2010, we entered into a development and license agreement with Intellikine under which we obtained rights to discover, develop and commercialize pharmaceutical products targeting the delta and/or gamma isoforms of PI3K, including our lead product candidate IPI-145, and we paid Intellikine a \$13.5 million up-front license fee. In January 2012, Intellikine was acquired by Takeda acting through its Millennium business unit. 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 worldwide development rights and regained commercialization rights for products arising from the agreement for all therapeutic indications, and we are solely responsible for research conducted under the agreement. Additionally, under the amended and restated agreement, Millennium waived certain commercial rights and, 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. During the six months ended June 30, 2014, we paid to Millennium the second installment of \$6.7 million. The remaining amount is due in January 2015, which we recorded as short-term liability due to Millennium on our condensed consolidated balance sheet.

In addition to developing IPI-145, we are seeking to develop our second potent, oral PI3K-delta,gamma inhibitor product candidate, 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 \$5 million in remaining success-based milestone payments for the development of two distinct product candidates, and up to \$450 million in success-based milestones for the approval and commercialization of two distinct products. In February 2014, we paid Millennium a \$10 million milestone payment in connection with the initiation of our Phase 3 study of IPI-145 in patients with relapsed or refractory CLL. We recognized the \$10 million payment as research and development expense during the six months ended June 30, 2014. In addition, we are obligated to pay Millennium tiered royalties on worldwide net sales ranging from 7 percent to 11 percent 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 of the royalties, and, in certain circumstances, limits on the number of products subject to a royalty obligation.

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.

In July 2014, we entered into an amendment to our agreement with Millennium that granted us an option to terminate our royalty obligations with respect to worldwide net sales in oncology indications of products containing or comprised of IPI-145. Further information regarding the terms and conditions of this amendment is described below under Note 10, Subsequent Events.

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

#### *Strategic Alliance Termination Agreements*

On July 17, 2012, we terminated our strategic alliance with Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products L.P., or Purdue, and entered into termination and revised relationship agreements with each of those entities, which we refer to as the 2012 Termination Agreements. We considered Mundipharma, Purdue and their respective associated entities to be related parties for financial reporting purposes prior to April 2013 because of their equity ownership in us. The alliance was previously governed by strategic alliance agreements that we entered into with each of Mundipharma and Purdue in November 2008. The strategic alliance agreement with Purdue was focused on the development and commercialization in the United States of products targeting fatty acid amide hydrolase, or FAAH. The strategic alliance agreement

**Table of Contents**

with Mundipharma was focused on the development and commercialization outside of the United States of all products and product candidates that inhibit or target the Hedgehog pathway, FAAH, phosphoinositide-3-kinase (or PI3K), and product candidates arising out of our early discovery projects in all disease fields. Our heat shock protein 90, or Hsp90, program was expressly excluded from the alliance.

Under the terms of the 2012 Termination Agreements:

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

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

Mundipharma and Purdue have no further obligation to provide research and development funding to us. Under the alliance, Mundipharma was obligated to reimburse us for research and development expenses we incurred, up to an annual aggregate cap for each alliance program other than FAAH. We did not record a liability for amounts previously funded by Purdue and Mundipharma as this relationship was not considered a financing arrangement.

We are obligated to pay Mundipharma and Purdue a 4 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 that were subject to the alliance, which products require 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 percent. 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 percent 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., or PPLP, that provided for the borrowing by us of one or more unsecured loans up to an aggregate maximum principal amount of \$50 million. 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 and, in connection therewith, to grant various rights to the BRP entities. The consideration was composed of extinguishment of approximately \$51 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.

*April 2013 Offering and 2013 Termination Agreement*

On April 16, 2013, the BRP entities, through two selling stockholders, sold 11,416,565 shares in an underwritten public offering at a price of \$40 per share, representing their entire holdings in our common stock. In connection with the public offering and sale of their common stock, we entered into an agreement with the BRP entities, pursuant to which the 2012 Securities Purchase Agreement, as amended in connection with the offering, terminated in its entirety. Following the closing of the offering, the BRP entities no longer owned any shares of our common stock at such time, and, as such, are no longer related parties.



---

**Table of Contents****8. Debt Facility Agreement***Facility Agreement*

On February 24, 2014, we entered into a facility agreement with affiliates of Deerfield Management Company, L.P., or Deerfield, which we refer to as the Facility Agreement. Pursuant to the Facility Agreement, Deerfield agreed to loan us up to \$100 million, subject to the terms and conditions set forth in the Facility Agreement. Under the terms of the Facility Agreement, we may draw down on the Facility Agreement in \$25 million minimum disbursements, which we refer to as the Loan Commitment, at any time until February 27, 2015, which we refer to as the Draw Period. Our ability to draw down under the Facility Agreement is subject to various customary conditions, including the entry into a guaranty and security agreement, or the Guaranty, with Deerfield and Infinity Discovery, Inc., or IDI, one of our wholly-owned subsidiaries, pursuant to which, as security for the repayment of our obligations under the Facility Agreement, IDI will guaranty all of our obligations under the Facility Agreement. As an additional condition to our initial draw down under the Facility Agreement, both IDI and we will grant to Deerfield a security interest in substantially all of our assets including intellectual property to secure our obligations under the Facility Agreement and the Guaranty. In exchange for the Loan Commitment, on February 24, 2014, we issued to Deerfield warrants to purchase 1,000,000 shares of our common stock at an exercise price of \$13.83 per share.

Any amounts drawn under the Facility Agreement accrue interest at a rate of 7.95 percent per annum, and such interest shall be payable quarterly in arrears on the first day of each June, September, December and March following the disbursement date, provided that, subject to the next sentence, during the first five interest payment dates of any draw under the Facility Agreement, we may elect to pay all or a portion of such accrued interest by adding it to the principal amount outstanding. All such accrued interest will, regardless of which draw it applies to, be payable on the last business day of the sixth calendar quarter following the date of the first draw under the Facility Agreement. We have the right to terminate the Facility Agreement and/or to prepay amounts owed under the Facility Agreement at any time, provided that, to the extent that any amount was drawn less than three years before such early termination or prepayment, we will be required to pay an additional amount equal to three years of interest on the amount being prepaid less the amount of interest previously paid on such amount. For amounts drawn under the Facility Agreement, we will be required to repay them to Deerfield in installments equal to one-third of the outstanding amount of the total principal amount drawn under the Facility Agreement on each of the third, fourth and fifth anniversaries of the first draw; the final payment, however, must be made by December 15, 2019.

On February 27, 2015, or upon the earlier termination or acceleration of the facility, we are required to pay a fee equal to 3 percent of the difference between the \$100 million commitment and the aggregate amount of disbursements under the Facility Agreement made prior to such date, which we refer to as the Facility Fee. As of June 30, 2014, we have not drawn under the Facility Agreement and have determined it probable that we will be required to pay the full Facility Fee amount of \$3 million on February 27, 2015. We have recorded the full \$3 million Facility Fee on the June 30, 2014 condensed consolidated balance sheet as a component of both the loan commitment asset and accrued expenses line items. The loan commitment asset is being amortized to interest expense in the condensed consolidated statements of operations and comprehensive loss on a straight line basis over the Draw Period.

Deerfield will have the right to accelerate payment of the facility in the event that we consummate a major transaction, which is generally defined as a change in control, a sale of all or substantially all of our assets, a tender or exchange offer for our common stock, a liquidation, bankruptcy, insolvency, dissolution or wind up, a delisting and/or the common stock ceases to be registered under the Securities Exchange Act of 1934, or the Exchange Act. Any amounts drawn under the Facility Agreement may become immediately due and payable upon (i) customary events of default, as defined in the Facility Agreement, or (ii) the consummation of certain major transactions, in which case Deerfield would have the right to require us to repay 100 percent of the principal amount of the loan, plus any accrued and

unpaid interest thereon, plus any applicable additional amounts relating to a prepayment or termination, as described above.

Principal and interest under the Facility Agreement may be paid in cash or freely tradable shares of common stock at our election, subject to specified conditions at any time of conversion. The Facility Agreement contains various representations and warranties, and affirmative covenants customary for agreements of this type, including the requirement that we maintain at all times a cash, cash equivalents and available-for-sales securities balance of not less than \$25 million, as well as negative covenants customary for financings of this type that are applicable upon the first draw under the Facility Agreement. Additionally, the Facility Agreement contains conditions that must be met prior to disbursements, including the condition that the number of shares of our common stock issued or issuable pursuant to all warrants following the proposed disbursement, together with payments made in our common stock under the Facility Agreement, will not exceed 9,500,000 shares, subject to appropriate adjustment to reflect any stock splits, stock combination, reclassification or similar adjustments in the number of outstanding shares of common stock.

**Table of Contents**

Our total cost of securing the Loan Commitment was \$11.8 million and is comprised of \$8.4 million representing the fair value of the 1,000,000 warrants issued on February 24, 2014, discussed below, \$3 million representing the Facility Fee and \$0.4 million of transaction costs. The total fair value, a Level 2 measurement, is considered a Loan Commitment Asset which has been classified as a current asset on the June 30, 2014 condensed consolidated balance sheets. This amount is considered a fee to secure the Loan Commitment and is being amortized to interest expense in the three and six months ended June 30, 2014 condensed consolidated statements of operations and comprehensive loss on a straight line basis over the Draw Period. We recorded \$2.9 million and \$4.1 million of interest expense associated with the amortization of the loan commitment asset for the three and six months ended June 30, 2014, respectively.

*Warrants*

In connection with the entry into the Facility Agreement, on February 24, 2014, we issued to Deerfield warrants to purchase 1,000,000 shares of our common stock at an exercise price of \$13.83 per share. As of June 30, 2014, all such warrants were outstanding and exercisable. The fair value of the warrants on February 24, 2014 was \$8.4 million. The warrants were valued as of February 24, 2014 using a Black Scholes model with the following assumptions: expected life of seven years; risk free rate of 2.2 percent; expected volatility of 59.01 percent; and no expected dividend yield. The warrants qualify for permanent treatment as equity and are classified as additional paid-in capital on the June 30, 2014 condensed consolidated balance sheet.

With each disbursement made by Deerfield, we have agreed to issue additional warrants to purchase a number of shares of our common stock equal to 50 percent times the quotient of the amount of such disbursement divided by an exercise price equal to the average daily volume weighted average price per share of our common stock for the 20 consecutive trading day period following Deerfield's receipt of the applicable disbursement request. The maximum number of shares of our common stock issued or issuable pursuant to all warrants and payments made in our common stock under the Facility Agreement is 9,500,000, subject to appropriate adjustment to reflect any stock splits, stock combination, reclassification or similar adjustments in the number of outstanding shares of common stock. The warrants have dividend rights to the same extent as if the warrants were exercised into shares of common stock.

Each warrant issued under the Facility Agreement expires on the seventh anniversary of its issuance and contains certain limitations that prevent the holder from acquiring shares upon exercise of a warrant that would result in the number of shares beneficially owned by it exceeding 9.985 percent of the total number of shares of common stock then issued and outstanding.

**9. Accrued Expenses**

Accrued expenses consisted of the following:

	<b>June 30, 2014</b>	<b>December 31, 2013</b>
	<b>(in thousands)</b>	
Accrued compensation and benefits	\$ 2,373	\$ 1,839
Accrued clinical studies	6,086	4,009
Accrued drug manufacturing costs	1,912	991
Accrued preclinical studies	122	303
Facility fee	3,000	

Other	2,529	2,022
Total accrued expenses	\$ 16,022	\$ 9,164

## 10. Subsequent Events

### *Millennium Amendment*

On July 29, 2014, we entered into an amendment to our agreement with Millennium, or the 2014 Millennium Amendment. Under the 2014 Millennium Amendment, we paid to Millennium a one-time upfront payment of \$5 million in exchange for the option to terminate our royalty obligations to Millennium under our existing agreement with respect to worldwide net sales in oncology indications of products containing or comprised of IPI-145. The option may be exercised by payment to Millennium of a fee of \$52.5 million on or before March 31, 2015. If the option is not exercised, our royalty obligations to Millennium will remain unchanged. We expect to recognize the \$5 million upfront payment as research and development expense in the third quarter of 2014.

### *FAAH Program License*

In August 2014, we licensed rights to our FAAH program to FAAH Pharma Inc., a start-up company that will continue the clinical development of IPI-940 and investigate its potential to treat neuropathic pain.

---

**Table of Contents****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, the possible achievement of discovery and development milestones in 2014, our future discovery and development efforts, our collaborations, and our future operating results and financial position, includes forward-looking statements that involve risks and uncertainties. We often use words such as anticipate, believe, estimate, expect, intend, may, plan, predict, project, target, potential, continue, and other words and terms of similar meaning to help identify forward-looking statements, although not all forward-looking statements contain these identifying words. You also can identify these forward-looking statements by the fact that they do not relate strictly to historical or current facts. There are a number of important risks and uncertainties that could cause actual results or events to differ materially from those indicated by forward-looking statements. These risks and uncertainties include those inherent in pharmaceutical research and development, such as adverse results in our drug discovery and clinical development activities, decisions made by the U.S. Food and Drug Administration, or FDA, and other regulatory authorities with respect to the development and commercialization of our product candidates, our ability to obtain, maintain and enforce intellectual property rights for our product candidates, our dependence on our alliance partners, competition, our ability to obtain any necessary financing to conduct our planned activities and other risk factors. 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. Unless required by law, we do not undertake any obligation to update any forward-looking statements.

***Business Overview***

We are an innovative biopharmaceutical company dedicated to discovering, developing and delivering best-in-class medicines to patients with difficult-to-treat diseases. We combine proven scientific expertise with a passion for developing novel small molecule drugs that target emerging disease pathways. We have worldwide development and commercialization rights to all of our development 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***

Phosphoinositide-3-kinases, or the PI3Ks, are a family of enzymes involved in multiple cellular functions, including cell proliferation and survival, cell differentiation, cell migration and immunity. The PI3K-delta and PI3K-gamma isoforms are preferentially expressed in white blood cells, where they have distinct and mostly non-overlapping roles in immune cell development and function. Targeting PI3K-delta and PI3K-gamma may provide multiple opportunities to develop differentiated therapies for the treatment of hematologic malignancies and inflammatory diseases. IPI-145, our lead product candidate, is a potent, oral inhibitor of Class I PI3K-delta and PI3K-gamma, which we refer to as PI3K delta,gamma inhibitor. We are investigating IPI-145 in both hematologic malignancies and inflammatory diseases. We believe that IPI-145 is the only PI3K-delta,gamma inhibitor being investigated in Phase 3 clinical trials.

***Hematologic Malignancies***

We are conducting DUETTS™, a worldwide investigation of IPI-145 in blood cancers. As part of the DUETTS program, we are conducting DYNAMO™, a Phase 2, open-label, single arm study evaluating the safety and efficacy of IPI-145 dosed at 25mg twice daily, or BID, in approximately 120 patients with indolent non-Hodgkin lymphoma, or iNHL, including follicular lymphoma, marginal zone lymphoma and small lymphocytic lymphoma, or SLL, whose disease is refractory to radioimmunotherapy or both rituximab and chemotherapy. Patients enrolled in the study must have progressed within six months of receiving their last therapy. The primary endpoint of the study is response rate according to the International Working Group Criteria, or IWGC. The FDA has granted orphan drug designation to IPI-145 for the potential treatment of follicular lymphoma, the most common subtype of iNHL. We intend to expand the DUETTS program in 2014 with the initiation of DYNAMO+R, a Phase 3 study of IPI-145 in combination with rituximab, a monoclonal antibody therapy, in patients with relapsed iNHL, as well as a Phase 2 study in treatment-naïve patients with iNHL and at least one additional clinical study in patients with hematologic malignancies.

Additionally, under the DUETTS program we are enrolling patients in DUO™, a Phase 3 study of IPI-145 in patients with chronic lymphocytic leukemia, or CLL. This randomized study is designed to evaluate the safety and efficacy of IPI-145 dosed at 25 mg BID compared to ofatumumab, a monoclonal antibody treatment, in approximately 300 patients with relapsed or refractory CLL. The primary endpoint of the study is progression-free survival. The FDA and the European Medicines Agency, or EMA, have granted orphan drug designation to IPI-145 for the potential treatment of CLL and SLL.

---

**Table of Contents**

These trials are supported by data from our ongoing 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. The dose-escalation portion of the trial is complete, with the maximum tolerated dose defined at 75 mg BID. We are continuing to evaluate IPI-145 across two 25mg BID expansion cohorts in patients with relapsed/refractory CLL, iNHL and mantle cell lymphoma, or MCL, and treatment-naïve CLL in high-risk patients (those patients who are over age 65 or have either of two genetic abnormalities known as a 17p deletion or p53 mutation). Additionally, we are continuing to evaluate IPI-145 across five 75mg BID expansion cohorts in patients with relapsed/refractory CLL, iNHL and MCL; T-cell lymphomas; aggressive B-cell lymphomas; myeloid neoplasms; and T-cell or B-cell acute lymphoblastic leukemia/lymphoma. Data from this study, presented in December 2013 at the Annual Meeting of the American Society for Hematology, or ASH, and in January 2014 at the 6<sup>th</sup> Annual T-Cell Lymphoma Forum, showed that IPI-145 is clinically active in CLL, iNHL, T-Cell lymphoma, as well as other hematologic malignancies.

An investigator-sponsored Phase 1b, open-label study of IPI-145 in patients with B-cell NHL, CLL and T-cell lymphoma in combination with rituximab, bendamustine (a chemotherapy), or both rituximab and bendamustine is also open for enrollment.

*Inflammatory and Autoimmune Diseases*

Within inflammatory diseases, IPI-145 is currently being evaluated in two Phase 2 trials. The first 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, or 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 20 response rate, or ACR20, which is defined as the proportion of patients who achieve at least a 20 percent improvement in ACR response criteria. The second trial is a Phase 2a randomized, double-blind, placebo-controlled trial of IPI-145 in 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 report topline data from these studies in 2014.

*Pipeline Expansion*

We are also developing our second PI3K product candidate, a potent, oral PI3K-delta, gamma inhibitor that we refer to as IPI-443. The nonclinical studies of IPI-443 required for Phase 1 development, and the data from the two Phase 2 studies of IPI-145 in inflammatory and autoimmune diseases will guide the next steps for the development of IPI-443.

*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 discovered IPI-940, a novel, orally available inhibitor of fatty acid amide hydrolase, or FAAH. It is believed that inhibition of FAAH may enable the body to bolster its own analgesic and anti-inflammatory response and may have applicability in a broad range of pain or inflammatory conditions. In August 2014, we licensed rights to our FAAH program to FAAH Pharma Inc., a start-up company that will continue the clinical development of IPI-940 and investigate its potential to treat neuropathic pain.

*Strategic Alliances**Millennium*

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

Under the terms of the amended and restated agreement, we retained worldwide development rights and regained commercialization rights for products arising from the agreement for all therapeutic indications, and we are solely responsible for research conducted under the agreement. Additionally, under the amended and restated agreement, Millennium waived certain commercial rights and, in consideration of such waiver, we agreed to pay to Millennium \$15 million, payable in installments.

In addition to developing IPI-145, we are seeking to develop our second potent, oral PI3K-delta,gamma inhibitor product candidate, 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 \$5 million in remaining success-based milestone payments for the



## **Table of Contents**

development of two distinct product candidates and up to \$450 million in success-based milestones for the approval and commercialization of two distinct products. In February 2014, we paid Millennium a \$10 million milestone payment in connection with the initiation of our Phase 3 study of IPI-145 in patients with relapsed or refractory CLL. In addition, we are obligated to pay Millennium tiered royalties on worldwide net sales ranging from 7 percent to 11 percent 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 of the royalties, and , in certain circumstances, limits on the number of products subject to a royalty obligation.

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.

On July 29, 2014, we entered into an amendment to our agreement with Millennium, or the 2014 Millennium Amendment. Under the 2014 Millennium Amendment, we paid to Millennium a one-time upfront payment of \$5 million in exchange for the option to terminate our royalty obligations to Millennium under our existing agreement with respect to worldwide net sales in oncology indications of products containing or comprised of IPI-145. The option may be exercised by payment to Millennium of a fee of \$52.5 million on or before March 31, 2015. If the option is not exercised, our royalty obligations to Millennium will remain unchanged.

## ***Mundipharma and Purdue***

### *Strategic Alliance Termination Agreements*

On July 17, 2012, we terminated our strategic alliance with Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products L.P., or 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 the United States of all products and product candidates that inhibit or target the Hedgehog pathway, FAAH, PI3K and product candidates arising out of our early discovery projects in all disease fields. Our Hsp90 program was expressly excluded from the alliance.

Under the terms of the 2012 Termination Agreements:

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

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

Mundipharma and Purdue have no further obligation to provide research and development funding to us. Under the alliance, Mundipharma was obligated to reimburse us for research and development expenses we incurred, up to an annual aggregate cap for each alliance program other than FAAH. We did not record a liability for amounts previously funded by Purdue and Mundipharma as this relationship was not considered a financing arrangement.

We are obligated to pay Mundipharma and Purdue a 4 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 that were subject to the alliance, which products require 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 percent. 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 percent of the amounts otherwise payable during the applicable royalty payment period.

---

**Table of Contents*****Strategic Debt Facility******Facility Agreement***

On February 24, 2014, we entered into a facility agreement with affiliates of Deerfield Management Company, L.P., or Deerfield, which we refer to as the Facility Agreement. Pursuant to the Facility Agreement, Deerfield agreed to loan us up to \$100 million, subject to the terms and conditions set forth in the Facility Agreement. Under the terms of the Facility Agreement, we may draw down on the Facility Agreement in \$25 million minimum disbursements, which we refer to as the Loan Commitment, at any time until February 27, 2015, which we refer to as the Draw Period. Our ability to draw down under the Facility Agreement is subject to various customary conditions, including the entry into a Guaranty and Security Agreement, or Guaranty, with Deerfield and Infinity Discovery, Inc., or IDI, our a wholly-owned subsidiary, pursuant to which, as security for the repayment of our obligations under the Facility Agreement, IDI will guaranty all our obligations under the Facility Agreement and, to secure the obligations under the Facility Agreement and the Guaranty, both we and IDI will grant to Deerfield a security interest in substantially all our assets including intellectual property.

Any amounts drawn under the Facility Agreement accrue interest at a rate of 7.95 percent per annum, and such interest shall be payable quarterly in arrears on the first day of each June, September, December and March following the disbursement date, provided that, subject to the next sentence, during the first five interest payment dates of any draw under the Facility Agreement, we may elect to pay all or a portion of such accrued interest by adding it to the principal amount outstanding. All such accrued interest will, regardless of which draw it applies to, be payable on the last business day of the sixth calendar quarter following the date of the first draw under the Facility Agreement. We have the right to terminate the Facility Agreement and/or to prepay amounts owed under the Facility Agreement at any time, provided that, to the extent that any amount was drawn less than three years before such early termination or prepayment, we will be required to pay an additional amount equal to three years of interest on the amount being prepaid less the amount of interest previously paid on such amount. For amounts drawn under the Facility Agreement, we will be required to repay them to Deerfield in installments equal to one-third of the outstanding amount of the total principal amount drawn under the Facility Agreement on each of the third, fourth and fifth anniversaries of the first draw; the final payment, however, must be made by December 15, 2019. On February 27, 2015, or upon the earlier termination or acceleration of the facility, we are required to pay a fee equal to 3 percent of the difference between the \$100 million commitment and the aggregate amount of disbursements under the Facility Agreement made prior to such date, which we refer to as the Facility Fee.

Deerfield will have the right to accelerate payment of the facility in the event that we consummate a major transaction, which is generally defined as a change in control, a sale of all or substantially all of our assets, a tender or exchange offer for our common stock, a liquidation, bankruptcy, insolvency, dissolution or wind up, a delisting and/or the common stock ceases to be registered under the Securities Exchange Act of 1934, or the Exchange Act. Any amounts drawn under the Facility Agreement may become immediately due and payable upon (i) customary events of default, as defined in the Facility Agreement, or (ii) the consummation of certain major transactions, in which case Deerfield would have the right to require us to repay 100 percent of the principal amount of the loan, plus any accrued and unpaid interest thereon, plus any applicable additional amounts relating to a prepayment or termination, as described above.

Principal and interest under the Facility Agreement may be paid in cash or freely tradable shares of common stock at our election, subject to specified conditions at any time of conversion. The Facility Agreement contains various representations and warranties, and affirmative covenants customary for agreements of this type, including the requirement that we maintain at all times a cash, cash equivalents and available-for-sale securities balance of not less than \$25 million, as well as negative covenants customary for financings of this type that are applicable upon the first

draw under the Facility Agreement. Additionally, the Facility Agreement contains conditions that must be met prior to disbursements, including the condition that the number of shares of our common stock issued or issuable pursuant to all warrants following the proposed disbursement, together with payments made in our common stock under the Facility Agreement, will not exceed 9,500,000 shares, subject to appropriate adjustment to reflect any stock splits, stock combination, reclassification or similar adjustments in the number of outstanding shares of common stock.

## **Table of Contents**

### *Warrants*

In connection with the execution of the Facility Agreement, we issued to Deerfield warrants to purchase an aggregate of 1,000,000 shares of common stock at an exercise price of \$13.83 per share, or the Initial Warrants. As noted above, pursuant to the Facility Agreement, we have the right to request from Deerfield one or more cash disbursements in the minimum amount of \$25 million per disbursement, which disbursements shall be accompanied by the issuance to Deerfield of warrants, which we refer to as the Draw Warrants, to purchase an aggregate number of shares of common stock equal to 50 percent times the quotient of the amount of such disbursement divided by an exercise price equal to the average daily volume weighted average price per share of our common stock for the 20 consecutive trading day period following Deerfield's receipt of the applicable disbursement request. We refer to the Initial Warrants and the Draw Warrants individually as a Warrant or together as the Warrants. The maximum number of shares of our common stock issued or issuable pursuant to all Warrants and payments made in our common stock under the Facility Agreement is 9,500,000, subject to appropriate adjustment to reflect any stock splits, stock combination, reclassification or similar adjustments in the number of outstanding shares of common stock. The Warrants have dividend rights to the same extent as if the Warrants were exercised into shares of common stock.

Each Warrant issued under the Facility Agreement expires on the seventh anniversary of its issuance and contains certain limitations that prevent the holder from acquiring shares upon exercise of a Warrant that would result in the number of shares beneficially owned by it exceeding 9.985 percent of the total number of shares of common stock then issued and outstanding.

### *Registration Rights Agreement*

In connection with the entry into the Facility Agreement and issuance of the Initial Warrants, we entered into a Registration Rights Agreement with Deerfield dated February 24, 2014. Pursuant to the terms of the Registration Rights Agreement, we filed, and on May 1, 2014 the Securities and Exchange Commission declared effective, a registration statement on Form S-3 registering for resale the 1,000,000 shares of common stock issuable upon the exercise of the Initial Warrants. Additionally, pursuant to the terms of the Registration Rights Agreement, we agreed to file one or more additional registration statements with the SEC to register for resale the shares of common stock issuable upon the exercise of the applicable Draw Warrants, on or prior to 30 days after issuance of each of the Draw Warrants.

### *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, as well as 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 to date has primarily consisted of the following:

compensation of personnel associated with research and development activities;

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

costs of comparator drugs used in clinical studies;

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;

**Table of Contents**

fees paid to external consultants;

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

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

depreciation of equipment; and

allocated costs of facilities.

***General and Administrative Expense***

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

***Other Income and Expense***

Investment and other income typically consists of interest earned on cash, cash equivalents and available-for-sale securities, net of interest expense and amortization of warrants. Interest expense is related to the amortization of the loan commitment asset recognized under our Facility Agreement with Deerfield.

***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 six months ended June 30, 2014. 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, 2013 for a discussion of our critical accounting policies and significant judgments and estimates.

***Results of Operations***

The following tables summarize our results of operations for each of the three and six months ended June 30, 2014 and 2013, together with the change in these items in dollars and as a percentage:

	<b>Three Months Ended June 30,</b>			
	<b>2014</b>	<b>2013</b>	<b>\$ Change</b>	<b>% Change</b>
	<b>(in thousands)</b>			
Research and development expense	\$ (28,165)	\$ (26,080)	\$ (2,085)	8%
General and administrative expense	(7,057)	(6,675)	(382)	6%
Interest expense	(2,938)		(2,938)	
Investment and other income	136	164	(28)	(17)%



**Table of Contents**

	<b>Six Months Ended June 30,</b>			
	<b>2014</b>	<b>2013</b>	<b>\$ Change</b>	<b>% Change</b>
	<b>(in thousands)</b>			
Research and development expense	\$ (62,656)	\$ (46,311)	\$ (16,345)	35%
General and administrative expense	(13,861)	(14,105)	244	(2)%
Interest expense	(4,077)		(4,077)	
Investment and other income	304	499	(195)	(39)%

*Research and Development Expense*

The \$2.1 million increase in research and development expense for the three months ended June 30, 2014 as compared to the three months ended June 30, 2013 was primarily due to an increase of \$6.0 million in clinical expenses related to clinical development activities of IPI-145. This is partially offset by a decrease of \$2.0 million in clinical expenses due to the conclusion of our development of retaspimycin HCl as well as a decrease of \$1.7 million in preclinical expenses. The \$16.3 million increase in research and development expense in the six months ended June 30, 2014 as compared to the six months ended June 30, 2013 is primarily due to a \$10 million milestone payment made to Millennium in connection with the initiation of our Phase 3 study of IPI-145 recognized during the six months ended June 30, 2014 and an \$11.1 million increase in clinical expenses related to increased clinical development activities of IPI-145. This is partially offset by a decrease of \$3.5 million in clinical expenses due to the conclusion of our development of retaspimycin HCl.

We began to track and accumulate expenses by major program starting on January 1, 2006. These expenses primarily relate to payroll and associated expenses for personnel working on the programs, process development and manufacturing, preclinical toxicology studies, clinical trial costs and allocated costs of facilities. During the three and six months ended June 30, 2014 and 2013, and from January 1, 2006 through June 30, 2014, we estimate that we incurred the following expenses by program:

<b>Program</b>	<b>Three Months Ended</b>				
	<b>June 30, 2014</b>	<b>June 30, 2013</b>	<b>June 30, 2014</b>	<b>June 30, 2013</b>	<b>January 1, 2006 to June 30, 2014</b>
	<b>(in millions)</b>				
PI3K inhibitor (1)	\$ 23.1	\$ 18.5	\$ 50.9	\$ 31.5	\$ 212.9
Hsp90 inhibitor	0.4	3.9	1.3	8.6	137.4
Hedgehog pathway inhibitor		0.2	0.1	0.7	164.0

(1) Six months ended June 30, 2014 includes a \$10 million milestone payment.

We expect expenses related to our PI3K inhibitor program to increase as we continue clinical development of IPI-145. We expect expenses related to our Hsp90 program to decrease significantly as we conclude development of retaspimycin HCl. We expect to incur minimal expenses related to our Hedgehog pathway inhibitor programs 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 programs 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 conducting or may commence in the future;

**Table of Contents**

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

clinical trial results;

the cost and availability of comparator drugs;

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 \$0.4 million increase in general and administrative expense for the three months ended June 30, 2014 as compared to the three months ended June 30, 2013 is primarily attributable to an increase in early commercial development expenses. General and administrative expense for the six months ended June 30, 2014 is comparable to general and administrative expense for the six months ended June 30, 2013.

*Interest Expense*

Interest expense for the three and six months ended June 30, 2014 is related to the amortization of the loan commitment asset recognized under our Facility Agreement with Deerfield.

*Investment and Other Income*

Investment and other income is comparable for the three months ended June 30, 2014 as compared to the three months ended June 30, 2013. Investment and other income decreased in the six months ended June 30, 2014 as compared to the six months ended June 30, 2013 primarily due to a non-recurring cash distribution received from one of our insurance carriers during the six months ended June 30, 2013.

*Liquidity and Capital Resources*

We have not generated any revenue from the sale of drugs to date, and we do not expect to generate any such revenue for the next several years, if at all. We have instead relied on the proceeds from sales of equity securities, interest on

investments, up-front license fees, expense reimbursement, milestones and cost sharing under our collaborations and debt to fund our operations. Our available-for-sale debt securities primarily trade in liquid markets, and the average days to maturity of our portfolio, as of June 30, 2014, is less than six months. Because our product candidates are in various stages of clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability.

Our significant capital resources are as follows:

	<b>June 30, 2014</b>	<b>December 31, 2013</b>
	<b>(in thousands)</b>	
Cash, cash equivalents and available-for-sale securities	\$ 141,703	\$ 214,468
Working capital	133,681	202,735
	<b>Six Months Ended June 30,</b>	
	<b>2014</b>	<b>2013</b>
	<b>(in thousands)</b>	
Cash provided by (used in):		
Operating activities	\$ (73,544)	\$ (51,047)
Investing activities	88,939	(73,075)
Capital expenditures (included in investing activities above)	(271)	(971)
Financing activities	2,007	3,628

## **Table of Contents**

### *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 six months ended June 30, 2014 compared to the six months ended June 30, 2013 increased primarily due to increased operating expenses, including a \$10 million milestone payment to Millennium associated with the achievement of a milestone related to the initiation of our Phase 3 study of IPI-145. During the six months ended June 30, 2014, we paid to Millennium the \$10 million milestone payment and \$6.7 million related to the second installment on a release payment. 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. We cannot be certain whether and when we may enter into any such collaboration agreements or in-licenses.

On February 24, 2014, we entered into a Facility Agreement with Deerfield, pursuant to which Deerfield agreed to loan us up to \$100 million, subject to the terms and conditions set forth in the Facility Agreement, including the condition that we at all times maintain a cash, cash equivalents and available-for-sales securities balance of not less than \$25 million. Under the terms of the Facility Agreement, we may draw down funds in minimum disbursements of \$25 million at any time until February 27, 2015. No funds were drawn under the Facility Agreement as of June 30, 2014. On February 27, 2015, or upon the earlier termination or acceleration of the Facility Agreement, we are required to pay a fee equal to 3 percent of the then undrawn portion of the \$100 million commitment

Net cash from investing activities for the six months ended June 30, 2014 included \$12.5 million in purchases of available-for-sale securities and proceeds of \$101.7 million from maturities of available-for-sale securities. Capital expenditures in the six months ended June 30, 2014 primarily consisted of computer equipment and software.

Net cash from financing activities for the six months ended June 30, 2014 included \$2.1 million of proceeds from issuances of common stock from stock option exercises related to stock incentive plans, \$0.4 million of proceeds from issuances of common stock related to our employee stock purchase plan and \$0.4 million of transaction costs related to the Facility Agreement with Deerfield.

### *Liquidity*

We will need substantial additional funds to support our planned operations. In the absence of additional funding or business development activities and based on our current operating plans, we expect that our current cash and investments are sufficient to fund our planned operations into 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 expectations, 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, without limitation, 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;

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

the cost of comparator drugs used in clinical studies;

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

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

Historically, we have relied on our strategic alliance with Mundipharma and Purdue for a significant portion of our research and development funding needs. Mundipharma and Purdue provided us approximately \$260 million in research and development funding during the term of our strategic alliance. Following the termination of the strategic alliance agreements with Mundipharma and Purdue on July 17, 2012, we 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.

## **Table of Contents**

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 six months ended June 30, 2014.

We are obligated to pay to Millennium up to \$5 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 June 30, 2014, 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, 2013 for a discussion of our contractual obligations.

Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the successful achievement of certain development, regulatory approval and commercial milestones, which may not be achieved.

### **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 the United States. 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 \$0.3 million decrease in the fair value of our investments as of June 30, 2014, as compared to an approximate \$0.8 million decrease as of December 31, 2013. 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 June 30, 2014. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2014, our principal executive and financial officers concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal quarter ended June 30, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.



**Table of Contents**

**PART II. OTHER INFORMATION**

**Item 1A. Risk Factors**

You should carefully consider the following risk factors, in addition to other information included in this quarterly report on Form 10-Q, in evaluating Infinity and our business. If any of the following risks occur, our business, financial condition and operating results could be materially adversely affected. These risk factors restate and supersede the risk factors set forth under the heading "Risk Factors" in our annual report on Form 10-K for the fiscal year ended December 31, 2013.

**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 retaspimycin hydrochloride in combination with docetaxel in patients with non-small cell lung cancer, which did not yield results consistent with results obtained from an earlier Phase 1b 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 June 30, 2014, we had an accumulated deficit of \$530.1 million. We expect to continue to spend significant resources to fund the research and development of IPI-145 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 without limitation 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;

**Table of Contents**

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

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.

We may seek to satisfy our need for additional funds by drawing down funds under the debt Facility Agreement we entered into with affiliates of Deerfield Management Company, L.P., or Deerfield, in February 2014. Under the Facility Agreement, Deerfield agreed to loan to us up to \$100 million subject to the terms and conditions of the Facility Agreement. Our ability to draw down under the Facility Agreement is subject to various customary conditions, however, there is no assurance that we will be able to satisfy these conditions and draw down any funds. If we draw down under the Facility Agreement, we will be required to grant to Deerfield a security interest in substantially all of our assets including intellectual property, issue additional warrants to Deerfield, and repay any amounts borrowed together with interest accruing at a rate of 7.95 percent per annum no later than December 15, 2019. Any amounts drawn under the Facility Agreement may become immediately due and payable upon customary events of default or the consummation of certain major transactions, in which case Deerfield would have the right to require us to repay 100 percent of the principal amount of the loan, together with any accrued and unpaid interest thereon, plus any applicable additional amounts relating to a prepayment or termination. Principal and interest under the Facility Agreement may be paid in cash or freely tradable shares of common stock at our election, subject to specified conditions at any time of conversion. There is no assurance that the conditions to our ability to repay the loan in shares of our common stock would be satisfied at the time that any outstanding principal and interest under the loan is due, in which case we would be obligated to repay the loan in cash, or that events permitting acceleration of the loan will not occur, in which event we would be required to repay any outstanding principal and interest sooner than anticipated.

We may also 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 as would be the case if we decided to draw down under the Facility Agreement with Deerfield. 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.

***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 into, and expect to enter into 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.

Much of the potential revenue from any alliance we may enter into in the future will likely consist of contingent payments, such as payments upon the achievement of specified milestones and 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, launch, 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;

**Table of Contents**

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.

***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.

***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, Pfizer, Inc., and Johnson & Johnson. 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 developing product candidates or selling products directed to the same biological targets that our own product candidates are designed to inhibit. Specifically:

we believe that Gilead Sciences, Inc., Amgen Inc., Rhizen Pharmaceuticals S.A, TG Therapeutics, Inc., and GlaxoSmithKline, are conducting clinical trials of drugs that target the delta and/or gamma isoforms of phosphoinositide-3-kinase, or PI3K, which is the target of IPI-145; and

many companies are developing product candidates or selling products directed to disease targets such as Bruton's Tyrosine Kinase (or BTK), Janus Kinase (or JAK), Spleen Tyrosine Kinase (or Syk), B-cell lymphoma 2 (or Bcl-2) or other isoforms of PI3K 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, including Pharmacyclics, Inc. through its collaboration with Janssen Biotech, Incyte Corporation, Rigel Pharmaceuticals, Inc., Ono Pharmaceutical Group, Acerta Pharma BV, Celgene Corporation, AbbVie, Inc. and Bayer.

**Table of Contents**

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, such as ibrutinib, a BTK inhibitor being developed and commercialized by Pharmacyclics, Inc. for the treatment of people with mantle cell lymphoma or chronic lymphocytic leukemia, 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 encounter difficulties in managing organizational change, which could adversely affect our operations.***

Our ability to effectively manage changes to our organization, including organizational growth, 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.



**Table of Contents**

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

As of June 30, 2014, we had approximately \$142 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 general credit, liquidity, market and interest rate risks and instability in the global financial markets. We may realize losses in the fair value of these investments or a complete loss of these investments. In addition, should our investments cease paying or reduce the amount of interest paid to us, our interest income would suffer. These market risks associated with our investment portfolio may have a material adverse effect on our financial results and the availability of cash to fund our operations.

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

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

Under our strategic alliance termination agreements, Mundipharma and Purdue continue to have the right to audit research and development expenses incurred by us during the term of our former strategic alliance, in order to verify the research and development funding amounts previously paid by Mundipharma and Purdue and have, in the past, exercised such rights. 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 it could adversely impact our financial results and available cash and 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 Food and Drug Administration, or 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 IPI-145, the lead compound in our PI3K inhibitor program, in all phases of clinical development and we anticipate initiating multiple additional trials of IPI-145 in 2014. If any of these trials or other trials of our product candidates are successful, we may need to conduct further clinical trials and will need to 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,

**Table of Contents**

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.

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.

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, comparator drugs 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.

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.

**Table of Contents**

*Our inability to enroll sufficient numbers of patients in our clinical trials, or any delays in patient enrollment, can result in increased costs and longer development periods for our 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 commitment of clinical investigators to identify eligible patients; and

competing studies or trials.

Additionally, the availability of safe and effective treatments for the relevant disease being studied may impact patient enrollment in our clinical trials. For example, Pharmacyclics, Inc. has received approval to manufacture and market, ibrutinib, a BTK inhibitor for the treatment of CLL, an indication in which we are currently evaluating IPI-145 in a Phase 3 clinical trial.

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 authorities 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.***

There has been limited success to date industry-wide in developing companion diagnostics. To be successful in developing a companion diagnostic, 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.

---

**Table of Contents**

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.

***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, or cGMPs, and other applicable government regulations and corresponding foreign standards. These regulations govern manufacturing processes and procedures and the implementation and operation of systems to control and assure the quality of products. The FDA and foreign regulatory authorities may, at any time, audit or inspect a manufacturing facility to ensure compliance with cGMPs and other quality standards. Any failure by our contract manufacturers to achieve and maintain high manufacturing and quality control standards could result in the inability of our 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.



**Table of Contents**

*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 or efficacy, or less convenient route of administration, compared to competitive 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;

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 lack of 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, cGMPs, 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

## **Table of Contents**

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.

In some foreign countries, particularly Canada and European Union member states, 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.

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 percent 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.

**Table of Contents**

***Our business could be harmed if we are unable to comply with applicable fraud and abuse and other laws and regulations where our 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;

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.

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**

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

We face exposure to significant product liability or other claims if any of our 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 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.

## **Table of Contents**

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

The U.S. Congress passed the Leahy-Smith America Invents Act, or the America Invents Act, which 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. 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 may be 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.



## **Table of Contents**

In addition, we rely on intellectual property assignment agreements with our strategic alliance partners, vendors, employees, consultants, clinical investigators, 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. 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 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 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.

## **Table of Contents**

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;

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;

**Table of Contents**

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 or our Facility Agreement with Deerfield;

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, including but not limited to litigation to enforce or defend any of our intellectual property rights or 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;

the drawing down of funds under our Facility Agreement with Deerfield;

healthcare reform measures, including 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.

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 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.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law statute, which generally prohibits a person who owns in excess of 15 percent of our outstanding voting stock from engaging in a transaction with us for a period of three years after the date on which such person acquired in excess of 15 percent of our outstanding voting common stock, unless the transaction is approved by our board of directors and holders of at least two-thirds of our outstanding voting stock, excluding shares held by such person. The prohibition against such transactions does not apply if, among other things, prior to the time that such person became an interested stockholder, our board of directors approved the transaction in which such person acquired 15 percent or more of our outstanding voting stock. 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, based on the number of shares of our common stock outstanding on June 30, 2014, stockholders holding 5 percent or more of our common stock, as well as our executive officers, directors, and their respective affiliates, owned in the aggregate approximately 56 percent 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: August 11, 2014

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 No.</b>	<b>Description</b>	<b>Incorporated by Reference</b>			<b>Filed with this 10-Q</b>
		<b>Form</b>	<b>SEC Filing date</b>	<b>Exhibit Number</b>	
3.1	Restated Certificate of Incorporation of the Registrant.	10-Q	08/09/07	3.1	
3.2	Amended and Restated Bylaws of the Registrant.	8-K	03/17/09	3.1	
4.1	Form of Common Stock Certificate.	10-K	03/14/08	4.1	
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended. Filed herewith.				X
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.				X
32.1	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Filed herewith.				X
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.				X
101	The following materials from the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2014, 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. Filed herewith.				X