INFINITY PHARMACEUTICALS, INC.
Form 10-Q
November 09, 2016
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549
FORM 10-Q
(Mark One)
ý QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2016
OR
¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to .
Commission file number 000-31141
INFINITY PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	33-0655706
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

784 Memorial Drive, Cambridge, Massachusetts 02139
(Address of principal executive offices) (zip code)
(617) 453-1000
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ý 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 ý No ¨

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

Large accelerated filer ý	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 ý

Number of shares of the registrant's Common Stock, $0.001 par value, outstanding on October 31, 2016: 49,729,719

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FOR THE QUARTER ENDED SEPTEMBER 30, 2016

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PART I. FINANCIAL INFORMATION

Item 1. Unaudited Condensed Consolidated Financial Statements

INFINITY PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets
(unaudited)
(in thousands, except share and per share amounts)

	September 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 98,507	$ 188,170
Available-for-sale securities	13,791	57,061
Prepaid expenses and other current assets	11,178	9,466
Total current assets	123,476	254,697
Property and equipment, net	24,451	28,240
Restricted cash	1,182	1,681
Long-term receivable (note 11)	2,453	1,821
Other assets	340	2,382
Total assets	$ 151,902	$ 288,821
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,786	$ 9,628
Accrued expenses	20,679	24,604
Deferred revenue, current	—	35,408
Financing obligation, current (note 11)	435	416
Total current liabilities	25,900	70,056
Deferred revenue, less current portion	—	95,531
Deferred rent (note 11)	4,527	4,632
Financing obligation, less current portion (note 11)	19,262	19,591
Other liabilities	92	454
Total liabilities	49,781	190,264
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, $0.001 par value; 1,000,000 shares authorized, no shares issued and outstanding at September 30, 2016 and December 31, 2015	—	—
Common Stock, $0.001 par value; 100,000,000 shares authorized, and 49,587,998 and 49,305,136 shares issued and outstanding, at September 30, 2016 and December 31, 2015, respectively	50	49
Additional paid-in capital	704,829	694,051
Accumulated deficit	(602,759)	(595,588)
Accumulated other comprehensive income	1	45
Total stockholders' equity	102,121	98,557
Total liabilities and stockholders' equity	$ 151,902	$ 288,821

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

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INFINITY PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Collaboration revenue	$—	$ 90,743	$ 18,723	$ 99,987
Operating expenses:				
Research and development	12,814	37,729	104,949	160,220
General and administrative	7,120	9,754	33,648	27,713
Total operating expenses	19,934	47,483	138,597	187,933
Gain on AbbVie Opt-Out (note 9)	—	—	112,216	—
Income (loss) from operations	(19,934)	43,260	(7,658)	(87,946)
Other income (expense):				
Interest expense	(305)	(311)	(921)	(1,058)
Investment and other income	741	75	1,408	298
Total other income (expense)	436	(236)	487	(760)
Income (loss) before income taxes	(19,498)	43,024	(7,171)	(88,706)
Income taxes	—	(480)	—	(480)
Net income (loss)	$(19,498)	$ 42,544	$(7,171)	$(89,186)
Earnings (loss) per common share:				
Basic	$(0.39)	$ 0.85	$(0.15)	$(1.82)
Diluted	$(0.39)	$ 0.84	$(0.15)	$(1.82)
Weighted average number of common shares outstanding:				
Basic	49,583,776	49,188,443	49,448,725	49,051,836
Diluted	49,583,776	49,764,910	49,448,725	49,051,836
Other comprehensive loss:				
Net unrealized holding losses on available-for-sale securities arising during the period	(1)	(104)	(44)	(115)
Comprehensive income (loss)	$(19,499)	$ 42,440	$(7,215)	$(89,301)

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

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INFINITY PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Cash Flows
(unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2016	2015
Operating activities		
Net loss	$(7,171)	$(89,186)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash gain on AbbVie Opt-Out	(112,216)	—
Depreciation	2,566	1,557
Stock-based compensation including 401(k) match	10,317	11,180
Impairment of property and equipment	771	—
Loss (gain) on sale of fixed assets	(488)	—
Amortization of loan commitment asset	—	647
Other, net	137	182
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	654	4,095
Due from AbbVie	—	(130,000)
Accounts payable, accrued expenses and other liabilities	(9,126)	10,093
Due to Takeda	—	(6,667)
Deferred revenue	(18,723)	30,012
Deferred rent	(109)	1,666
Net cash used in operating activities	(133,388)	(166,421)
Investing activities		
Purchases of property and equipment	(661)	(5,416)
Proceeds from sale of assets	1,146	—
Purchases of available-for-sale securities	(52,490)	(64,440)
Proceeds from maturities of available-for-sale securities	11,953	63,841
Proceeds from sales of available-for-sale securities	83,625	464
Net cash provided by (used in) investing activities	43,573	(5,551)
Financing activities		
Proceeds from issuances of common stock related to stock incentive plans and awards	444	1,788
Proceeds from issuances of common stock related to employee stock purchase plan	18	472
Payments on construction liability	—	(273)
Payments on financing obligation	(310)	(136)
Net cash provided by financing activities	152	1,851
Net decrease in cash and cash equivalents	(89,663)	(170,121)
Cash and cash equivalents at beginning of period	188,170	307,405
Cash and cash equivalents at end of period	$98,507	$137,284
Supplemental cash flow information		
Cash paid for interest	$921	$411
Cash paid for income taxes	$—	$175
Supplemental schedule of noncash investing and financing activities		
Property and equipment in accrued expenses	$—	$189
Increase in property and equipment for amount paid by landlord	$—	$5,059

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

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Infinity Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Organization

Infinity Pharmaceuticals, Inc. is an innovative biopharmaceutical company dedicated to developing 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, 2016 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2016.

The information presented in the condensed consolidated financial statements and related footnotes at September 30, 2016, and for the three and nine months ended September 30, 2016 and 2015, is unaudited, and the condensed consolidated balance sheet amounts and related footnotes at December 31, 2015 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, 2015, which was filed with the U.S. Securities and Exchange Commission on February 23, 2016 (our “2015 Annual Report on Form 10-K”).

Liquidity

We have generated an accumulated deficit of $602.8 million and will require substantial additional capital to fund operations. Our future success is dependent on our ability to develop IPI-549 and ultimately upon our ability to attain profitable operations. We are in the process of reviewing a range of strategic alternatives that could result in potential changes to our current business strategy and future operations. We are subject to a number of risks similar to other life science companies, including, but not limited to, successful development of IPI-549 and our need for additional funding, which may not be available.

On October 29, 2016, we and Verastem, Inc., or Verastem, entered into a license agreement, which we and Verastem amended and restated on November 1, 2016, effective as of October 29, 2016. We refer to the amended and restated license agreement as the Verastem Agreement. Under the Verastem Agreement, we granted to Verastem an exclusive worldwide license for the research, development, commercialization, and manufacture in oncology indications of products containing duvelisib, an investigational, oral, dual inhibitor of phosphoinositide-3 kinase (PI3K)-delta and PI3K-gamma, or the Licensed Products (see Note 13).

As of September 30, 2016, we had cash, cash equivalents and short-term investments of $112.3 million. Excluding the potential $6 million and $22 million contingent payments in cash or stock from Verastem, we believe that our existing cash, cash equivalents and available-for-sale securities at September 30, 2016, will be adequate to satisfy our capital

needs into the first quarter of 2018 based on our operational plans, which do not include duvelisib expenses beyond the first quarter of 2017. Our operational plans also include lower 2017 monthly cash burn as a result of the restructuring plan announced in June 2016 and our restructuring plans in both September 2016 (see Note 12) and October 2016 (see Note 13).

On June 24, 2016, AbbVie Inc., or AbbVie, delivered to us a written notice to terminate the collaboration and license agreement, dated September 2, 2014, between us and AbbVie (the "AbbVie Agreement") unilaterally upon 90 days' written notice. The termination of the AbbVie Agreement became effective on September 23, 2016 (see Note 9). We will not receive

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additional payments from AbbVie. For more information, refer to the section titled “Liquidity and Capital Resources” in Item 2, Management’s Discussion and Analysis of Financial Condition and Results of Operations.

3. Significant Accounting Policies

Our significant accounting policies are described in Note 2, “Summary of Significant Accounting Policies,” in our 2015 Annual Report on Form 10-K.

Segment Information

We operate in one business segment, which focuses on drug 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 since September 2006 have been generated under research collaboration agreements.

Basic and Diluted Net Income (Loss) per Common Share

Basic net income (loss) per share is based upon the weighted average number of common shares outstanding during the period, excluding restricted stock that has been issued but has not yet vested. Diluted net income (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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Stock options	7,795,707	5,755,283	7,795,707	8,216,230
Warrants (excluded from treasury stock method)	1,000,000	1,000,000	1,000,000	1,000,000
Unvested restricted stock	1,341,600	—	1,341,600	—

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(in thousands, except share and per share amounts)			
Basic				
Net income (loss)	$(19,498)	$ 42,544	$(7,171)	$(89,186)
Undistributed earnings allocated to warrants	—	(848)	—	—
Net income (loss)	$(19,498)	$ 41,696	$(7,171)	$(89,186)
Weighted average common shares outstanding	49,583,776	49,188,443	49,448,725	49,051,836
Basic earnings (loss) per common share	$(0.39)	$ 0.85	$(0.15)	$(1.82)
Diluted				
Net income (loss)	$(19,498)	$ 42,544	$(7,171)	$(89,186)
Undistributed earnings allocated to warrants	—	(838)	—	—
Net income (loss)	$(19,498)	$ 41,706	$(7,171)	$(89,186)
Weighted average common shares outstanding	49,583,776	49,188,443	49,448,725	49,051,836
Effect of dilutive options	—	576,467	—	—
Weighted average common shares outstanding assuming dilution	49,583,776	49,764,910	49,448,725	49,051,836
Diluted earnings (loss) per common share	$(0.39)	$ 0.84	$(0.15)	$(1.82)

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 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. Revisions in the scope of a contract are recognized in expense in the period in which the facts that give rise to the revision become reasonably certain. During the three and nine months ended September 2016, we recognized a credit to research and development expense of $2.8 million as a result of negotiations with one of our clinical research organizations. This reduced our research and development expense and net loss by $2.8 million during the three and nine months ended September 30, 2016.

New Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (the “FASB”) issued Accounting Standard Update (“ASU”) No. 2014-15, Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern (“ASU No. 2014-15”), which provides guidance on determining when and how to disclose going concern uncertainties in the financial statements. The new standard requires management to perform interim and annual assessments of an entity’s ability to continue as a going concern. ASU No. 2014-15 is effective for the annual period ending after December 15,

2016, and for annual periods and interim periods thereafter. Early application is permitted. The adoption of this guidance would not have resulted in additional disclosure in our financial statements as of September 30, 2016 had we adopted. See Note 2 for additional information on our existing cash, cash equivalents and available-for-sale securities. We will continue to evaluate the potential impact that ASU No. 2014-15 may have.

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In February 2016, the FASB issued ASU No. 2016-02, Leases ("ASU No. 2016-02"), which requires lessees to recognize the assets and liabilities arising from leases on the balance sheet. ASU No. 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. We are currently evaluating the method of adoption and the potential impact that ASU No. 2016-02 may have on our financial position and results of operations.

In March 2016, the FASB issued ASU No. 2016-09, Improvements to Employee Share-Based Payment Accounting ("ASU No. 2016-09"), which simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. ASU No. 2016-09 is effective for annual periods beginning after December 15, 2016, and for interim periods within those annual periods. Early adoption is permitted in any interim or annual period. We are currently evaluating the method of adoption and the potential impact that ASU No. 2016-09 may have on our financial position and results of operations.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments ("ASU No. 2016-15"). The new standard clarifies classification of certain cash receipts and cash payments on the statement of cash flows to reduce existing diversity in practice. The new accounting guidance will be effective on January 1, 2018. We are currently evaluating the method of adoption and the potential impact that ASU No. 2016-15 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, 2016 and 2015 was comprised of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(in thousands)			
Research and development	$1,075	$2,102	$5,041	$6,474
General and administrative	1,714	1,713	5,276	4,706
Total stock-based compensation expense	$2,789	$3,815	$10,317	$11,180

As of September 30, 2016, we had approximately $8.0 million of total unrecognized compensation cost, net of estimated forfeitures, related to unvested stock options, which are expected to be recognized over a weighted-average period of 2.0 years.

Restricted Stock

In July 2016, our board of directors approved grants of 1,486,600 shares of restricted common stock to eligible employees who continue employment with us to explore and execute our future strategic options. Our board of directors approved additional grants of 35,000 shares of restricted common stock in September 2016. The restricted stock was granted pursuant to our 2010 stock incentive plan, is subject to forfeiture and will vest based on the achievement of specified performance conditions. The grant date fair value of the restricted stock is based on the closing price of our common stock on each of the grant dates. During the nine months ended September 30, 2016, 180,000 shares of restricted stock were forfeited, and no restricted stock vested. As of September 30, 2016, 1,341,600 shares are issued and unvested. We did not recognize any expense for the three months ended September 30, 2016. See Note 13, Subsequent Events, for additional detail on restricted stock.

Stock Options

During the nine months ended September 30, 2016, we granted options to purchase 1,617,472 shares of our common stock at a weighted average fair value of $3.75 per share and a weighted average exercise price of $6.14 per share. 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. For the nine months ended September 30, 2016 and 2015, the fair values were estimated using the Black-Scholes valuation model using the following weighted-average assumptions:

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	Nine Months Ended September 30,	
	2016	2015
Risk-free interest rate	1.8 %	1.5 %
Expected annual dividend yield	—	—
Expected stock price volatility	73.0 %	70.9 %
Expected term of options	5.4 years	5.3 years

During the nine months ended September 30, 2016, options to purchase 67,077 shares of common stock were exercised, with a weighted-average exercise price of $5.57.

Employee Stock Purchase Plan

The weighted-average fair value of each purchase right granted during the nine months ended September 30, 2016 and 2015 was $2.91 and $4.24, respectively. We suspended the Employee Stock Purchase Plan program on June 24, 2016. For the nine months ended September 30, 2016 and 2015, the fair values were estimated using the Black-Scholes valuation model using the following weighted-average assumptions:

	Nine Months Ended September 30,	
	2016	2015
Risk-free interest rate	0.8 %	0.4 %
Expected annual dividend yield	—	—
Expected stock price volatility	63.5 %	60.3 %
Expected term	1.3 years	1.3 years

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

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

	September 30, 2016			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	(in thousands)			
Cash and cash equivalents due in 90 days or less	$98,507	$ —	$ —	$98,507
Available-for-sale securities:				
U.S. government-sponsored enterprise obligations due in one year or less	13,790	1	—	13,791
Total available-for-sale securities	13,790	1	—	13,791
Total cash, cash equivalents and available-for-sale securities	$112,297	$ 1	$ —	$112,298

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	December 31, 2015			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	(in thousands)			
Cash and cash equivalents due in 90 days or less	$188,170	$ —	$ —	$188,170
Available-for-sale securities:				
Corporate obligations due in one year or less	46,049	52	(4)	46,097
Asset-backed securities due in one year or less	10,967	—	(3)	10,964
Total available-for-sale securities	57,016	52	(7)	57,061
Total cash, cash equivalents and available-for-sale securities	$245,186	$ 52	$ (7)	$245,231

We held five debt securities at September 30, 2016 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 $9.4 million. There were no material unrealized losses from these securities. As of September 30, 2016, we held no securities in foreign financial institutions. 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, 2016.

We had no material realized gains or losses on our available-for-sale securities for the three and nine months ended September 30, 2016 and 2015. There were no other-than-temporary impairments recognized for the three and nine months ended September 30, 2016 and 2015.

6. Fair Value

We use a valuation hierarchy for disclosure of the inputs used to measure fair value. This hierarchy prioritizes the inputs into three broad levels. Level 1 inputs, which we consider the highest level inputs, are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value. The classification of a financial asset or liability within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement. For our fixed income securities, we reference pricing data supplied by our custodial agent and nationally known pricing vendors, using a variety of daily data sources, largely readily-available market data and broker/dealer 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, 2016 and December 31, 2015.

The following table provides the assets carried at fair value measured on a recurring basis as of September 30, 2016:

	Level 1	Level 2
	(in thousands)	
Assets:		
Cash and cash equivalents	$88,143	$10,364
U.S. government-sponsored enterprise obligations	—	13,791
Total	$88,143	$24,155

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:

- 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 including TRACE® reported trades.

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 our valuation methods during the nine months ended September 30, 2016. 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, 2016. We had no available-for-sale securities that were classified as Level 3 at any point during the nine months ended September 30, 2016 or during the year ended December 31, 2015.

7. Prepaid expenses and other current assets

Prepaid expenses and other current assets consist of the following:

	September 30, 2016	December 31, 2015
	(in thousands)	
Other prepaid expenses	$9,256	$ 6,898
Other current assets	1,422	1,383
Restricted cash	500	—
Short-term receivable (note 11)	—	1,185
Total prepaid expenses and other current assets	$11,178	$ 9,466

8. Other assets

Other assets consist of the following:

	September 30, 2016	December 31, 2015
	(in thousands)	
Long term prepaid expenses	$235	$ 284
Long term value-added tax receivable	60	2,034
Other assets	45	64
Total other assets	$340	$ 2,382

9. Collaborations

AbbVie

The AbbVie Agreement

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On September 2, 2014, we entered into the AbbVie Agreement. Under the AbbVie Agreement, we and AbbVie agreed to develop and commercialize in oncology indications products containing duvelisib, an oral, dual inhibitor of the delta and gamma isoforms of phosphoinositide-3-kinase, or PI3K. We refer to products containing duvelisib as Duvelisib Products. IPI-549, an orally administered, selective PI3K-gamma inhibitor, was excluded from the collaboration.

Under the terms of the AbbVie Agreement, we and AbbVie agreed to share equally commercial profits or losses of Duvelisib Products in the United States, including sharing equally the existing royalty obligations to Mundipharma and 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. For more information about such obligations, refer to the section below titled “Takeda.”

AbbVie 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. This tiered royalty could have been further reduced based on specified factors, including patent expiry, generic entry, and royalties paid to third parties.

We and AbbVie shared oversight of development and agreed to use diligent efforts, as defined in the AbbVie Agreement, to carry out our development activities under an agreed upon development plan. We had primary responsibility for the conduct of development of Duvelisib Products, unless otherwise agreed, and AbbVie had responsibility for the conduct of certain contemplated combination clinical studies, including those examining duvelisib and venetoclax, a selective first-in-class B-cell lymphoma 2 inhibitor, which we refer to as the AbbVie Studies. The development and manufacturing costs for the AbbVie Studies were shared equally. During the nine months ended September 30, 2016, we recognized an expense of $1.0 million in research and development expense related to our share of the AbbVie Studies cost. 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 had the responsibility to manufacture Duvelisib Products until the transition of manufacturing responsibility to AbbVie, which we expected to occur as promptly as practicable while ensuring continuity of supply. Excluding the AbbVie Studies, we were responsible for all costs to develop and manufacture Duvelisib Products up to a maximum amount of $667 million. During the nine months ended September 30, 2016, we recognized an expense of $6.6 million in research and development expense related to costs incurred by AbbVie for other than the AbbVie Studies. 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.

We and AbbVie shared operational responsibility and decision making authority for commercialization of Duvelisib Products in the United States. Prior to commercialization and regulatory approval, we recognized the cost of manufacturing as a component of research and development and the cost of commercialization as a component of general and administrative expenses. During the three and nine months ended September 30, 2016 and 2015, we accounted for AbbVie’s share of the costs as a reduction of the related expense. We recognized a credit of approximately $0.1 million and $2.6 million in research and development expense and general and administrative expense, respectively, related to these costs during the nine months ended September 30, 2016. We recognized credits of $0.1 million and $0.5 million during the three and nine months ended September 30, 2015, respectively, in research and development expense related to these costs. We recognized credits of $0.6 million and $0.9 million during the three and nine months ended September 30, 2015, respectively, in general and administrative expense related to these costs.

Under the AbbVie Agreement, AbbVie 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, our Phase 2 clinical study evaluating the efficacy and safety of duvelisib in patients with refractory indolent non-Hodgkin

lymphoma, or iNHL. Of the total $405 million received from AbbVie, we allocated $234.3 million to the license which was recognized as revenue upon receipt of the upfront payment and achievement of the milestone payment. Revenue related to development services and committee services was recognized using the proportionate performance method. We initially estimated that services would be performed through 2019.

The AbbVie Agreement was intended to remain in effect until all development, manufacturing and commercialization of Duvelisib Products ceased, unless terminated earlier. AbbVie had the right to terminate the AbbVie Agreement for convenience after a specified notice period as described below.

AbbVie Opt-Out

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On June 24, 2016, AbbVie delivered to us a written notice that AbbVie was exercising its right to terminate the AbbVie Agreement unilaterally upon 90 days' written notice, which we refer to as the AbbVie Opt-Out. The termination of the AbbVie agreement was effective on September 23, 2016.

The AbbVie Opt-Out was irrevocable, and we had no obligation to continue to provide AbbVie any services related to Duvelisib Products after June 24, 2016. We did not recognize revenue during the three months ended September 30, 2016. We recognized revenue of $18.7 million during the nine months ended September 30, 2016 related to the development and committee services provided through June 24, 2016. We recorded the remaining amounts already received from AbbVie and allocated to development and committee services of $112.2 million as a gain during the nine months ended September 30, 2016, reflecting the fact that we are no longer obligated to provide any such services and have no obligation to refund any of the payments received to date.

Upon formal termination of the AbbVie Agreement on September 23, 2016, we received all rights to the regulatory filings related to duvelisib, our license to AbbVie terminated, and AbbVie granted us an exclusive, perpetual, irrevocable, royalty-free license, under certain patent rights and know-how controlled by AbbVie, to develop, manufacture and commercialize in oncology indications worldwide products containing duvelisib, excluding any compound which is covered by patent rights controlled by AbbVie or its affiliates.

Other than pursuant to the wind-down plan described below, which did not include any development or committee service obligations for us, neither party has any financial obligation to the other. In connection with the AbbVie Opt-Out, AbbVie will not pay any royalties or any of the additional $400 million in milestone payments that we could have potentially earned under the AbbVie Agreement.

Wind-Down Plan

During the three months ended September 30, 2016, we and AbbVie finalized the wind-down plan to ensure a smooth transition of the responsibilities of the parties to us.

We recorded $1.9 million in research and development expense for AbbVie's clinical wind-down services during the three months ended September 30, 2016 for services rendered during the quarter. In connection with finalization of the wind-down plan, we received $2.7 million from AbbVie for reimbursement of our wind-down activities in medical affairs and commercial services, which was recorded as a credit to research and development expense of $0.9 million and a credit to general and administrative expense of $1.8 million during the three months ended September 30, 2016.

We do not expect to receive any other proceeds from AbbVie for our wind-down activities, and we do not expect to incur any additional expenses for their clinical wind-down services.

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, which covers duvelisib and IPI-549. In January 2012, Intellikine was acquired by Takeda, acting through its Millennium business unit. In December 2012, we amended and restated our development and license agreement with Takeda. We refer to our PI3K inhibitor program licensor as Takeda and to the amended and restated development and license agreement as the Takeda Agreement.

Under the terms of the Takeda Agreement, as amended by the July 2014 and September 2016 amendments described in more detail below, we are obligated to pay Takeda an aggregate of up to $5 million in 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 $165 million in success-based milestone payments related to the approval and commercialization of one product, which could be IPI-549.

Except for duvelisib 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.

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The Takeda 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 in accordance with its terms. Either party may terminate the Takeda 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 Takeda 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 Takeda 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 Takeda Agreement also provides for customary reciprocal indemnification obligations of the parties.

September 2016 Amendment

In September 2016, we entered into a second amendment with Takeda. Under the second amendment, effective upon our license, sublicense or asset sale of duvelisib, which we refer to as a qualifying transaction, we are no longer obligated to pay Takeda any remaining milestone payments for the development, approval or commercialization of duvelisib. Additionally, upon entry into a qualifying transaction, our obligation to use diligent efforts to develop products is reduced from two products to one product. In return, we are obligated to pay Takeda 50 percent of all revenue arising from each qualifying transaction for duvelisib, subject to certain exceptions. We believe the Verastem Agreement constitutes a qualifying transaction.

July 2014, Amendment

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 Takeda Agreement to pay to Takeda tiered royalties 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 year ended December 31, 2015, respectively, as there is no alternative future use beyond the existing research and development activities.

10. Accrued Expenses

Accrued expenses consisted of the following:

	September 30, 2016	December 31, 2015
	(in thousands)	
Accrued restructuring	$7,998	$ —
Accrued compensation and benefits	2,749	8,732
Accrued drug manufacturing costs	304	3,494
Accrued clinical studies	6,375	8,531
Accrued preclinical studies	142	539
Deferred rent, current	258	261
Other	2,853	3,047
Total accrued expenses	$20,679	$ 24,604

11. Leases

We lease our facilities under two separate lease agreements with BHX, LLC, as trustee of 784 Realty Trust for space in Cambridge, Massachusetts at 784 Memorial Drive and ARE-770/784/790 Memorial Drive, LLC for space at 780 and 790 Memorial Drive.

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. The term of the Lease commenced on November 1, 2014, the Commencement Date, and expires on March 31, 2025. 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. We provided a

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security deposit to BHX, LLC 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 have been included in our accompanying condensed consolidated balance sheets as prepaid expenses and other current assets and restricted cash (see Note 7). 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 and no later than 12 months prior to the expiration of the Lease.

On the Commencement Date, building construction was initiated to suit our then-anticipated 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 bearing the risk of cost overruns. As such, we were deemed the owner of the building for accounting purposes, and we recorded the building in our fixed asset balance, although legal ownerships remains with BHX, LLC. Our balance sheet also reflects a financing obligation related to this building. Depreciation on the building and building improvements commenced in June 2015.

At September 30, 2016, future minimum payments under the Lease for 784 Memorial Drive were approximately $18.6 million, which is comprised of $0.5 million for the remainder of 2016, $2.0 million for each of calendar years 2017 through 2019, $2.3 million for the calendar year 2020 and $9.8 million through March 2025.

We divide our future payments under the Lease 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 which commenced in November 2014 and is recorded on a straight-line basis over the initial term of the Lease. Rent expense pertaining to the land was approximately $0.1 million and $0.3 million for the three and nine months ended September 30, 2016 and September 30, 2015, respectively.

780/790 Memorial Drive Lease Arrangement
On November 6, 2014, we entered into a Seventh Amendment to Lease, or the Lease Amendment, by and between us and ARE-770/784/790 Memorial Drive, LLC, or ARE, 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 54,837 square feet, of which 51,000 square feet are located at 780 Memorial Drive, or the 780 Premises, and the remaining 3,837 square feet are located at 790 Memorial Drive, or the 790 Premises; effective February 1, 2016, we surrendered 13,183 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).

At September 30, 2016, future minimum payments under the lease for 780 / 790 Memorial Drive were approximately $31.9 million, which is comprised of $0.9 million for the remainder of 2016, $3.6 million for each of calendar years 2017 through 2018, $3.8 million for each of the calendar years 2019 through 2024 and $1.0 million through March 2025.

We also received the right to receive allowances totaling $3.0 million for the design and construction of tenant improvements. Upon execution of the Lease Amendment, the allowances totaling $3.0 million were reflected on our condensed consolidated balance sheets as a receivable, with a corresponding amount included in deferred rent liability. See Note 12 for Restructuring Activities.

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 security deposit has been included in our accompanying condensed consolidated balance sheets as restricted cash.

On November 8, 2016, we and ARE entered into an agreement for termination of lease and voluntary surrender of premises effective October 31, 2016. See Note 13, Subsequent Events, for additional detail on the lease termination agreement.

12. Restructuring Activities

In June 2016, we reported the top line data from DYNAMO™, a registration-focused Phase 2 monotherapy study evaluating the efficacy and safety of duvelisib, an investigational, oral, dual inhibitor of phosphoinositide-3-kinase (PI3K)-delta and PI3K-gamma, in patients with refractory indolent non-Hodgkin lymphoma (iNHL). The study met its primary endpoint

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with an overall response rate of 46 percent, all of which were partial responses, among 129 patients with iNHL. On June 24, 2016, AbbVie delivered to us a written notice that AbbVie was exercising its right to terminate the AbbVie Agreement unilaterally upon 90 days' written notice, which we refer to as the AbbVie Opt-Out.

June 2016 Restructurings

As a result of our discussions with AbbVie regarding our collaboration and the subsequent AbbVie Opt-Out, our board of directors approved a strategic restructuring in order to preserve our resources as we determine future strategic plans, which included significant employee headcount reductions during June 2016. We recognized a credit of $1.0 million and additional expense of $0.7 million in total restructuring charges for the three months ended September 30, 2016 in research and development expenses and general and administrative expenses, respectively. We recognized $10.9 million and $5.5 million in total restructuring charges for the nine months ended September 30, 2016 in research and development expenses and general and administrative expenses, respectively.

We continue to evaluate the leases for the various facilities that we currently occupy at this time. See Note 13 for Subsequent Event regarding our facility lease at 780 / 790 Memorial Drive and our future additional cash outlays. If we pursue and successfully restructure the 784 Memorial Drive facility lease later in 2016 or 2017, we could potentially incur additional charges upon our exit from the space. Such potential future charges could include further impairments and lease exit payments related to our office space at 784 Memorial Drive in Cambridge, Massachusetts. At September 30, 2016 and December 31, 2015, the accompanying condensed consolidated balance sheets reflect the 784 Memorial Drive building and accumulated construction costs of $22.3 million and $23.0 million, respectively, and a total financing obligation of approximately $19.7 million and $20.0 million, respectively.

We reduced our employee headcount by approximately 66 percent compared to our employee headcount as of December 31, 2015. We have existing severance plans which outline contractual termination benefits. We recognized all contractual severance and benefits outlined in the plan when termination was probable and reasonably estimable in accordance with FASB ASC Topic 712, Compensation - Nonretirement Postemployment Benefits.

In June 2016, we made strategic decisions to close BRAVURA, a Phase 3 study of duvelisib in patients with relapsed iNHL, and decided not to enroll additional patients in CONTEMPO, a Phase 1b/2 study of duvelisib in treatment-naïve patients with follicular lymphoma. We incurred approximately $1.0 million during the three months ended September 30, 2016 related to BRAVURA and CONTEMPO clinical and development expenses. On October 29, 2016, we and Verastem entered into a license agreement, which we and Verastem amended and restated on November 1, 2016, effective as of October 29, 2016 (see Note 13). Under the Verastem Agreement, we will assume financial responsibility for the shutdown of certain specified clinical studies up to a maximum of $4.5 million, including the CONTEMPO and BRAVURA studies.

Approximately $0.5 million and $1.7 million of expense was recorded during the three and nine months ended September 30, 2016, respectively, related to the write-off of prepaid expenses that were not expected to continue and other payments that were due as a result of early terminations.

We identified and recorded the impairment of approximately $1.0 million of unique and identifiable laboratory equipment, as well as $0.4 million in furniture and fixtures during the three months ended June 30, 2016. During the three months ended September 30, 2016, we realized proceeds of $1.6 million related to sale of the laboratory equipment and recognized a credit of $1.1 million in research and development expense and $0.5 million in investment and other income.

In performing the recoverability test for the 780 / 790 Memorial Drive asset group, we concluded that the asset group was not recoverable. We recorded an impairment charge of $0.1 million and $0.8 million related to 780 / 790 Memorial Drive assets, including the related tenant improvement allowance (see Note 11), after comparing the fair value (using probability weighted scenarios with discounted cash flows) to the asset group's carrying value, for the three and nine months ended September 30, 2016, respectively.

In performing the recoverability test for the 784 Memorial Drive asset group, we concluded that the asset group was not recoverable. We had an independent appraisal performed for the 784 Memorial building and improvements. We concluded no impairment was needed as the fair market value (considering the cost approach, sales comparison approach and the income approach) exceeded the asset group's carrying value.

September 2016 Restructuring

As a result of our progress on strategic initiatives with duvelisib in September 2016, our board of directors approved further headcount reductions during September 2016. The September 2016 restructuring reduced our employee headcount by approximately four percent compared to our employee headcount as of December 31, 2015. Included in the table below, we recognized $0.4 million and $0.2 million in total restructuring charges for the three months ended September 30, 2016 in

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research and development expenses and general and administrative expenses, respectively, related to the September restructuring.

Summary Table

The following table summarizes the impact of the June 2016 and September 2016 restructuring activities on our operating expenses and payments for the nine months ended September 30, 2016 and the current liability remaining on our balance sheet as of September 30, 2016, in thousands:

	Charges incurred during the nine months ended September 30, 2016 (in thousands)	Amounts paid through September 30, 2016	Less non-cash charges during the nine months ended September 30, 2016	Amounts accrued at September 30, 2016
Employee severance, benefits and related costs for work force reduction	$ 13,791	$ 5,226	$ 907	$ 7,658
Long-lived asset impairment	1,324	—	1,324	—
Contract termination, prepaid expense write-offs and other related costs	1,806	424	1,042	340
Total restructuring	$ 16,921	$ 5,650	$ 3,273	$ 7,998

13. Subsequent Events

Verastem

On October 29, 2016, we and Verastem entered into a license agreement, which we and Verastem amended and restated on November 1, 2016, effective as of October 29, 2016. We refer to the amended and restated license agreement as the Verastem Agreement. Under the Verastem Agreement, we granted to Verastem an exclusive worldwide license for the research, development, commercialization, and manufacture in oncology indications of products containing duvelisib, an investigational, oral, dual inhibitor of PI3K-delta and PI3K-gamma, or the Licensed Products. Upon entry into the Verastem Agreement, Verastem assumed financial responsibility for activities that were part of our ongoing duvelisib program, including a randomized, Phase 3 monotherapy clinical study in patients with relapsed/refractory chronic lymphocytic leukemia which we refer to as the DUO Study. We will assume financial responsibility for the shutdown of certain specified clinical studies up to a maximum of $4.5 million. Following a short transition period, Verastem will assume all operational responsibility for the duvelisib program. Verastem is obligated to use diligent efforts to develop and commercialize one Licensed Product. During the term of the Verastem Agreement, we have agreed not to research, develop, manufacture or commercialize duvelisib in any indication in humans or animals.

Pursuant to the terms of the Verastem Agreement, Verastem is required to make the following payments to us in cash or, at Verastem’s election, in whole or in part, in shares of Verastem common stock: (i) $6 million upon the completion of the DUO Study if the results of the DUO Study meet certain pre-specified criteria and (ii) $22 million upon the approval of a new drug application in the United States or an application for marketing authorization with a regulatory authority outside of the United States for a Licensed Product. For any portion of any of the foregoing payments which

Verastem elects to issue in shares of common stock in lieu of cash, the number of shares of common stock to be issued would be determined by multiplying (1) 1.025 by (2) the number of shares of common stock equal to (a) the amount of the payment to be paid in shares of common stock divided by (b) the average closing price of a share of common stock as quoted on NASDAQ for a twenty day period following the public announcement of the applicable milestone event. The shares of common stock would be issued as unregistered securities, and Verastem would have an obligation to promptly file a registration statement with the SEC to register such shares for resale. Any issuance of shares would be subject to the satisfaction of closing conditions, including that all material authorizations, consents, approvals and the like necessary for such issuance shall have been obtained.

Verastem is also obligated to pay us royalties on worldwide net sales of Licensed Products ranging from the mid-single digits to the high single-digits. The royalties will expire on a product-by-product and country-by-country basis until the latest to occur of (i) the last-to-expire patent right covering the applicable Licensed Product in the applicable country, (ii) the last-to-expire patent right covering the manufacture of the applicable Licensed Product in the country of manufacture of such Licensed Product, (iii) the expiration of non-patent regulatory exclusivity in such country and (iv) ten years following the first commercial sale of a Licensed Product in a country, provided that if royalties on net sales for a Licensed Product in the United States are payable solely on the basis of non-patent regulatory exclusivity, the applicable royalty on net sales for such Licensed

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Product in the United States will be reduced by 50%. The royalties are also subject to reduction by 50% of certain third-party royalty payments or patent litigation damages or settlements which might be required to be paid by Verastem if litigation were to arise, with any such reductions capped at 50% of the amounts otherwise payable during the applicable royalty payment period.

In addition to the foregoing, Verastem is obligated to pay us an additional royalty of 4% on worldwide net sales of Licensed Products to cover the reimbursement of research and development costs owed by us to Mundipharma International Corporation Limited, or Mundipharma and Purdue Pharmaceutical Products L.P., or Purdue. Once we have fully reimbursed Mundipharma and Purdue, the royalty obligations will be reduced to 1% of net sales in the United States, which we refer to as the Trailing Mundipharma Royalties. The Trailing Mundipharma Royalties are payable until the later to occur of the last-to-expire of specified patent rights and the expiration of non-patent regulatory exclusivities in a country. Each of the above royalty rates is reduced by 50% on a product-by-product and country-by-country basis if the applicable royalty is payable solely on the basis of non-patent regulatory exclusivity. In addition, the Trailing Mundipharma Royalties are subject to reduction by 50% of certain third-party royalty payments or patent litigation damages or settlements which might be required to be paid by Verastem if litigation were to arise, with any such reductions capped at 50% of the amounts otherwise payable during the applicable royalty payment period.

We and Verastem have made customary representations and warranties and have agreed to certain customary covenants, including confidentiality and indemnification.

The Verastem Agreement expires when each party no longer has any obligations to the other party. Verastem has the right to terminate the Verastem Agreement upon at least 180 prior written notice to us at any time following the determination that the DUO Study has or has not met its pre-specified primary endpoint. Each party can terminate the Verastem Agreement if the other party materially breaches or defaults in the performance of its obligations. If we terminate the Verastem Agreement for Verastem's material breach, patent challenge, or insolvency, or if Verastem terminates for convenience, then, at our request and subject to our execution of a waiver of certain types of damages, Verastem will transition the duvelisib program back to us at Verastem's cost. If Verastem terminates for our breach or insolvency, Verastem will effect a more limited transition of the duvelisib program to us at our request and cost, subject to our execution of a waiver of certain types of damages, and we will thereafter pay to Verastem a low single-digit royalty on net sales of Licensed Products.

October Restructuring

On October 28, 2016, our Board of Directors approved a strategic restructuring in connection with and subject to the entry into the Verastem Agreement. The restructuring included workforce reductions of 19 positions across the organization representing approximately 54 percent of our workforce at the time of the restructuring. We expect the workforce restructuring to be fully completed by January 6, 2017. We currently expect to incur severance, benefits and related costs of approximately $5 million, to be paid during the year ended December 31, 2017. We are continuing to review the potential impact of the restructuring and is unable to estimate any additional restructuring costs or charges at this time.

Restricted Stock

On October 31, 2016, our board of directors approved the vesting of restricted stock with performance conditions related to strategic options for duvelisib. 751,789 shares of restricted stock vested as of October 31, 2016, and the resulting expense will be recorded in the three months ended December 31, 2016.

In October 2016 and November 2016, our board of directors approved grants of 205,400 shares and 65,250 shares, respectively, of restricted common stock to eligible employees who continue employment with us to explore and execute our future strategic options. The restricted stock was granted pursuant to our 2010 stock incentive plan, is subject to forfeiture and will vest based on the achievement of specified performance or other conditions.

780/ 790 Memorial Drive Lease Termination

On November 8, 2016, we and ARE-770/784/790 Memorial Drive, LLC, or ARE, entered into an agreement for termination of lease and voluntary surrender of premises effective October 31, 2016, or the 780 / 790 Memorial Drive Termination Agreement. Under the 780 / 790 Memorial Drive Termination Agreement, we and ARE terminated by mutual consent our lease agreement, by and between us and ARE, dated as of July 2, 2002, as amended, which we refer to as the 780 / 790 Memorial Drive Lease Agreement, regarding our facilities at 780 Memorial Drive and 790 Memorial Drive, Cambridge, MA 02139, which we refer to as the Leased Properties. We have elected to terminate the 780 / 790 Memorial Drive Lease Agreement to consolidate our facilities as part of our strategic restructuring efforts.

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The 780 / 790 Memorial Drive Lease Agreement was previously scheduled to expire on May 31, 2025. Under the 780 / 790 Memorial Drive Lease Agreement, we also had two separate five-year options to extend our possession of the Leased Properties until 2035. Pursuant to the 780 / 790 Memorial Drive Termination Agreement, subject to our surrender of the Leased Properties, the Lease Agreement expiration date will be accelerated to October 31, 2016, which we refer to as the Termination Date.

As a result of our early termination, we owe to ARE a termination payment of approximately $1.8 million, comprised of a $1.7 million fee as consideration for ARE's agreement to enter into the 780 / 790 Memorial Drive Termination Agreement and a payment of approximately $64 thousand by us to ARE in lieu of our performance of certain restoration requirements with regards to the Leased Properties. Pursuant to the terms of the 780 / 790 Memorial Drive Lease Agreement, ARE will refund a portion of our $0.6 million security deposit.

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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 goals and 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," "seek," "target," "goal," "potenti "could," "should," "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 made herein. 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, our ability to implement our strategic plans, our ability to achieve cost-savings benefits from our restructuring and other risk factors described herein. We have included, and you should review, important factors in the cautionary statements included in this Quarterly Report on Form 10-Q, particularly in the section titled "Risk Factors" in Part II, 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 developing best-in-class medicines for patients with difficult-to-treat diseases. We combine proven scientific expertise with a passion for developing novel small molecule drugs that target disease pathways for potential applications in oncology.

On October 29, 2016, we and Verastem, Inc., or Verastem, entered into a license agreement, which we and Verastem amended and restated on November 1, 2016, effective as of October 29, 2016. We refer to the amended and restated license agreement as the Verastem Agreement. Under the terms of the Verastem Agreement, we granted to Verastem an exclusive worldwide license for the research, development, commercialization, and manufacture in oncology indications of products containing duvelisib, an investigational, oral, dual inhibitor of phosphoinositide-3 kinase (PI3K)-delta and PI3K-gamma, or the Licensed Products. A detailed description of the terms and conditions of the Verastem Agreement is contained below under the heading "Strategic Alliances - Verastem".

In October 2016, our board of directors approved an additional strategic restructuring in connection with and subject to the entry into the Verastem Agreement. As part of this restructuring, we will eliminate 19 positions across the organization representing approximately 54 percent of our workforce at the time of approval. Including this most recent restructuring, since June 2016 our board of directors has approved a total of 4 restructurings of the organization that have reduced our employee headcount by an aggregate of 174 positions representing approximately 79 percent of our employee headcount as of December 31, 2015. Further information regarding restructuring activities is described below under the heading "Liquidity and Capital Resources-Organizational Restructuring."

With the transition of the duvelisib program to Verastem, we are focusing our efforts on our lead product candidate, IPI-549, an orally administered, clinical-stage, immuno-oncology product candidate that selectively inhibits the gamma isoform of PI3K. IPI-549 is currently being evaluated in a Phase 1 clinical study in solid tumors. Preclinical data from studies investigating IPI-549 indicates that IPI-549 has the potential to heighten an anti-cancer response by targeting and inhibiting immune-suppressive macrophages within the 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 cancer, colon cancer and breast cancer.

Additionally, mice treated with IPI-549 in combination with a type of therapy called a “checkpoint inhibitor” showed greater tumor growth inhibition than treatment with either IPI-549 or the checkpoint inhibitor alone. Preclinical in vivo data also demonstrated that T-cells, a type of cell that plays a role in the human immune system, are required for the anti-tumor activity of IPI-549. These data were presented at CRI-CIMT-EATI-AACR - The Inaugural International Cancer Immunotherapy Conference, or AACR, in September 2015.

Based on our preclinical data generated to date, we have initiated a Phase 1 study evaluating IPI-549 in approximately 175 patients with advanced solid tumors. The study includes a dose-escalation phase to evaluate the safety, tolerability,

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pharmacokinetics, and pharmacodynamics of IPI-549 as a monotherapy, as well as a dose-escalation phase evaluating IPI-549 in combination with nivolumab, also known as Opdivo, a “checkpoint inhibitor” therapy being commercialized by Bristol-Myers Squibb, or BMS, that targets a receptor in the human body called programmed death receptor 1, or PD-1. In connection with our Phase 1 study of IPI-549, we have entered into a clinical supply agreement with BMS under which BMS agreed to provide nivolumab at no cost to us for use in our Phase 1 study of IPI-549. Under the agreement with BMS, we would provide BMS with clinical data from the study. If supported by data from the initial portion of the study, a Phase 1b portion would investigate IPI-549 in patients with selected solid tumors, including non-small cell lung cancer, melanoma and squamous cell carcinoma of the head and neck.

In September 2016, we announced initial clinical data from our Phase 1 study of IPI-549. Preliminary results from nine patients with advanced solid tumors showed that the safety, pharmacokinetics and pharmacodynamics of IPI-549 monotherapy treatment appeared favorable. These data were presented in a poster session at the Second CRI-CIMT-EATI-AACR International Cancer Immunotherapy Conference: Translating Science into Survival.

We believe that, with the transition of the duvelisib program to Verastem, our existing cash, cash equivalents and available-for-sale securities at September 30, 2016, will be adequate to satisfy our capital needs into the first quarter of 2018. We intend to focus our working capital resources on the development of IPI-549.

Strategic Alliances

Since our inception, corporate alliances have been integral to our strategy. These alliances have provided access to breakthrough science, significant research and development support and funding, and innovative drug development programs, all intended to help us realize the full potential of our product pipeline. All of our revenues since September 2006 have been generated under research collaborative agreements including our corporate alliances.

Verastem

Under the Verastem Agreement, we granted to Verastem an exclusive worldwide license for the research, development, commercialization, and manufacture in oncology indications of the Licensed Products. Upon entry into the Verastem Agreement, Verastem assumed financial responsibility for activities that were part of our ongoing duvelisib program, including a randomized, Phase 3 monotherapy clinical study in patients with relapsed/refractory chronic lymphocytic leukemia which we refer to as the DUO Study. We will assume financial responsibility for the shutdown of certain specified clinical studies up to a maximum of $4.5 million. Following a short transition period, Verastem will assume all operational responsibility for the duvelisib program. Verastem is obligated to use diligent efforts to develop and commercialize one Licensed Product. During the term of the Verastem Agreement, we have agreed not to research, develop, manufacture or commercialize duvelisib in any indication in humans or animals.

Pursuant to the terms of the Verastem Agreement, Verastem is required to make the following payments to us in cash or, at Verastem’s election, in whole or in part, in shares of Verastem common stock: (i) $6.0 million upon the completion of the DUO Study if the results of the DUO Study meet certain pre-specified criteria and (ii) $22.0 million upon the approval of a new drug application in the United States or an application for marketing authorization with a regulatory authority outside of the United States for a Licensed Product. For any portion of any the foregoing payments which Verastem elects to issue in shares of common stock in lieu of cash, the number of shares of common stock to be issued would be determined by multiplying (1) 1.025 by (2) the number of shares of common stock equal to (a) the amount of the payment to be paid in shares of common stock divided by (b) the average closing price of a share of common stock as quoted on NASDAQ for a twenty day period following the public announcement of the applicable milestone event. The shares of common stock would be issued as unregistered securities, and Verastem would have an obligation to promptly file a registration statement with the Securities and Exchange Commission, or SEC, to register such shares for resale. Any issuance of shares would be subject to the satisfaction of closing conditions, including that all material authorizations, consents, approvals and the like necessary for such issuance shall have been obtained.

Verastem is also obligated to pay us royalties on worldwide net sales of Licensed Products ranging from the mid-single digits to the high single-digits. The royalties will expire on a product-by-product and country-by-country basis until the latest to occur of (i) the last-to-expire patent right covering the applicable Licensed Product in the applicable country, (ii) the last-to-expire patent right covering the manufacture of the applicable Licensed Product in the country of manufacture of such Licensed Product, (iii) the expiration of non-patent regulatory exclusivity in such country and (iv) ten years following the first commercial sale of a Licensed Product in a country, provided that if royalties on net sales for a Licensed Product in the United States are payable solely on the basis of non-patent regulatory exclusivity, the applicable royalty on net sales for such Licensed Product in the United States will be reduced by 50%. The royalties are also subject to reduction by 50% of certain third-party

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royalty payments or patent litigation damages or settlements which might be required to be paid by Verastem if litigation were to arise, with any such reductions capped at 50% of the amounts otherwise payable during the applicable royalty payment period.

In addition to the foregoing, Verastem is obligated to pay us an additional royalty of 4% on worldwide net sales of Licensed Products to cover the reimbursement of research and development costs owed by us to Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products L.P., or Purdue. Once we have fully reimbursed Mundipharma and Purdue, the royalty obligations will be reduced to 1% of net sales in the United States, which we refer to as the Trailing Mundipharma Royalties. The Trailing Mundipharma Royalties are payable until the later to occur of the last-to-expire of specified patent rights and the expiration of non-patent regulatory exclusivities in a country. Each of the above royalty rates is reduced by 50% on a product-by-product and country-by-country basis if the applicable royalty is payable solely on the basis of non-patent regulatory exclusivity. In addition, the Trailing Mundipharma Royalties are subject to reduction by 50% of certain third-party royalty payments or patent litigation damages or settlements which might be required to be paid by Verastem if litigation were to arise, with any such reductions capped at 50% of the amounts otherwise payable during the applicable royalty payment period.

We and Verastem have made customary representations and warranties and have agreed to certain customary covenants, including confidentiality and indemnification.

The Verastem Agreement expires when each party no longer has any obligations to the other party. Verastem has the right to terminate the Verastem Agreement upon at least 180 days prior written notice to us at any time following the determination that the DUO Study has or has not met its pre-specified primary endpoint. Each party can terminate the Verastem Agreement if the other party materially breaches or defaults in the performance of its obligations. If we terminate the Verastem Agreement for Verastem's material breach, patent challenge, or insolvency, or if Verastem terminates for convenience, then, at the Company's request and subject to our execution of a waiver of certain types of damages, Verastem will transition the duvelisib program back to us at Verastem's cost. If Verastem terminates for our breach or insolvency, Verastem will effect a more limited transition of the duvelisib program to us at our request and cost, subject to our execution of a waiver of certain types of damages, and we will thereafter pay to Verastem a low single-digit royalty on net sales of Licensed Products.

AbbVie

The AbbVie Agreement

On September 2, 2014, we entered into the collaboration and license agreement between us and AbbVie Inc., which we refer to as the AbbVie Agreement. Under the AbbVie Agreement, we and AbbVie Inc., which we refer to as AbbVie, agreed to develop and commercialize in oncology indications products containing duvelisib. We refer to products containing duvelisib included under the AbbVie Agreement as Duvelisib Products. IPI-549, an orally administered, selective PI3K-gamma inhibitor, was excluded from the collaboration. As further described below, on June 24, 2016, AbbVie delivered to us a written notice that AbbVie was exercising its right to terminate the AbbVie Agreement unilaterally upon 90 days' written notice, which we refer to as the AbbVie Opt-Out. The termination of the AbbVie agreement was effective on September 23, 2016.

Under the terms of the AbbVie Agreement, we and AbbVie agreed to share equally commercial profits or losses of Duvelisib Products in the United States, including sharing equally the existing royalty obligations to Mundipharma and 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. For more information about such obligations, refer to the section below titled "Takeda."

AbbVie 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. This tiered royalty could have been further reduced based on specified factors, including patent expiry, generic entry,

and royalties paid to third parties.

We and AbbVie shared oversight of development and agreed to use diligent efforts, as defined in the AbbVie Agreement, to carry out our development activities under an agreed upon development plan. We had primary responsibility for the conduct of development of Duvelisib Products, unless otherwise agreed, and AbbVie had responsibility for the conduct of certain contemplated combination clinical studies, including those examining duvelisib and venetoclax, a selective first-in-class B-cell lymphoma 2 inhibitor, which we refer to as the AbbVie Studies. The development and manufacturing costs for the AbbVie Studies were shared equally.

We had the responsibility to manufacture Duvelisib Products until the transition of manufacturing responsibility to AbbVie, which we expected to occur as promptly as practicable while ensuring continuity of supply. Excluding the AbbVie

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Studies, we were responsible for all costs to develop and manufacture Duvelisib Products up to a maximum amount of $667 million.

We and AbbVie shared operational responsibility and decision making authority for commercialization of Duvelisib Products in the United States. Prior to commercialization and regulatory approval, we recognized the cost of manufacturing as a component of research and development and the cost of commercialization as a component of general and administrative expenses. During the three and nine months ended September 30, 2016 and 2015, we accounted for AbbVie's share of the costs as a reduction of the related expense.

Under the AbbVie Agreement, AbbVie 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, our Phase 2 clinical study evaluating the efficacy and safety of duvelisib in patients with refractory indolent non-Hodgkin lymphoma, or iNHL. Of the total $405 million received from AbbVie, we allocated $234.3 million to the license which was recognized as revenue upon receipt of the upfront payment and achievement of the milestone payment. Revenue related to development services and committee services was recognized using the proportionate performance method. We initially estimated that services would be performed through 2019.

The AbbVie Agreement was intended to remain in effect until all development, manufacturing and commercialization of Duvelisib Products ceased, unless terminated earlier. AbbVie had the right to terminate the AbbVie Agreement for convenience after a specified notice period as described below.

AbbVie Opt-Out

The June 2016 AbbVie Opt-Out was irrevocable, and we had no obligation to continue to provide AbbVie any services related to Duvelisib Products after June 24, 2016. We did not recognize revenue during the three months ended September 30, 2016. We recognized revenue of $18.7 million during the nine months ended September 30, 2016 related to the development and committee services provided through June 24, 2016. We recorded the remaining amounts already received from AbbVie and allocated to development and committee services of $112.2 million as a gain during the nine months ended September 30, 2016, reflecting the fact that we are no longer obligated to provide any such services and have no obligation to refund any of the payments received to date.

Upon formal termination of the AbbVie Agreement on September 23, 2016, we received all rights to the regulatory filings related to duvelisib, our license to AbbVie terminated, and AbbVie granted us an exclusive, perpetual, irrevocable, royalty-free license, under certain patent rights and know-how controlled by AbbVie, to develop, manufacture and commercialize in oncology indications worldwide products containing duvelisib, excluding any compound which is covered by patent rights controlled by AbbVie or its affiliates.

Other than pursuant to the wind-down plan described below, which did not include any development or committee service obligations for us, neither party has any financial obligation to the other. In connection with the AbbVie Opt-Out, AbbVie will not pay any royalties or any of the additional $400 million in milestone payments that we could have potentially earned under the AbbVie Agreement.

Wind-Down Plan

During the three months ended September 30, 2016, we and AbbVie finalized the wind-down plan to ensure a smooth transition of the responsibilities of the parties to us.

We recorded $1.9 million in research and development expense for AbbVie's clinical wind-down services during the three months ended September 30, 2016 for services rendered during the quarter. In connection with finalization of the

wind-down plan, we received $2.7 million from AbbVie for reimbursement of our wind-down activities in medical affairs and commercial services, which was recorded as a credit to research and development expense of $0.9 million and a credit to general and administrative expense of $1.8 million during the three months ended September 30, 2016.

We do not expect to receive any other proceeds from AbbVie for our wind-down activities, and we do not expect to incur any additional expenses for their clinical wind-down services.

Takeda

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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, which covers duvelisib and IPI-549. In January 2012, Intellikine was acquired by Takeda, acting through its Millennium business unit. In December 2012, we amended and restated our development and license agreement with Takeda. We refer to our PI3K inhibitor program licensor as Takeda and to the amended and restated development and license agreement as the Takeda Agreement.

Under the terms of the Takeda Agreement, as amended by the July 2014 and September 2016 amendments described in more detail below, we are obligated to pay Takeda an aggregate of up to $5 million in 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 $165 million in success-based milestone payments related to the approval and commercialization of one product, which could be IPI-549.

Except for duvelisib 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 Takeda 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 in accordance with its terms. Either party may terminate the Takeda 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 Takeda 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 Takeda 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 Takeda Agreement also provides for customary reciprocal indemnification obligations of the parties.

September 2016 Amendment

In September 2016, we entered into a second amendment with Takeda. Under the second amendment, effective upon our license, sublicense or asset sale of duvelisib, which we refer to as a qualifying transaction, we are no longer obligated to pay Takeda any remaining milestone payments for the development, approval or commercialization of duvelisib. Additionally, upon entry into a qualifying transaction, our obligation to use diligent efforts to develop products is reduced from two products to one product. In return, we are obligated to pay Takeda 50 percent of all revenue arising from each qualifying transaction for duvelisib, subject to certain exceptions. We believe the Verastem Agreement constitutes a qualifying transaction.

July 2014 Amendment

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 Takeda Agreement to pay to Takeda tiered royalties 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 year ended December 31, 2015, respectively, as there is no alternative future use beyond the existing research and development activities.

Financial Overview

Revenue

To date, all of our revenue has been generated under research collaboration agreements, and all our revenue during 2015 and during the nine months ended September 30, 2016 was derived from our former 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

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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 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.

In the event of an early termination of a collaboration agreement, any deferred revenue is recognized in the period in which all our obligations under the agreement have been fulfilled.

Research and Development Expense

We are a drug development company. Our research and development expense has historically consisted primarily of the following:

- compensation of personnel associated with research and development activities;
- clinical testing costs, including payments made to contract research organizations;
- costs of comparator drugs used in clinical studies;
- costs of purchasing laboratory supplies and materials;
- costs of manufacturing product candidates for preclinical testing and clinical studies;
- costs associated with the licensing of research and development programs;
- preclinical testing costs, including costs of toxicology studies;
- 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, early commercial efforts 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. During the three months ended September 30, 2016, we recognized $0.5 million in other income related to the sale of laboratory equipment. Interest expense is currently related to the 784 Memorial Drive lease (see Note 11).

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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, 2016. 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, 2015 for a discussion of our critical accounting policies and significant judgments and estimates.

Results of Operations

The following tables summarize our results of operations for each of the three and nine months ended September 30, 2016 and 2015, together with the change in these items in dollars and as a percentage:

	Three Months Ended September 30,		$ Change	% Change
	2016	2015		
	(in thousands)			
Collaboration revenue	$—	$90,743	$(90,743)	(100)%
Research and development expense	(12,817)	(37,732)	24,915	(66)%
General and administrative expense	(7,120)	(9,754)	2,634	(27)%
Interest expense	(305)	(311)	6	(2)%
Investment and other income	741	75	666	888 %
Income taxes	—	(480)	480	(100)%

	Nine Months Ended September 30,		$ Change	% Change
	2016	2015		
	(in thousands)			
Collaboration revenue	$18,723	$99,987	$(81,264)	(81)%
Research and development expense:				
Programs	(104,949)	(107,720)	2,771	(3)%
Takeda payments	—	(52,500)	52,500	(100)%
Total research and development expense	(104,949)	(160,220)	55,271	(34)%
General and administrative expense	(33,648)	(27,713)	(5,935)	21 %
Gain on AbbVie Opt-Out (note 9)	112,216	—	112,216	—
Interest expense	(921)	(1,058)	137	(13)%
Investment and other income	1,408	298	1,110	372 %
Income taxes	—	(480)	480	(100)%

Collaboration Revenue

Collaboration revenue for the nine months ended September 30, 2016 and the three and nine months ended September 30, 2015 relates to research and development revenue from the AbbVie Agreement up through the AbbVie Opt-Out on June 24, 2016.

We recognized license revenue upon execution of the AbbVie Agreement and completion of enrollment in our DYNAMO™ study. Revenue related to development services and committee services was recognized using the proportionate performance method as services were provided through the AbbVie Opt-Out. We do not expect to recognize any revenue after

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June 24, 2016 related to the AbbVie Agreement due to the AbbVie Opt-Out. We did not recognize any revenue in the three months ended September 30, 2016 and we recognized $18.7 million in collaboration revenue in the nine months ended September 30, 2016. We recognized $90.7 million and $100.0 million in collaboration revenue during the three and nine months ended September 30, 2015, respectively.

Research and Development Expense

The $24.9 million decrease in research and development expense for the three months ended September 30, 2016 as compared to the three months ended September 30, 2015 was primarily due to a decrease of $16.3 million related to clinical and development expenses for duvelisib, including a credit of $2.8 million as a result of negotiations with one of our clinical research organizations. In addition, compensation expense decreased by approximately $5.4 million primarily attributable to the June restructuring activities.

The $2.8 million decrease in research and development programs expense for the nine months ended September 30, 2016 as compared to the nine months ended September 30, 2015 was primarily due to a decrease of $4.1 million in clinical expenses related to development activities for duvelisib. Further information regarding restructuring activities is described below under the heading “Liquidity and Capital Resources—Organizational Restructuring.”

Research and development expense during the nine months ended September 30, 2015 included the $52.5 million payment we made to Takeda 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. There was no such expense or payment during the nine months ended September 30, 2016.

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, 2016 and 2015, and from January 1, 2006 through September 30, 2016, we estimate that we incurred the following expenses by program:

Program	Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015	January 1, 2006 to September 30, 2016
	(in millions)				
PI3K inhibitor (1)	$14.5	$ 35.6	$ 102.8	$ 153.1	$ 575.2
Hsp90 inhibitor	—	—		0.1	137.8
Hedgehog pathway inhibitor	—	—	—	—	164.1

(1) Includes both duvelisib and IPI-549. 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 this option to Takeda in 2015.

We do not believe that the historical costs associated with our drug development programs are indicative of the future costs associated with these programs. 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 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:

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- 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;
- the cost and timing of regulatory approvals; and
- the effect of competing technological and market developments.

General and Administrative Expense

The $2.6 million decrease in general and administrative expense for the three months ended September 30, 2016 as compared to the three months ended September 30, 2015 was primarily attributable to a decrease of $2.7 million related to early duvelisib commercial activities, including a credit of $1.8 million for our commercial wind-down services rendered related to AbbVie. The $5.9 million increase in general and administrative expense for the nine months ended September 30, 2016 as compared to the nine months ended September 30, 2015 was primarily attributable to an expense of $4.8 million for compensation-related restructuring activities. Further information regarding restructuring activities is described below under the heading “Liquidity and Capital Resources—Organizational Restructuring.”

Gain on AbbVie Opt-Out

The gain on AbbVie Opt-Out of collaboration was non-recurring and due to the written notice of termination received from AbbVie on June 24, 2016. The AbbVie Opt-Out was irrevocable, and we had no obligation to continue to provide AbbVie any services related to Duvelisib Products after June 24, 2016. The termination of the AbbVie Agreement became effective on September 23, 2016.

Interest Expense

Interest expense for the three and nine months ended September 30, 2016 and the three months ended September 30, 2015 was due to the financing obligation related to our 784 Memorial Drive lease. Interest expense for the nine months ended September 30, 2015 was 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) increased in the three and nine months ended September 30, 2016 as compared to the three and nine months ended September 30, 2015 primarily as a result of a gain on the sale of laboratory equipment and income from subleases at 784 Memorial Drive.

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 product sales to date, and we do not expect to generate any such revenue for the foreseeable future, if at all. We have instead relied on the proceeds from sales of equity securities, debt, interest on investments, up-front license fees, expense reimbursement, and milestones and cost sharing under our collaborations to fund our operations. Our available-for-sale debt securities primarily trade in liquid markets, and the average days to

maturity of our portfolio, as of September 30, 2016, is less than six months. Because our product candidates are in various stages of clinical 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:

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	September 30, 2016	December 31, 2015
	(in thousands)	
Cash, cash equivalents and available-for-sale securities	$112,298	$245,231
Working capital	97,576	184,641

	Nine Months Ended September 30,	
	2016	2015
	(in thousands)	
Cash provided by (used in):		
Operating activities	$(133,388)	$(166,421)
Takeda payments (included in operating activities above)	—	(59,167)
Investing activities	43,573	(5,551)
Capital expenditures (included in investing activities above)	(661)	(5,416)
Financing activities	152	1,851

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, 2016 compared to the nine months ended September 30, 2015, decreased primarily due to lower research and development expenses. Research and development expenses in the nine months ended September 30, 2015 included a $52.5 million payment in March 2015 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 and $6.7 million related to the final installment on a release payment. Our cash flow used in operating activities in future periods may vary significantly.

AbbVie paid us a $130 million non-refundable milestone payment in November 2015 associated with the completion of enrollment in DYNAMO in September 2015, and a $275 million upfront payment during the year ended December 31, 2014.

Net cash from investing activities for the nine months ended September 30, 2016 included purchases of available-for-sale securities of $52.5 million, proceeds of $12.0 million from maturities of available-for-sale securities, proceeds of $83.6 million for sales of available for sale securities, and proceeds from the sale of assets of $1.1 million. Capital expenditures primarily consisted of leasehold improvements related to 780 Memorial Drive.

Net cash from financing activities for the nine months ended September 30, 2016 included approximately $0.4 million of proceeds from issuances of common stock in connection with stock option exercises related to stock incentive plans, which was offset by $0.3 million of payments on the financing obligation related to our 784 Memorial Drive lease.

At-the-Market Facility

In May 2016, we entered into an at-the-market sales agreement, or Sales Agreement, with Cantor Fitzgerald & Co., or Cantor Fitzgerald, as agent, pursuant to which we may from time to time, at our option, offer and sell shares of our common stock having an aggregate offering price of up to $50 million through Cantor Fitzgerald, acting as our sales agent. Cantor Fitzgerald will be entitled to a commission of up to 3.0% of the gross proceeds from sales of shares of our common stock under the Sales Agreement. Sales of shares of our common stock under the Sales Agreement may be made by any method permitted by law that is deemed an “at the market” offering as defined in Rule 415 under the Securities Act of 1933, as amended, including sales made through the Nasdaq Global Select Market, on any other

existing trading market for our common stock or to or through a market maker. We may also authorize Cantor Fitzgerald to sell shares in negotiated transactions. As of September 30, 2016, we had not used the at-the-market facility. We have no obligation to sell shares of our common stock and cannot provide any assurances that we will issue any shares pursuant to the Sales Agreement. We may also suspend the offering of shares of our common stock upon notice and subject to other conditions.

Organizational Restructuring

In June 2016, we reported the top line data from DYNAMO™, a registration-focused Phase 2 monotherapy study evaluating the efficacy and safety of duvelisib in patients with refractory indolent non-Hodgkin lymphoma (iNHL). The study

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met its primary endpoint with an overall response rate of 46 percent, all of which were partial responses, among 129 patients with iNHL.

June 2016 Restructurings

As a result of our discussions with AbbVie regarding our collaboration and the subsequent AbbVie Opt-Out, our board of directors approved a strategic restructuring in order to preserve our resources as we determine future strategic plans, which included significant employee headcount reductions during June 2016. We recognized a credit of $1.0 million and additional expense of $0.7 million in total restructuring charges for the three months ended September 30, 2016 in research and development expenses and general and administrative expenses, respectively. We recognized $10.9 million and $5.5 million in total restructuring charges for the nine months ended September 30, 2016 in research and development expenses and general and administrative expenses, respectively. In November 2016, we entered into a termination agreement with ARE-770/784/790 Memorial Drive, LLC, or ARE, in which we and ARE agreed to terminate our lease agreement regarding our facilities at 780 Memorial Drive and 790 Memorial Drive in Cambridge, Massachusetts, which we refer to collectively as 780 / 790 Memorial Drive. We refer to this as our 780 / 790 Memorial Drive Lease Termination. As a result the 780 / 790 Memorial Drive Lease Termination, we agreed to pay ARE approximately $1.8 million including consideration for ARE's entering into the termination agreement and payments by us to ARE in lieu of certain restoration requirements regarding 780 / 790 Memorial Drive. Further information regarding the 780 / 790 Lease Termination is described below under the heading "Item 5-Other Information."

As we consider whether to restructure our lease for 784 Memorial Drive, we could potentially incur additional charges upon our exit from the space. Such potential future charges could include further impairments and lease exit payments related to our office space at 784 Memorial Drive in Cambridge, Massachusetts. At September 30, 2016 and December 31, 2015, the accompanying condensed consolidated balance sheets reflect the 784 Memorial Drive building and accumulated construction costs of $22.3 million and $23.0 million, respectively, and a total financing obligation of approximately $19.7 million and $20.0 million, respectively.

We reduced our employee headcount by approximately 0.66 percent compared to our employee headcount as of December 31, 2015. We have existing severance plans which outline contractual termination benefits. We recognized all contractual severance and benefits outlined in the plan when termination was probable and reasonably estimable in accordance with FASB ASC Topic 712, Compensation - Nonretirement Postemployment Benefits.

In June 2016, we made strategic decisions to close BRAVURA, a Phase 3 study of duvelisib in patients with relapsed iNHL, and not enroll additional patients in CONTEMPO, a Phase 1b/2 study of duvelisib in treatment-naïve patients with follicular lymphoma. We incurred approximately $1.0 million during the three months ended September 30, 2016 related to BRAVURA and CONTEMPO clinical and development expenses. On October 29, 2016, we and Verastem entered into the Verastem Agreement pursuant to which we granted to Verastem an exclusive worldwide license for the research, development, commercialization, and manufacture in oncology indications of products containing duvelisib (see Note 13). Under the Verastem Agreement, we will assume financial responsibility for the shutdown of certain specified clinical studies up to a maximum of $4.5 million, including the CONTEMPO and BRAVURA studies.

Approximately $0.5 million and $1.7 million of expense was recorded during the three and nine months ended September 30, 2016, respectively, related to the write-off of prepaid expenses that were not expected to continue and other payments that were due as a result of early terminations.

We identified and recorded the impairment of approximately $1.0 million of unique and identifiable laboratory equipment, as well as $0.4 million in furniture and fixtures during the three months ended June 30, 2016. During the three months ended September 30, 2016, we realized proceeds of $1.6 million related to sale of the laboratory equipment and recognized a credit of $1.1 million in research and development expense and $0.5 million in investment and other income.

In performing the recoverability test for the 780 / 790 Memorial Drive asset group, we concluded that the asset group was not recoverable. We recorded an impairment charge of $0.1 million and $0.8 million related to 780 / 790 Memorial Drive assets, including the related tenant improvement allowance (see Note 11), after comparing the fair value (using probability weighted scenarios with discounted cash flows) to the asset group's carrying value, for the

three and nine months ended September 30, 2016, respectively.

In performing the recoverability test for the 784 Memorial Drive asset group, we concluded that the asset group was not recoverable. We had an independent appraisal performed for the 784 Memorial building and improvements. We concluded no impairment was needed as the fair market value (considering the cost approach, sales comparison approach and the income approach) exceeded the asset group's carrying value.

September 2016 Restructuring

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As a result of our progress on strategic initiatives relating to duvelisib, our board of directors approved further headcount reductions during September 2016. The September 2016 restructuring reduced our employee headcount by approximately four percent compared to our employee headcount as of December 31, 2015. Included in the table below, we recognized $0.4 million and $0.2 million in total restructuring charges for the three months ended September 30, 2016 in research and development expenses and general and administrative expenses, respectively, related to the September restructuring.

Summary Table

The following table summarizes the impact of the June 2016 and September 2016 restructuring activities on our operating expenses and payments for the nine months ended September 30, 2016 and the current liability remaining on our balance sheet as of September 30, 2016, in thousands:

	Charges incurred during the nine months ended September 30, 2016 (in thousands)	Amounts paid through September 30, 2016	Less non-cash charges during the nine months ended September 30, 2016	Amounts accrued at September 30, 2016
Employee severance, benefits and related costs for work force reduction	$ 13,791	$ 5,226	$ 907	$ 7,658
Long-lived asset impairment	1,324	—	1,324	—
Contract termination, prepaid expense write-offs and other related costs	1,806	424	1,042	340
Total restructuring	$ 16,921	$ 5,650	$ 3,273	$ 7,998

October Restructuring

On October 28, 2016, our Board of Directors approved a strategic restructuring in connection with and subject to the entry into the Verastem Agreement.

The restructuring included workforce reductions of 19 positions across the organization representing approximately 54 percent of our workforce at the time of the restructuring. We expect the workforce restructuring to be fully completed by January 6, 2017. We currently expect to incur severance, benefits and related costs of approximately $5 million, to be paid during the year ended December 31, 2017. We are continuing to review the potential impact of the restructuring and is unable to estimate any additional restructuring costs or charges at this time.

Operating Capital Requirements

As of September 30, 2016, we had cash, cash equivalents and short-term investments of $112.3 million. Excluding the potential $6 million and $22 million contingent payments in cash or stock from Verastem, we believe that our existing cash, cash equivalents and available-for-sale securities at September 30, 2016, will be adequate to satisfy our capital needs into the first quarter of 2018 based on our operational plans, which do not include duvelisib expenses beyond

the first quarter of 2017. Our operational plans also include lower 2017 monthly cash burn as a result of the restructuring plan announced in June 2016 and our restructuring plans in both September 2016 (see Note 12) and October 2016 (see Note 13).

On October 29, 2016, we and Verastem entered into a license agreement, which we and Verastem amended and restated on November 1, 2016, effective as of October 29, 2016 (see Note 13). Verastem assumed financial responsibility for activities that were part of our ongoing duvelisib program, including expenses related to the DUO Study. We will assume financial responsibility for the shutdown of certain specified clinical studies up to a maximum of $4.5 million. Following a short transition period, Verastem will assume all operational responsibility for the duvelisib program.

On June 24, 2016, AbbVie delivered to us a written notice to terminate the AbbVie Agreement unilaterally upon 90 days' written notice. The termination of the AbbVie Agreement became effective on September 23, 2016 (see Note 9). We will not receive additional payments from AbbVie. For more information, refer to the section titled "Liquidity and Capital Resources" in Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations.

Our estimate as to how long we expect our existing cash, cash equivalents and available-for-sale securities to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could

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cause us to consume capital significantly faster than we currently anticipate. Our future funding requirements, both short-term and long-term, will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of researching and developing IPI-549 currently in clinical development;
- our ability to secure alternative leasing or subleasing arrangements for our current lease and to achieve related cost savings;
- our ability to realize the planned cost savings benefits of a strategic restructurings we effected in June and September 2016, which included a significant reduction in our workforce, in order to preserve capital to support the development of IPI-549;
- the timing of, and the costs involved in, obtaining regulatory approvals for IPI-549;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the absence of any breach, acceleration event or event of default under any agreements with third parties;
- the outcome of any lawsuits that could be brought against us;
- 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; and
- 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.

Contractual Obligations and Off-Balance Sheet Arrangements

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

There have been no material changes to our contractual obligations during the nine months ended September 30, 2016 with the exception of the second amendment of our agreement with Takeda (Note 9).

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. Under the second amendment entered into with Takeda in September 2016, we are obligated to pay Takeda up to an aggregate of $165 million in success-based milestone payments for the approval and commercialization of IPI-549. Because the achievement of these milestones had not occurred as of September 30, 2016, such contingencies have not been recorded in our financial statements.

As a result of our early termination, we owe to ARE a termination payment of $1.8 million, comprised of a $1.7 million fee as consideration for ARE's agreement to enter into the 780 / 790 Memorial Drive Termination Agreement and approximately $64 thousand payment by us to ARE in lieu of our performance of certain restoration requirements with regards to the Leased Properties. Pursuant to the terms of the 780 / 790 Memorial Drive Lease Agreement, ARE will refund a portion of our $0.6 million security deposit.

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, 2015 for a discussion of our judgments and estimates.

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

A hypothetical 100 basis point increase in interest rates would result in an approximate $41,000 decrease in the fair value of our investments as of September 30, 2016, as compared to an approximate $0.4 million decrease as of December 31, 2015. 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, 2016. 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

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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, 2016, 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, 2016 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, 2015.

Risks Related to Our Financial Position and Need for Additional Capital

We are considering alternatives to our current business strategy that could significantly impact our future operations and financial position.

We are in the process of reviewing a range of strategic alternatives that could result in potential changes to our current business strategy and future operations. As part of this process, we are reviewing alternatives with a goal of maximizing shareholder value. During this process, we entered into an agreement with Verastem, Inc., or Verastem, pursuant to which we granted to Verastem an exclusive worldwide license for the research, development, commercialization, and manufacture in oncology indications of products containing duvelisib, an investigational, oral, dual inhibitor of PI3K-delta and PI3K-gamma, or the Licensed Products. We refer to this agreement as the Verastem Agreement. We may determine to engage in one or more additional potential transactions, such as the sale of our company, a strategic partnership with one or more parties or the licensing, sale or divestiture of some of our assets or proprietary technologies, or to continue to operate our business in accordance with our existing business strategy. Pending any decision to change strategic direction, we are continuing to advance IPI-549. We cannot provide any commitment regarding when or if this strategic review process will result in any type of transaction and no assurance can be given that we will determine to pursue a potential sale, strategic partnership or licensing arrangement. If we determine to pursue an alternative strategy or engage in a strategic transaction, our future business, prospects, financial position and operating results could be significantly different than those in historical periods or projected by our management. Because of the significant uncertainty regarding our future plans, we are not able to accurately predict the impact of a potential change in our existing business strategy.

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, 2016, we had an accumulated deficit of $602.8 million. Pending any decision to change strategic direction, we expect to

continue to spend significant resources to fund IPI-549, the wind-down of duvelisib, and restructuring related expenses. 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 continue. In addition, if we proceed to seek and possibly obtain regulatory approval of IPI-549, we would expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. As a result, we expect that our accumulated deficit would also increase significantly.

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IPI-549 is under 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 IPI-549 successfully completes clinical trials and receives regulatory approval. We do not expect to generate revenue from product sales for the foreseeable future. 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. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, and cause a decline in the value of our common stock.

We will need substantial additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or future commercialization efforts.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time consuming, expensive and uncertain process that takes years to complete. We will need substantial additional funds to support our planned operations. In the absence of additional funding or business development activities, we believe that our existing cash, cash equivalents and available-for-sale securities at September 30, 2016 will be adequate to satisfy our capital needs into the first quarter of 2018 based on our operating plans.

Our estimate as to how long we expect our existing cash, cash equivalents and available-for-sale securities to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate. Our future funding requirements, both short-term and long-term, will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of developing IPI-549, currently in clinical development;
- our ability to realize the planned cost savings benefits of strategic restructurings we effected in 2016, which included a significant reduction in our workforce, in order to preserve capital to support the development of IPI-549;
- our ability to secure alternative leasing or subleasing arrangements for our current leases and to achieve related cost savings;
- the timing of, and the costs involved in, obtaining regulatory approvals for IPI-549;
- our ability to effectively transition the duvelisib program to Verastem;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the absence of any breach, acceleration event or event of default under any agreements with third parties;
- the outcome of any lawsuits that could be brought against us;
- 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; and
- a loss in our investments due to general market conditions or other reasons.

In addition, we will not receive additional milestone payments from AbbVie Inc., which we refer to as AbbVie, as a result of the termination by AbbVie of the collaboration and license agreement between us and AbbVie, dated September 2, 2014, which we refer to as the AbbVie Agreement.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We may seek additional funding through public or private financings of equity or debt securities, but such financing may not be available on acceptable terms, 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 adversely affect the rights of our existing stockholders including liquidation or other preferences and anti-dilution protections. 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, make capital expenditures, create liens, redeem stock, declare dividends, and acquire, sell or license intellectual property rights, or other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly

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harm our business, financial condition and prospects. In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

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, terminate, sell or license IPI-549 or to scale back, suspend or terminate our business operations.

Risks Related to the Development and Commercialization of IPI-549

In the near term, we are dependent on the success of IPI-549, our only product candidate in development.

Our prospects are substantially dependent on our ability to develop, obtain marketing approval for and successfully commercialize product candidates in one or more disease indications.

We currently have no products approved for sale and are investing a significant portion of our efforts and financial resources in the development of IPI-549, our PI3K gamma-selective inhibitor.

The success of IPI-549 will depend on several factors, including the following:

- initiation and successful enrollment and completion of clinical trials, including in combination with other agents;
- a safety, tolerability and efficacy profile that is satisfactory to the U.S. Food and Drug Administration, or FDA, or any comparable foreign regulatory authority for marketing approval;
- timely receipt of marketing approvals from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishment of supply arrangements with third-party raw materials suppliers and manufacturers;
- establishment of arrangements with third-party manufacturers to obtain finished drug product that is appropriately packaged for sale;
- adequate ongoing availability of raw materials and drug product for clinical development and any commercial sales;
- obtaining and maintaining patent, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protection of our rights in our intellectual property portfolio;
- successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors; and
- our ability to compete with other therapies.

Many of these factors are beyond our control, including clinical development, the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts of any collaborator. If we are unable to develop, receive marketing approval for and successfully commercialize IPI-549, on our own or with any collaborator, or experience delays as a result of any of these factors or otherwise, our business could be substantially harmed.

IPI-549 remains subject to clinical testing and regulatory approval. This process is highly uncertain, and we may never be able to obtain marketing approval for IPI-549.

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.

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For example, we are evaluating IPI-549, our only product candidate, in clinical development. If our Phase 1 clinical trial of IPI-549 is successful, we will 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 IPI-549 will not obtain marketing approval. Even if IPI-549 has a beneficial effect, that effect may not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of IPI-549 that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity of or intolerability caused by IPI-549, or mistakenly believe that IPI-549 is toxic or not well tolerated when that is not in fact the case.

IPI-549 must undergo rigorous clinical trials prior to receipt of regulatory approval. Any problems in these clinical trials could delay or prevent commercialization of IPI-549.

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 IPI-549:

- 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 IPI-549 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 IPI-549, for any of the foregoing reasons, could adversely affect our ability to obtain regulatory approval for and to commercialize IPI-549, increase our operating expenses and have a material adverse effect on our financial results.

Adverse events or undesirable side effects caused by, or other unexpected properties of, IPI-549, alone or in combination with other agents, may be identified during development and could delay or prevent IPI-549 marketing approval or limit its use.

Adverse events or undesirable side effects caused by, or other unexpected properties of, IPI-549 could cause us, any collaborators, an institutional review board or regulatory authorities to interrupt, delay or halt clinical trials of IPI-549 and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities. If IPI-549 is associated with adverse events or undesirable side effects or has properties

that are unexpected, we, or any collaborators, may need to abandon development or limit development of IPI-549 to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause undesirable or unexpected side effects that prevented further development of the compound.

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If we, or any current or future collaborators, experience any of a number of possible unforeseen events in connection with clinical trials of IPI-549, potential clinical development, marketing approval or commercialization of IPI-549 could be delayed or prevented.

We, or any collaborators, may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent clinical development, marketing approval or commercialization of IPI-549, including:

- regulators or institutional review boards may not authorize us, any collaborators or our or their investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we, or any collaborators, may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of IPI-549 may produce unfavorable or inconclusive results;
- we, or any collaborators, may decide, or regulators may require us or them, to conduct additional clinical trials or abandon IPI-549;
- the number of patients required for clinical trials of IPI-549 may be larger than we, or any collaborators, anticipate, patient enrollment in these clinical trials may be slower than we, or any collaborators, anticipate or participants may drop out of these clinical trials at a higher rate than we, or any collaborators, anticipate;
- the cost of planned clinical trials of IPI-549 may be greater than we anticipate;
- our third-party contractors or those of any collaborators, including those manufacturing IPI-549 or components or ingredients thereof or conducting clinical trials on our behalf or on behalf of any collaborators, may fail to comply with regulatory requirements or meet their contractual obligations to us or any collaborators in a timely manner or at all;
- patients that enroll in a clinical trial may misrepresent their eligibility to do so or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the patients from the clinical trial, increase the needed enrollment size for the clinical trial or extend the clinical trial's duration;
- we, or any collaborators, may have to delay, suspend or terminate clinical trials of IPI-549 for various reasons, including a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of IPI-549;
- regulators or institutional review boards may require that we, or any collaborators, or our or their investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or their standards of conduct, a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of IPI-549 or findings of undesirable effects caused by a chemically or mechanistically similar product or product candidate;
- the FDA or comparable foreign regulatory authorities may disagree with our, or any collaborators', clinical trial designs or our or their interpretation of data from preclinical studies and clinical trials;
- the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we, or any collaborators, enter into agreements for clinical and commercial supplies;
- the supply or quality of raw materials or manufactured product candidates or other materials necessary to conduct clinical trials of IPI-549 may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient to obtain marketing approval.

Product development costs for us, or any collaborators, will increase if we, or they, experience delays in testing or pursuing marketing approvals and we, or they, may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of IPI-549. We do not know whether any clinical trials will begin as planned, will need to be restructured, or will be completed on schedule or at all. Significant preclinical study or clinical trial delays also could shorten any periods during which we, or any collaborators, may have the exclusive right to commercialize IPI-549 or allow our competitors, or the competitors of any current or future collaborators, to bring products to market before we, or any collaborators, do and impair our ability, or the ability of any collaborators, to successfully commercialize IPI-549 and may harm our business and results of operations. In addition, many of the

factors that lead to clinical trial delays may ultimately lead to the denial of marketing approval of IPI-549, or, in the event that our clinical trials remain unable to demonstrate meaningful clinical benefit, our failure to reach the marketing approval stage at all.

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Results of preclinical studies and early clinical trials may not be successful, and even if they are successful, may not be predictive of results of future late-stage clinical trials.

We are in clinical development for IPI-549. The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials do not necessarily predict success in future clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we could face similar setbacks. The design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial to support marketing approval. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if we, or any collaborators, believe that the results of clinical trials for IPI-549 warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of IPI-549.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. If we fail to receive positive results in clinical trials of IPI-549, the development timeline and regulatory approval and commercialization prospects for IPI-549 and, correspondingly, our business and financial prospects, would be negatively impacted.

Our inability to enroll sufficient numbers of patients in our clinical trials, or any delays in patient enrollment, could 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 and nature of the patient population;
- the severity of the disease under investigation;
- the nature and complexity of the trial protocol, including eligibility criteria for the trial;
- the number of clinical trial sites and the proximity of patients to those sites;
- standard of care in disease under investigation;
- the commitment of clinical investigators to identify eligible patients;
- competing studies or trials; and
- clinicians' and patients' perceptions as to the potential advantages and risks of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

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 ability 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.

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We have never obtained marketing approval for a product candidate, and we may be unable to obtain, or may be delayed in obtaining, marketing approval for IPI-549 that we, or any collaborators, may develop.

We have never obtained marketing approval for a product candidate. It is possible that the FDA may refuse to accept for substantive review any new drug applications, or NDAs, that we submit for IPI-549 or may conclude after review of our data that our application is insufficient to obtain marketing approval of IPI-549. If the FDA does not accept or approve our NDAs for IPI-549, it may require that we conduct additional clinical trials, preclinical studies or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA-required trials or studies, approval of any NDA or application that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional trials or studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDAs.

Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing IPI-549 or any companion diagnostics, generating revenues and achieving and sustaining profitability. If any of these outcomes occurs, we may be forced to abandon our development efforts for IPI-549, which could significantly harm our business.

Even if IPI-549 receives marketing approval, we or others may later discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, which could compromise our ability, or that of any collaborator, to market IPI-549, and we could become subject to costly and damaging product liability claims.

Even if we receive regulatory approval for IPI-549, we will have tested it in only a small number of patients in carefully defined subsets 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 IPI-549 for a longer period of time, IPI-549 might be less effective than indicated by our clinical trials. Furthermore, new risks and side effects associated with IPI-549 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 IPI-549 (including a “black box” warning or a contraindication) or the manner in which it is administered, reformulate IPI-549 or make changes and obtain new approvals for our and our suppliers’ manufacturing facilities. We also might have to withdraw or recall IPI-549 from the marketplace, and regulators might seize IPI-549. We might be subject to fines, injunctions, or the imposition of civil or criminal penalties. Any safety concerns with respect to IPI-549 may also result in a significant drop in the potential sales of IPI-549, damage to our reputation in the marketplace, or result in our and our collaborators’ 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 and could negatively impact our stock price.

Even if IPI-549 receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, in which case we may not be able to generate significant revenues from product sales to become profitable.

Even if IPI-549 obtains regulatory approval, that product may not gain market acceptance among physicians, patients, managed care organizations, third-party payors, 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 government payors, managed care plans and other third-party payors;

- prevalence and severity of side effects;
- potential advantages of alternative treatment methods;
- whether the product is designated under physician treatment guidelines as a first, second or third line therapy;
- changes in the standard of care for the targeted indications for the product;

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- limitations or warnings, including distribution or use restrictions, contained in the product's approved labeling;
- 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 IPI-549 or other product candidates we may develop in the future, we could lose our regulatory approvals and our business would be adversely affected if we, our collaborators, or our contract manufacturers fail to comply with continuing regulatory requirements.

The FDA 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, the FDA's current good manufacturing practices, or 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 we are unable to establish sales, marketing and distribution capabilities or enter into sales, marketing and distribution arrangements with third parties, we may not be successful in commercializing any product candidates if approved.

We do not have a sales, marketing or distribution infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties. The development of sales, marketing and distribution capabilities would require substantial resources, would be time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and distribution capabilities is delayed or does not occur for any reason, we could have prematurely or unnecessarily incurred these commercialization costs. This may be costly, and our investment could be lost if we cannot retain or reposition our sales and marketing personnel. In addition, we may not be able to hire or retain a sales force in the United States that is sufficient in size or has adequate expertise in the medical markets that we choose to target. If we are unable to establish or retain a sales force and marketing and distribution capabilities, our operating results may be adversely affected. If a potential partner has development or commercialization expertise that we believe is particularly relevant to one of our products, then we may seek to collaborate with that potential partner even if we believe we could otherwise develop and commercialize the product independently.

As a result of entering into any such arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues may be lower, perhaps substantially lower, than if we were to directly market and sell products in those markets. Furthermore, we may be unsuccessful in entering into the necessary arrangements with third parties or may be unable to do so on terms that are favorable to us. In addition, we may have little or no control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively.

If we do not establish sales, marketing and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing any of our product candidates that receive marketing approval.

Our competitors and potential competitors may develop products that make IPI-549 less attractive or obsolete.

IPI-549 offers many potential opportunities in oncology diseases as an immuno-oncology product candidate. Immuno-oncology 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. At this point, we are unable to define the specific competitors for IPI-549. Through our Phase 1 clinical study of IPI-549, we expect to identify potential solid tumor indications for which to investigate IPI-549 as a therapeutic and to be able

to identify specific competitors for IPI-549. We

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currently face, and expect to continue to face, intense and increasing competition as new products enter the market and advanced technologies become available.

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 collaborators may for IPI-549. These competitive products may have superior safety or efficacy, have more attractive pharmacologic properties, or may be manufactured less expensively than IPI-549. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, the development of our product candidates.

If we are unable to compete effectively against these companies on the basis of safety, efficacy or cost, then we may not be able to commercialize IPI-549 or achieve a competitive position in the market. This would adversely affect our ability to generate revenues.

Even if we, or any future collaborators, are able to commercialize IPI-549, the product may become subject to unfavorable pricing regulations, third-party payor reimbursement practices or healthcare reform initiatives, any of which could harm our business.

The commercial success of IPI-549 will depend substantially, both domestically and abroad, on the extent to which the costs of IPI-549 will be paid by third-party payors, including government health care programs and private health insurers. If coverage is not available, or reimbursement is limited, we, or any future collaborators, may not be able to successfully commercialize IPI-549. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us, or any future collaborators, to establish or maintain pricing sufficient to realize a sufficient return on our or their investments. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved drugs. Marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we, or any future collaborators, might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, which may negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability or the ability of any future collaborators to recoup our or their investment in IPI-549, even if IPI-549 obtains marketing approval.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Therefore, our ability, and the ability of any future collaborators, to commercialize successfully IPI-549 will depend in part on the extent to which coverage and adequate reimbursement for IPI-549 and related treatments will be available from third-party payors. Third-party payors decide which medications they will cover and establish reimbursement levels. The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability or that of any future collaborators to sell IPI-549 profitably. These payors may not view IPI-549 as cost-effective, and coverage and reimbursement may not be available to our customers, or those of any future collaborators, or may not be sufficient to allow IPI-549 to be marketed on a competitive basis. Cost-control initiatives could cause us, or any future collaborators, to decrease the price we, or they, might establish for IPI-549, which could result in lower than anticipated product revenues. If the prices for IPI-549 decrease or if governmental

and other third-party payors do not provide coverage or adequate reimbursement, our prospects for revenue and profitability will suffer.

There may also be delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Reimbursement rates may vary, by way of example,

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according to the use of the product and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost drugs or may be incorporated into existing payments for other services.

In addition, increasingly, third-party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging the prices charged. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for IPI-549 could significantly harm our operating results, our ability to raise capital needed to commercialize IPI-549 and our overall financial condition.

If the FDA or comparable foreign regulatory authorities approve generic versions of IPI-549 that receive marketing approval, or such authorities do not grant IPI-549 appropriate periods of data exclusivity before approving generic versions of IPI-549, the sales of IPI-549 could be adversely affected.

Once an NDA is approved, the product covered thereby becomes a “reference-listed drug” in the FDA’s publication, “Approved Drug Products with Therapeutic Equivalence Evaluations,” or the Orange Book. Manufacturers may seek approval of generic versions of reference-listed drugs through submission of abbreviated new drug applications, or ANDAs, in the United States. In support of an ANDA, a generic manufacturer need not conduct clinical trials. Rather, the applicant generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labeling as the reference-listed drug and that the generic version is bioequivalent to the reference-listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference-listed drug and companies that produce generic products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference-listed drug may be typically lost to the generic product.

The FDA may not approve an ANDA for a generic product until any applicable period of non-patent exclusivity for the reference-listed drug has expired. The Federal Food, Drug, and Cosmetic Act, or FDCA, provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity, or NCE. Specifically, in cases where such exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification that a patent covering the reference-listed drug is either invalid or will not be infringed by the generic product, in which case the applicant may submit its application four years following approval of the reference-listed drug. When the composition of matter patents underlying our product candidates expire, it is possible that another applicant could obtain approval to produce generic versions of our product candidates. If any product we develop does not receive five years of NCE exclusivity, the FDA may approve generic versions of such product three years after its date of approval, subject to the requirement that the ANDA applicant certifies to any patents listed for our products in the Orange Book. Manufacturers may seek to launch these generic products following the expiration of the applicable marketing exclusivity period, even if we still have patent protection for our product.

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 IPI-549 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 IPI-549 or duvelisib in clinical trials. We currently have clinical trial insurance and will seek to obtain product liability insurance prior to the commercial launch of IPI-549. 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 IPI-549, 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 IPI-549, or expand our business.

Risks Related to Our Dependence on Third Parties

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

In October 2016, we entered into an exclusive license agreement with Verastem to develop and commercialize products based on duvelisib. We may in the future seek other third-party collaborators. The success of a strategic alliance with

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any 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:

- 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;
- decides not to pursue development and commercialization of the program or to continue or renew development or commercialization programs, based on clinical trial results, changes in the collaborators' strategic focus or available funding, the belief that other product candidates may have a higher likelihood of obtaining regulatory approval or potential to generate a greater return on investment, or external factors, such as an acquisition, that divert resources or create competing priorities;
- does not perform its obligations as expected;
- does not have sufficient resources necessary or is otherwise unable to carry the program through clinical development, regulatory approval and commercialization;
- cannot obtain the necessary regulatory approvals;
- delays clinical trials, provides insufficient funding for a clinical trial program, stops a clinical trial or abandons the program, repeats or conducts new clinical trials or requires a new formulation of the program for clinical testing;
- independently develops, or develops with third parties, products that compete directly or indirectly with the program;
- does not commit sufficient resources to the marketing and distribution of such product or products;
- does not properly maintain or defend our intellectual property rights or uses our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- infringes the intellectual property rights of third parties, which may expose us to litigation and potential liability; or
- terminates the collaboration prior to its completion.

If such partner were to terminate its arrangements with us, as was the case with AbbVie, or breach such arrangements, 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 collaborator for such product candidate. For example, as a result of AbbVie's termination of our strategic collaboration, we are not entitled to receive payments for any milestone that was not achieved prior to AbbVie's delivery to us of its termination notice, and neither party has any financial obligation to the other, other than pursuant to the wind-down plan.

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. 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 collaborators', 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 collaborators.

If any future collaborator fails to develop or effectively commercialize IPI-549, we may not be able to develop and commercialize IPI-549 independently, and our financial condition and operations would be negatively impacted.

We might seek to establish collaborations in the future and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

In the future, we might seek out one or more other collaborators for the development and commercialization of IPI-549. Likely collaborators may include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. In addition, if we are able to obtain marketing approval for IPI-549 from foreign regulatory authorities, we might enter into strategic relationships with international biotechnology or pharmaceutical companies for the commercialization of IPI-549 outside of the United States.

We would face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for an additional collaboration will depend, among other things, upon our assessment of the collaborator's resources

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expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of a number of factors. Those factors may include the potential differentiation of IPI-549 from competing product candidates, design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities and the regulatory pathway for any such approval, the potential market for IPI-549, the costs and complexities of manufacturing and delivering the product to patients and the potential of competing products. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for IPI-549.

If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop IPI-549 or bring it to market and generate product revenue.

Additional collaborations would be complex and time consuming to negotiate and document.

Any collaboration agreements that we enter into in the future may contain restrictions on our ability to enter into potential collaborations or to otherwise develop IPI-549.

Further, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of IPI-549, reduce or delay its development, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

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 ability to obtain regulatory approval for and to commercialize IPI-549 could be delayed.

In addition, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocol for the trial. The FDA requires us to comply with certain standards, referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. If any of our trial investigators or third-party contractors does not comply with good clinical practices, we may not be able to use the data and reported results from the trial. If this noncompliance were to occur, our ability to obtain regulatory approval for and to commercialize IPI-549 could be delayed.

We currently rely on third-party manufacturers to produce our preclinical and clinical drug supplies, and we may also rely upon third-party manufacturers to produce commercial supplies of IPI-549.

IPI-549 requires precise, high quality manufacturing. The third-party manufacturers on which we rely may not be able to comply with 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 IPI-549 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 IPI-549, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of IPI-549, operating restrictions and/or criminal prosecution, any of which could

significantly and adversely affect supply of IPI-549 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 IPI-549 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, the

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demand for such services is high 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, IPI-549 has been manufactured for preclinical testing and clinical trials primarily by third-party manufacturers. If the FDA or other regulatory agencies approve IPI-549 for commercial sale, we expect that we would continue to rely, at least initially, on third-party manufacturers to produce commercial quantities of IPI-549. These manufacturers may not be able to successfully increase the manufacturing capacity for IPI-549 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 IPI-549, 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.

Risks Related to Our Intellectual Property

If we fail to obtain or maintain necessary or useful intellectual property rights, we could encounter substantial delays in the research, development and commercialization of IPI-549.

We currently have rights to certain intellectual property, through licenses from third parties, to develop IPI-549 and other product candidates under our PI3K inhibitor program. In addition, we have rights to certain intellectual property, through licenses from third parties, that we have exclusively license to Verastem to research, develop, manufacture and commercialize duvelisib. We may decide to license additional third-party technology that we deem necessary or useful for our business. However, we may be unable to acquire or in-license any compositions, methods of use, processes or other intellectual property rights from third parties that we identify as necessary for IPI-549 at a reasonable cost, or at all. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us.

We sometimes collaborate with non-profit and academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution’s rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us or we may decide not to execute such option if we believe such license is not necessary to pursue our program. If we are unable or opt not to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

If we do not obtain or maintain these intellectual property rights which we require, we could encounter substantial delays in developing and commercializing IPI-549 while we attempt to develop alternative technologies, methods and product candidates, which we may not be able to accomplish. If we are ultimately unable to do so, we may be unable to develop or commercialize IPI-549, which could harm our business significantly.

If we fail to comply with our obligations under our existing and any future intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are party to several license agreements under which we license patent rights and other intellectual property related to our business, including an amended and restated development and license agreement with Takeda under which we obtained rights to discover, develop and commercialize pharmaceutical products targeting the delta and/or gamma isoforms of PI3K, including IPI-549 and duvelisib. We may enter into additional license agreements in the future. Our license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under these licenses, our licensors may have the right to terminate these license agreements, in which event we might not be able to market

IPI-549 that is covered by these agreements, or our licensors may convert the license to a non-exclusive license, which could adversely affect the value of IPI-549 being developed under the license agreement. Termination of these license agreements or reduction or elimination of our licensed rights may also result in our having to negotiate new or reinstated licenses with less favorable terms. If we fail to use diligent efforts to develop and commercialize products licensed under the Takeda Agreement, for example, or if Verastem materially breaches the Verastem Agreement, we could lose our license rights under the Takeda Agreement, including rights to IPI-549.

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Our intellectual property licenses with third parties may be subject to disagreements over contract interpretations, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.

The agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could harm our business, financial condition, results of operations and prospects.

Our success depends substantially upon our ability to obtain and maintain intellectual property protection for IPI-549. We own or hold exclusive licenses to a number of U.S. and foreign patents and patent applications directed to IPI-549. Our success depends on our ability to obtain patent protection both in the United States and in other countries for IPI-549, our methods of manufacture and our methods of use. Our ability to protect IPI-549 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. Issued patents that we have or may obtain or license may not provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

If we do not obtain adequate intellectual property protection for our products in the United States, competitors could duplicate them without repeating the extensive testing that we will have been required to undertake to obtain approval by the FDA. Regardless of any patent protection, under the current statutory framework, the FDA is prohibited by law from approving any generic version of any of our products for up to five years after it has approved our product. Upon the expiration of that period, or if that time period is altered, the FDA could approve a generic version of our product unless we have patent protection sufficient for us to block that generic version. Without sufficient patent protection, the applicant for a generic version of our product would only be required to conduct a relatively inexpensive study to show that its product is bioequivalent to our product and would not have to repeat the studies that we conducted to demonstrate that the product is safe and effective.

In the absence of adequate patent protection in other countries, competitors may similarly be able to obtain regulatory approval in those countries for products that duplicate IPI-549. 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.

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In addition, we rely on intellectual property assignment agreements with our collaborators, 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.

Other agreements through which we license patent rights may not give us control over patent prosecution or maintenance, so that we may not be able to control which claims or arguments are presented and may not be able to secure, maintain, or successfully enforce necessary or desirable patent protection from those patent rights. If we are unable to obtain control over patent prosecution in these other agreements, we cannot be certain that patent prosecution and maintenance activities by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents.

We, or any future partners, collaborators or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection for them. Therefore, we may miss potential opportunities to strengthen our patent position.

It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If we or our partners, collaborators, licensees, or licensors, whether current or future, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our partners, collaborators, licensees or licensors, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business. As a result, our ownership of key intellectual property could be compromised.

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, collaborators, 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.

Patent interference, opposition or similar proceedings relating to our intellectual property portfolio are costly, and an unfavorable outcome could prevent us from commercializing IPI-549.

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, IPI-549 or its therapeutic use. In the event that a third party has also filed a U.S. patent application relating to IPI-549 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.

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 IPI-549.

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 IPI-549. We may not have identified

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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 IPI-549, even when we are aware of third-party patents that may be relevant to IPI-549, 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 IPI-549.

While we are not currently aware of any litigation or third-party claims of intellectual property infringement related to IPI-549, the biopharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents and claim that the use of our technologies infringes these patents or that we are employing their proprietary technology without authorization. We could incur substantial costs and diversion of management and technical personnel in defending against any claims that the manufacture and sale of our potential products or use of our technologies infringes any patents, or defending against any claim that we are employing any proprietary technology without authorization. The outcome of patent litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of the adverse party, especially in pharmaceutical patent cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. In the event of a successful claim of infringement against us, we may be required to:

- pay substantial damages;
- stop developing, manufacturing and/or commercializing IPI-549;
- 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 IPI-549, 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.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the PTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees and our licensors' employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, some of which may be competitors or potential competitors. Some of these employees, including each member of our senior management, executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we

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try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

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.

Risks Related to Regulatory Approval and Marketing of IPI-549 and Other Legal Compliance Matters

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of IPI-549. If we or our collaborators are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we or they will not be able to commercialize IPI-549, and our ability to generate revenue will be materially impaired.

IPI-549 and the activities associated with its development and commercialization, including its design, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertising, promotion, sale and distribution, export and import, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the European Medicines Agency and comparable regulatory authorities in other countries. Failure to obtain marketing approval for IPI-549 will prevent us from commercializing IPI-549. We and our collaborators have not received approval to market IPI-549 from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party contract research organizations to assist us in this process.

Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate’s safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. IPI-549 may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval

or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of IPI-549. Any marketing approval we or our collaborators ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

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Accordingly, if we or our collaborators experience delays in obtaining approval or if we or they fail to obtain approval of IPI-549, the commercial prospects for IPI-549 may be harmed, and our ability to generate revenues will be materially impaired.

Failure to obtain marketing approval in foreign jurisdictions would prevent IPI-549 from being marketed in such jurisdictions.

In order to market and sell our medicines in the European Union and many other jurisdictions, we or our third party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, a product must be approved for reimbursement before the product can be approved for sale in that country. We or our third party collaborators may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize IPI-549 in any market.

Even if we or our collaborators obtain marketing approvals for IPI-549, the terms of approvals and ongoing regulation of IPI-549 may limit how we manufacture and market IPI-549, which could impair our ability to generate revenue.

Once marketing approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation. We, and any collaborators, must therefore comply with requirements concerning advertising and promotion for IPI-549. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we and any collaborators will not be able to promote any products we develop for indications or uses for which they are not approved.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, our contract manufacturers, any collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs.

Accordingly, assuming we, or any of our collaborators, receive marketing approval for IPI-549, we, our collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control.

If we, and any collaborators, are not able to comply with post-approval regulatory requirements, we, and our collaborators, could have the marketing approvals for our products withdrawn by regulatory authorities and our, or any collaborators', ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

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IPI-549 could be subject to restrictions or withdrawal from the market and we may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with IPI-549, when and if it is approved.

Any product candidate for which we or our collaborators obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control and manufacturing, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of IPI-549 is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine, including the requirement to implement a risk evaluation and mitigation strategy.

The FDA and other agencies, including the Department of Justice, or the DOJ, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations and enforcement actions alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on distribution or use of a product;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure;
- injunctions or the imposition of civil or criminal penalties; and
- litigation involving patients using our products.

Non-compliance with European Union requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the European Union's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Our relationships with healthcare providers, physicians and third party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which, in the event of a violation, could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with

healthcare providers, physicians and third party payors may expose us to broadly applicable fraud and abuse and other healthcare laws and

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regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties, currently set at $5,500 to $11,000 per false claim;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs to report payments and other transfers of value to physicians and teaching hospitals; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws and transparency statutes, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, 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.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including

exclusions from government funded healthcare programs.

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Current and future legislation may increase the difficulty and cost for us and any collaborators to obtain marketing approval of IPI-549 and affect the price we, or they, may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of IPI-549, restrict or regulate post-approval activities and affect our ability, or the ability of any collaborators, to profitably sell any products for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products.

For example, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the PPACA. Among the provisions of the PPACA of potential importance to our business and IPI-549 are the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- expansion of healthcare fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- a new Independent Payment Advisory Board, or IPAB, which has authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription drugs; and
- established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models.

Other legislative changes have been proposed and adopted since the PPACA was enacted. These changes include the Budget Control Act of 2011, which, among other things, led to aggregate reductions to Medicare payments to providers of up to 2% per fiscal year that started in 2013 and, due to subsequent legislation, will continue until 2025. In addition, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which regulatory approval is obtained.

We expect that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Moreover,

legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We

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cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the United States Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us and any collaborators to more stringent product labeling and post-marketing testing and other requirements.

We are subject to U.S. and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. In addition, we may engage third party intermediaries to promote our clinical research activities abroad and/or to obtain necessary permits, licenses, and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners, and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

We cannot assure you that our employees and third party intermediaries will comply with such anti-corruption laws. Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage, and other collateral consequences. If any subpoenas, investigations, or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens.

We are subject to governmental export and import controls that could impair our ability to compete in international markets due to licensing requirements and subject us to liability if we are not in compliance with applicable laws.

Our products and solutions are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls. Exports of our products and solutions outside of the United States must be made in compliance with these laws and regulations. If we fail to comply with these laws and regulations, we and certain of our employees could be subject to substantial civil or criminal penalties, including the possible loss of export or import privileges; fines, which may be imposed on us and responsible employees or managers; and, in extreme cases, the incarceration of responsible employees or managers. In addition, changes in our products or solutions or changes in applicable export or import laws and regulations may create delays in the introduction, provision, or sale of our products and solutions in international markets, prevent customers from using our products and solutions or, in some cases, prevent the export or import of our products and solutions to certain countries, governments or persons altogether. Any limitation on our ability to export, provide, or sell our products and solutions could adversely affect our business, financial condition and results of operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third

parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

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We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the most recent global financial crisis, could result in a variety of risks to our business, including weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. This is particularly true in the European Union, which is undergoing a continued severe economic crisis. A weak or declining economy could strain our suppliers, possibly resulting in supply disruption, or cause delays in payments for our services by third-party payors or our collaborators. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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

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

Our employees may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards 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 and results of operations, including the imposition of significant fines or other sanctions.

Risks Related to Employee Matters and Managing Growth

If we are not able to 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.

Retaining qualified scientific and business personnel is also critical to our success. Our industry has experienced a high rate of turnover of management personnel in recent years. If we lose one or more of our executive officers or other key

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employees, our ability to implement our business strategy successfully could be seriously harmed. This competition is particularly intense near our headquarters in Cambridge, Massachusetts. 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. In addition, as a result of our restructurings throughout 2016, we may face additional challenges in retaining our existing senior management and key employees for our company as our business needs change.

We also experience competition in the hiring of scientific personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development strategy. Our consultants and advisors may be employed by other entities, have commitments under consulting or advisory contracts with third parties that limit their availability to us, or both.

We may 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 businesses, products, product candidates or technologies 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.

Risks Related to 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 IPI-549;
- the timing and costs associated with the wind-down of our involvement with duvelisib;
- future sales of, and the trading volume in, our common stock;
- announcements of strategic transactions relating to our programs or our company;
- our entry into key agreements, including those related to the acquisition or in-licensing of new programs, or the termination of key agreements, including our amended and restated development and license agreement with Takeda or the Verastem Agreement;
- the results and timing of regulatory reviews relating to the approval of IPI-549;

- 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;

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- the failure of IPI-549, if approved, to achieve commercial success;
- the results of clinical trials conducted by others on drugs that would compete with IPI-549;
- the regulatory approval of drugs that would compete with IPI-549;
- issues in manufacturing IPI-549;
- 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.

If we fail to meet the requirements for continued listing on the NASDAQ Global Select Market, our common stock could be delisted from trading, which would decrease the liquidity of our common stock and our ability to raise additional capital.

Our common stock is currently listed for quotation on the NASDAQ Global Select Market. We are required to meet specified requirements in order to maintain our listing on the NASDAQ Global Select Market, including, among other things, a minimum bid price of $1.00 per share. Our bid price has been below $2.00 per share since June 2016. If our bid price falls further to below $1.00 per share for 30 consecutive business days, we will receive a deficiency notice from NASDAQ advising us that we have 180 days to regain compliance by maintaining a minimum bid price of at least $1.00 for a minimum of ten consecutive business days. Under certain circumstances, NASDAQ could require that the minimum bid price exceed $1.00 for more than ten consecutive days before determining that a company complies.

If we fail to satisfy the NASDAQ Global Select Market's continued listing requirements, we may transfer to the NASDAQ Capital Market, which generally has lower financial requirements for initial listing, to avoid delisting, or, if we fail to meet its listing requirements, the OTC Bulletin Board. A transfer of our listing to the NASDAQ Capital Market or having our common stock trade on the OTC Bulletin Board could adversely affect the liquidity of our common stock. Any such event could make it more difficult to dispose of, or obtain accurate quotations for the price of, our common stock, and there also would likely be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further. We may also face other material adverse consequences in such event, such as negative publicity, a decreased ability to obtain additional financing, diminished investor and/or employee confidence, and the loss of business development opportunities, some or all of which may contribute to a further decline in our stock price.

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

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses. Such estimates and judgments include those related to revenue recognition, impairment of long-lived assets, restructuring, 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

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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.

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, which could be impacted by our restructuring or employee turnover, 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.

We might not be able to utilize a significant portion of our net operating loss carryforwards and research and development tax credit carryforwards.

We have incurred significant net losses since our inception and cannot guarantee when, if ever, we will become profitable. To the extent that we continue to generate federal and state taxable losses, unused net operating loss and tax credit carryforwards will carry forward to offset future taxable income. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. In addition, we have not conducted a detailed study to document whether our historical activities qualify to support the research and development credit carryforwards. A detailed study could result in adjustment to our research and development credit carryforwards. If we determine that an ownership change has occurred and our ability to use our historical net operating loss and tax credit carryforwards is materially limited, or if our research and development carryforwards are adjusted, it would harm our future operating results by effectively increasing our future tax obligations.

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 and growing infrastructure and personnel to support our commercialization efforts. Therefore, we do not anticipate paying cash dividends in the future. As a result, only appreciation of the price of our common stock will provide a return to stockholders. Investors seeking cash dividends should not invest in our common stock.

Our 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 31, 2016, 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 60% 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.

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

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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.

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

As of September 30, 2016, we had $112.3 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.

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Item 5. Other Information

On November 8, 2016, we and ARE-770/784/790 Memorial Drive, LLC, or ARE, entered into an agreement for termination of lease and voluntary surrender of premises effective October 31, 2016, or the 780 / 790 Memorial Drive Termination Agreement. Under the 780 / 790 Memorial Drive Termination Agreement, we and ARE terminated by mutual consent our lease agreement, by and between us and ARE, dated as of July 2, 2002, as amended, which we refer to as the 780 / 790 Memorial Drive Lease Agreement, regarding our facilities at 780 Memorial Drive and 790 Memorial Drive, Cambridge, MA 02139, which we refer to as the Leased Properties. We have elected to terminate the 780 / 790 Memorial Drive Lease Agreement to consolidate our facilities as part of our strategic restructuring efforts. The 780 / 790 Memorial Drive Lease Agreement was previously scheduled to expire on May 31, 2025. Under the 780 / 790 Memorial Drive Lease Agreement, we also had two separate five-year options to extend our possession of the Leased Properties until 2035. Pursuant to the 780 / 790 Memorial Drive Termination Agreement, subject to our surrender of the Leased Properties, the Lease Agreement expiration date will be accelerated to October 31, 2016, which we refer to as the Termination Date.

As a result of our early termination, we owe to ARE a termination payment of $1,764,227, comprised of a $1,700,000 fee as consideration for ARE’s agreement to enter into the 780 / 790 Memorial Drive Termination Agreement and a $64,227 payment by us to ARE in lieu of our performance of certain restoration requirements with regards to the Leased Properties. Pursuant to the terms of the 780 / 790 Memorial Drive Lease Agreement, ARE will refund a portion of our $630,901.50 security deposit.

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Item 6. Exhibits

(a) Exhibits.

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

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 9, 2016 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)

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EXHIBIT INDEX

Exhibit No.	Description	Incorporated by Reference			Filed with this 10-Q
		Form	SEC Filing date	Exhibit Number	
3.1	Restated Certificate of Incorporation of the Registrant.	10-Q	8/9/2007	3.1	
3.2	Amended and Restated Bylaws of the Registrant.	8-K	3/17/2009	3.1	
4.1	Form of Common Stock Certificate.	10-K	3/14/2008	4.1	
10.1	Second Amendment to Amended and Restated Development and License Agreement, dated September 27, 2016, by and between the Registrant and Intellikine LLC.				X
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, 2016, formatted in XBRL (eXtensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations and Comprehensive Loss, (iii) the Condensed Consolidated Statements of Cash Flows, and (iv) Notes to Condensed Consolidated Financial Statements. Filed herewith.				X