

INFINITY PHARMACEUTICALS, INC.

Form 10-Q

November 05, 2015

[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 September 30, 2015**

**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**  
**(State or other jurisdiction of**  
**incorporation or organization)**  
**784 Memorial Drive, Cambridge, Massachusetts 02139**  
**(Address of principal executive offices) (zip code)**  
**(617) 453-1000**  
**(Registrant's telephone number, including area code)**

**33-0655706**  
**(I.R.S. Employer**  
**Identification No.)**

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

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

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

Large accelerated filer  Accelerated filer

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

Number of shares of the registrant's Common Stock, \$0.001 par value, outstanding on October 30, 2015: 49,230,508

Table of Contents

**INFINITY PHARMACEUTICALS, INC.**

**FORM 10-Q**

**FOR THE QUARTER ENDED SEPTEMBER 30, 2015**

**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 September 30, 2015 and December 31, 2014</u>	1
<u>Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) for the Three and Nine Months Ended September 30, 2015 and 2014</u>	2
<u>Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2015 and 2014</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>	16
<b>Item 3.</b>	
<b><u>Quantitative and Qualitative Disclosures About Market Risk</u></b>	28
<b>Item 4.</b>	
<b><u>Controls and Procedures</u></b>	28
<b>PART II</b>	
<b><u>OTHER INFORMATION</u></b>	28
<b>Item 1A.</b>	
<b><u>Risk Factors</u></b>	28
<b>Item 6.</b>	
<b><u>Exhibits</u></b>	44
<b><u>Signatures</u></b>	45

**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>September 30, 2015</b>	<b>December 31, 2014</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 137,284	\$ 307,405
Available-for-sale securities	25,677	25,321
Due from AbbVie	130,000	
Loan commitment asset, net (note 9)		647
Prepaid expenses and other current assets	7,354	11,195
Total current assets	300,315	344,568
Property and equipment, net	28,077	18,970
Long-term available-for-sale securities		519
Restricted cash	1,681	1,680
Long-term receivable (note 11)	2,806	3,006
Other assets	347	401
Total assets	\$ 333,226	\$ 369,144
<b>Liabilities and stockholders equity</b>		
Current liabilities:		
Accounts payable	\$ 11,214	\$ 5,947
Accrued expenses	22,890	17,768
Due to Takeda		6,667
Deferred revenue, current	39,799	24,495
Financing obligation, current (note 11)	409	
Total current liabilities	74,312	54,877
Deferred revenue, less current portion	100,218	85,510
Deferred rent (note 11)	5,041	3,375
Financing obligation, less current portion (note 11)	19,697	
Construction liability (note 11)		15,456
Other liabilities	347	454
Total liabilities	199,615	159,672

## Commitments and contingencies

## Stockholders' equity:

Preferred Stock, \$0.001 par value; 1,000,000 shares authorized, no shares issued and outstanding at September 30, 2015 and December 31, 2014

Common Stock, \$0.001 par value; 100,000,000 shares authorized, and 49,197,956 and 48,878,828 shares issued and outstanding, at September 30, 2015 and December 31, 2014, respectively

	49	49
Additional paid-in capital	689,961	676,521
Accumulated deficit	(556,398)	(467,212)
Accumulated other comprehensive income (loss)	(1)	114

Total stockholders' equity	133,611	209,472
----------------------------	---------	---------

Total liabilities and stockholders' equity	\$ 333,226	\$ 369,144
--	------------	------------

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Collaboration revenue	\$ 90,743	\$ 160,639	\$ 99,987	\$ 160,639
Operating expenses:				
Research and development	37,729	44,895	160,220	107,551
General and administrative	9,754	8,042	27,713	21,903
Total operating expenses	47,483	52,937	187,933	129,454
Income (loss) from operations	43,260	107,702	(87,946)	31,185
Other income (expense):				
Interest expense	(311)	(4,537)	(1,058)	(8,615)
Investment and other income	75	52	298	356
Total other income (expense)	(236)	(4,485)	(760)	(8,259)
Income (loss) before income taxes	43,024	103,217	(88,706)	22,926
Income tax	(480)		(480)	
Net income (loss)	\$ 42,544	\$ 103,217	\$ (89,186)	\$ 22,926
Earnings (loss) per common share:				
Basic	\$ 0.85	\$ 2.08	\$ (1.82)	\$ 0.47
Diluted	\$ 0.84	\$ 2.03	\$ (1.82)	\$ 0.46
Weighted average number of common shares outstanding:				
Basic	49,188,443	48,632,888	49,051,836	48,497,305
Diluted	49,764,910	49,735,303	49,051,836	49,533,122
Other comprehensive income (loss):				
Net unrealized holding losses on available-for-sale securities arising during the period	(104)	(31)	(115)	(25)
Comprehensive income (loss)	\$ 42,440	\$ 103,186	\$ (89,301)	\$ 22,901

*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>Nine Months Ended September 30,</b>	
	<b>2015</b>	<b>2014</b>
<b>Operating activities</b>		
Net income (loss)	\$ (89,186)	\$ 22,926
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation	1,557	1,367
Stock-based compensation including 401(k) match	11,180	9,623
Net amortization of premium/discount on available-for-sale securities	268	1,128
Non-cash interest expense on Due to Takeda amount		158
Amortization of loan commitment asset	647	8,615
Other, net	(86)	25
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	4,095	637
Due from AbbVie	(130,000)	
Accounts payable, accrued expenses and other liabilities	10,093	12,522
Due to Takeda	(6,667)	(6,667)
Deferred revenue	30,012	114,361
Deferred rent	1,666	
Net cash provided by (used in) operating activities	(166,421)	164,695
<b>Investing activities</b>		
Purchases of property and equipment	(5,416)	(364)
Purchases of available-for-sale securities	(64,440)	(21,789)
Sales of available-for-sale securities	464	
Proceeds from maturities of available-for-sale securities	63,841	108,711
Net cash provided by (used in) investing activities	(5,551)	86,558
<b>Financing activities</b>		
Proceeds from issuances of common stock related to stock incentive plans and awards	1,788	2,973
Proceeds from issuances of common stock related to employee stock purchase plan	472	393
Payments on construction liability	(273)	
Payments on financing obligation	(136)	
Restricted cash		(1,030)
Deferred transaction costs		(446)

Net cash provided by financing activities	1,851	1,890
Net increase (decrease) in cash and cash equivalents	(170,121)	253,143
Cash and cash equivalents at beginning of period	307,405	68,114
Cash and cash equivalents at end of period	\$ 137,284	\$ 321,257
<b>Supplemental cash flow information</b>		
Cash paid for interest	\$ 411	\$
Cash paid for income taxes	\$ 175	\$
<b>Supplemental schedule of noncash investing and financing activities</b>		
Loan commitment asset	\$	\$ 9,850
Facility fee	\$	\$ 1,500
Property and equipment in accrued expenses	\$ 189	\$
Increase in property and equipment for amount paid by landlord	\$ 5,059	\$
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 nine months ended September 30, 2015 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2015.

The information presented in the condensed consolidated financial statements and related footnotes at September 30, 2015, and for the three and nine months ended September 30, 2015 and 2014, is unaudited, and the condensed consolidated balance sheet amounts and related footnotes at December 31, 2014 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, 2014, which was filed with the U.S. Securities and Exchange Commission on February 24, 2015.

**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 and corporate obligations, 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 September 30, 2015 and December 31, 2014 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 to determine whether an other-than-temporary impairment exists. An unrealized loss exists when the current fair value of an individual security is less than its amortized cost basis. Unrealized losses on available-for-sale debt securities that are determined to be temporary, and not related to credit loss, are recorded, net of tax, in accumulated other comprehensive income (loss).

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

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. The two-class method is used for outstanding warrants as it is considered to be a participating security, and it is more dilutive than the treasury stock method. The following outstanding shares of common stock equivalents were excluded from the computation of net income (loss) per share attributable to common stockholders for the periods presented because including them would have been antidilutive:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Stock Options	5,755,283	3,711,997	8,216,230	3,715,825
Warrants (excluded from treasury stock method)	1,000,000	1,000,000	1,000,000	1,000,000

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

	<b>Three Months Ended September 30,</b>	<b>Nine Months Ended September 30,</b>
--	---	--

	2015	2014	2015	2014
	(in thousands, except share and per share amounts)			
<b>Basic</b>				
Net income (loss)	\$ 42,544	\$ 103,217	\$ (89,186)	\$ 22,926
Undistributed earnings allocated to warrants	(848)	(2,080)		(362)
Net income (loss)	\$ 41,696	\$ 101,137	\$ (89,186)	\$ 22,564
Weighted average common shares outstanding	49,188,443	48,632,888	49,051,836	48,497,305
Basic earnings (loss) per common share	\$ 0.85	\$ 2.08	\$ (1.82)	\$ 0.47
<b>Diluted</b>				
Net income (loss)	\$ 42,544	\$ 103,217	\$ (89,186)	\$ 22,926
Undistributed earnings allocated to warrants	(838)	(2,034)		(354)
Net income (loss)	\$ 41,706	\$ 101,183	\$ (89,186)	\$ 22,572
Weighted average common shares outstanding	49,188,443	48,632,888	49,051,836	48,497,305
Effect of dilutive options	576,467	1,102,415		1,035,817
Weighted average common shares outstanding assuming dilution	49,764,910	49,735,303	49,051,836	49,533,122
Diluted earnings (loss) per common share	\$ 0.84	\$ 2.03	\$ (1.82)	\$ 0.46

**Table of Contents**

***Comprehensive Income (Loss)***

Comprehensive income (loss) is comprised of net income (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 nine months ended September 30, 2015, there were no material reclassifications out of accumulated other comprehensive income (loss).

***Stock-Based Compensation Expense***

For awards granted to employees and directors, including awards under 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, upfront license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved, and/or royalties on product sales. We evaluate all deliverables within an arrangement to determine whether or not they provide value on a stand-alone basis. Based on this evaluation, the deliverables are separated into units of accounting. For each unit of accounting identified within an arrangement, we determine the period over which the performance obligation occurs. Revenue is then recognized using the proportional performance method. The proportional performance method is used when the level of effort to complete the performance obligations under an arrangement can be reasonably estimated. We recognize revenue based upon our best estimate of the selling price for each element when there is no other means to determine the fair value of that item and allocate the consideration based on the relative values. The process for determining the best estimate of the selling price involves significant judgment and estimates.

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 is not considered substantive, we recognize the amount associated with the applicable milestone based on the period over which the performance obligation occurs for each deliverable in the arrangement.

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 upfront 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. Prepaid comparator drug expenses are capitalized and then recognized



## **Table of Contents**

as expense when title transfers to us. 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 incurred by us, we evaluate the terms of the arrangement to determine whether the reimbursement should be recorded as revenue or as an offset to research and development expense. If the arrangement provides for us to reimburse the collaborator for research and development expenses or for the achievement of a development milestone for which a payment is due, we record the reimbursement or the achievement of the development milestone as research and development expense.

## ***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 of such change.

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 September 30, 2015 and December 31, 2014.

## ***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.

## ***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. Assets included in construction-in-progress are not depreciated until placed into service. When placed into service, these assets are depreciated over the lease term to a residual value approximately equal to the remaining financing obligation at the end of the financing term. 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, building improvements and capital leases is recorded as depreciation expense and included in research and development and general and administrative expense, as applicable. 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
Building and building improvements	10 to 50 years, less estimated residual value at the end of the financing obligation term
Furniture and fixtures	7 to 10 years

**Table of Contents*****New Accounting Pronouncement***

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update, or ASU, No. 2014-09, *Revenue from Contracts with Customers*, which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. ASU No. 2014-09 is effective for interim and annual periods beginning after December 15, 2016. In August 2015, the FASB issued a one year deferral of the effective date of this standard to annual reporting periods, and interim reporting periods within those years, beginning after December 15, 2017. Entities are allowed to adopt the standard as of the original effective date. We are currently evaluating the method of adoption and the potential impact that ASU No. 2014-09 may have on our financial position and results of operations.

**4. Stock-Based Compensation**

Total stock-based compensation expense related to all equity awards for the three and nine months ended September 30, 2015 and 2014 comprised the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(in thousands)			
Research and development	\$ 2,102	\$ 1,760	\$ 6,474	\$ 5,736
General and administrative	1,713	1,172	4,706	3,887
<b>Total stock-based compensation expense</b>	<b>\$ 3,815</b>	<b>\$ 2,932</b>	<b>\$ 11,180</b>	<b>\$ 9,623</b>

As of September 30, 2015, we had approximately \$21.5 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 2.4 years.

***Stock Options***

During the nine months ended September 30, 2015, we granted options to purchase 2,322,891 shares of our common stock at a weighted average fair value of \$8.77 per share and a weighted average exercise price of \$14.57 per share. During the nine months ended September 30, 2014, we granted options to purchase 1,532,384 shares of our common stock at a weighted average fair value of \$7.43 per share and a weighted average exercise price of \$12.57 per share. For the three and nine months ended September 30, 2015 and 2014, the fair values were estimated using the Black-Scholes valuation model using the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Risk-free interest rate	1.6%	1.7%	1.5%	1.7%
Expected annual dividend yield				

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

Expected stock price volatility	70.3%	69.8%	70.9%	70.9%
Expected term of options	5.2 years	5.0 years	5.3 years	5.1 years

During the nine months ended September 30, 2015, options to purchase 215,028 shares of common stock were exercised, with a weighted-average exercise price of \$7.99.

*Employee Stock Purchase Plan*

The weighted-average fair value of each purchase right granted during the nine months ended September 30, 2015 and 2014 was \$4.24 and \$5.66, respectively. For the nine months ended September 30, 2015 and 2014, the fair values were estimated using the Black-Scholes valuation model using the following weighted-average assumptions:

	<b>Nine Months Ended September 30, 2015</b>	<b>Nine Months Ended September 30, 2014</b>
Risk-free interest rate	0.4%	0.3%
Expected annual dividend yield		
Expected stock price volatility	60.3%	66.7%
Expected term of options	1.25 years	1.25 years

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

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

	Cost	September 30, 2015		Estimated Fair Value
		Gross Unrealized Gains	Gross Unrealized Losses	
(in thousands)				
Cash and cash equivalents due in 90 days or less	\$ 137,284	\$	\$	\$ 137,284
Available-for-sale securities:				
Corporate obligations due in one year or less	25,678	5	(6)	25,677
Total available-for-sale securities	25,678	5	(6)	25,677
Total cash, cash equivalents and available-for-sale securities	\$ 162,962	\$ 5	\$ (6)	\$ 162,961

	Cost	December 31, 2014		Estimated Fair Value
		Gross Unrealized Gains	Gross Unrealized Losses	
(in thousands)				
Cash and cash equivalents due in 90 days or less	\$ 307,405	\$	\$	\$ 307,405
Available-for-sale securities:				
Corporate obligations due in one year or less	21,324	6	(1)	21,329
Mortgage-backed securities due after ten years	412	107		519
U.S. government-sponsored enterprise obligations due in one year or less	3,990	2		3,992
Total available-for-sale securities	25,726	115	(1)	25,840
Total cash, cash equivalents and available-for-sale securities	\$ 333,131	\$ 115	\$ (1)	\$ 333,245

We held nine debt securities at September 30, 2015 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 of these securities was \$28.5 million. There were no material unrealized losses incurred from these securities. We evaluated our securities for other-than-temporary impairments based on quantitative and qualitative factors. We considered the decline in market value for these 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 basis. Based on our analysis, we do not consider these

investments to be other-than-temporarily impaired as of September 30, 2015.

As of September 30, 2015, we held seven debt securities from other companies located in Canada, the United Kingdom, Sweden, the Netherlands and Germany with an aggregate fair value of \$20.8 million. These securities are short term in nature and are scheduled to mature within twelve months. There were no material unrealized losses incurred from these securities. Based on our analysis, we do not consider these investments to be other-than-temporarily impaired as of September 30, 2015.

We had no material realized gains or losses on our available-for-sale securities for the three and nine months ended September 30, 2015 and 2014. There were no other-than-temporary impairments recognized for the three and nine months ended September 30, 2015 and 2014.

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 believe that, our existing cash, cash equivalents and available-for-sale securities at September 30, 2015, together with the \$130 million milestone payment received from AbbVie Inc., or AbbVie, in November 2015, will be adequate to satisfy our capital needs through at least the next twelve months.

## **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

**Table of Contents**

observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value. The classification of a financial asset or liability within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement. For our fixed income securities, we reference pricing data supplied by our custodial agent and nationally known pricing vendors, using a variety of daily data sources, largely readily-available market data and broker quotes. We validate the prices provided by our third party pricing services by reviewing their pricing methods and obtaining market values from other pricing sources. After completing our validation procedures, we did not adjust or override any fair value measurements provided by our pricing services as of September 30, 2015 and December 31, 2014.

The following table provides the assets carried at fair value measured on a recurring basis as of September 30, 2015:

	<b>Level 1</b>	<b>Level 2</b>
	<b>(in thousands)</b>	
<i>Assets:</i>		
Cash and cash equivalents	\$ 117,436	\$ 19,848
Corporate obligations (including commercial paper)		25,677
<b>Total</b>	<b>\$ 117,436</b>	<b>\$ 45,525</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 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 nine months ended September 30, 2015. We evaluate transfers between levels at the end of each reporting period. There were no transfers of assets or liabilities between Level 1 and Level 2 during the nine months ended September 30, 2015. We had no available-for-sale securities that were classified as Level 3 at any point during the nine months ended September 30, 2015 or during the year ended December 31, 2014.

## 7. Prepaid expenses and other current assets

Prepaid expenses and other current assets consist of the following:

	September 30, 2015	December 31, 2014
	(in thousands)	
Prepaid comparator drug	\$	\$ 5,085
Other prepaid expenses	4,945	4,124
Other current assets	2,409	1,986
Total prepaid expenses and other current assets	\$ 7,354	\$ 11,195

## 8. Collaborations

### *AbbVie*

On September 2, 2014, we entered into a collaboration and license agreement with AbbVie, which we refer to as the AbbVie Agreement. Under the AbbVie Agreement, we are collaborating with AbbVie to develop and commercialize



---

**Table of Contents**

products containing duvelisib, an oral, dual inhibitor of the delta and gamma isoforms of phosphoinositide-3-kinase, or PI3K, which we refer to as Duvelisib Products, in oncology indications. Under the terms of the AbbVie Agreement, we have granted to AbbVie licenses under applicable patents, patent applications, know-how and trademarks to develop, commercialize and manufacture Duvelisib Products in oncology indications. These licenses are generally co-exclusive with rights we retain, except that we have granted AbbVie exclusive licenses to commercialize Duvelisib Products outside the United States. We and AbbVie retain the rights to perform our respective obligations and exercise our respective rights under the AbbVie Agreement, and we and AbbVie may each grant sublicenses to affiliates or third parties.

Under the AbbVie Agreement, we and AbbVie have created a governance structure, including committees and working groups to manage the development, manufacturing and commercialization responsibilities for Duvelisib Products. Generally, we and AbbVie must mutually agree on decisions, although in specified circumstances either we or AbbVie would be able to break a deadlock.

We and AbbVie share oversight of development and have each agreed to use diligent efforts, as defined in the AbbVie Agreement, to carry out our development activities under an agreed upon development plan. We have primary responsibility for the conduct of development of Duvelisib Products, unless otherwise agreed, and AbbVie has responsibility for the conduct of certain contemplated combination clinical studies, which we refer to as the AbbVie Studies. We have the responsibility to manufacture Duvelisib Products until we transition manufacturing responsibility to AbbVie, which we expect to occur as promptly as practicable while ensuring continuity of supply. Excluding the AbbVie Studies, we are responsible for all costs to develop and manufacture Duvelisib Products up to a maximum amount of \$667 million after which we will share Duvelisib Product development and manufacturing costs equally with AbbVie. During the three and nine months ended September 30, 2015, we recognized an expense of \$1.8 million and \$6.0 million, respectively, in research and development expense related to costs incurred by AbbVie for other than the AbbVie Studies. The development and manufacturing costs for the AbbVie Studies are shared equally. During the three and nine months ended September 30, 2015, we recognized an expense of \$0.4 million and \$0.6 million, respectively, in research and development expense related to our share of the AbbVie Studies cost.

We and AbbVie share operational responsibility and decision making authority for commercialization of Duvelisib Products in the United States. Specifically, we have the primary responsibility for advertising, distribution, and booking sales, and we share certain other commercialization functions with AbbVie. Assuming regulatory approval, we and AbbVie are obligated to each provide half of the sales representative effort to promote Duvelisib Products in the United States. Outside the United States, AbbVie has, with limited exceptions, operational responsibility and decision making authority to commercialize Duvelisib Products. We and AbbVie will share the cost of manufacturing and supply for commercialization of Duvelisib Products in the United States, and AbbVie will bear the cost of manufacturing and supply for commercialization of Duvelisib Products outside the United States. Prior to commercialization and regulatory approval, we will recognize these costs as a component of research and development and general and administrative expenses. Subsequent to regulatory approval and commercial launch, the cost of manufacturing will be recorded as cost of goods sold. During the three and nine months ended September 30, 2015, we recognized credits of \$0.1 million and \$0.5 million, respectively, in research and development expense and credits of \$0.6 million and \$0.9 million, respectively, in general and administrative expense related to these costs.

AbbVie has paid us a non-refundable \$275 million upfront payment in 2014 and a \$130 million milestone payment in November 2015 associated with the completion of enrollment of DYNAMO™ in September 2015. DYNAMO is a Phase 2, open-label, single-arm monotherapy study evaluating the safety and efficacy of duvelisib dosed at 25 mg 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, whose disease is refractory to rituximab and to either chemotherapy or radioimmunotherapy. Further, AbbVie has agreed to pay us up to an

additional \$400 million in potential future milestone payments comprised of \$275 million associated with the achievement of specified regulatory filing and approval milestones and up to \$125 million associated with the achievement of specified commercialization milestones. We recognized the \$130 million as a receivable on our condensed consolidated balance sheets as of September 30, 2015 as the clinical development milestone was achieved as of that date.

Under the terms of the AbbVie Agreement, we and AbbVie will equally share commercial profits or losses of Duvelisib Products in the United States, including sharing equally the existing royalty obligations to Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products L.P., or Purdue, for sales of Duvelisib Products in the United States, as well as sharing equally the existing U.S. milestone payment obligations to Takeda Pharmaceutical Company Limited, or Takeda, our PI3K program licensor.

Additionally, AbbVie has agreed to pay us tiered royalties on net sales of Duvelisib Products outside the United States ranging from 23.5% to 30.5%, depending on annual net sales of Duvelisib Products by AbbVie, its affiliates and its sublicensees. We are responsible for the existing royalty obligations to Mundipharma and Purdue outside the United States, and AbbVie has agreed to reimburse us for our existing Duvelisib Product milestone payment obligations to Takeda outside the United States. The tiered royalty from AbbVie is subject to a reduction of 4% at each tier if our royalties to Mundipharma and Purdue are reduced according to the

---

**Table of Contents**

terms of our respective agreements with Mundipharma and Purdue. This tiered royalty can further be reduced based on specified factors, including patent expiry, generic entry, and royalties paid to third parties with blocking intellectual property. These royalties are payable on a product-by-product and country-by-country basis until AbbVie ceases selling the product in the country. We have evaluated the deliverables within the AbbVie Agreement to determine whether or not they provide value on a stand-alone basis. Based on our evaluation, we have determined that there are three deliverables: the license, the development services and the committee services. Each deliverable provides value on a stand-alone basis and represents a separate unit of accounting. We determined the best estimate of selling price for each unit of accounting using a discounted cash-flow model. The valuation for each deliverable involves significant estimates and assumptions, including but not limited to, expected market opportunity, assumed royalty rates, pricing objectives, clinical trial timelines, likelihood of success and projected costs. The resulting estimate of selling prices for the license and development services consider the benefits that have been retained by us.

Of the \$275 million upfront payment received during the year ended December 31, 2014, \$159.1 million was allocated to the license, \$115.6 million to the development services and \$0.3 million to committee services based on the allocation of best estimate of selling price on a relative basis. We determined the best estimate of selling prices for the license unit of accounting based on estimates and assumptions resulting in an expected future cash flow which was discounted based on estimated weighted average cost of capital of 11.5%. We determined the best estimate of selling prices for development and committee services based on the nature of the services to be performed and estimates of the associated efforts and third-party rates for similar services using a discount rate of 8% for development services and 11.5% for committee services. We recognized license revenue upon execution of the arrangement. Revenue related to development services and committee services is being recognized using the proportionate performance method as services are provided over the estimated service period of approximately five years. We have determined that the clinical development milestone achieved on September 30, 2015 is not substantive based on risk and effort involved and have applied the proportionate performance method to recognizing the related revenue. Of the \$130 million milestone achieved, \$75.2 million was allocated to the license, \$54.7 million to the development services and \$0.1 million to committee services based on the same allocation of best estimate of selling price on a relative basis as determined at the inception of the arrangement. Upon achievement of the milestone on September 30, 2015, we recognized the \$75.2 million allocated to the license as revenue and \$9.8 million of revenue related to the development and committee services performed from the inception of the AbbVie Agreement through September 30, 2015. During the three and nine months ended September 30, 2015, we recognized \$90.7 million and \$100.0 million, respectively, of revenue related to the license and development and committee services. We have recorded the remaining amount related to development and committee services of \$39.8 million and \$100.2 million as short-term and long-term deferred revenue, respectively, as of September 30, 2015.

The regulatory and commercialization milestones represent non-refundable amounts that would be paid by AbbVie to us if certain milestones are achieved in the future. We have elected to apply the milestones method of revenue recognition to all remaining milestones. We have determined that all remaining milestones, if achieved, are substantive because (i) they relate solely to past performance, (ii) are commensurate with estimated enhancement of value associated with the achievement of each milestone as a result of our performance, which are reasonable relative to other deliverables and terms of the arrangement, and (iii) are unrelated to the delivery of any further elements under the arrangement.

Subject to limited exceptions, we have agreed that we and our affiliates will not commercialize, or assist others in commercializing, in oncology indications any product that is a PI3K delta, gamma inhibitor that meets certain agreed-to criteria, other than Duvelisib Products, and AbbVie has agreed to similar restrictions. Registration-directed clinical trials and commercialization of Duvelisib Products for uses outside of oncology indications would require our and AbbVie's mutual consent.

The AbbVie Agreement will remain in effect until all development, manufacturing and commercialization of Duvelisib Products cease, unless terminated earlier. Either we or AbbVie may terminate the AbbVie Agreement if the other party is subject to certain insolvency proceedings or if the other party materially breaches the AbbVie Agreement and the breach remains uncured for a specified period, which may be extended in certain circumstances. However, we may terminate the AbbVie Agreement only on a country-by-country basis in the event AbbVie is not using diligent efforts to obtain regulatory approval or to commercialize Duvelisib Products in a country outside the United States. AbbVie may also terminate the AbbVie Agreement for convenience after a specified notice period. In the event there is a material uncured breach by either us or AbbVie of development or commercialization obligations, the non-breaching party may also have the right to assume and conduct such applicable development or commercialization obligations. If AbbVie or any of its affiliates or sublicensees challenges the patents we have licensed to AbbVie, we can terminate the AbbVie Agreement if the challenge is not withdrawn after a specified notice period.

If the AbbVie Agreement is terminated, we would receive all rights to the regulatory filings related to duvelisib upon our request, our license to AbbVie would terminate, and AbbVie would grant us a perpetual, irrevocable license to develop, manufacture and commercialize products containing duvelisib, excluding any compound which is covered by patent rights controlled by AbbVie or its affiliates. This license would be royalty-free, unless the AbbVie Agreement is terminated for material breach, in which case, depending on the breaching party and the timing of the material breach, a royalty rate may be payable by us ranging from a low single-digit percentage to a low double-digit percentage of net sales, and, in some cases, subject to a payment cap.

---

**Table of Contents**

If the AbbVie Agreement is terminated, we would not be entitled to receive payment for any milestone achieved after notice of termination but before the effective date of termination. Further, if the AbbVie Agreement is terminated, there are certain wind-down obligations to ensure a smooth transition of the responsibilities of the parties including, unless the AbbVie Agreement is terminated by AbbVie for our material breach, the continued conduct of certain development and commercialization activities by AbbVie for a limited transition period and the continued funding by AbbVie of its half of the cost of the AbbVie Studies ongoing at the time of termination, except for those AbbVie Studies that may be transitioned to Infinity following termination.

***Takeda***

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 duvelisib and IPI-549, 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. We refer to our PI3K inhibitor program licensor as Takeda. In December 2012, we amended and restated our development and license agreement with Takeda.

Under the terms of the amended and restated agreement, we retained worldwide development rights and, in exchange for an agreement to pay Takeda \$15 million in installments, we regained commercialization rights for products arising from the agreement for all therapeutic indications and we are solely responsible for research conducted under the agreement. 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 year ended December 31, 2014, we paid to Takeda the second installment of \$6.7 million. During the nine months ended September 30, 2015, we paid to Takeda the final installment of \$6.7 million.

We are obligated to pay to Takeda up to \$5 million in remaining success-based milestone payments for the development of a product candidate other than duvelisib, which could include IPI-549. We are also obligated to pay Takeda up to an aggregate of \$450 million in success-based milestone payments for the approval and commercialization of two distinct products, of which one could be a Duvelisib Product and the other a product containing IPI-549, if we achieve the applicable milestones. In February 2014, we paid Takeda a \$10 million milestone payment in connection with the initiation of DUO™. DUO is a randomized, Phase 3 monotherapy study designed to evaluate the safety and efficacy of duvelisib dosed at 25 mg BID compared to ofatumumab, a monoclonal antibody therapy, in approximately 300 patients with relapsed or refractory chronic lymphocytic leukemia. We recognized the \$10 million payment as research and development expense during the year ended December 31, 2014. In addition, other than for sales of duvelisib products in oncology indications, we are obligated to pay Takeda tiered royalties ranging from 7% to 11% on worldwide net sales of products described in the agreement, which could include IPI-549 if successfully developed and commercialized. 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. Takeda 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 Takeda, demonstrate to Takeda's reasonable satisfaction that we have not failed to be diligent. The foregoing periods are subject to extension in certain

circumstances. Additionally, Takeda 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 March 31, 2015, we paid to Takeda a \$52.5 million fee to exercise an option that we purchased from them in July 2014 for a one-time upfront payment of \$5 million. As a result of our exercise of this option, we are no longer obligated under the amended and restated development and license agreement to pay to Takeda the tiered 7% to 11% royalty with respect to worldwide net sales in oncology indications of products containing or comprised of duvelisib. We recognized the \$5 million upfront payment and the \$52.5 million exercise payment as research and development expense during the year ended December 31, 2014 and the nine months ended September 30, 2015, respectively, as there is no alternative future use beyond the existing research and development activities.

## **9. Debt Facility Agreement**

On February 24, 2014, we entered into a facility agreement with affiliates of Deerfield Management Company, L.P., or Deerfield, pursuant to which Deerfield agreed to loan us up to \$100 million, subject to the terms and conditions set forth in the facility

**Table of Contents**

agreement. On September 22, 2014, we amended the facility agreement with Deerfield to reduce the maximum principal amount that we may draw down to \$50 million. We refer to the facility agreement with Deerfield, as amended, as the Facility Agreement. Under the terms of the Facility Agreement, we had the right to draw down on the Facility Agreement in \$25 million minimum disbursements, which we refer to as the Loan Commitment, at any time during a pre-specified draw period. The draw period expired without our having drawn down on the Facility Agreement.

On February 25, 2015, we paid a \$1.5 million fee to Deerfield representing 3% of the total amount not drawn under the amended facility. 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. The warrants have dividend rights to the same extent as if the warrants were exercised into shares of common stock. The warrants expire on the seventh anniversary of their issuance and contain 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 the holder exceeding 9.985% of the total number of shares of common stock then issued and outstanding.

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; \$3.0 million representing the original facility fee; and \$0.4 million of transaction costs. As a result of the amendment of the Facility Agreement, the original facility fee was reduced by 50%, or \$1.5 million, and we recorded a corresponding decrease in the loan commitment asset. In addition, since our borrowing capacity was reduced by 50%, the remaining loan commitment asset outstanding as of September 22, 2014 was also reduced by 50% resulting in an additional expense of \$1.8 million during the year ended December 31, 2014. The total fair value is considered a Loan Commitment Asset which was classified as a current asset on the December 31, 2014 consolidated balance sheet. This amount is considered a fee to secure the Loan Commitment and was being amortized to interest expense on a straight line basis over the draw period. We recorded \$0.6 million and \$9.6 million of interest expense associated with the amortization and write-off of the loan commitment asset pursuant to the modification of the facility for the nine months ended September 30, 2015 and the year ended December 31, 2014, respectively. We did not record any interest expense associated with the amortization and write-off of the loan commitment asset pursuant to the modification of the facility for the three months ended September 30, 2015.

**10. Accrued Expenses**

Accrued expenses consisted of the following:

	September 30, 2015	December 31, 2014
	(in thousands)	
Accrued compensation and benefits	\$ 7,966	\$ 7,353
Accrued drug manufacturing costs	2,729	1,280
Accrued clinical studies	7,658	5,134
Accrued preclinical studies	253	543
Facility fee		1,500
Other	4,284	1,958
<b>Total accrued expenses</b>	<b>\$ 22,890</b>	<b>\$ 17,768</b>

## 11. Leases

### *784 Memorial Drive Lease Arrangement*

On September 25, 2014, we entered into a lease agreement, or the Lease, with BHX, LLC, as trustee of 784 Realty Trust, or the Landlord, for the lease of office space at 784 Memorial Drive, Cambridge, Massachusetts. The term of the Lease commenced on November 1, 2014, the Commencement Date, and expires on March 31, 2025, the Expiration Date. Pursuant to the Lease, on the Commencement Date we agreed to lease 61,000 square feet of the leased premises, which represents the entire building, the Leased Premises.

From the Commencement Date until April 1, 2015, the total base rent of the Lease was zero dollars per month. From April 1, 2015 through March 31, 2020, the total base rent of the Lease is \$170,292 per month. From April 1, 2020 until the Expiration Date, the total base rent of the Lease will be \$190,625 per month. In addition to the base rent, we are also responsible for our share of the operating expenses, utility costs and real estate taxes, in accordance with the terms of the Lease. Pursuant to the terms of the Lease, we provided a security deposit in the form of a letter of credit in the initial amount of \$1.0 million, which may be reduced by up to \$750,000 over time in accordance with the terms of the Lease. The letter of credit plus the associated bank fee of \$30,000 has been included in our accompanying condensed consolidated balance sheets as restricted cash. The Landlord agreed to pay up to \$5,856,100 for certain updates and repairs to be made to the Leased Premises. We have two consecutive rights to extend the term of the Lease for five years under each extension, provided that we provide notice to the Landlord no earlier than 18 months or later than 12 months prior to expiration of the Lease. The base rent for each extension term shall be equal to 95% of the then fair market base rent per square foot for the premises.



---

**Table of Contents**

Upon signing the lease agreement, we paid the first month's rent for April 2015 in the amount of \$170,292, which was recorded as a prepaid expense on the accompanying condensed consolidated balance sheet at December 31, 2014.

Upon the Commencement Date, building construction was initiated to suit our future needs. We were responsible for the construction project, including having responsibility to pay for a portion of the structural elements of the building and bear the risk of cost overruns. Therefore, we were deemed for accounting purposes to be the owner of the building during the construction period. Accordingly, we determined the fair value of the building as of November 1, 2014 through an independent appraisal and recorded the building as an asset on our condensed consolidated balance sheet, together with a corresponding construction liability, in November 2014 when the lease and construction commenced. On our condensed consolidated balance sheet, we record project construction costs as an asset during the construction period and reflect an increase in the construction financing obligation for the amount of Landlord incentives received. The construction was substantially complete and the Leased Premises was available for occupancy in June 2015. The construction-in-progress was then placed in service, and the construction liability was reclassified to a financing obligation as such transaction did not qualify for sale-leaseback accounting due to a prohibited form of continuing involvement. This determination was based on our continuing involvement with the property in the form of non-recourse financing to the lessor as well as our obligation to pay for all costs in excess of the specified Landlord allowances. Depreciation on the building and building improvements commenced in June 2015 and will be recorded over the initial term of the lease using a residual value equal to the financing obligation at the end of the lease term, which approximates the net book value using the estimated useful lives of the respective assets. Interest expense is recorded on a monthly basis using an estimated incremental borrowing rate based on comparable 10 year secured financings and commenced in June 2015 when the building was placed into service. In April and May 2015, the construction financing obligation was reduced by that portion of the lease payment allocated to the construction financing obligation principal. Commencing in June 2015, the financing obligation is reduced on a monthly basis by that portion of the lease payment allocated to the financing obligation principal. At September 30, 2015, future minimum payments under the Lease were approximately \$20.6 million, which is composed of \$0.5 million for the remainder of 2015, \$2.0 million for each of calendar years 2016 through 2019, \$2.2 million for the calendar year 2020 and \$9.7 million through March 2025.

At September 30, 2015 and December 31, 2014, the accompanying condensed consolidated balance sheet reflects the building and accumulated construction costs of approximately \$23.2 million and \$16.0 million, respectively, a financing obligation of approximately \$20.1 million at September 30, 2015 and a construction liability of approximately \$15.5 million at December 31, 2014.

We divide our future lease payments into a portion that is allocated to the financing obligation and a portion that is allocated to the land on which the building is located. The portion of the lease obligation allocated to the land is treated for accounting purposes as an operating lease commencing in November 2014 and recorded on a straight-line basis over the initial lease term. Rent expense pertaining to the land was approximately \$0.1 million and \$0.3 million, for the three and nine months ended September 30, 2015, respectively.

#### *780/790 Memorial Drive Lease Arrangement*

On November 6, 2014, we entered into a Seventh Amendment to Lease, the Lease Amendment, by and between us and ARE-770/784/790 Memorial Drive, LLC, the landlord, which amends the original lease agreement dated July 2, 2002, as amended to date, or the Original Lease. We refer to the Original Lease together with the Lease Amendment as the Memorial Drive Lease. We refer to the area rented under the Memorial Drive Lease as the Premises.

Under the Lease Amendment: (i) the Premises consist of 54,861 square feet, of which 51,000 square feet are located at 780 Memorial Drive, or the 780 Premises, and the remaining 3,861 square feet are located at 790 Memorial Drive, or

the 790 Premises; effective February 1, 2016 we will surrender 13,159 square feet of the previously leased 17,020 square feet at the 790 Premises; (ii) we have extended the base term of the Memorial Drive Lease through March 31, 2025; and (iii) we have two separate five-year options to extend the term of the Memorial Drive Lease to 2035 on the same terms and conditions (other than with respect to base rent or any work letter). The Memorial Drive Lease provides that we shall continue to pay the base rent as provided in the Original Lease until January 31, 2016. The base rent shall then increase to \$69.00 per square foot of the Premises on February 1, 2016 and again to \$70.00 per square foot of the Premises on February 1, 2018. The Memorial Drive Lease provides that no base rent for the Premises shall be due (i) for the period commencing on February 1, 2015 through July 31, 2015, (ii) for the period commencing on February 1, 2016 through February 29, 2016, (iii) for the period commencing on February 1, 2017 through February 28, 2017, and (iv) for the period commencing on February 1, 2018 through February 28, 2018. We also received allowances of \$3.0 million for the design and construction of tenant improvements. The total of these allowances of \$3.0 million has been reflected on our condensed consolidated balance sheets as a receivable, with a corresponding amount included in deferred rent liability. The deferred rent is being amortized to rent expense over the term of the lease. Pursuant to the terms of the Lease Amendment, the security deposit in the form of a letter of credit has been reduced from \$1.1 million to \$0.6 million. The letter of credit has been included in our accompanying condensed consolidated balance sheets as restricted cash.

---

**Table of Contents**

We have determined that the proposed improvements on the 780 Premises generally consist of normal tenant improvements and that we will not be deemed for accounting purposes to be the owner of the building during the construction period.

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

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, 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, will, 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. Our most advanced product candidate is duvelisib, also known as IPI-145, an oral, dual inhibitor of the delta and gamma isoforms of phosphoinositide-3-kinase, or PI3K, which we are investigating in hematologic malignancies. Our dedicated discovery research program continues to work toward the goal of generating new product candidates, and as a result, in September 2015 we announced the expansion of our pipeline with the addition of IPI-549, a pre-clinical immuno-oncology product candidate that selectively inhibits the gamma isoform of PI3K.

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

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 have distinct and mostly non-overlapping roles believed to support the growth and survival of malignant B-cells. Specifically, preclinical data suggest that PI3K-delta signaling can lead to the proliferation of malignant B-cells, and that both PI3K-gamma and PI3K-delta play an important role in the formation and maintenance of the supportive tumor microenvironment.

### **Dual Inhibition of PI3K Delta and Gamma Isoforms: Targeting Hematologic Malignancies**

We believe that dual inhibition of PI3K-delta and PI3K-gamma may provide multiple opportunities to develop differentiated therapies for the treatment of hematologic malignancies. Our lead product candidate, duvelisib, is an oral, dual inhibitor of PI3K-delta and PI3K-gamma, and we believe that duvelisib is the only dual inhibitor of PI3K-delta and PI3K-gamma being investigated in Phase 3 clinical trials. Duvelisib is an investigational compound, and its safety and efficacy have not yet been evaluated by the FDA or any other health authority.

We are conducting DUETTS (**Duvelisib Trials in Hematologic Malignancies**), a worldwide investigation of duvelisib in blood cancers initially focusing on lymphoma and chronic lymphocytic leukemia, or CLL.

As part of the DUETTS program in lymphoma, we are conducting DYNAMO , a Phase 2, open-label, single arm monotherapy study evaluating the safety and efficacy of duvelisib dosed at 25 mg twice daily, or BID, in approximately 120 patients with indolent non-Hodgkin lymphoma, or iNHL. DYNAMO enrollment criteria include patients with follicular lymphoma, the most common subtype of iNHL, marginal zone lymphoma, and small lymphocytic lymphoma, or SLL, whose disease is refractory to rituximab and to either chemotherapy or radioimmunotherapy and who must have progressed within six months of receiving their last

---

**Table of Contents**

therapy. The primary endpoint of the study is response rate according to the International Working Group Criteria. In September 2015, we enrolled the 120<sup>th</sup> patient in DYNAMO, which triggered a \$130 million milestone payment from AbbVie Inc., or AbbVie, our global commercial and development partner for duvelisib in oncology. We anticipate that we will report topline data from DYNAMO in the third quarter of 2016.

The DYNAMO study is designed with the potential to support accelerated approval of duvelisib in patients with follicular lymphoma and SLL, assuming we are able to generate positive safety and efficacy data from the study and on the condition that we conduct a confirmatory study. The FDA has granted orphan drug designation to duvelisib for the potential treatment of follicular lymphoma, and has granted fast track designation to the investigation of duvelisib for the treatment of patients with follicular lymphoma who have received at least two prior therapies. The availability of accelerated approval is dependent on a number of factors including whether duvelisib has demonstrated a meaningful benefit relative to available therapies. For a further discussion of certain risks related to our ability to seek accelerated approval for duvelisib, see **Risk Factors** **Risks Related to the Development and Commercialization of Our Product Candidates** elsewhere in this report.

Additional DUETTS clinical studies in lymphoma include DYNAMO+R and CONTEMPO. DYNAMO+R is a Phase 3 randomized, placebo-controlled study evaluating duvelisib dosed at 25 mg BID in combination with rituximab, a monoclonal antibody treatment, compared to placebo plus rituximab in approximately 400 patients with previously treated follicular lymphoma and is designed to serve as a confirmatory study in the event we are able to receive accelerated approval of duvelisib for the treatment of patients with follicular lymphoma or SLL based on the results of the DYNAMO study. The CONTEMPO study is a Phase 1b/2 clinical study of duvelisib in combination with obinutuzumab, a monoclonal antibody treatment, or rituximab in patients with previously untreated follicular lymphoma.

We intend to expand our DUETTS program in lymphoma with the initiation of two additional studies in iNHL in 2015. The first, BRAVURA, is a Phase 3, double-blind, placebo-controlled study in patients with relapsed iNHL designed to evaluate the safety and efficacy of duvelisib plus rituximab and bendamustine, a chemotherapy, compared to placebo plus rituximab and bendamustine in approximately 600 patients. The primary endpoint is progression-free survival. We intend to request advice from the FDA to determine if BRAVURA, as designed, can serve as a confirmatory study if DYNAMO supports an accelerated approval. The second study, FRESCO, is a Phase 2 study in patients with relapsed or refractory follicular lymphoma that is designed to evaluate the safety and efficacy of duvelisib plus rituximab compared to chemotherapy plus rituximab in approximately 200 patients. The primary endpoint of FRESCO is progression-free survival.

As part of the DUETTS investigation in CLL, we are enrolling patients in DUO<sup>TM</sup> and SYNCHRONY. DUO is a randomized, Phase 3 monotherapy study designed to evaluate the safety and efficacy of duvelisib dosed at 25 mg BID compared to ofatumumab, a monoclonal antibody therapy, in approximately 300 patients with relapsed or refractory CLL. The primary endpoint of the study is progression-free survival. We expect to complete enrollment of DUO by the end of 2015. SYNCHRONY is a Phase 1b trial of duvelisib in combination with obinutuzumab in CLL patients whose disease has progressed following treatment with a Bruton's tyrosine kinase, or BTK, inhibitor. The FDA and the European Medicines Agency, or EMA, have granted orphan drug designation to duvelisib for the potential treatment of CLL and SLL. The FDA has granted fast track designation to the investigation of duvelisib for the potential treatment of patients with CLL who have received at least one prior therapy

These duvelisib trials are supported by data from our Phase 1, open-label, dose-escalation study designed to evaluate the safety, pharmacokinetics and clinical activity of duvelisib in patients with advanced hematologic malignancies. The maximum tolerated dose of duvelisib was defined at 75 mg BID, and we have closed the trial to further enrollment. Data from this study, presented in December 2014 at the Annual Meeting of the American Society for

Hematology, or ASH, showed that duvelisib is clinically active in CLL, iNHL, and T-cell lymphoma, as well as other hematologic malignancies. Additionally, new clinical data from this study, presented in May 2015 at the Annual Meeting of the American Society of Clinical Oncology, or ASCO, demonstrated clinical activity of duvelisib dosed at 25 mg BID in previously untreated patients with CLL, with an 88% overall response rate (15 partial responses out of 17 evaluable patients, with two additional patients exhibiting stable disease) based on International Workshop on Chronic Lymphocytic Leukemia, or iwCLL, criteria. The study included 18 treatment-naïve CLL patients who were high-risk, defined as age 65 or over or having certain genetic abnormalities known as 17p deletions or p53 mutations. The median time to response was 3.7 months; the median progression-free survival and median overall survival have not yet been reached. The majority of adverse events were grade 1 or grade 2 and clinically manageable. The most common grade 3 side effects among the 18 enrolled patients were diarrhea (22%, four patients), an increase in alanine aminotransferase (ALT) and aspartame aminotransferase (AST) (17%, three patients), and rash (11%, two patients). Five patients (28%) had grade 4 neutropenia or decreases in neutrophil count. There were no grade 4 events of diarrhea, increases in ALT/AST or rash. Six patients discontinued treatment due to an adverse event.

We are pursuing duvelisib in oncology in collaboration with AbbVie. As part of our collaboration, we expect that AbbVie will initiate the first clinical study of duvelisib and venetoclax, a selective first-in-class B-cell lymphoma 2, or BCL-2, inhibitor, by the end of 2015. This Phase 1b/2 trial of duvelisib and venetoclax will be designed to evaluate the safety and activity of the combination across a range of hematologic malignancies. Preclinical data for duvelisib presented at ASCO demonstrates synergy with standards-of-care and emerging therapeutics in development for hematologic malignancies, including duvelisib in combination with venetoclax. For information regarding our collaboration, please see below under the heading *AbbVie* in the section entitled Strategic Alliances.

## **Table of Contents**

### **Selective Inhibition of the PI3K Gamma Isoform: Targeting Solid Tumors**

In September 2015 we announced the expansion of our pipeline to include IPI-549, a preclinical immuno-oncology development candidate that we intend to investigate as a treatment in solid tumors. Preclinical data show that IPI-549, a selective PI3K-gamma inhibitor, has the potential to heighten an anti-cancer response by targeting macrophages in the immune-suppressive tumor microenvironment and may have the potential to treat a broad range of solid tumors. IPI-549 has demonstrated dose-dependent, single-agent, anti-tumor activity in multiple solid tumor models, including mouse models of lung, colon and breast cancer. Additionally, mice treated with IPI-549 in combination with a certain type of drug called checkpoint inhibitors showed greater tumor growth inhibition than either treatment as a monotherapy. Preclinical in vivo data also demonstrated that T-cells, a type of cell that plays a role in your immune system, are required for the anti-tumor activity of IPI-549, which is a hallmark of immunotherapy. These data were presented at CRI-CIMT-EATI-AACR - The Inaugural International Cancer Immunotherapy Conference in September 2015. We expect to begin a Phase 1 clinical study of IPI-549 in the first quarter of 2016 designed to explore the safety and activity of IPI-549. The study will include a dose escalation phase evaluating IPI-549 as a monotherapy as well as a dose-escalation phase evaluating IPI-549 in combination with a therapy that targets a receptor in your body called programmed death receptor 1, or PD-1. An expansion phase is planned in patients with selected solid tumors, including non-small cell lung cancer and melanoma.

### **Strategic Alliances**

#### ***AbbVie***

On September 2, 2014, we entered into a collaboration and license agreement with AbbVie, which we refer to as the AbbVie Agreement. Under the AbbVie Agreement, we are collaborating with AbbVie to develop and commercialize products containing duvelisib, which we refer to as Duvelisib Products, in oncology indications. Under the terms of the AbbVie Agreement, we have granted to AbbVie licenses under applicable patents, patent applications, know-how and trademarks to develop, commercialize and manufacture Duvelisib Products in oncology indications. These licenses are generally co-exclusive with rights we retain, except that we have granted AbbVie exclusive licenses to commercialize Duvelisib Products outside the United States. We and AbbVie retain the rights to perform our respective obligations and exercise our respective rights under the AbbVie Agreement, and we and AbbVie may each grant sublicenses to affiliates or third parties.

Under the AbbVie Agreement, we and AbbVie have created a governance structure, including committees and working groups to manage the development, manufacturing and commercialization responsibilities for Duvelisib Products. Generally, we and AbbVie must mutually agree on decisions, although in specified circumstances either we or AbbVie would be able to break a deadlock.

We and AbbVie share oversight of development and have each agreed to use diligent efforts, as defined in the AbbVie Agreement, to carry out our development activities under an agreed upon development plan. We have primary responsibility for the conduct of development of Duvelisib Products, unless otherwise agreed, and AbbVie has responsibility for the conduct of certain contemplated combination clinical studies, which we refer to as the AbbVie Studies. We have the responsibility to manufacture Duvelisib Products until we transition manufacturing responsibility to AbbVie, which we expect to occur as promptly as practicable while ensuring continuity of supply. Excluding the AbbVie Studies, we are responsible for all costs to develop and manufacture Duvelisib Products up to a maximum amount of \$667 million after which we will share Duvelisib Product development and manufacturing costs equally with AbbVie. The development and manufacturing costs of the AbbVie Studies will be shared equally.

We and AbbVie share operational responsibility and decision making authority for commercialization of Duvelisib Products in the United States. Specifically, we have the primary responsibility for advertising, distribution, and booking sales, and we share certain other commercialization functions with AbbVie. Assuming regulatory approval, we and AbbVie are obligated to each provide half of the sales representative effort to promote Duvelisib Products in the United States. Outside the United States, AbbVie has, with limited exceptions, operational responsibility and decision making authority to commercialize Duvelisib Products. We and AbbVie will share the cost of manufacturing and supply for commercialization of Duvelisib Products in the United States, and AbbVie will bear the cost of manufacturing and supply for commercialization of Duvelisib Products outside the United States.

AbbVie has paid us a non-refundable \$275 million upfront payment in 2014 and a \$130 million milestone payment in November 2015 associated with the completion of enrollment of DYNAMO in September 2015. Further, AbbVie has agreed to pay us up to an additional \$400 million in potential future milestone payments comprised of \$275 million associated with the achievement of specified regulatory filing and approval milestones and up to \$125 million associated with the achievement of specified commercialization milestones. Under the terms of the AbbVie Agreement, we and AbbVie will equally share commercial profits or losses of Duvelisib Products in the United States, including sharing equally the existing royalty obligations to Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products L.P., or Purdue, for sales of Duvelisib Products in the United States, as well as sharing equally the existing U.S. milestone payment obligations to Takeda Pharmaceutical Company Limited, or Takeda.



---

**Table of Contents**

Additionally, AbbVie has agreed to pay us tiered royalties on net sales of Duvelisib Products outside the United States ranging from 23.5% to 30.5%, depending on annual net sales of Duvelisib Products by AbbVie, its affiliates and its sublicensees. We are responsible for the existing royalty obligations to Mundipharma and Purdue outside the United States, and AbbVie has agreed to reimburse us for our existing Duvelisib Product milestone payment obligations to Takeda outside the United States. The tiered royalty from AbbVie is subject to a reduction of 4% at each tier if our royalties to Mundipharma and Purdue are reduced according to the terms of our respective agreements with Mundipharma and Purdue. This tiered royalty can further be reduced based on specified factors, including patent expiry, generic entry, and royalties paid to third parties with blocking intellectual property. These royalties are payable on a product-by-product and country-by-country basis until AbbVie ceases selling the product in the country.

Subject to limited exceptions, we have agreed that we and our affiliates will not commercialize, or assist others in commercializing, in oncology indications any product that is a PI3K delta, gamma inhibitor that meets certain agreed-to criteria, other than Duvelisib Products, and AbbVie has agreed to similar restrictions. Registration-directed clinical trials and commercialization of Duvelisib Products for uses outside of oncology indications would require our and AbbVie's mutual consent.

The AbbVie Agreement will remain in effect until all development, manufacturing and commercialization of Duvelisib Products cease, unless terminated earlier. Either we or AbbVie may terminate the AbbVie Agreement if the other party is subject to certain insolvency proceedings or if the other party materially breaches the AbbVie Agreement and the breach remains uncured for a specified period, which may be extended in certain circumstances. However, we may terminate the AbbVie Agreement only on a country-by-country basis in the event AbbVie is not using diligent efforts to obtain regulatory approval or to commercialize Duvelisib Products in a country outside the United States. AbbVie may also terminate the AbbVie Agreement for convenience after a specified notice period. In the event there is a material uncured breach by either us or AbbVie of development or commercialization obligations, the non-breaching party may also have the right to assume and conduct such applicable development or commercialization obligations. If AbbVie or any of its affiliates or sublicensees challenges the patents we have licensed to AbbVie, we can terminate the AbbVie Agreement if the challenge is not withdrawn after a specified notice period.

If the AbbVie Agreement is terminated, we would receive all rights to the regulatory filings related to duvelisib upon our request, our license to AbbVie would terminate, and AbbVie would grant us a perpetual, irrevocable license to develop, manufacture and commercialize products containing duvelisib, excluding any compound which is covered by patent rights controlled by AbbVie or its affiliates. This license would be royalty-free, unless the AbbVie Agreement is terminated for material breach, in which case, depending on the breaching party and the timing of the material breach, a royalty rate may be payable by us ranging from a low single-digit percentage to a low double-digit percentage of net sales, and, in some cases, subject to a payment cap.

If the AbbVie Agreement is terminated, we would not be entitled to receive payment for any milestone achieved after notice of termination but before the effective date of termination. Further, if the AbbVie Agreement is terminated, there are certain wind-down obligations to ensure a smooth transition of the responsibilities of the parties including, unless the AbbVie Agreement is terminated by AbbVie for our material breach, the continued conduct of certain development and commercialization activities by AbbVie for a limited transition period and the continued funding by AbbVie of its half of the cost of the AbbVie Studies ongoing at the time of termination, except for those AbbVie Studies that may be transitioned to Infinity following termination.

***Takeda***

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 duvelisib and IPI-549, and we paid Intellikine a \$13.5 million upfront license fee. In January 2012, Intellikine was acquired by Takeda, acting through its Millennium business unit. We refer to our PI3K inhibitor program licensor as Takeda. In December 2012, we amended and restated our development and license agreement with Takeda.

Under the terms of the amended and restated agreement, we retained worldwide development rights and in exchange for an agreement to pay Takeda \$15 million in installments, we regained commercialization rights for products arising from the agreement for all therapeutic indications, and we are solely responsible for research conducted under the agreement.

We are obligated to pay to Takeda up to \$5 million in remaining success-based milestone payments for the development of a product candidate other than duvelisib, which could include IPI-549. We are also obligated to pay Takeda up to an aggregate of \$450 million in success-based milestone payments for the approval and commercialization of two distinct products, of which one could be a Duvelisib Product and the other a product containing IPI-549, if we achieve the applicable milestones. In February 2014, we paid Takeda a \$10 million milestone payment in connection with the initiation of DUO, our Phase 3 study of duvelisib in patients with relapsed or refractory CLL. In addition, other than

## **Table of Contents**

for sales of duvelisib products in oncology indications, we are obligated to pay Takeda tiered royalties ranging from 7% to 11% on worldwide net sales of products described in the agreement, which could include IPI-549 if successfully developed and commercialized. 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. Takeda 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 Takeda, demonstrate to Takeda's reasonable satisfaction that we have not failed to be diligent. The foregoing periods are subject to extension in certain circumstances. Additionally, Takeda 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 March 31, 2015, we paid a \$52.5 million fee to exercise an option that we purchased from Takeda in July 2014 for a one-time upfront payment of \$5 million. As a result of our exercise of this option, we are no longer obligated under the amended and restated development and license agreement to pay to Takeda the tiered 7% to 11% royalty with respect to worldwide net sales in oncology indications of products containing or comprised of duvelisib.

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

On July 17, 2012, we terminated our strategic alliance with Mundipharma and Purdue, and we entered into termination and revised relationship agreements with each of those entities, which we refer to as the 2012 Termination Agreements. The strategic alliance was previously governed by strategic alliance agreements that we entered into with each of Mundipharma and Purdue in November 2008. The strategic alliance agreement with Purdue was focused on the development and commercialization in the United States of products targeting fatty acid amide hydrolase, or FAAH. The strategic alliance agreement with Mundipharma was focused on the development and commercialization outside 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.

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 resulting in the return to us of 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 strategic alliance, Mundipharma was obligated to reimburse us for research and development expenses we incurred, up to an annual aggregate cap for each strategic 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% 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 1% royalty on net sales in the United States of products that were previously subject to the strategic alliance. All payments are contingent upon the successful commercialization of products 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%. In addition, royalties payable under these agreements after Mundipharma and Purdue have recovered all research and development expenses paid to us are subject to reduction on account of third-party royalty payments or patent litigation damages or settlements which might be required to be paid by us if litigation were to arise, with any such reductions capped at 50% of the amounts otherwise payable during the applicable royalty payment period.

## **Table of Contents**

### ***Debt Facility Agreement***

On February 24, 2014, we entered into a facility agreement with affiliates of Deerfield Management Company, L.P., or 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. On September 22, 2014, we amended the facility agreement with Deerfield to reduce the maximum principal amount that we may draw down to \$50 million. We refer to the facility agreement with Deerfield, as amended, as the Facility Agreement. Under the terms of the Facility Agreement, we had the right to draw down on the Facility Agreement in \$25 million minimum disbursements, which we refer to as the Loan Commitment, at any time during a pre-specified draw period. The draw period expired without our having drawn down on the Facility Agreement.

On February 25, 2015, we paid a \$1.5 million fee to Deerfield representing 3% of the total amount not drawn under the Facility Agreement. 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. The warrants have dividend rights to the same extent as if the warrants were exercised into shares of common stock. The warrants expire on the seventh anniversary of their issuance and contain 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 the holder exceeding 9.985% of the total number of shares of common stock then issued and outstanding.

### ***Financial Overview***

#### ***Revenue***

To date, all of our revenue has been generated under research collaboration agreements, and all our revenue during 2014 and during the three and nine months ended September 30, 2015 was derived from our strategic alliance with AbbVie. The terms of these research collaboration agreements may include payment to us of non-refundable, upfront license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved, and/or royalties on product sales. We evaluate all deliverables within an arrangement to determine whether or not they provide value on a stand-alone basis. Based on this evaluation, the deliverables are separated into units of accounting. For each unit of accounting identified within an arrangement, we determine the period over which the performance obligation occurs. Revenue is then recognized using the proportional performance method. The proportional performance method is used when the level of effort to complete the performance obligations under an arrangement can be reasonably estimated. We recognize revenue based upon our best estimate of the selling price for each element when there is no other means to determine the fair value of that item and allocate the consideration based on the relative values. The process for determining the best estimate of the selling price involves significant judgment and estimates.

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 based on the period over which the performance obligation occurs for each deliverable in the arrangement.

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***

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

compensation of personnel associated with research and development activities;

**Table of Contents**

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;

fees paid to external consultants;

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

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

depreciation of equipment; and

allocated costs of facilities.

***General and Administrative Expense***

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

***Other Income and Expense***

Interest and investment income typically consists of interest earned on cash, cash equivalents and available-for-sale securities, net of interest expense. Interest expense is related to the amortization of the loan commitment asset recognized under our Facility Agreement with Deerfield and the financing obligation related to the 784 Memorial Drive lease (see footnote 11).

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

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

There have been no material changes to our critical accounting policies during the nine months ended September 30, 2015. 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, 2014 for a discussion of our critical accounting policies and significant judgments and estimates.



**Table of Contents****Results of Operations**

The following tables summarize our results of operations for each of the three and nine months ended September 30, 2015 and 2014, together with the change in these items in dollars and as a percentage:

	<b>Three Months</b>			
	<b>Ended September 30,</b>			
	<b>2015</b>	<b>2014</b>	<b>\$ Change</b>	<b>% Change</b>
	<b>(in thousands)</b>			
Collaboration revenue	\$ 90,743	\$ 160,639	\$ (69,896)	(44)%
Research and development expense:				
Programs	(37,729)	(39,895)	2,166	(5)%
Takeda payments		(5,000)	5,000	(100)%
<b>Total research and development expense</b>	<b>(37,729)</b>	<b>(44,895)</b>	<b>7,166</b>	<b>(16)%</b>
General and administrative expense	(9,754)	(8,042)	(1,712)	21%
Interest expense	(311)	(4,537)	4,226	(93)%
Investment and other income	75	52	23	44%
Income taxes	(480)		(480)	

	<b>Nine Months</b>			
	<b>Ended September 30,</b>			
	<b>2015</b>	<b>2014</b>	<b>\$ Change</b>	<b>% Change</b>
	<b>(in thousands)</b>			
Collaboration revenue	\$ 99,987	\$ 160,639	\$ (60,652)	(38)%
Research and development expense:				
Programs	(107,720)	(92,551)	(15,169)	16%
Takeda payments	(52,500)	(15,000)	(37,500)	250%
<b>Total research and development expense</b>	<b>(160,220)</b>	<b>(107,551)</b>	<b>(52,669)</b>	<b>49%</b>
General and administrative expense	(27,713)	(21,903)	(5,810)	27%
Interest expense	(1,058)	(8,615)	7,557	(88)%
Investment and other income (loss)	298	356	(58)	(16)%
Income taxes	(480)		(480)	

**Revenue**

Collaboration revenue for the three and nine months ended September 30, 2015 relates to license and research and development revenue from our collaboration agreement with AbbVie. Of the \$275 million upfront payment received during the three months ended September 30, 2014 and the \$130 million milestone earned during the three months ended September 30, 2015, \$234.3 million was allocated to the license, \$170.3 million to development services and \$0.4 million to the committee services. We recognized license revenue upon execution of the agreement and completion of enrollment in our DYNAMO study, respectively. Revenue related to development services and committee services are being recognized using the proportionate performance method as services are provided over the estimated service period of approximately five years. Upon achievement of the \$130 million milestone on September 30, 2015, we recognized the \$75.2 million allocated to the license as revenue and \$9.8 million of revenue

related to the development and committee services performed from the inception of the AbbVie Agreement through September 30, 2015. During the three and nine months ended September 30, 2015, we recognized \$90.7 million and \$100.0 million, respectively, of revenue related to the license and development and committee services. We have recorded the remaining amount related to development and committee services of \$39.8 million and \$100.2 million as short-term and long-term deferred revenue, respectively, as of September 30, 2015.

The regulatory and commercialization milestones represent non-refundable amounts that would be paid by AbbVie to us if certain milestones are achieved in the future. We have elected to apply the milestones method of revenue recognition to all remaining milestones. We have determined that all remaining milestones, if achieved, are substantive because (i) they relate solely to past performance, (ii) are commensurate with estimated enhancement of value associated with the achievement of each milestone as a result of our performance, which are reasonable relative to other deliverables and terms of the arrangement, and (iii) are unrelated to the delivery of any further elements under the arrangement.

#### *Research and Development Expense*

The \$2.2 million decrease in research and development programs expense for the three months ended September 30, 2015 as compared to the three months ended September 30, 2014 was primarily due to a decrease of \$2.0 million in clinical expenses related to development activities for duvelisib. The \$15.2 million increase in research and development programs expense in the nine months ended September 30, 2015 as compared to the nine months ended September 30, 2014 is primarily due to a \$8.3 million increase in clinical and development expenses related to increased activities for duvelisib, including charges from AbbVie for costs incurred by AbbVie for other than the AbbVie Studies and for our share of the AbbVie Studies, an increase in research and development compensation of \$3.8 million and an increase of \$1.4 million related to preclinical expenses primarily due to IPI-549.

**Table of Contents**

The \$5.0 million decrease in Takeda payments included in research and development expense for the three months ended September 30, 2015 as compared to the three months ended September 30, 2014 was due to the \$5 million option fee payment to Takeda in July 2014. The \$37.5 million increase in Takeda payments included in research and development expense for the nine months ended September 30, 2015 as compared to the nine months ended September 30, 2014 was due to the \$52.5 million payment we made to Takeda during the nine months ended September 30, 2015 in connection with our exercise of an option we purchased from Takeda for \$5 million in July 2014 to eliminate our obligation to pay Takeda a tiered 7% to 11% royalty with respect to worldwide net sales in oncology indications of products containing or comprised of duvelisib, offset by the \$10 million milestone payment made to Takeda in connection with the initiation of our first Phase 3 study of duvelisib and the \$5 million option fee payment we made to Takeda in July 2014, which were recognized during the nine months ended September 30, 2014.

We began to track and accumulate expenses by major program starting on January 1, 2006. These expenses primarily relate to payroll and related expenses for personnel working on our programs, process development and manufacturing, preclinical toxicology studies, clinical trial costs and allocated costs of facilities. During the three and nine months ended September 30, 2015 and 2014, and from January 1, 2006 through September 30, 2015, we estimate that we incurred the following expenses by program:

Program	Three Months Ended		Nine Months Ended		January 1, 2006 to September 30, 2015
	September 30, 2015	September 30, 2014	September 30, 2015	September 30, 2014	
			(in millions)		
PI3K inhibitor (1)	\$ 35.6	\$ 38.1	\$ 153.1	\$ 89.0	\$ 435.9
Hsp90 inhibitor		0.3	0.1	1.5	137.8
Hedgehog pathway inhibitor				0.1	164.1

(1) Includes an upfront license fee of \$13.5 million in 2010, \$4 million in development milestones in 2011, \$14.4 million recorded as fair value for the release payment for the amended and restated Takeda agreement and \$6 million in development milestones in 2012, \$10 million development milestone payment and a \$5 million option fee payment in 2014, as well as a \$52.5 million payment related to the exercise of an option to Takeda in 2015.

We expect expenses related to our PI3K inhibitor program to increase as we continue clinical development of duvelisib. 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;

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

clinical trial results;

the cost of establishing clinical supplies of any product candidates

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;

**Table of Contents**

the cost and timing of regulatory approvals;

the effect of competing technological and market developments.

*General and Administrative Expense*

The \$1.7 million increase in general and administrative expense for the three months ended September 30, 2015 as compared to the three months ended September 30, 2014 is primarily attributable to an increase of \$0.7 million in compensation related costs and \$0.7 million in consulting expenses. The \$5.8 million increase in general and administrative expense for the nine months ended September 30, 2015 as compared to the nine months ended September 30, 2014 is primarily attributable to an increase of \$3.1 million in compensation related costs primarily related to contingent cash compensation, \$1.5 million in market research, and \$1.4 million in consulting.

*Interest Expense*

Interest expense for the three and nine months ended September 30, 2015 is due to the financing obligation related to our 784 Memorial Drive lease. Interest expense for the nine months ended September 30, 2015 and the three and nine months ended September 30, 2014 is related to the amortization of the loan commitment asset recognized under our Facility Agreement with Deerfield, which ended in February 2015.

*Investment and Other Income (Loss)*

Investment and other income (loss) for the three and nine months ended September 30, 2015 is primarily related to realized gains on investments, offset by foreign currency losses.

*Income Taxes*

Our income tax expense of approximately \$0.5 million for the nine months ended September 30, 2015 is primarily related to alternative minimum tax which is driven by revenue recognized during the period in connection with the collaboration agreement with AbbVie, which we entered into during the year ended December 31, 2014.

*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 at least the next two years, if at all. We have instead relied on the proceeds from our collaborations, such as up-front license fees, milestone payments, expense reimbursement and cost sharing, as well as proceeds from sales of equity securities, interest on investments, and debt to fund our operations. Our available-for-sale debt securities primarily trade in liquid markets, and the average days to maturity of our portfolio, as of September 30, 2015, is less than six months. Because our product candidates are in various stages of clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability.

Our significant capital resources are as follows:

**September 30, 2015    December 31, 2014**  
**(in thousands)**

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

Cash, cash equivalents and available-for-sale securities	\$ 162,961	\$ 333,245
Working capital	226,003	289,691

**Nine Months Ended September 30,**  
**2015**                      **2014**  
**(in thousands)**

Cash provided by (used in):		
Operating activities	\$ (166,421)	\$ 164,695
Takeda payments (included in operating activities above)	(59,167)	(21,667)
Investing activities	(5,551)	86,558
Capital expenditures (included in investing activities above)	(5,416)	(364)
Financing activities	1,851	1,890

---

**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 nine months ended September 30, 2015 compared to the nine months ended September 30, 2014 increased primarily due to increased operating expenses, including a \$52.5 million payment to Takeda associated with the exercise of an option that we purchased in July 2014 to eliminate our obligation to pay Takeda a tiered 7% to 11% royalty with respect to worldwide net sales in oncology indications of products containing or comprised of duvelisib. During the nine months ended September 30, 2015, we paid to Takeda the \$52.5 million option exercise payment and \$6.7 million related to the final installment on a release payment. During the nine months ended September 30, 2014, we paid Takeda a \$10 million milestone payment for the initiation of the first Phase 3 study for duvelisib, a \$6.7 million release payment and a \$5 million option 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.

AbbVie paid us a \$275 million upfront payment during the year ended December 31, 2014, a \$130 million milestone payment in November 2015 associated with the completion of enrollment in DYNAMO in September 2015, and has agreed to pay us up to an aggregate of \$400 million associated with the achievement of specified regulatory and commercialization milestones. We have recorded the \$130 million as a receivable on our condensed consolidated balance sheet as of September 30, 2015.

On February 24, 2014, we entered into a Facility Agreement with Deerfield. The draw period has expired without our having drawn down on the Facility Agreement. During the nine months ended September 30, 2015, we paid a \$1.5 million fee to Deerfield related to not drawing down any amount under the Facility Agreement.

Net cash from investing activities for the nine months ended September 30, 2015 included purchases of available-for-sale securities of \$64.4 million and proceeds of \$63.8 million from maturities of available-for-sale securities. Capital expenditures primarily consisted of building improvements and furniture and fixtures related to our 784 Memorial Drive lease arrangement.

Net cash from financing activities for the nine months ended September 30, 2015 included \$1.8 million of proceeds from issuances of common stock in connection with stock option exercises related to stock incentive plans and \$0.5 million of proceeds from issuances of common stock in connection with the employee stock purchase plan.

***Operating Capital Requirements***

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 believe that, our existing cash, cash equivalents and available-for-sale securities at September 30, 2015, together with the \$130 million milestone payment received from AbbVie, will be adequate to satisfy our capital needs through at least the next twelve months. Until we can generate sufficient levels of cash from operations, which we do not expect to achieve for at least the next two years, if at all, and because sufficient funds may not be available to us when needed from collaborations, we expect that we will be required to continue to fund our operations in part through the sale of debt or equity securities, and/or through licensing select programs or partial economic rights that could include payments to us of up-front, royalty and/or milestone payments. 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 businesses, technologies, products or product candidates;

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

the cost or quantity required of comparator drugs used in clinical studies increases;



**Table of Contents**

the receipt of any potential milestone payments from our strategic collaborator AbbVie is delayed beyond our original assumptions;

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.

While we may seek additional funding through public or private financings of equity or debt securities, such financing may not be available on acceptable terms, if at all. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders, increased fixed payment obligations and result in the existence of securities with rights that may be senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects. 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 during the nine months ended September 30, 2015.

We are obligated to pay to Takeda up to \$5 million in remaining success-based milestone payments for the development of a product candidate other than duvelisib, and up to \$450 million in success-based milestone payments for the approval and commercialization of two distinct products, one of which could be a Duvelisib Product if we achieve the applicable milestones with a Duvelisib Product. Because the achievement of these milestones had not occurred as of September 30, 2015, 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, 2014 for a discussion of our judgments and estimates.

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.

## **Table of Contents**

### **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 \$40,000 decrease in the fair value of our investments as of September 30, 2015, as compared to an approximate \$0.1 million decrease as of December 31, 2014. 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 September 30, 2015. 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 September 30, 2015, 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 September 30, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

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

You should carefully consider the following risk factors, in addition to other information included in this quarterly report on Form 10-Q, in evaluating Infinity and our business. If any of the following risks occur, our business, financial condition and operating results and strategic plans 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, 2014.

### **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 and 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.

---

**Table of Contents**

***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 September 30, 2015, we had an accumulated deficit of \$556.4 million. We expect to continue to spend significant resources to fund the research and development of duvelisib and our other product candidates. While we may have net income in some 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. In addition, in connection with seeking and possibly obtaining regulatory approval of any of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. 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. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or commercialization efforts. In the absence of additional funding or business development activities and based on our current operating plans, we believe that, our existing cash, cash equivalents and available-for-sale securities at September 30, 2015, together with the \$130 million milestone payment received from AbbVie Inc., or AbbVie, in November 2015, will be adequate to satisfy our capital needs through at least the next twelve months. Until we can generate sufficient levels of cash from operations, which we do not expect to achieve for at least the next two years, if at all, and because sufficient funds may not be available to us when needed from collaborations, we expect that we will be required to continue to fund our operations in part through the sale of debt or equity securities, and/or through licensing select programs or partial economic rights that could include payments to us of up-front, royalty and/or milestone payments. 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;

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 or quantity required of comparator drugs used in clinical studies increases;

the receipt of any potential milestone payments from our strategic collaborator AbbVie is delayed beyond our original assumptions;

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.

While we may seek additional funding through public or private financings of equity or debt securities, such financing may not be available on acceptable terms, if at all. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders, increased fixed payment obligations and the existence of securities with rights that may be senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects. 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

---

**Table of Contents**

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.

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

We have a strategic collaboration with AbbVie to research, develop and jointly commercialize products containing or comprised of duvelisib, which we refer to as Duvelisib Products, in oncology indications. We refer to this agreement as the AbbVie Agreement. Pursuant to the AbbVie Agreement, AbbVie has committed to providing substantial funding, as well as significant capabilities in development, marketing and sales. However, we may not be able to maintain our alliance with AbbVie or any other future alliance partner if, for example, development or approval of duvelisib or other product candidates is delayed or sales of Duvelisib Products or other products are disappointing. Further, AbbVie may be the only alliance we are able to successfully execute, making us overly dependent on the success of duvelisib in oncology indications and therefore particularly vulnerable if duvelisib or the alliance with AbbVie fails, as discussed in the next risk factor.

***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.***

The success of a strategic alliance, whether with AbbVie or any future partner, is largely dependent on the resources, efforts, technology and skills brought to such alliance by such partner. The benefits of such alliances will be reduced or eliminated if any such partner does not devote sufficient time and resources to its alliance arrangements with us and our results of operations may be adversely affected. In addition, if such partner were to breach or terminate its arrangements with us or fail to maintain the financial resources necessary to continue financing its portion of development, manufacturing, and commercialization costs, as applicable, we may not have the financial resources or capabilities necessary to continue development and commercialization of the product candidate on our own. Consequently, the development and commercialization of the affected product candidate could be delayed, curtailed or terminated, and we may find it difficult to attract a new alliance partner for such product candidate. For example, if AbbVie were to terminate our strategic collaboration, we would not be entitled to receive payment for any milestone that is not achieved prior to AbbVie's delivery to us of a termination notice, and AbbVie has limited obligations to continue the conduct and funding of ongoing development and commercialization activities.

Disputes and difficulties in these types of relationships are common, often due to priorities changing over time, conflicting priorities or conflicting interests. Merger and acquisition activity may exacerbate these conflicts. For example, in May 2015, AbbVie acquired Pharmacyclics, Inc., or Pharmacyclics, a competitor of ours that had received approval to manufacture and market ibrutinib for the treatment of chronic lymphocytic leukemia, or CLL, and is developing ibrutinib in follicular lymphoma, which are indications for which we are developing duvelisib. As part of our collaboration, we and AbbVie must agree on the development and commercialization strategy for Duvelisib Products, which could lead to difficulties as a result of competing priorities or conflicts of interest related to the development and potential commercialization of duvelisib in competition with ibrutinib. Any difficulties we encounter may have an adverse effect on the development of duvelisib and, consequently, our business.

As is the case with our strategic collaboration with AbbVie, much of the potential revenue from alliances consists of payments contingent 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. Under the AbbVie Agreement, for instance, we have granted

AbbVie exclusive licenses to commercialize Duvelisib Products outside the United States. AbbVie or any future alliance partner may fail to develop or effectively commercialize duvelisib or future drug products if it:

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

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

cannot obtain the necessary regulatory approvals.

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

---

**Table of Contents**

***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 diseases, which is a highly competitive and rapidly changing segment 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 oncology diseases. 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 this segment 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.

Duvelisib is a dual inhibitor of the delta and gamma isoforms of phosphoinositide-3-kinase, or PI3K. We are aware of a number of companies developing product candidates or selling products directed to isoforms of PI3K. Specifically, we believe that Gilead Sciences, Inc., or Gilead; Incyte Corporation, Acerta Pharma BV; Rhizen Pharmaceuticals S.A.; Amgen, Inc.; TG Therapeutics, Inc.; and SignalRx Pharmaceuticals are conducting clinical trials of drugs that target the delta isoform of PI3K. We also believe that Bayer AG is conducting clinical trials of a drug that targets the delta and alpha isoforms of PI3K, and that Novartis AG is conducting clinical trials of a drug that targets the delta, gamma, alpha, and beta isoforms of PI3K.

Additionally, many companies are developing product candidates or selling products directed to disease targets such as Bruton's Tyrosine Kinase (or BTK), B-cell lymphoma 2 (or BCL-2), Janus Kinase (or JAK), B-lymphocyte antigen CD-19, and programmed death 1/ligand 1 (or PD-1/PD-L1), Cluster of Differentiation 79B antibody-drug conjugate (or CD79B ADC), histone deacetylase (or HDAC), and pleiotropic pathways in the fields of hematology-oncology, including in the specific diseases for which we are currently developing duvelisib, or for which we may develop duvelisib in the future, including: AbbVie; BeiGene Co., Ltd; Janssen Biotech through its collaboration with AbbVie; Celgene Corporation; a joint collaboration between Gilead and Ono Pharmaceutical Group under their exclusive



license agreement; Acerta Pharma BV; Incyte Corporation; MorphoSys AG; Novartis AG; Principia Biopharma, Roche Group and its subsidiary Genentech; Bristol-Myers Squibb Company; and AstraZeneca PLC.

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 that are in later-stage clinical development than our own product candidates, or have been approved by the FDA, such as ibrutinib, a BTK inhibitor being developed and commercialized by AbbVie for the treatment of people with mantle cell lymphoma or CLL, and idelalisib, a compound targeting the delta isoform of PI3K, being developed and commercialized by Gilead for the treatment of people with CLL, follicular B-cell non-Hodgkin lymphoma, or small lymphocytic lymphoma.

## **Table of Contents**

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 organizational changes and growth depends upon the continual improvement of our processes and procedures and the preservation of our corporate culture. Under the AbbVie Agreement, we and AbbVie have created a governance structure, including committees and working groups to manage the development, manufacturing and commercialization responsibilities for the Duvelisib Products. Generally, we and AbbVie must mutually agree on decisions, although in specified circumstances either we or AbbVie would be able to break a deadlock. Any future alliance may also require implementation of a similarly complex governing structure. We may not be able to implement improvements in an efficient or timely manner or to maintain our corporate culture during periods of organizational change. If we do not meet these challenges, we may be unable to take advantage of market opportunities, execute our business strategies or respond to competitive pressures, which in turn may give rise to inefficiencies that would increase our losses or delay our programs.

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

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

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

In addition, we will likely incur significant expenses in connection with our efforts, if any, to consummate acquisitions. These expenses may include fees and expenses for investment bankers, attorneys, accountants and other

advisers in connection with our efforts and could be incurred whether or not an acquisition is consummated. Even if we consummate a particular acquisition, we may incur as part of such acquisition substantial closure costs associated with, among other things, elimination of duplicate operations and facilities. In such case, the incurrence of these costs could adversely affect our financial results for particular quarterly or annual periods.

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

As of September 30, 2015, we had approximately \$163 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.

---

**Table of Contents**

***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, 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 with Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products L.P., or Purdue, 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 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 require us to restate prior period revenue.

***If we are not able to maintain effective internal control 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 control and requires our independent auditors to attest to the effectiveness of our internal control over financial reporting. Any failure by us to maintain the effectiveness of our internal control in accordance with the requirements of Section 404 of the Sarbanes-Oxley Act, as such requirements exist today or may be modified, supplemented or amended in the future, could have a material adverse effect on our business, operating results and stock price.

**Risks Related to the Development and Commercialization of Our Product Candidates**

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

To date, we have not obtained approval from the FDA, or any foreign regulatory authority to market or sell any of our product candidates. Our product candidates are subject to extensive governmental regulations relating to development, clinical trials, manufacturing and commercialization. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process are required in the United States and in many foreign jurisdictions prior to the commercial sale of medicinal products like our product candidates. For example, we are evaluating duvelisib, the lead compound in our PI3K inhibitor program, in all phases of clinical development, and we anticipate initiating multiple additional trials of duvelisib in 2015 (see Management's Discussion and Analysis of Financial Condition and Results of Operation Research and Development Programs above). 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, including approval by the FDA and comparable foreign regulatory agencies.

***We may not qualify for accelerated approval or expedited review for any of our product candidates, and qualification for such programs does not guarantee we will be able to develop or market our product more quickly.***

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 such as the FDA's accelerated approval program, 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. For example, the DYNAMO study is designed with the potential to support accelerated approval of duvelisib for treatment of patients with follicular lymphoma or small lymphocytic lymphoma, or SLL. The availability of accelerated approval is dependent on a number of factors including whether we generate positive safety and efficacy data from the study and duvelisib has demonstrated a meaningful benefit over available therapies. In addition, even after receiving accelerated approval, companies are required to conduct studies to confirm the anticipated clinical benefit of a drug, known as confirmatory trials. If the confirmatory trial shows that the drug actually provides a

**Table of Contents**

clinical benefit, then the FDA grants traditional approval for the drug. If the confirmatory trial does not show that the drug provides clinical benefit, FDA has regulatory procedures in place that could lead to removing the drug from the market. We cannot guarantee that duvelisib will qualify for accelerated approval or, even if it receives accelerated approval, that we would successfully complete a confirmatory study. In particular, we are aware that Gilead has received accelerated approval for idelalisib, its product, to treat follicular lymphoma and SLL. Idelalisib is currently approved by the FDA for CLL. If Gilead is able to complete its confirmatory study and receive full approval to market idelalisib for the treatment of follicular lymphoma or SLL faster than anticipated, our efforts to seek accelerated approval for duvelisib for the treatment of follicular lymphoma or SLL may be materially adversely affected. Moreover, even if we are able to receive accelerated approval for duvelisib the FDA may upon review of data from DYNAMO+R later decide that duvelisib no longer meets the conditions for approval resulting in revocation of approval.

***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, Infinity, or an Infinity vendor, 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.

***Although we have received fast track designation by the FDA for duvelisib for a certain indication, that designation may not actually lead to a faster development or regulatory review or approval process and it does not ensure that we will receive marketing approval.***

The FDA has designated as a fast track development program both the investigation of duvelisib for treatment of patients with follicular lymphoma who have received at least two prior therapies and the investigation of duvelisib for the treatment of patients with CLL who have received at least one prior therapy. Any drug sponsor may apply for such designation if their product candidate is intended for the treatment of a serious or life-threatening disease or condition and the product candidate demonstrates the potential to

**Table of Contents**

address an unmet medical need. The FDA has broad discretion whether or not to grant fast track designation. Although duvelisib has received such designation this may not actually result in a faster development process, review or approval compared to standard FDA procedures. The FDA may withdraw fast track designation if it believes that the clinical development program does not continue to meet the criteria for fast track designation.

***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, AbbVie has received approval to manufacture and market ibrutinib, a BTK inhibitor for the treatment of CLL, an indication for which we are currently evaluating duvelisib in our DUO and SYNCHRONY clinical trials, and Gilead has received accelerated approval to manufacture and market idelalisib for the treatment of follicular lymphoma and SLL, indications for which we are currently evaluating duvelisib.

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. For example, we have designed our DYNAMO study with the potential to support accelerated approval of duvelisib for the treatment of follicular lymphoma and SLL, indications for which Gilead has received accelerated approval to manufacture and market idelalisib. If we experience delays in the conduct of our DYNAMO study, or Gilead is able to complete its confirmatory study and receive full approval to market idelalisib for the treatment of follicular lymphoma or SLL faster than anticipated, our efforts to seek accelerated approval for duvelisib for the treatment of follicular lymphoma or SLL may be materially adversely affected.

***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 noncompliance 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 may not be able to successfully transition responsibilities for the manufacturing of Duvelisib Products to AbbVie.***

We may be unsuccessful in transferring the responsibility to manufacture Duvelisib Products to AbbVie. The transition process may be more complicated, time consuming and expensive than originally intended, which may negatively affect the supply of Duvelisib Products. Should the strategic collaboration with AbbVie terminate, the process of transitioning manufacturing back to us may be time consuming and expensive, and we may become unable to maintain an adequate supply of Duvelisib Products worldwide.

***We currently have limited marketing, sales and distribution experience and capabilities and are dependent upon AbbVie to commercialize Duvelisib Products outside the United States.***

We and AbbVie share the obligations to commercialize Duvelisib Products in oncology in the United States, and AbbVie has the sole obligation to commercialize Duvelisib Products in oncology outside the United States. To successfully commercialize Duvelisib Products, we will need to, and we intend to, establish adequate marketing, sales and distribution capabilities for commercialization in the United States. Failure to establish these capabilities, whether due to insufficient resources or some other cause, will limit or potentially halt our ability to successfully commercialize any product candidates, thereby adversely affecting 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, managed care organizations, third-party payers, 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 or more difficult route of administration, compared to competitive products;

lack of cost-effectiveness;

lack of reimbursement from managed care plans and other third-party payors;

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 our 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 payers. As a threshold for coverage and reimbursement, third-party payers in the United States generally require that product candidates have been approved for marketing by

## **Table of Contents**

the FDA. Third-party payers 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 twelve 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 managed care organizations and additional legislative proposals.

### ***Healthcare reform measures could hinder or prevent our future products commercial success.***

The United States government and other governments have shown significant interest in pursuing healthcare reform, as evidenced by the passing of the Patient Protection and Affordable Care Act, or PPACA, and the Health Care and Education Reconciliation Act. These healthcare reform laws have the effect of increasing the number of individuals who receive health insurance coverage and closing 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 laws, however, also implement 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 healthcare reform laws 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 healthcare reform laws' provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program (commonly known as the donut hole), we will also be required to provide a 50% discount on brand name prescription drugs sold to beneficiaries who fall within the donut hole.

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

royalties payable to us.

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

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

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

the anti-kickback provisions of the Social Security Act, which prohibit, 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;

## **Table of Contents**

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 payers that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers;

the 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 payer, 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.

***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

## **Table of Contents**

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.

Further, the America Invents Act created for the first time new procedures to challenge the validity of issued patents in the United States, including post-grant review and inter partes review, or IPR, proceedings, which some third parties have been using to cause the cancellation of selected or all claims of issued patents of competitors. For a patent with a priority date of March 16, 2013 or later, a petition for post-grant review can be filed by a third party in a nine-month window from issuance of the patent. A petition for IPR can be filed immediately following the issuance of a patent if the patent was filed prior to March 16, 2013. A petition for IPR can be filed after the nine-month period for filing a post-grant review petition has expired for a patent with a priority date of March 16, 2013 or later. Post-grant review proceedings can be brought on any ground of challenge, whereas IPR proceedings can only be brought to raise a challenge based on published prior art. These adversarial actions at the PTO review patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts, and use a lower burden of proof than used in litigation in U.S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a U.S. patent cancelled in a PTO post-grant review or IPR proceeding than invalidated in a litigation in a U.S.

federal court.

If any of our patents were to be challenged by a third party in such a PTO proceeding, we would need to devote substantial resources to such proceedings. There also is no guarantee that we or our licensors will be successful in defending the patent, which would result in a loss of the challenged patent right to us. In the first half of 2015, for example, a hedge fund and its affiliates, acting under the name the Coalition for Affordable Drugs, or CFAD, filed IPR petitions with the PTO to challenge the validity of patents underlying six pharmaceutical products. The review of CFAD's petitions remains underway, but, if the Patent Trial and Appeal Board were to invalidate the patents, the businesses of the patent owners could be materially harmed. Although none of the patents underlying our intellectual property portfolio has been similarly challenged to date, were they to be challenged, we could not provide any assurance concerning the duration or outcome of such proceedings.

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

## **Table of Contents**

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 lose valuable intellectual property rights. In addition, the legal protection afforded to inventors and owners of intellectual property in countries outside of the United States may not be as protective of intellectual property rights as in the United States, and we may, therefore, be unable to acquire and protect intellectual property developed by these contractors to the same extent as if these development activities were being conducted in the United States. If we encounter difficulties in protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

In addition, we rely on intellectual property assignment agreements with our strategic alliance partners, vendors, employees, consultants, 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 or derivation proceedings declared by the PTO or the third party to determine priority of invention in the United States. An adverse decision in an interference or derivation 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

**Table of Contents**

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.

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.***

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 Takeda, we could lose our license rights under that agreement, including rights to duvelisib.

**Table of Contents**

**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 we expect it to 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;

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 collaboration and license agreement with AbbVie, or our amended and restated development and license agreement with Takeda;

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;

the regulatory approval of 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;

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 bylaws 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.



**Table of Contents**

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% 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% 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% 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.

*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 October 23, 2015, stockholders holding 5% or more of our common stock, as well as our executive officers, directors, and their respective affiliates, owned in the aggregate approximately 64% 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: November 5, 2015

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>Form</b>	<b>Incorporated by Reference</b>		<b>Filed with this 10-Q</b>
			<b>SEC Filing date</b>	<b>Exhibit Number</b>	
3.1	Restated Certificate of Incorporation of the Registrant.	10-Q	8/9/07	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	3/14/08	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 September 30, 2015, formatted in XBRL (eXtensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations and Comprehensive Income (Loss), (iii) the Condensed Consolidated Statements of Cash Flows, and (iv) Notes to Condensed Consolidated Financial Statements. Filed herewith.				X