INFINITY PHARMACEUTICALS, INC.
Form 10-Q
May 04, 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 March 31, 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 April 29, 2016: 49,447,019

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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)

	March 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$113,755	$ 188,170
Available-for-sale securities	79,213	57,061
Prepaid expenses and other current assets	15,073	9,466
Total current assets	208,041	254,697
Property and equipment, net	27,918	28,240
Restricted cash	1,681	1,681
Long-term receivable (note 11)	503	1,821
Other assets	2,357	2,382
Total assets	$240,500	$ 288,821
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$9,097	$ 9,628
Accrued expenses	22,952	24,604
Deferred revenue, current	34,301	35,408
Financing obligation, current (note 11)	422	416
Total current liabilities	66,772	70,056
Deferred revenue, less current portion	87,383	95,531
Deferred rent (note 11)	4,808	4,632
Financing obligation, less current portion (note 11)	19,483	19,591
Other liabilities	408	454
Total liabilities	178,854	190,264
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, $0.001 par value; 1,000,000 shares authorized, no shares issued and outstanding at March 31, 2016 and December 31, 2015	—	—
Common Stock, $0.001 par value; 100,000,000 shares authorized, and 49,349,577 and 49,305,136 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	49	49
Additional paid-in capital	697,809	694,051
Accumulated deficit	(636,252)	(595,588)
Accumulated other comprehensive income (loss)	40	45
Total stockholders' equity	61,646	98,557
Total liabilities and stockholders' equity	$240,500	$ 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 Loss
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2016	2015
Collaboration revenue	$9,256	$4,363
Operating expenses:		
Research and development	39,188	88,428
General and administrative	10,836	8,550
Total operating expenses	50,024	96,978
Loss from operations	(40,768)	(92,615)
Other income (expense):		
Interest expense	(309)	(647)
Investment and other income (loss)	413	(40)
Total other income (expense)	104	(687)
Net loss	$(40,664)	$(93,302)
Basic and diluted loss per common share	$(0.82)	$(1.91)
Basic and diluted weighted average number of common shares outstanding	49,339,888	48,939,383
Other comprehensive loss:		
Net unrealized holding losses on available-for-sale securities arising during the period	(5)	(4)
Comprehensive loss	$(40,669)	$(93,306)

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)

	Three Months Ended March 31,	
	2016	2015
Operating activities		
Net loss	$(40,664)	$(93,302)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	693	354
Stock-based compensation including 401(k) match	3,715	3,751
Net amortization of premium/discount on available-for-sale securities	56	72
Amortization of loan commitment asset	—	647
Other, net	—	1
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(4,264)	4,921
Accounts payable, accrued expenses and other liabilities	(2,327)	(5,778)
Due to Takeda	—	(6,667)
Deferred revenue	(9,255)	(4,364)
Deferred rent	173	707
Net cash used in operating activities	(51,873)	(99,658)
Investing activities		
Purchases of property and equipment	(270)	(1,112)
Purchases of available-for-sale securities	(34,323)	—
Proceeds from maturities of available-for-sale securities	12,110	15,248
Net cash provided by (used in) investing activities	(22,483)	14,136
Financing activities		
Proceeds from issuances of common stock related to stock incentive plans and awards	43	1,162
Payments on financing obligation	(102)	—
Net cash provided by (used in) financing activities	(59)	1,162
Net decrease in cash and cash equivalents	(74,415)	(84,360)
Cash and cash equivalents at beginning of period	188,170	307,405
Cash and cash equivalents at end of period	$113,755	$223,045
Supplemental cash flow information		
Cash paid for interest	$309	$—
Supplemental schedule of noncash investing and financing activities		
Property and equipment in accrued expenses	$101	$367
Increase in property and equipment for amount paid by landlord	$—	$2,626

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

2. Basis of Presentation

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

The accompanying condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring accruals and revisions of estimates, considered necessary for a fair presentation of the accompanying condensed consolidated financial statements have been included. Interim results for the three months ended March 31, 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 March 31, 2016, and for the three months ended March 31, 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.

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 March 31, 2016 will be adequate to satisfy our capital needs based on planned levels of spending through the first quarter of 2017. We have not included any of the future potential $400 million of AbbVie milestone payments in this forecast (see note 8). 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

The Company’s significant accounting policies are described in Note 2, “Summary of Significant Accounting Policies,” in the Company’s 2015 Annual Report on Form 10-K.

Segment Information

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

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

Basic and Diluted Net Loss per Common Share

Basic net loss per share is based upon the weighted average number of common shares outstanding during the period. Diluted net loss per share is based upon the weighted average number of common shares outstanding during the period plus the effect of additional weighted average common equivalent shares outstanding during the period when the effect of adding such shares is dilutive. Common equivalent shares result from the assumed exercise of outstanding stock options and the exercise of outstanding warrants (the proceeds of which are then assumed to have been used to repurchase outstanding stock using the treasury stock method). In addition, the assumed proceeds under the treasury stock method include the average unrecognized compensation expense of stock options that are in-the-money. This results in the “assumed” buyback of additional shares,

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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 loss per share attributable to common stockholders for the periods presented because including them would have been antidilutive:

	Three Months Ended March 31,	
	2016	2015
Stock Options	9,507,338	8,039,498
Warrants (excluded from treasury stock method)	1,000,000	1,000,000

New Accounting Pronouncements

In August 2014, the FASB issued ASU No. 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, 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 guidance would have resulted in additional disclosure in our financial statements as of March 31, 2016 had we adopted. We will continue to evaluate the potential impact that ASU No. 2014-15 may have.

In February 2016, the FASB issued ASU No. 2016-02, Leases, 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, 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 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.

4. Stock-Based Compensation

Total stock-based compensation expense related to all equity awards for the three months ended March 31, 2016 and 2015 comprised the following:

	Three Months Ended March 31,	
	2016	2015
	(in thousands)	
Research and development	$1,876	$2,236
General and administrative	1,839	1,515
Total stock-based compensation expense	$3,715	$3,751

As of March 31, 2016, we had approximately $21.1 million of total unrecognized compensation cost, net of estimated forfeitures, related to unvested stock options and awards under our ESPP, which are expected to be recognized over a weighted-average period of 2.4 years.

Stock Options

During the three months ended March 31, 2016, we granted options to purchase 1,404,972 shares of our common stock at a weighted average fair value of $4.07 per share and a weighted average exercise price of $6.68 per share. During the three months ended March 31, 2015, we granted options to purchase 1,643,841 shares of our common stock at a weighted average fair value of $9.43 per share and a weighted average exercise price of $15.56 per share. For the three months ended March 31, 2016 and 2015, the fair values were estimated using the Black-Scholes valuation model using the following weighted-average assumptions:

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	Three Months Ended March 31,	
	2016	2015
Risk-free interest rate	1.8 %	1.4 %
Expected annual dividend yield	—	—
Expected stock price volatility	70.8 %	71.5 %
Expected term of options	5.4 years	5.4 years

During the three months ended March 31, 2016, options to purchase 12,117 shares of common stock were exercised, with a weighted-average exercise price of $3.48.

Employee Stock Purchase Plan

The weighted-average fair value of each purchase right granted during the three months ended March 31, 2016 and 2015 was $2.91 and $7.62, respectively. For the three months ended March 31, 2016 and 2015, the fair values were estimated using the Black-Scholes valuation model using the following weighted-average assumptions:

	Three Months Ended March 31,	Three Months Ended March 31,
	2016	2015
Risk-free interest rate	0.8 %	0.4 %
Expected annual dividend yield	—	—
Expected stock price volatility	63.5 %	70.3 %
Expected term of options	1.3 years	1.2 years

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

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

	March 31, 2016			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	(in thousands)			
Cash and cash equivalents due in 90 days or less	$113,755	$ —	$ —	$113,755
Available-for-sale securities:				
Corporate obligations due in one year or less	50,437	32	(1)	50,468
Asset-backed securities due in one year or less	11,961	5	—	11,966
U.S. government-sponsored enterprise obligations due in one year or less	16,775	4	—	16,779
Total available-for-sale securities	79,173	41	(1)	79,213
Total cash, cash equivalents and available-for-sale securities	$192,928	$ 41	$ (1)	$192,968

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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 four debt securities at March 31, 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 $20.7 million. There were no material unrealized losses from these securities. We evaluated our securities for other-than-temporary impairments based on quantitative and qualitative factors. We considered the decline in market value for these securities to be primarily attributable to current economic and market conditions. It is not more likely than not that we will be required to sell these securities, and we do not intend to sell these securities before the recovery of their amortized cost basis. Based on our analysis, we do not consider these investments to be other-than-temporarily impaired as of March 31, 2016.

As of March 31, 2016, we held five securities in financial institutions and other corporate debt securities located in Japan, the United Kingdom, Australia and Switzerland with an aggregate fair value of $32.7 million. These securities are short term in nature and are scheduled to mature within twelve months. There were no material unrealized losses from these securities. Based on our analysis, we do not consider these investments to be other-than-temporarily impaired as of March 31, 2016.

We had no material realized gains or losses on our available-for-sale securities for the three months ended March 31, 2016 and 2015. There were no other-than-temporary impairments recognized for the three months ended March 31, 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 quotes. We validate the prices provided by our third party pricing services by reviewing their pricing methods and obtaining market values from other pricing sources. After completing our validation procedures, we did not adjust or override any fair value measurements provided by our pricing services as of March 31, 2016 and December 31, 2015.

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The following table provides the assets carried at fair value measured on a recurring basis as of March 31, 2016:

	Level 1	Level 2
	(in thousands)	
Assets:		
Cash and cash equivalents	$102,994	$10,761
Corporate obligations (including commercial paper)	—	50,468
Asset-backed securities	—	11,966
U.S. government-sponsored enterprise obligations	—	16,779
Total	$102,994	$89,974

The fair value of the available-for-sale securities and cash and cash equivalents (including asset types listed below with maturities of three months or less at the time of purchase) is based on the following inputs:

- Corporate Obligations:
- Commercial paper: calculations by custodian based on the three month Treasury bill published on the last business day of the month.
- Other: benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data, including TRACE® reported trades.
- Asset-Backed Securities: benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data, new issue data, monthly payment information and collateral performance.
- U.S. Government-Sponsored Enterprise Obligations: benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data 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 the valuation methods during the three months ended March 31, 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 three months ended March 31, 2016. We had no available-for-sale securities that were classified as Level 3 at any point during the three months ended March 31, 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:

	March 31, 2016	December 31, 2015
	(in thousands)	
Prepaid comparator drug	$1,756	$ —
Other prepaid expenses	9,969	6,898
Other current assets	844	1,383
Short-term receivable (note 11)	2,504	1,185
Total prepaid expenses and other current assets	$15,073	$ 9,466

8. Collaborations

AbbVie

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

commercialize products containing duvelisib, an oral, dual inhibitor of the delta and gamma isoforms of phosphoinositide-3-kinase, or PI3K, which we refer to as Duvelisib Products, in oncology indications. IPI-549, an orally administered, selective PI3K-gamma inhibitor, is excluded from the collaboration. Under the terms of the AbbVie Agreement, we have granted to AbbVie licenses under applicable patents, patent applications, know-how and trademarks to develop, commercialize and manufacture Duvelisib Products in oncology indications. These licenses are generally co-exclusive with rights we retain, except that we have granted AbbVie exclusive licenses to commercialize Duvelisib Products outside the United States. We and AbbVie

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retain the rights to perform our respective obligations and exercise our respective rights under the AbbVie Agreement, and we and AbbVie may each grant sublicenses to affiliates or third parties.

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

We and AbbVie share oversight of development and have each agreed to use diligent efforts, as defined in the AbbVie Agreement, to carry out our development activities under an agreed upon development plan. We have primary responsibility for the conduct of development of Duvelisib Products, unless otherwise agreed, and AbbVie has responsibility for the conduct of certain contemplated combination clinical studies, including those examining duvelisib and venetoclax, which we refer to as the AbbVie Studies. The development and manufacturing costs for the AbbVie Studies are shared equally. During the three months ended March 31, 2016 and March 31, 2015, we recognized an expense of $0.6 million and $0.2 million, respectively, in research and development expense related to our share of the AbbVie Studies cost.

We have the responsibility to manufacture Duvelisib Products until we transition manufacturing responsibility to AbbVie, which we expect to occur as promptly as practicable while ensuring continuity of supply. Excluding the AbbVie Studies, we are responsible for all costs to develop and manufacture Duvelisib Products up to a maximum amount of $667 million after which we will share Duvelisib Product development and manufacturing costs equally with AbbVie. During the three months ended March 31, 2016 and March 31, 2015, we recognized an expense of $3.8 million and $1.0 million, respectively, in research and development expense related to costs incurred by AbbVie for other than the AbbVie Studies.

We and AbbVie share operational responsibility and decision making authority for commercialization of Duvelisib Products in the United States. Specifically, we have the primary responsibility for advertising, distribution, and recording product sales, and we share certain other commercialization functions with AbbVie. Assuming regulatory approval, we and AbbVie are obligated to each provide half of the sales representative effort to promote Duvelisib Products in the United States. Outside the United States, AbbVie has, with limited exceptions, operational responsibility and decision making authority to commercialize Duvelisib Products. We and AbbVie will share the cost of manufacturing and supply for commercialization of Duvelisib Products in the United States, and AbbVie will bear the cost of manufacturing and supply for commercialization of Duvelisib Products outside the United States. Prior to commercialization and regulatory approval, we will recognize the cost of manufacturing as a component of research and development and the cost of commercialization as a component of general and administrative expenses. Subsequent to regulatory approval and commercial launch, the cost of manufacturing will be recorded as cost of goods sold. During the three months ended March 31, 2016 and 2015, we accounted for AbbVie’s share of the costs as a reduction of the related expense or as additional expense. We recognized an expense of approximately $25,000 and a credit of $0.2 million in research and development expense related to these costs during the three months ended March 31, 2016 and 2015, respectively. During the three months ended March 31, 2016 and 2015, we recognized credits of $1.0 million and $0.3 million, respectively, in general and administrative expense related to these costs.

AbbVie has paid us a non-refundable $275 million upfront payment in 2014 and a $130 million non-refundable milestone payment in November 2015 associated with the completion of enrollment of DYNAMO™ in September 2015. DYNAMO is a Phase 2, open-label, single-arm monotherapy study evaluating the safety and efficacy of duvelisib dosed at 25 mg twice daily, or BID, in approximately 120 patients with indolent non-Hodgkin lymphoma, or iNHL, including follicular lymphoma, marginal zone lymphoma and small lymphocytic lymphoma, whose disease is refractory to rituximab and to either chemotherapy or radioimmunotherapy. Further, AbbVie has agreed to pay us up to an additional $400 million in potential future milestone payments comprised of $125 million associated with the

acceptance by the U.S. Food and Drug Administration, or FDA, of the first New Drug Application, or NDA, submission for duvelisib, $75 million associated with the acceptance of the first Marketing Authorization Application, or MAA, submission for duvelisib, up to $75 million associated with the achievement of specified regulatory approval milestones, and up to $125 million associated with the achievement of specified commercialization milestones.

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

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

We have evaluated the deliverables within the AbbVie Agreement to determine whether or not they provide value on a stand-alone basis. Based on our evaluation, we have determined that there are three deliverables: the license, the development services and the committee services. Each deliverable provides value on a stand-alone basis and represents a separate unit of accounting. We determined the best estimate of selling price for each unit of accounting using a discounted cash-flow model. The valuation for each deliverable involves significant estimates and assumptions, including but not limited to, expected market opportunity, assumed royalty rates, pricing objectives, clinical trial timelines, likelihood of success and projected costs. The resulting estimate of selling prices for the license and development services consider the benefits that have been retained by us.

Of the $275 million upfront payment received during the year ended December 31, 2014, $159.1 million was allocated to the license, $115.6 million to the development services and $0.3 million to committee services based on the allocation of best estimate of selling price on a relative basis. We determined the best estimate of selling prices for the license unit of accounting based on estimates and assumptions resulting in an expected future cash flow which was discounted based on estimated weighted average cost of capital of 11.5%. We determined the best estimate of selling prices for development and committee services based on the nature of the services to be performed and estimates of the associated efforts and third-party rates for similar services using a discount rate of 8% for development services and 11.5% for committee services. We recognized license revenue upon execution of the arrangement. Revenue related to development services and committee services is being recognized using the proportionate performance method as services are provided over the estimated service period of approximately five years. We have determined that the clinical development milestone achieved on September 30, 2015 was not substantive based on risk and effort involved and, therefore, have applied the proportionate performance method to recognizing the related revenue. Of the $130 million milestone achieved, $75.2 million was allocated to the license, $54.7 million to the development services and $0.1 million to committee services based on the same allocation of best estimate of selling price on a relative basis as determined at the inception of the arrangement. Upon achievement of the milestone on September 30, 2015, we recognized the $75.2 million allocated to the license as revenue and $9.8 million of revenue related to the development and committee services performed from the inception of the AbbVie Agreement through September 30, 2015. During the three months ended March 31, 2016 and March 31, 2015, we recognized $9.3 million and $4.4 million, respectively, of revenue related to the development and committee services. We have recorded the remaining amounts related to development and committee services of $34.3 million and $87.4 million as short-term and long-term deferred revenue, respectively, as of March 31, 2016.

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

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

The AbbVie Agreement will remain in effect until all development, manufacturing and commercialization of Duvelisib Products cease, unless terminated earlier. Either we or AbbVie may terminate the AbbVie Agreement if the other party is subject to certain insolvency proceedings or if the other party materially breaches the AbbVie Agreement and the breach remains uncured for a specified period, which may be extended in certain circumstances. However, we may terminate the AbbVie Agreement only on a country-by-country basis in the event AbbVie is not using diligent efforts to obtain regulatory approval or to commercialize Duvelisib Products in a country outside the United States. AbbVie may also terminate the AbbVie

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Agreement for convenience after a specified notice period. In the event there is a material uncured breach by either us or AbbVie of development or commercialization obligations, the non-breaching party may also have the right to assume and conduct such applicable development or commercialization obligations. If AbbVie or any of its affiliates or sublicensees challenges the patents we have licensed to AbbVie, we can terminate the AbbVie Agreement if the challenge is not withdrawn after a specified notice period.

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

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

Takeda

In July 2010, we entered into a development and license agreement with Intellikine, Inc., or Intellikine, under which we obtained rights to discover, develop and commercialize pharmaceutical products targeting the delta and/or gamma isoforms of PI3K, which covers duvelisib and IPI-549, and we paid Intellikine a $13.5 million upfront license fee. In January 2012, Intellikine was acquired by Takeda, acting through its Millennium business unit. We refer to our PI3K inhibitor program licensor as Takeda.

In December 2012, we amended and restated our development and license agreement with Takeda. Under the terms of the amended and restated agreement, we retained worldwide development rights and, in exchange for an agreement to pay Takeda $15 million in installments, we regained commercialization rights for products arising from the agreement for all therapeutic indications and we are solely responsible for research conducted under the agreement. During the year ended December 31, 2012, we paid $1.7 million of the $15 million, and we recorded the $15 million release payment at its fair value of $14.4 million in research and development expenses. During the year ended December 31, 2014, we paid to Takeda the second installment of $6.7 million. During the year ended December 31, 2015, we paid to Takeda the final installment of $6.7 million.

We are obligated to pay to Takeda up to $5 million in remaining success-based milestone payments for the development of a product candidate other than duvelisib, which could include IPI-549. We are also obligated to pay Takeda up to an aggregate of $450 million in success-based milestone payments for the approval and commercialization of two distinct products, of which one could be a Duvelisib Product and the other could be a product containing IPI-549. AbbVie has agreed to share in the cost of such milestone payments to the extent related to a Duvelisib Product. Please see above under the heading "AbbVie" for more information. In February 2014, we paid Takeda a $10 million milestone payment in connection with the initiation of DUO™. DUO is a randomized, Phase 3 monotherapy study designed to evaluate the safety and efficacy of duvelisib dosed at 25 mg BID compared to ofatumumab, a monoclonal antibody therapy, in approximately 300 patients with relapsed or refractory chronic lymphocytic leukemia. We recognized the $10 million payment as research and development expense during the year ended December 31, 2014.

On March 31, 2015, we paid a $52.5 million fee to exercise an option that we purchased from Takeda in July 2014 for a one-time upfront payment of $5 million. As a result of our exercise of this option, we are no longer obligated under the amended and restated development and license agreement to pay to Takeda the tiered 7% to 11% royalty with respect to worldwide net sales in oncology indications of products containing or comprised of duvelisib. 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.

Except for Duvelisib Products in oncology indications, we are obligated to pay Takeda tiered royalties ranging from 7% to 11% on worldwide net sales of products described in the agreement, which could include IPI-549 if successfully

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developed and commercialized. Such royalties are payable until the later to occur of the expiration of specified patent rights and the expiration of non-patent regulatory exclusivities in a country, subject to reduction of the royalties and, in certain circumstances, limits on the number of products subject to a royalty obligation.

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

9. Debt Facility Agreement

On February 24, 2014, we entered into a facility agreement with affiliates of Deerfield Management Company, L.P., or Deerfield, pursuant to which Deerfield agreed to loan us up to $100 million, subject to the terms and conditions set forth in the facility agreement. On September 22, 2014, we amended the facility agreement with Deerfield to reduce the maximum principal amount that we may draw down to $50 million. We refer to the facility agreement with Deerfield, as amended, as the Facility Agreement. Under the terms of the Facility Agreement, we had the right to draw down on the Facility Agreement in $25 million minimum disbursements, which we refer to as the Loan Commitment, at any time during a pre-specified draw period. The draw period expired without our having drawn down on the Facility Agreement.

On February 25, 2015, we paid a $1.5 million fee to Deerfield representing 3% of the total amount not drawn under the amended facility. In connection with the execution of the Facility Agreement, we issued to Deerfield warrants to purchase an aggregate of 1,000,000 shares of common stock at an exercise price of $13.83 per share. The warrants have dividend rights to the same extent as if the warrants were exercised into shares of common stock. The warrants expire on the seventh anniversary of their issuance and contain certain limitations that prevent the holder from acquiring shares upon exercise of a warrant that would result in the number of shares beneficially owned by the holder exceeding 9.985% of the total number of shares of common stock then issued and outstanding.

Our total cost of securing the Loan Commitment was $11.8 million and is comprised of $8.4 million representing the fair value of the 1,000,000 warrants issued on February 24, 2014; $3 million representing the original facility fee; and $0.4 million of transaction costs. As a result of the amendment of the Facility Agreement, the original facility fee was reduced by 50%, or $1.5 million, and we recorded a corresponding decrease in the loan commitment asset. In addition, since our borrowing capacity was reduced by 50%, the remaining loan commitment asset outstanding as of September 22, 2014 was also reduced by 50% resulting in an additional expense of $1.8 million during the year ended December 31, 2014. The total fair value is considered a Loan Commitment Asset which was classified as a current asset on the December 31, 2014 consolidated balance sheet. This amount is considered a fee to secure the Loan Commitment and was being amortized to interest expense on a straight line basis over the draw period. We recorded $0.6 million of interest expense associated with the amortization and write-off of the loan commitment asset pursuant to the modification of the facility for the three months ended March 31, 2015. We did not record any interest expense associated with the amortization and write-off of the loan commitment asset pursuant to the modification of the facility for the three months ended March 31, 2016.

10. Accrued Expenses

Accrued expenses consisted of the following:

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	March 31, 2016	December 31, 2015
	(in thousands)	
Accrued compensation and benefits	$4,558	$ 8,732
Accrued drug manufacturing costs	1,524	3,494
Accrued clinical studies	10,206	8,531
Accrued preclinical studies	336	539
Deferred rent, current	258	261
Other	6,070	3,047
Total accrued expenses	$22,952	$ 24,604

11. Leases

We lease our office and laboratory space 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, the Expiration Date. Pursuant to the Lease, on the Commencement Date we agreed to lease 61,000 square feet of the leased premises, which represents the entire building, the Leased Premises.

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

Upon the Commencement Date, building construction was initiated to suit our future needs. We were responsible for the construction project, including having responsibility to pay for a portion of the structural elements of the building and bearing the risk of cost overruns. Therefore, we were deemed for accounting purposes to be the owner of the building during the construction period. Accordingly, we determined the fair value of the building as of November 1, 2014 through an independent appraisal and recorded the building as an asset on our condensed consolidated balance sheet, together with a corresponding construction liability, in November 2014 when the lease and construction commenced. On our condensed consolidated balance sheet, we recorded project construction costs as an asset during the construction period and reflected an increase in the construction financing obligation for the amount of Landlord incentives received. The construction was substantially complete, and the Leased Premises was available for occupancy in June 2015. The construction-in-progress was then placed in service, and the construction liability was reclassified to a financing obligation as such transaction did not qualify for sale-leaseback accounting due to our

continuing involvement with the property in the form of non-recourse financing to the lessor as well as our obligation to pay for all costs in excess of the specified Landlord allowances. Depreciation on the building and building improvements commenced in June 2015 and will be recorded over the initial term of the lease using a residual value equal to the financing obligation at the end of the lease term, which approximates the net book value using the estimated useful lives of the respective assets. Interest expense is recorded on a monthly basis using an estimated incremental borrowing rate based on comparable 10 year secured financings and commenced in June 2015 when the building was placed into service. In April and May 2015, the construction financing obligation was reduced by that portion of the lease payment allocated to the construction financing obligation principal. Commencing in June 2015, the financing obligation has

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been, and will continue to be, reduced on a monthly basis by that portion of the lease payment allocated to the financing obligation principal.

At March 31, 2016, future minimum payments under the Lease were approximately $19.6 million, which is composed of $1.5 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.

At March 31, 2016 and December 31, 2015, the accompanying condensed consolidated balance sheet reflects the building and accumulated construction costs of approximately $22.8 million and $23.0 million, respectively, and a financing obligation of approximately $19.9 million and $20.0 million, respectively.

We divide our future lease payments into a portion that is allocated to the financing obligation and a portion that is allocated to the land on which the building is located. The portion of the lease obligation allocated to the land is treated for accounting purposes as an operating lease which commenced in November 2014 and is recorded on a straight-line basis over the initial lease term. Rent expense pertaining to the land was approximately $0.1 million for the three months ended March 31, 2016 and March 31, 2015.

In November 2015 we subleased approximately 12,000 square feet of the Leased Premises to two tenants with initial terms ending in July 2017 and October 2017, respectively. We also granted each tenant an option to extend the term for one year. For the three months ended March 31, 2016, sublease income of approximately $0.2 million is included in other income in our condensed consolidated statements of operations and comprehensive loss and is not offset against rent expense because, for accounting purposes, we are considered the owner of the building. Minimum future sublease income under these noncancelable subleases is approximately $0.6 million for the remainder of 2016 and $0.5 million in 2017.

780/790 Memorial Drive Lease Arrangement
On November 6, 2014, we entered into a Seventh Amendment to Lease, the Lease Amendment, by and between us and ARE-770/784/790 Memorial Drive, LLC, the landlord, which amends the original lease agreement dated July 2, 2002, as amended to date, or the Original Lease. We refer to the Original Lease together with the Lease Amendment as the Memorial Drive Lease. We refer to the area rented under the Memorial Drive Lease as the Premises.

Under the Lease Amendment: (i) the Premises consist of 54,861 square feet, of which 51,000 square feet are located at 780 Memorial Drive, or the 780 Premises, and the remaining 3,861 square feet are located at 790 Memorial Drive, or the 790 Premises; effective February 1, 2016, we surrendered 13,159 square feet of the previously leased 17,020 square feet at the 790 Premises; (ii) we have extended the base term of the Memorial Drive Lease through March 31, 2025; and (iii) we have two separate five-year options to extend the term of the Memorial Drive Lease to 2035 on the same terms and conditions (other than with respect to base rent or any work letter). The Memorial Drive Lease provides that we continued to pay the base rent as provided in the Original Lease until January 31, 2016. The base rent then increased to $69.00 per square foot of the Premises on February 1, 2016 and shall increase again to $70.00 per square foot of the Premises on February 1, 2018. The Memorial Drive Lease provides that no base rent for the Premises was due (i) for the period commencing on February 1, 2015 through July 31, 2015 and (ii) for the period commencing on February 1, 2016 through February 29, 2016, and that no base rent shall be due (i) for the period commencing on February 1, 2017 through February 28, 2017, and (ii) for the period commencing on February 1, 2018 through February 28, 2018. We also received allowances of $3 million for the design and construction of tenant improvements. The total of these allowances of $3 million has been reflected on our condensed consolidated balance sheets as a receivable, with a corresponding amount included in deferred rent liability. Of this $3 million, approximately $2.5 million and $1.2 million has been classified as a current asset at March 31, 2016 and December 31, 2015, respectively, representing the estimated improvements that will be performed within a year. The deferred rent is being amortized to rent expense over the term of the lease. Pursuant to the terms of the Lease

Amendment, the security deposit in the form of a letter of credit has been reduced from $1.1 million to $0.6 million. The letter of credit has been included in our accompanying condensed consolidated balance sheets as restricted cash.

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

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

The following discussion of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and related notes included elsewhere in this report. Some of the information

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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," "potential," "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 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 discovering, developing and delivering best-in-class medicines to patients with difficult-to-treat diseases. We combine proven scientific expertise with a passion for developing novel small molecule drugs that target disease pathways for potential applications in oncology. Our most advanced product candidate is duvelisib, also known as IPI-145, an oral, dual-inhibitor of the delta and gamma isoforms of phosphoinositide-3-kinase, or PI3K, which is currently being evaluated for the treatment of hematologic malignancies, or blood cancers. We believe that duvelisib is the only inhibitor of PI3K-delta and gamma being investigated in Phase 3 clinical trials. We are pursuing duvelisib in oncology through a strategic collaboration with AbbVie Inc., or AbbVie. For information regarding our collaboration, please see below under the heading "AbbVie" in the section entitled "Strategic Alliances."

Through the efforts of our dedicated discovery research program, during 2015 we expanded our pipeline with the addition of IPI-549, an orally administered, clinical-stage, immuno-oncology product candidate that selectively inhibits the gamma isoform of PI3K. In addition to duvelisib and IPI-549, we are working to generate new product candidates for potential investigation in oncology.

Product Development Pipeline

Historically, our product development programs have arisen from a combination of internally developed programs and strategic licensing arrangements. We focus on targets that have the potential to fundamentally change how disease is treated and where we believe that we can use our scientific capabilities to identify differentiated product candidates with well-defined development paths. We seek to leverage what we believe to be our innovative approaches to drug discovery and translational medicine and our robust internal capabilities across all of the relevant scientific disciplines, including medicinal chemistry, cell biology, biochemistry, pharmacology and molecular pathology. Our goal is to integrate these disciplines to rapidly identify product candidates and to better understand which populations of patients may benefit most from our product candidates.

The table below summarizes key information about each clinical trial of our product candidates, duvelisib and IPI-549. None of our product candidates is approved for any indication by the United States Food and Drug Administration, or FDA, or any other regulatory agency.

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Duvelisib: Dual Inhibitor of PI3K Delta and Gamma

Clinical Trial	Indication	Status
Indolent non-Hodgkin Lymphoma		
DYNAMO™	Refractory indolent non-Hodgkin lymphoma	l Phase 2, open-label, single-arm clinical study l Designed with potential to support accelerated approval l Primary endpoint: response rate according to the International Working Group, or IWG, criteria l Enrollment complete: 129 patients l Expect to report topline data in the third quarter of 2016
CONTEMPO	Previously untreated follicular lymphoma	l Phase 1b/2 open label, two-arm clinical study l Duvelisib plus obinutuzumab or rituximab l Targeting approximately 100 patients l Primary endpoint: Safety; complete response rate according to IWG criteria l Enrollment ongoing l Expect to report initial data from this study in the second half of 2016
BRAVURA	Relapsed indolent non-Hodgkin lymphoma	l Phase 3, double-blind, placebo-controlled clinical study l Duvelisib plus rituximab and bendamustine compared to placebo plus rituximab and bendamustine l Targeting approximately 600 patients l Primary endpoint: progression-free survival l Enrollment ongoing
FRESCO	Relapsed or refractory follicular lymphoma	l Phase 2 randomized clinical study l Duvelisib plus rituximab compared to a combination of chemotherapies plus rituximab l Targeting approximately 230 patients l Primary endpoint: progression-free survival l Enrollment ongoing
DYNAMO+R	Previously treated follicular lymphoma	l Phase 3 randomized, placebo-controlled clinical study l Duvelisib plus rituximab compared to placebo plus rituximab l Study identified for closure
Chronic Lymphocytic Leukemia		
DUO™	Relapsed or refractory chronic lymphocytic leukemia	l Phase 3, randomized, monotherapy clinical study of Duvelisib compared to ofatumumab l Primary endpoint: progression-free survival l Enrollment complete: 319 patients l Expect to report topline data in the second half of 2016

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Duvelisib: Dual Inhibitor of PI3K Delta and Gamma		
Clinical Trial	Indication	Status
SYNCHRONY	Patients with chronic lymphocytic leukemia whose disease has progressed following treatment with a Bruton's tyrosine kinase inhibitor	l Phase 1b open-label clinical study l Duvelisib plus obinutuzumab l Primary endpoint: Safety l Targeting approximately 64 patients l Enrollment ongoing
Advanced Hematologic Malignancies		
Duvelisib + Venetoclax	Relapsed or refractory indolent or aggressive non-Hodgkin lymphoma, chronic lymphocytic leukemia, or small lymphocytic lymphoma	l Phase 1b/2 open label clinical study l Duvelisib plus venetoclax l Targeting approximately 174 patients l Initiated
IPI-549: PI3K Gamma-Selective Inhibitor		
Solid Tumors	Patients with a range of solid tumors, including melanoma and non-small cell lung cancer	l Phase 1 clinical study l Includes a dose-escalation phase and an expansion phase, and is designed to evaluate IPI-549 as a monotherapy as well as in combination with an anti-PD-1 antibody therapy l Enrollment ongoing

PI3 Kinase Inhibitor Program

The PI3Ks are a family of enzymes involved in multiple cellular functions, including cell proliferation and survival, cell differentiation, cell migration, and immunity. PI3K-delta and PI3K-gamma are two proteins with distinct and mostly non-overlapping roles believed to support the growth and survival of malignant B-cells. Specifically, preclinical data suggest that PI3K-delta signaling can lead to the proliferation of malignant B-cells, and that both PI3K-gamma and PI3K-delta play an important role in the formation and maintenance of the supportive tumor microenvironment.

Duvelisib: Targeting Hematologic Malignancies by Dual Inhibition of PI3K Delta and Gamma Isoforms

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

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

Indolent Non-Hodgkin Lymphoma

As part of the DUETTS program in lymphoma, we are conducting DYNAMO™, a Phase 2, open-label, single-arm monotherapy study evaluating the safety and efficacy of duvelisib dosed at 25 mg twice daily in 129 patients with indolent non-Hodgkin lymphoma, or iNHL. DYNAMO enrollment criteria include patients with follicular lymphoma, the most common subtype of iNHL, marginal zone lymphoma, and small lymphocytic lymphoma, or SLL, whose disease is refractory to rituximab, a monoclonal antibody treatment, and to either chemotherapy or radioimmunotherapy and who must have progressed within six months of receiving their last therapy. The primary endpoint of the study is response rate according to the International Working Group, or IWG, Criteria. We completed

enrollment in DYNAMO in September 2015 and expect to report topline data early in the third quarter of 2016.

The DYNAMO study is designed with the potential to support accelerated approval of duvelisib in patients with follicular lymphoma and SLL, assuming that we are able to generate positive safety and efficacy data from the study and on the condition that we conduct a confirmatory study. The FDA has granted orphan drug designation to duvelisib for the potential treatment of follicular lymphoma, and has granted fast track designation to the investigation of duvelisib for the treatment of

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patients with follicular lymphoma who have received at least two prior therapies. The availability of accelerated approval is uncertain and is dependent on a number of factors including whether duvelisib has demonstrated a meaningful benefit relative to available therapies. For a further discussion of certain risks related to our ability to seek accelerated approval for duvelisib, see “Risk Factors—Risks Related to the Discovery, Development and Commercialization of Product Candidates” elsewhere in this report.

Additional DUETTS clinical studies in lymphoma include CONTEMPO, BRAVURA, and FRESCO. CONTEMPO is a Phase 1b/2 clinical study of duvelisib in combination with obinutuzumab, a monoclonal antibody treatment, or rituximab in patients with previously untreated follicular lymphoma. We expect to report initial data from CONTEMPO in the second half of 2016. BRAVURA is a Phase 3, double-blind, placebo-controlled study in patients with relapsed iNHL designed to evaluate the safety and efficacy of duvelisib plus rituximab and bendamustine, a chemotherapy, compared to placebo plus rituximab and bendamustine in approximately 600 patients. The primary endpoint is progression-free survival. We requested advice from the FDA to determine if BRAVURA, as designed, can serve as a confirmatory study if DYNAMO supports an accelerated approval. FRESCO is a Phase 2 randomized study in patients with relapsed or refractory follicular lymphoma that is designed to evaluate the safety and efficacy of duvelisib plus rituximab compared to rituximab plus a combination of chemotherapies referred to as “CHOP” in approximately 230 patients. The chemotherapies included in CHOP are cyclophosphamide, doxorubicin hydrochloride, vincristine sulfate, and prednisone. The primary endpoint of FRESCO is progression-free survival. DYNAMO+R, a Phase 3 randomized, placebo-controlled study evaluating duvelisib dosed at 25 mg BID in combination with rituximab compared to placebo plus rituximab in patients with previously treated follicular lymphoma has been identified for closure and is no longer enrolling patients.

Chronic Lymphocytic Leukemia

As part of the DUETTS investigation in CLL, we are conducting DUO™ and SYNCHRONY. DUO is a randomized, Phase 3 monotherapy study designed to evaluate the safety and efficacy of duvelisib dosed at 25 mg BID compared to ofatumumab, a monoclonal antibody treatment, in 319 patients with relapsed or refractory CLL. The primary endpoint of the study is progression-free survival. Enrollment of DUO was completed in November 2015, and we expect to report topline data in the second half of 2016 if supported by the interim analysis discussed in more detail below under the heading "Duvelisib Global Regulatory Filings." SYNCHRONY is a Phase 1b trial of duvelisib in combination with obinutuzumab in CLL patients whose disease has progressed following treatment with a Bruton’s tyrosine kinase, or BTK, inhibitor. This study is supported by Phase 1 data of duvelisib in six CLL patients previously treated with ibrutinib, a BTK inhibitor, which was presented in December 2014 at the Annual Meeting of the American Society for Hematology, or ASH 2014. Early clinical activity was observed, with partial responses in one CLL patient and stable disease in five CLL patients. The safety profile of duvelisib in these patients appeared consistent with the safety profile observed in other patients with advanced hematologic malignancies treated with duvelisib in the Phase 1 study. The FDA and the European Medicines Agency, or EMA, have granted orphan drug designation to duvelisib for the potential treatment of CLL and SLL. The FDA has granted fast track designation to the investigation of duvelisib for the potential treatment of patients with CLL who have received at least one prior therapy.

Investigating Duvelisib in Combination with Venetoclax

As part of our collaboration, AbbVie has initiated the first clinical study investigating duvelisib in combination with venetoclax, a first-in-class, investigational, selective B-cell lymphoma 2 inhibitor. This Phase 1b/2 trial is designed to evaluate the safety and activity of duvelisib in combination with venetoclax in approximately 174 patients with relapsed or refractory, iNHL, aggressive non-Hodgkin lymphoma, or aNHL, CLL or SLL. Preclinical data for duvelisib presented at the annual meeting of the American Society of Clinical Oncology in June 2015 demonstrates synergy with standards-of-care and emerging therapeutics in development for hematologic malignancies, including duvelisib in combination with venetoclax. For information regarding our collaboration with AbbVie, please see below under the heading “AbbVie” in the section entitled “Strategic Alliances.”

Duvelisib Global Regulatory Filings

We expect to report topline data from our DYNAMO study early in the third quarter of 2016, and if supported by the DYNAMO data, we anticipate that we will submit a New Drug Application, or NDA, in the fourth quarter of 2016

seeking accelerated approval of duvelisib from the FDA for the treatment of follicular lymphoma and SLL. In addition, we expect to conduct a planned interim analysis of data from our DUO study in the second half of 2016. If supported by the interim analysis of data from our DUO study, we expect to report topline data from our DUO study in the second half of 2016 and submit an NDA in the fourth quarter of 2016 seeking regular approval of duvelisib from the FDA for the treatment of certain patients with CLL. Additionally, if supported by an interim analysis of data from the DUO study and data from our DYNAMO study, we expect that AbbVie will submit a Marketing Authorization Application, or MAA, in the fourth quarter of 2016 seeking approval from the EMA to market duvelisib for certain patients with follicular lymphoma and CLL.

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IPI-549: Targeting Solid Tumors by Selective Inhibition of the PI3K Gamma Isoform

In 2015, we expanded our pipeline to include IPI-549, an orally administered, selective PI3K-gamma inhibitor that we intend to evaluate as a potential treatment 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 macrophages in the immune-suppressive tumor microenvironment and may have the potential to treat a broad range of solid tumors. IPI-549 has demonstrated dose-dependent, single-agent, anti-tumor activity in multiple solid tumor models, including mouse models of lung 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 in September 2015.

Based on our preclinical data generated to date, we have initiated a Phase 1 first-in-human study that includes a dose-escalation phase to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of IPI-549 as a monotherapy, as well as a dose-escalation phase evaluating IPI-549 in combination with a “checkpoint inhibitor” therapy that targets a receptor in the human body called programmed death receptor 1, or PD-1. 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 and melanoma.

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 to date have been generated under research collaborative agreements including our corporate alliances.

AbbVie

On September 2, 2014, we entered into a collaboration and license agreement with AbbVie, which we refer to as the AbbVie Agreement. Under the AbbVie Agreement, we are collaborating with AbbVie to develop and commercialize products containing duvelisib, which we refer to as Duvelisib Products, in oncology indications. IPI-549 is excluded from the collaboration. Under the terms of the AbbVie Agreement, we have granted to AbbVie licenses under applicable patents, patent applications, know-how and trademarks to develop, commercialize and manufacture Duvelisib Products in oncology indications. These licenses are generally co-exclusive with rights we retain, except that we have granted AbbVie exclusive licenses to commercialize Duvelisib Products outside the United States. We and AbbVie retain the rights to perform our respective obligations and exercise our respective rights under the AbbVie Agreement, and we and AbbVie may each grant sublicenses to affiliates or third parties.

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

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

costs of the AbbVie Studies will be shared equally.

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

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Products in the United States, and AbbVie will bear the cost of manufacturing and supply for commercialization of Duvelisib Products outside the United States.

AbbVie paid us a non-refundable $275 million upfront payment in 2014 and a $130 million milestone payment in November 2015 associated with the completion of enrollment of DYNAMO in September 2015. Further, AbbVie has agreed to pay us up to an additional $400 million in potential future milestone payments comprised of $125 million associated with the acceptance by the FDA of the first NDA submission for duvelisib, $75 million associated with the acceptance of the first MAA submission for duvelisib, up to $75 million associated with the achievement of specified regulatory approval milestones, and up to $125 million associated with the achievement of specified commercialization milestones. Under the terms of the AbbVie Agreement, we and AbbVie will equally share commercial profits or losses of Duvelisib Products in the United States, including sharing equally the existing royalty obligations to Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products L.P., or Purdue, for sales of Duvelisib Products in the United States, as well as sharing equally the existing U.S. milestone payment obligations to Takeda Pharmaceutical Company Limited, or Takeda. For more information about such obligations, refer to the sections below titled “Takeda” and “Mundipharma and Purdue.”

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

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

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

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

If the AbbVie Agreement is terminated, we would not be entitled to receive payment for any milestone achieved after notice of termination. Further, if the AbbVie Agreement is terminated, there are certain wind-down obligations to

ensure a smooth transition of the responsibilities of the parties including, unless the AbbVie Agreement is terminated by AbbVie for our material breach, the continued conduct of certain development and commercialization activities by AbbVie for a limited transition period and the continued funding by AbbVie of its half of the cost of the AbbVie Studies ongoing at the time of termination, except for those AbbVie Studies that may be transitioned to us following termination.

Takeda

In July 2010, we entered into a development and license agreement with Intellikine, Inc., or Intellikine, under which we obtained rights to discover, develop and commercialize pharmaceutical products targeting the delta and/or gamma isoforms of PI3K, which covers duvelisib and IPI-549, and we paid Intellikine a $13.5 million upfront license fee. In January 2012,

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Intellikine was acquired by Takeda, acting through its Millennium business unit. We refer to our PI3K inhibitor program licensor as Takeda.

In December 2012, we amended and restated our development and license agreement with Takeda. Under the terms of the amended and restated agreement, we retained worldwide development rights and, in exchange for an agreement to pay Takeda $15 million in installments, we regained commercialization rights for products arising from the agreement for all therapeutic indications, and we are solely responsible for research conducted under the agreement.

We are obligated to pay to Takeda up to $5 million in remaining success-based milestone payments for the development of a product candidate other than duvelisib, which could include IPI-549. We are also obligated to pay Takeda up to an aggregate of $450 million in success-based milestone payments for the approval and commercialization of two distinct products, of which one could be a Duvelisib Product and the other could be a product containing IPI-549. AbbVie has agreed to share in the cost of such milestone payments to the extent related to a Duvelisib Product. Please see above under the heading "AbbVie" for more information. In February 2014, we paid Takeda a $10 million milestone payment in connection with the initiation of DUO, our Phase 3 study of duvelisib in patients with relapsed or refractory CLL. On March 31, 2015, we paid a $52.5 million fee to exercise an option that we purchased from Takeda in July 2014 for a one-time upfront payment of $5 million. As a result of our exercise of this option, we are no longer obligated under the amended and restated development and license agreement to pay to Takeda tiered royalties with respect to worldwide net sales in oncology indications of products containing or comprised of duvelisib.

Except for duvelisib products in oncology indications, we are obligated to pay Takeda tiered royalties ranging from 7% to 11% on worldwide net sales of products described in the agreement, which could include IPI-549 if successfully developed and commercialized. Such royalties are payable until the later to occur of the expiration of specified patent rights and the expiration of non-patent regulatory exclusivities in a country, subject to reduction of the royalties and, in certain circumstances, limits on the number of products subject to a royalty obligation.

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

Mundipharma and Purdue

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

Under the terms of the 2012 Termination Agreements we are obligated to pay Mundipharma and Purdue a 4% royalty in the aggregate, subject to reduction as described below, on worldwide net sales of products that were covered by the alliance until such time as they have recovered approximately $260 million, representing the research and development funding paid to us for research and development services performed by us through the termination of the strategic alliance. After this cost recovery, our royalty obligations to Mundipharma and Purdue will be reduced to a 1% royalty on net sales in the United States of products that were previously subject to the strategic alliance. All

payments are contingent upon the successful commercialization of products that were subject to the alliance, which products require significant further development. As such, there is significant uncertainty about whether any such products will ever be approved or commercialized. If no products are commercialized, no payments will be due by us to Mundipharma and Purdue; therefore, no amounts have been accrued.

Royalties are payable under these agreements until the later to occur of the last-to-expire of specified patent rights and the expiration of non-patent regulatory exclusivities in a country, provided that if royalties are payable solely on the basis of non-patent regulatory exclusivity, each of the royalty rates is reduced by 50%. In addition, royalties payable under these agreements after Mundipharma and Purdue have recovered all research and development expenses paid to us are subject to

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

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 three months ended March 31, 2016 was derived from our strategic alliance with AbbVie. The terms of these research collaboration agreements may include payment to us of non-refundable, upfront license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved, and/or royalties on product sales. We evaluate all deliverables within an arrangement to determine whether or not they provide value on a stand-alone basis. Based on this evaluation, the deliverables are separated into units of accounting. For each unit of accounting identified within an arrangement, we determine the period over which the performance obligation occurs. Revenue is then recognized using the proportional performance method. The proportional performance method is used when the level of effort to complete the performance obligations under an arrangement can be reasonably estimated. We recognize revenue based upon our best estimate of the selling price for each element when there is no other means to determine the fair value of that item and allocate the consideration based on the relative values. The process for determining the best estimate of the selling price involves significant judgment and estimates.

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

- the consideration is commensurate with either (1) our performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from our performance to achieve the milestone,
- the consideration relates solely to past performance, and
- the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement.

In making this assessment, we evaluate factors such as the clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required, and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement. We recognize revenues related to substantive milestones in full in the period in which the substantive milestone is achieved. If a milestone payment is not considered substantive, we recognize the amount associated with the applicable milestone based on the period over which the performance obligation occurs for each deliverable in the arrangement.

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

Research and Development Expense

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

- compensation of personnel associated with research and development activities;
- 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

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commercial functions. Other costs include facilities costs not otherwise included in research and development expense, external expenses in preparation for the potential 2017 duvelisib launch and professional fees for legal and accounting services. General and administrative expense also consists of the costs of maintaining our intellectual property portfolio.

Other Income and Expense

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

Critical Accounting Policies and Significant Judgments and Estimates

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

There have been no material changes to our critical accounting policies during the three months ended March 31, 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 months ended March 31, 2016 and 2015, together with the change in these items in dollars and as a percentage:

	Three Months Ended March 31,		$ Change	% Change
	2016	2015		
	(in thousands)			
Collaboration revenue	$9,256	$4,363	$4,893	112 %
Research and development expense:				
Programs	(39,188)	(35,928)	(3,260)	9 %
Takeda payments	—	(52,500)	52,500	(100)%
Total research and development expense	(39,188)	(88,428)	49,240	(56)%
General and administrative expense	(10,836)	(8,550)	(2,286)	27 %
Interest expense	(309)	(647)	338	(52)%
Investment and other income (loss)	413	(40)	453	(1,133)%

Revenue

Collaboration revenue for the three months ended March 31, 2016 and 2015 relates to research and development revenue from our collaboration agreement with AbbVie.

We recognized license revenue upon execution of the agreement and completion of enrollment in our DYNAMO study. Revenue related to development services and committee services are being recognized using the proportionate performance method as services are provided over the estimated service period of approximately five years. During

the three months ended March 31, 2016 and 2015, we recognized $9.3 million and $4.4 million, respectively, of revenue related to the development and committee services. We have recorded the remaining amount related to development and committee services of $34.3 million and $87.4 million as short-term and long-term deferred revenue, respectively, as of March 31, 2016.

The regulatory and commercialization milestones represent non-refundable amounts that would be paid by AbbVie to us if certain milestones are achieved in the future. We have elected to apply the milestone method of revenue recognition to these milestones. We have determined that all remaining milestones, if achieved, are substantive as they relate solely to past

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performance, are commensurate with estimated enhancement of value associated with the achievement of each milestone as a result of our performance, which are reasonable relative to other deliverables and terms of the arrangement, and are unrelated to the delivery of any further elements under the arrangement.

Research and Development Expense

The $3.3 million increase in research and development programs expense for the three months ended March 31, 2016 as compared to the three months ended March 31, 2015 was primarily due to an increase of $1.8 million in clinical expenses related to development activities for duvelisib, including charges from AbbVie for costs incurred by AbbVie for other than the AbbVie Studies and for our share of the AbbVie Studies and an increase in research and development staffing expense of $1.0 million.

The $52.5 million decrease in Takeda payments included in research and development expense for the three months ended March 31, 2016 as compared to the three months ended March 31, 2015 was due to the $52.5 million payment we made to Takeda during the three months ended March 31, 2015 in connection with our exercise of an option we purchased from Takeda for $5 million in July 2014 to eliminate our obligation to pay Takeda a tiered 7% to 11% royalty with respect to worldwide net sales in oncology indications of products containing or comprised of duvelisib.

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 months ended March 31, 2016 and 2015, and from January 1, 2006 through March 31, 2016, we estimate that we incurred the following expenses by program:

Program	Three Months Ended March 31, 2016	Three Months Ended March 31, 2015	January 1, 2006 to March 31, 2016
	(in millions)		
PI3K inhibitor (1)	$38.0	$ 84.9	$ 510.4
Hsp90 inhibitor	—	0.1	137.8
Hedgehog pathway inhibitor	—	—	164.1

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

We expect expenses related to our PI3K programs to increase as we continue clinical development of duvelisib and IPI-549. We do not believe that the historical costs associated with our lead drug development programs are indicative of the future costs associated with these programs, nor represent what any other future drug development programs we initiate may cost. Due to the variability in the length of time and scope of activities necessary to develop a product candidate and uncertainties related to our cost estimates and our ability to obtain marketing approval for our product candidates, accurate and meaningful estimates of the total costs required to bring our product candidates to market are not available.

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

- the nature, timing and estimated costs of the efforts necessary to complete the development of our programs;
- the completion dates of these programs; or

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

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

- the scope, rate of progress and cost of our clinical trials that we are currently conducting or may commence in the future;
- the scope and rate of progress of our preclinical studies and other research and development activities;
- clinical trial results;
- the cost of establishing clinical supplies of any product candidates;
- the cost and availability of comparator drugs;

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- 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 $2.3 million increase in general and administrative expense for the three months ended March 31, 2016 as compared to the three months ended March 31, 2015 is primarily attributable to an increase of $1.7 million in compensation costs primarily due to an increase in staffing, an increase of $0.4 million in consulting expenses and an increase of $0.3 million related to external commercial expenses in preparation for the potential 2017 duvelisib launch.

Interest Expense

Interest expense for the three months ended March 31, 2016 is due to the financing obligation related to our 784 Memorial Drive lease. Interest expense for the three ended March 31, 2015 is related to the amortization of the loan commitment asset recognized under our Facility Agreement with Deerfield, which ended in February 2015.

Investment and Other Income (Loss)

Investment and other income (loss) increased in the three months ended March 31, 2016 as compared to the three months ended March 31, 2015 primarily as a result of income from subleases at 784 Memorial Drive and an increase in interest income due to higher yields.

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 at least the next year, 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 March 31, 2016, is less than six months. Because our product candidates are in various stages of clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability.

Our significant capital resources are as follows:

	March 31, 2016	December 31, 2015
	(in thousands)	
Cash, cash equivalents and available-for-sale securities	$192,968	$245,231
Working capital	141,269	184,641

	Three Months Ended March 31,	
	2016	2015
	(in thousands)	
Cash provided by (used in):		
Operating activities	$(51,873)	$(99,658)
Takeda payments (included in operating activities above)	—	(59,167)
Investing activities	(22,483)	14,136
Capital expenditures (included in investing activities above)	(270)	(1,112)

Financing activities	(59	) 1,162

Cash Flows

The principal use of cash in operating activities in all periods presented was related to our research and development programs. Our cash flow used in operating activities for the three months ended March 31, 2016 compared to the three months ended March 31, 2015, decreased primarily due to decreased operating expenses, including 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

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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 due to various factors, including potential cash inflows from future collaboration agreements and potential cash outflows for licensing new programs from third parties. We cannot be certain whether and when we may enter into any such collaboration agreements or in-licenses.

AbbVie paid us a $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. Further, AbbVie has agreed to pay us up to an additional $400 million in potential future milestone payments comprised of $125 million associated with the acceptance by the FDA of the first NDA submission for duvelisib, $75 million associated with the acceptance of the first MAA submission for duvelisib, up to $75 million associated with the achievement of specified regulatory approval milestones, and up to $125 million associated with the achievement of specified commercialization milestones.

On February 24, 2014, we entered into a Facility Agreement with Deerfield. The draw period has expired without our having drawn down on the Facility Agreement. During the three months ended March 31, 2015, we paid a $1.5 million fee to Deerfield related to not drawing down any amount under the Facility Agreement.

Net cash from investing activities for the three months ended March 31, 2016 included purchases of available-for-sale securities of $34.3 million and proceeds of $12.1 million from maturities of available-for-sale securities. Capital expenditures primarily consisted of leasehold improvements related to 780 Memorial Drive.

Net cash from financing activities for the three months ended March 31, 2016 included approximately $43,000 of proceeds from issuances of common stock in connection with stock option exercises related to stock incentive plans, which was offset by $0.1 million of payments on the financing obligation related to our 784 Memorial Drive lease.

Operating Capital Requirements

We will need substantial additional funds to support our planned operations. AbbVie has paid us a $130 million enrollment milestone payment during the year ended December 31, 2015 and a $275 million upfront payment during the year ended December 31, 2014. In addition, AbbVie has agreed to pay us up to an aggregate of $400 million in future potential milestone payments associated with the achievement of specified regulatory and commercialization events. We expect to accrue in 2016 the next two anticipated milestones of $125 million associated with the acceptance by the FDA of the first NDA submission for duvelisib and $75 million associated with the acceptance of the first MAA submission for duvelisib. In the absence of additional funding or business development activities, we believe that our existing cash, cash equivalents and marketable securities will be adequate to satisfy our capital needs through the first quarter of 2017. We have not included any of the $400 million of potential future AbbVie milestone payments in this forecast. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize one of our current or future product candidates. Until we can generate sufficient levels of cash from operations, which we do not expect to achieve for at least the next two years, if at all, and because sufficient funds may not be available to us when needed from collaborations, we expect that we will be required to continue to fund our operations in part through the sale of debt or equity securities, or through licensing select programs or partial economic rights that include up-front, royalty and/or milestone payments. Our need to raise additional funds may be accelerated if our research and development expenses exceed our current expectations, if we acquire a third party, or if we acquire or license rights to additional product candidates or new technologies from one or more third parties. Our need to raise additional funds may also be accelerated for other reasons, including, without limitation, if:

- our product candidates require more extensive clinical or preclinical testing than we currently expect;
- we advance our product candidates into clinical trials for more indications than we currently expect;
- we advance more of our product candidates than expected into costly later stage clinical trials;
- we advance more preclinical product candidates than expected into early stage clinical trials;

- we acquire additional businesses, technologies, products or product candidates;
- the cost of acquiring raw materials for, and of manufacturing, our product candidates is higher than anticipated;
- the cost or quantity required of comparator drugs used in clinical studies increases;
- the costs of commercialization activities for any of our product candidates that receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities, increases, to the extent such costs are not the responsibility of any collaborators;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims increases;
- the receipt of any potential milestone payments from our strategic collaborator AbbVie is delayed beyond our original assumptions;

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- we are required, or consider it advisable, to acquire or license intellectual property rights from one or more third parties; or
- we experience a loss in our investments due to general market conditions or other reasons.

While we may seek additional funding through public or private financings of equity or debt securities, such financing may not be available on acceptable terms, if at all. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders, increased fixed payment obligations and result in the existence of securities with rights that may be senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects. We may also seek additional funds through arrangements with collaborators or other third parties, or through project financing. These arrangements would generally require us to relinquish or encumber rights to some of our technologies or product candidates, and we may not be able to enter into such agreements on acceptable terms, if at all. If we are unable to obtain additional funding on a timely basis, we may be required to curtail or terminate some or all of our development programs or to scale back, suspend or terminate our business operations.

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 three months ended March 31, 2016.

We are obligated to pay to Takeda up to $5 million in remaining success-based milestone payments for the development of a product candidate other than duvelisib, which could include IPI-549. We are also obligated to pay Takeda up to an aggregate of $450 million in success-based milestone payments for the approval and commercialization of two distinct products, of which one could be a Duvelisib Product and the other could be a product containing IPI-549. AbbVie has agreed to share in the cost of such milestone payments to the extent related to a Duvelisib Product. Please see the "Strategic Alliances" section, under the heading "AbbVie" for more information. Because the achievement of these milestones had not occurred as of March 31, 2016, such contingencies have not been recorded in our financial statements.

Please refer to Part II, Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations” of our annual report on Form 10-K for the fiscal year ended December 31, 2015 for a discussion of our judgments and estimates.

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

A hypothetical 100 basis point increase in interest rates would result in an approximate $0.2 million decrease in the fair value of our investments as of March 31, 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 March 31, 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 and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the

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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 March 31, 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 March 31, 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 have a history of operating losses, expect to incur significant and increasing operating losses in the future, may never become profitable, or if we become profitable, we may not remain profitable.

We have a limited operating history for you to evaluate our business. We have no approved products and have generated no product revenue from sales. We have primarily incurred operating losses. As of March 31, 2016, we had an accumulated deficit of $636.3 million. We expect to continue to spend significant resources to fund the research and development of duvelisib and our other product candidates. While we may have net income in some periods as the result of non-recurring collaboration revenue, we expect to incur substantial operating losses over the next several years as our clinical trial and drug manufacturing activities increase. In addition, in connection with seeking and possibly obtaining regulatory approval of any of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. As a result, we expect that our accumulated deficit will also increase significantly.

Our product candidates are in varying stages of preclinical and clinical development and may never be approved for sale or generate any revenue. We will not be able to generate product revenue unless and until one of our product candidates successfully completes clinical trials and receives regulatory approval. We do not expect to generate any revenue from product sales until at least 2017, assuming we are able to file for regulatory approval for duvelisib in 2016 and receive approval in 2017. 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, diversify our pipeline of product candidates or continue our operations and cause a decline in the value of our common stock.

We have no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

To date, our operations have focused on financing and staffing our company, developing our product pipeline and conducting preclinical and clinical research. We have not yet demonstrated an ability to obtain marketing approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and

marketing activities necessary for successful product commercialization. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, especially clinical stage biopharmaceutical companies such as ours. Any predictions you make about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

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We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We are transitioning from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

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 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, and we expect our expenses to increase in connection with seeking and possibly obtaining regulatory approval of any of our product candidates and building our product sales, marketing, manufacturing and distribution capabilities. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or commercialization efforts.

In the absence of additional funding or business development activities and based on our current operating plans, we believe that our existing cash, cash equivalents and available-for-sale securities at March 31, 2016 will be adequate to satisfy our capital needs through the first quarter of 2017. Until we can generate sufficient levels of cash from operations, which we do not expect to achieve for at least the next two years, if at all, and because sufficient funds may not be available to us when needed from collaborations, we expect that we will be required to continue to fund our operations in part through the sale of debt or equity securities, and/or through licensing select programs or partial economic rights that could include payments to us of up-front, royalty and/or milestone payments. Our need to raise additional funds may be accelerated if our research and development or commercialization expenses exceed our current expectation, if we acquire a third party, or if we acquire or license rights to additional product candidates or new technologies from one or more third parties. Our need to raise additional funds may also be accelerated for other reasons, including without limitation if:

- our product candidates require more extensive clinical or preclinical testing than we currently expect;
- we advance our product candidates into clinical trials for more indications than we currently expect;
- we advance more of our product candidates than expected into costly later stage clinical trials;
- we advance more preclinical product candidates than expected into early stage clinical trials;
- we acquire additional business, technologies, products or product candidates;
- the cost of acquiring raw materials for, and of manufacturing, our product candidates is higher than anticipated;
- the cost or quantity required of comparator drugs used in clinical studies increases;
- the costs of commercialization activities for any of our product candidates that receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities, increases, to the extent such costs are not the responsibility of any collaborators;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims increases;
- the receipt of any potential milestone payments from our strategic collaborator AbbVie Inc., or AbbVie, is delayed beyond our original assumptions;
- we are required, or consider it advisable, to acquire or license intellectual property rights from one or more third parties; or
- we experience a loss in our investments due to general market conditions or other reasons.

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

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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 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 or terminate some or all of our development programs or to scale back, suspend or terminate our business operations.

Risks Related to the Discovery, Development and Commercialization of Product Candidates

In the near term, we are dependent on the success of our PI3K inhibitor programs including duvelisib and IPI-549. If we are unable to complete the clinical development of, obtain marketing approval for or successfully commercialize these product candidates, either alone or with collaborators, or if we experience significant delays in doing so, our business could be substantially harmed.

We currently have no products approved for sale and are investing a significant portion of our efforts and financial resources in the development of our phosphoinositide-3-kinase, or PI3K, inhibitor programs including duvelisib and IPI-549. Our prospects are substantially dependent on our ability, or that of AbbVie or any future collaborator, to develop, obtain marketing approval for and successfully commercialize product candidates in one or more disease indications.

The success of our PI3K inhibitor programs will depend on several factors, including the following:

- initiation and successful enrollment and completion of clinical trials;
- 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 performance of AbbVie;
- 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 duvelisib, IPI-549, or any other product candidates under our PI3K inhibitor programs, 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.

We may fail to discover and develop additional potential product candidates.

A significant portion of the research that we are conducting involves our PI3K inhibitor programs including duvelisib and IPI-549. We may not be successful in identifying additional compounds that have commercial value or therapeutic

utility.

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Our drug discovery process may fail to yield viable product candidates for clinical development or commercialization for a number of reasons, including:

- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval and achieve market acceptance;
- competitors may develop alternative therapies that render our potential product candidates non-competitive or less attractive; or
- a potential product candidate may not be capable of being produced at an acceptable cost.

Our research programs to identify new product candidates will require substantial technical, financial and human resources, and we may be unsuccessful in our efforts to identify new product candidates. If we are unable to identify suitable additional compounds for preclinical and clinical development, our ability to develop product candidates and obtain product revenues in future periods could be compromised, which could result in significant harm to our financial position and adversely impact our stock price.

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

To date, we have not obtained approval from the FDA or any foreign regulatory authority to market or sell any of our product candidates. Our product candidates are subject to extensive governmental regulations relating to development, clinical trials, manufacturing and commercialization. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process are required in the United States and in many foreign jurisdictions prior to the commercial sale of medicinal products like our product candidates.

For example, we are evaluating duvelisib, our most advanced product candidate, in all phases of clinical development. If any of these trials or other trials of our product candidates are successful, we may need to conduct further clinical trials and will need to apply for regulatory approval before we may market or sell any of our future products. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that none of the product candidates we are developing, or may in the future develop, either alone or with collaborators, will obtain marketing approval. Even if one or more of our product candidates 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 a product candidate 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 our product candidates, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not in fact the case.

Our product candidates must undergo rigorous clinical trials prior to receipt of regulatory approval. Any problems in these clinical trials could delay or prevent commercialization of our product candidates.

We cannot predict whether we will encounter problems with any of our ongoing or planned clinical trials that will cause us or regulatory authorities to delay, suspend, or discontinue clinical trials or to delay the analysis of data from ongoing clinical trials. Any of the following could delay or disrupt the clinical development of our product candidates:

- unfavorable results of discussions with the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- delays in receiving, or the inability to obtain, required approvals from institutional review boards or other reviewing entities at clinical sites selected for participation in our clinical trials;
- delays in enrolling patients into clinical trials;
- a lower than anticipated retention rate of patients in clinical trials;
- the need to repeat or discontinue clinical trials as a result of inconclusive or negative results or unforeseen complications in testing or because the results of later trials may not confirm positive results from earlier preclinical studies or clinical trials;
- inadequate supply, delays in distribution or deficient quality of, or inability to purchase or manufacture drug product, comparator drugs or other materials necessary to conduct our clinical trials;
- unfavorable FDA or other foreign regulatory inspection and review of a clinical trial site, Infinity, or an Infinity vendor, or records of any clinical or preclinical investigation;

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- serious and unexpected drug-related side effects experienced by participants in our clinical trials, which may occur even if they were not observed in earlier trials or only observed in a limited number of participants;
- a finding that the trial participants are being exposed to unacceptable health risks;
- the placement by the FDA or a foreign regulatory authority of a clinical hold on a trial; or
- any restrictions on, or post-approval commitments with regard to, any regulatory approval we ultimately obtain that render the product candidate not commercially viable.

We may suspend, or the FDA or other applicable regulatory authorities may require us to suspend, clinical trials of a product candidate at any time if we or they believe the patients participating in such clinical trials, or in independent third-party clinical trials for drugs based on similar technologies, are being exposed to unacceptable health risks or for other reasons.

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

Adverse events or undesirable side effects caused by, or other unexpected properties of, product candidates that we develop may be identified during development and could delay or prevent their marketing approval or limit their use.

Adverse events or undesirable side effects caused by, or other unexpected properties of, any current or future product candidates that we may develop could cause us, any collaborators, an institutional review board or regulatory authorities to interrupt, delay or halt clinical trials of one or more of our product candidates 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 any of our product candidates 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 that product candidate 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. We believe this to be the case with idelalisib, a PI3K delta inhibitor of Gilead Sciences, Inc., or Gilead, a key competitor of ours. Gilead, which received approval from the FDA to market idelalisib for the treatment of chronic lymphocytic leukemia, or CLL, follicular lymphoma and small lymphocytic lymphoma, or SLL, confirmed that they are stopping six clinical trials in patients with CLL, SLL and indolent non-Hodgkin lymphoma, or iNHL, following reports of increased rates of adverse events, including deaths, in trials evaluating idelalisib in combination with other cancer therapies.

If we, or any current or future collaborators, experience any of a number of possible unforeseen events in connection with clinical trials of our current or future product candidates that we, or any collaborators, may develop, potential clinical development, marketing approval or commercialization of our product candidates 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 our current or future product candidates that we, or any collaborators, may develop, 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 our product candidates 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 product development programs;
- the number of patients required for clinical trials of our product candidates 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 our product candidates may be greater than we anticipate;
- our third-party contractors or those of any collaborators, including those manufacturing our product candidates or components or ingredients thereof or conducting clinical trials on our behalf or on behalf of any

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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 our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate;
- 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 the product candidate 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 our product candidates 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 our product candidates. We do not know whether any preclinical tests or 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 our product candidates 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 our product candidates and may harm our business and results of operations. We have designed our DYNAMO study with the potential to support accelerated approval of duvelisib for the treatment of follicular lymphoma and SLL, indications for which Gilead has received accelerated approval to manufacture and market idelalisib. If we experience delays in the conduct of our DYNAMO study, or Gilead is able to complete a confirmatory study and receive full approval to market idelalisib for the treatment of follicular lymphoma or SLL faster than anticipated, our efforts to seek accelerated approval for duvelisib for the treatment of follicular lymphoma or SLL may be materially adversely affected. In addition, many of the factors that lead to clinical trial delays may ultimately lead to the denial of marketing approval of any of our product candidates.

Results of preclinical studies and early clinical trials may not be predictive of results of future late-stage clinical trials. We have completed a small number of clinical trials for our lead product candidate duvelisib, and we are currently conducting several additional trials for duvelisib and 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 our product candidates warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of our product candidates.

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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 our product candidates, the development timeline and regulatory approval and commercialization prospects for our most advanced product candidates 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.

Additionally, the availability of safe and effective treatments for the relevant disease being studied may impact patient enrollment in our clinical trials. For example, AbbVie has received approval to manufacture and market ibrutinib, a Bruton's tyrosine kinase, or BTK, inhibitor for the treatment of CLL, an indication for which we are currently evaluating duvelisib in our DUO™ and SYNCHRONY clinical trials, and Gilead has received accelerated approval to manufacture and market idelalisib for the treatment of follicular lymphoma and SLL, indications for which we are currently evaluating duvelisib.

Our failure to enroll patients in a clinical trial could delay the initiation or completion of the clinical trial beyond current expectations. In addition, the FDA or other foreign regulatory authorities could require us to conduct clinical trials with a larger number of patients than has been projected for any of our product candidates. As a result of these factors, we may not be able to enroll a sufficient number of patients in a timely or cost-effective manner. Furthermore, enrolled patients may drop out of a clinical trial, which could impair the validity or statistical significance of the clinical trial. A number of factors can influence the patient discontinuation rate, including, but not limited to:

- the inclusion of a placebo arm in a trial;
- possible inactivity or low activity of the product candidate being tested at one or more of the dose levels being tested;
- the occurrence of adverse side effects, whether or not related to the product candidate; and
- the availability of numerous alternative treatment options, including clinical trials evaluating competing product candidates, that may induce patients to discontinue their participation in the trial.

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

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 our current or future product candidates 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 our product candidates or may conclude after review of our data that our application is insufficient to obtain marketing approval of our product candidates. If the FDA does not accept or approve our NDAs for any of our product candidates, 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

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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 our product candidates 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 our product candidates, which could significantly harm our business.

Even if any product candidates that we, or any collaborators, may develop receive 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 the product, and we could become subject to costly and damaging product liability claims.

Even if we receive regulatory approval for any of our product candidates, we will have tested them in only a small number of patients 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 our products for a longer period of time, the product candidate might be less effective than indicated by our clinical trials. Furthermore, new risks and side effects associated with our products may be discovered or previously observed risks and side effects may become more prevalent and/or clinically significant, as was the case with Gilead's idelalisib, a PI3K delta-specific inhibitor and a key competitor of ours. Gilead, which received approval from the FDA to market idelalisib for the treatment of CLL, follicular lymphoma and SLL, confirmed that they are stopping six clinical trials in patients with CLL, SLL and iNHL following reports of increased rates of adverse events, including deaths, in trials evaluating idelalisib in combination with other cancer therapies.

In addition, supplemental clinical trials that may be conducted on a drug following its initial approval may produce findings that are inconsistent with the trial results previously submitted to regulatory authorities. As a result, regulatory authorities may revoke their approvals, or we may be required to conduct additional clinical trials, make changes in labeling of our product (including a "black box" warning or a contraindication) or the manner in which it is administered, reformulate our product or make changes and obtain new approvals for our and our suppliers' manufacturing facilities. We also might have to withdraw or recall our products from the marketplace, and regulators might seize our products. We might be subject to fines, injunctions, or the imposition of civil or criminal penalties. Any safety concerns with respect to a product may also result in a significant drop in the potential sales of that product, damage to our reputation in the marketplace, or result in our 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 any product candidates that we, or any collaborators, may develop receive 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 any of our product candidates 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 our product candidates, we could lose our regulatory approvals and our business would be adversely affected if we, our collaborators, or our contract manufacturers fail to comply with continuing regulatory requirements.

The FDA 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. We plan to build focused capabilities to commercialize development programs for certain indications where we believe that the medical specialists for the indications are sufficiently concentrated to allow us to effectively promote the product with a targeted sales team. The development of sales, marketing and distribution capabilities will require substantial resources, will 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 plan 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.

In certain indications, we plan to seek to enter into collaborations that we believe may contribute to our ability to advance development and ultimately commercialize our product candidates. We also intend to seek to enter into collaborations where we believe that realizing the full commercial value of our development programs will require access to broader geographic markets or the pursuit of broader patient populations or indications. Under our collaboration and license agreement with AbbVie, which we refer to as the AbbVie Agreement, for example, we and AbbVie are obligated to each provide half of the sales representative effort to promote products containing duvelisib, which we refer to as Duvelisib Products, in the United States. Outside the United States, AbbVie has, with limited exceptions, operational responsibility and decision making authority to commercialize Duvelisib Products. We and AbbVie will share the cost of manufacturing and supply for commercialization of Duvelisib Products in the United States, and AbbVie will bear the cost of manufacturing and supply for commercialization of Duvelisib Products outside the United States.

As a result of entering into arrangements such as the AbbVie Agreement 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.

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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 ours less attractive or obsolete.
In building our product development pipeline, we have intentionally pursued targets with applicability across multiple therapeutic areas and indications. This approach gives us several product opportunities in oncology diseases, which is a highly competitive and rapidly changing segment of the pharmaceutical industry. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations are pursuing the development of novel drugs that target various oncology diseases. We currently face, and expect to continue to face, intense and increasing competition as new products enter the market and advanced technologies become available. Moreover, there are a number of large pharmaceutical companies currently marketing and selling products in this segment including Bristol-Myers Squibb Company; the Roche Group and its subsidiary Genentech; Novartis AG; Pfizer, Inc.; and Johnson & Johnson. In addition to currently approved drugs, there are a significant number of drugs that are currently under development and may become available in the future for the treatment of various forms of cancer.
Duvelisib is a dual inhibitor of the delta and gamma isoforms of PI3K. We are aware of a number of companies developing product candidates or selling products directed to isoforms of PI3K. Specifically, we believe that Gilead; Incyte Corporation; Acerta Pharma BV; TG Therapeutics, Inc., and Hutchison China Meditech Ltd. are conducting clinical trials of drugs that target the delta isoform of PI3K. We also believe that Rhizen Pharmaceuticals S.A. is conducting clinical trials of a drug that targets both the delta and gamma isoforms of PI3K. We also believe that SignalRx Pharmaceuticals is conducting a clinical trial of a drug that targets the delta, gamma, and alpha isoforms of PI3K, and that Novartis AG, Bayer, and Genentech are each conducting clinical trials of drugs that target the delta, gamma, alpha, and beta isoforms of PI3K.
Additionally, many companies are developing product candidates or selling products directed to disease targets such as BTK, B-cell lymphoma 2 (or BCL-2), Janus Kinase (or JAK), B-lymphocyte antigen CD-19, and programmed death 1/ligand 1 (or PD-1/PD-L1), Cluster of Differentiation 79B antibody-drug conjugate (or CD79B ADC), and pleiotropic pathways in the fields of hematology-oncology, including in the specific diseases for which we are currently developing duvelisib, or for which we may develop duvelisib in the future, including: AbbVie; Pharmacyclics LLC, a wholly-owned subsidiary of AbbVie; BeiGene Co., Ltd; Janssen Biotech through its collaboration with AbbVie; Celgene Corporation; a joint collaboration between Gilead and Ono Pharmaceutical Group under their exclusive license agreement; Acerta Pharma BV; Incyte Corporation; MorphoSys AG; Novartis AG; Roche Group and its subsidiary Genentech; Bristol-Myers Squibb Company; and AstraZeneca PLC.
Many of our competitors have:

- significantly greater financial, technical and human resources than we have, and may be better equipped to discover, develop, manufacture and commercialize product candidates than we are;
- more experience in preclinical testing and clinical trials, obtaining regulatory approvals and manufacturing and marketing products than we do; and/or
- product candidates that are in later-stage clinical development than our own product candidates, or have been approved by the FDA, such as ibrutinib, a BTK inhibitor being developed and commercialized by AbbVie for the treatment of people with mantle cell lymphoma or CLL, and idelalisib, a compound targeting the delta isoform of PI3K, being developed and commercialized by Gilead for the treatment of people with CLL, follicular B-cell non-Hodgkin lymphoma, or small lymphocytic lymphoma.

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 our own product candidates. These competitive products may have superior safety or efficacy, have more attractive pharmacologic properties, or may be manufactured less expensively than our future products. 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 our future products or achieve a competitive position in the market. This would adversely affect our ability to generate revenues.

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Even if we, or any future collaborators, are able to commercialize any product candidate that we, or they, develop, 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 our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates 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 our product candidates. 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 one or more product candidates, even if our product candidates obtain 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 any of our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products 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 our product candidates profitably. These payors may not view our products, if any, 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 our products, if any, 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 products, which could result in lower than anticipated product revenues. If the prices for our products, if any, 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, 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 any of our product candidates for which we, or any future collaborator, obtain marketing approval could significantly harm our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

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

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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 any of our product candidates is alleged to have caused harm. These risks are inherent in the testing, manufacturing and marketing of human medicinal products. Although we do not currently commercialize any products, claims could be made against us based on the use of our product candidates in clinical trials. We currently have clinical trial insurance and will seek to obtain product liability insurance prior to the commercial launch of any of our product candidates. Our insurance may not, however, provide adequate coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain current amounts of insurance coverage or obtain additional or sufficient insurance at a reasonable cost. If we are sued for any injury caused by our product candidates or future products, our liability could exceed our insurance coverage and our total assets, and we would need to divert management attention to our defense. Claims against us, regardless of their merit or potential outcome, may also generate negative publicity or hurt our ability to recruit investigators and patients to our clinical trials, obtain physician acceptance of our future products, or expand our business.

Risks Related to Our Dependence on Third Parties

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

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

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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.

The success of a strategic alliance, whether with AbbVie or any future partner, is largely dependent on the resources, efforts, technology and skills brought to such alliance by such partner. The benefits of such alliances will be reduced or eliminated if any such partner:

- 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 our product candidates 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 product candidate 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 a product candidate, repeats or conducts new clinical trials or requires a new formulation of a product candidate for clinical testing;
- independently develops, or develops with third parties, products that compete directly or indirectly with our product candidates;
- 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 breach or terminate its arrangements with us or fail to maintain the financial resources necessary to continue financing its portion of development, manufacturing, and commercialization costs, as applicable, we may not have the financial resources or capabilities necessary to continue development and commercialization of the product candidate on our own. Consequently, the development and commercialization of the affected product candidate could be delayed, curtailed or terminated, and we may find it difficult to attract a new collaborator for such product candidate. For example, if AbbVie were to terminate our strategic collaboration, we would not be entitled to receive payment for any milestone that is not achieved prior to AbbVie's delivery to us of a termination notice, and AbbVie has limited obligations to continue the conduct and funding of ongoing development and commercialization activities.

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

As is the case with our strategic collaboration with AbbVie, much of the potential revenue from alliances consists of payments contingent upon the achievement of specified milestones and royalties payable on sales of any successfully developed drugs. Any such contingent revenue will depend upon our, and our 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. Under the AbbVie Agreement, for instance, we have granted AbbVie exclusive licenses to commercialize Duvelisib Products outside the United States.

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

We might seek to establish additional 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.

We might seek one or more collaborators for the development and commercialization of one or more of our product candidates. 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 product candidates from foreign regulatory authorities, we might enter into strategic relationships with international biotechnology or pharmaceutical companies for the commercialization of such product candidates 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 and 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 our product candidate 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 the product candidate, 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 our product candidate. 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 our product candidates or bring them to market and generate product revenue.

Such 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 specified product candidates. In the AbbVie Agreement, for example, we and AbbVie have agreed, subject to limited exceptions, that we will not commercialize, or assist others in commercializing, in oncology indications certain PI3K delta, gamma inhibitors, and AbbVie has agreed to similar restrictions.

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 the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, 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 efforts to obtain regulatory approval for and to commercialize our product candidates may be delayed.

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

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We currently rely on third-party manufacturers to produce our preclinical and clinical drug supplies, and we intend to rely upon third-party manufacturers to produce commercial supplies of any approved product candidates.

Our product candidates require 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 our product candidates to be released for use in one or more countries. In addition, such a failure could result in, among other things, patient injury or death, product liability claims, penalties or other monetary sanctions, the failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and/or criminal prosecution, any of which could significantly and adversely affect supply of our product candidates and seriously hurt our business.

Contract manufacturers may also encounter difficulties involving production yields or delays in performing their services. We do not have control over third-party manufacturers' performance and compliance with applicable regulations and standards. If, for any reason, our manufacturers cannot perform as agreed, we may be unable to replace such third-party manufacturers in a timely manner, and the production of our product candidates would be interrupted, resulting in delays in clinical trials and additional costs. Switching manufacturers may be difficult because the number of potential manufacturers is limited, the 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, our product candidates have been manufactured for preclinical testing and clinical trials primarily by third-party manufacturers. If the FDA or other regulatory agencies approve any of our product candidates for commercial sale, we expect that we would continue to rely, at least initially, on third-party manufacturers to produce commercial quantities of our approved product candidates. These manufacturers may not be able to successfully increase the manufacturing capacity for any approved product candidates in a timely or economical manner, or at all. Significant scale-up of manufacturing might entail changes in the manufacturing process that have to be submitted to or approved by the FDA or other regulatory agencies. If contract manufacturers engaged by us are unable to successfully increase the manufacturing capacity for a product candidate, or we are unable to establish our own manufacturing capabilities, the commercial launch of any approved products may be delayed or there may be a shortage in supply.

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

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

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

We and AbbVie share the obligations to commercialize Duvelisib Products in oncology in the United States, and AbbVie has the sole obligation to commercialize Duvelisib Products in oncology outside the United States. To successfully commercialize Duvelisib Products, we will need to, and we intend to, establish adequate marketing, sales and distribution capabilities for commercialization in the United States. Failure to establish these capabilities, whether due to insufficient resources or some other cause, will limit or potentially halt our ability to successfully commercialize any product candidates, thereby adversely affecting our financial results. Even if we do develop such

capabilities, we will compete with other companies that have more experienced and well-funded marketing, sales and distribution operations.

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 our product candidates.

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We currently have rights to certain intellectual property, through licenses from third parties, to develop duvelisib, IPI-549 and other product candidates under our PI3K inhibitor programs. 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 any of our product candidates 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 our product candidates 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 the affected product candidate, 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 duvelisib and IPI-549. 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 any product 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 the product candidate 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, we could lose our license rights under that agreement, including rights to duvelisib.

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 our product candidates.

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

Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and molecular diagnostics and the claim scope of these patents, our ability to obtain and enforce

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

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

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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 our product candidates.

Patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the PTO for the entire time prior to issuance as a U.S. patent. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Consequently, we cannot be certain that we were the first to invent, or the first to file patent applications on, our product candidates or their therapeutic use. In the event that a third party has also filed a U.S. patent application relating to our product candidates or a similar invention, we may have to participate in interference or derivation proceedings declared by the PTO or the third party to determine priority of invention in the United States. An adverse decision in an interference or derivation proceeding may result in the loss of rights under a patent or patent application. In addition, the cost of interference proceedings could be substantial.

Claims by third parties of intellectual property infringement are costly and distracting, and could deprive us of valuable rights we need to develop or commercialize our product candidates.

Our commercial success will depend on whether there are third-party patents or other intellectual property relevant to our potential products that may block or hinder our ability to develop and commercialize our product candidates. We may not have identified all U.S. and foreign patents or published applications that may adversely affect our business either by blocking our ability to manufacture or commercialize our drugs or by covering similar technologies that adversely affect the applicable market. In addition, we may undertake research and development with respect to product candidates, even when we are aware of third-party patents that may be relevant to such product candidates, on the basis that we may challenge or license such patents. There are no assurances that such licenses will be available on commercially reasonable terms, or at all. If such licenses are not available, we may become subject to patent litigation and, while we cannot predict the outcome of any litigation, it may be expensive and time consuming. If we are unsuccessful in litigation concerning patents owned by third parties, we may be precluded from selling our products. While we are not currently aware of any litigation or third-party claims of intellectual property infringement related to our product candidates, the biopharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents and claim that the use of our technologies infringes these patents or that we are employing their proprietary technology without authorization. We could incur substantial costs and diversion of management and technical personnel in defending against any claims that the manufacture and

sale of our potential products or use of our technologies infringes any patents, or defending against any claim that we are employing any proprietary technology without authorization. The outcome of patent litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of the adverse party, especially in pharmaceutical

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patent cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. In the event of a successful claim of infringement against us, we may be required to:

- pay substantial damages;
- stop developing, manufacturing and/or commercializing the infringing product candidates or approved products;
- develop non-infringing product candidates, technologies and methods; and
- obtain one or more licenses from other parties, which could result in our paying substantial royalties or the granting of cross-licenses to our technologies.

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

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

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

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 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

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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 Our Product Candidates 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 some or all of our product candidates. 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 our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, 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 a product candidate will prevent us from commercializing the product candidate. We and our collaborators have not received approval to market any of our product candidates 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. Our product candidates 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 a product candidate. 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.

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

Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates 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

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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 our products in any market.

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

The FDA has designated as a fast track development program both the investigation of duvelisib for treatment of patients with follicular lymphoma who have received at least two prior therapies and the investigation of duvelisib for the treatment of patients with CLL who have received at least one prior therapy. Any drug sponsor may apply for such designation if their product candidate is intended for the treatment of a serious or life-threatening disease or condition and the product candidate demonstrates the potential to address an unmet medical need. The FDA has broad discretion whether or not to grant fast track designation. Although duvelisib has received such designation, this may not actually result in a faster development process, review or approval compared to standard FDA procedures. The FDA may withdraw fast track designation if it believes that the clinical development program does not continue to meet the criteria for fast track designation.

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

Some of our product candidates may be eligible for the FDA's programs that are designed to facilitate the development and expedite the review of certain drugs such as the FDA's accelerated approval program, but we cannot provide any assurance that any of our product candidates will qualify for one or more of these programs. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product candidate no longer meets the conditions for qualification. For example, the DYNAMO™ study is designed with the potential to support accelerated approval of duvelisib for treatment of patients with follicular lymphoma or SLL. The availability of accelerated approval is dependent on a number of factors including whether we generate positive safety and efficacy data from the study and duvelisib has demonstrated a meaningful benefit over available therapies. In addition, even after receiving accelerated approval, companies are required to conduct studies to confirm the anticipated clinical benefit of a drug, known as confirmatory trials. If the confirmatory trial shows that the drug actually provides a clinical benefit, then the FDA grants regular approval for the drug. If the confirmatory trial does not show that the drug provides clinical benefit, FDA has regulatory procedures in place that could lead to removing the drug from the market. We cannot guarantee that duvelisib will qualify for accelerated approval or, even if it receives accelerated approval, that we would successfully complete a confirmatory study. In particular, we are aware that Gilead has received accelerated approval for idelalisib, its product, to treat follicular lymphoma and SLL. Idelalisib is currently approved by the FDA for CLL. If Gilead is able to complete a confirmatory study and receive full approval to market idelalisib for the treatment of follicular lymphoma or SLL faster than anticipated, our efforts to seek accelerated approval for duvelisib for the treatment of follicular lymphoma or SLL may be materially adversely affected. Moreover, even if we are able to receive accelerated approval for duvelisib the FDA may upon review of data from our confirmatory study later decide that duvelisib no longer meets the conditions for approval resulting in revocation of approval.

Even if we or our collaborators obtain marketing approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our products, 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 any of our product candidates for which we or they obtain marketing approval. 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.

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Accordingly, assuming we, or any of our collaborators, receive marketing approval for one or more of our product candidates, 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.

Any product candidate for which we or our collaborators obtain marketing approval 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 our product candidates, when and if any of them are 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 a product candidate 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

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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 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,

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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.

Current and future legislation may increase the difficulty and cost for us and any collaborators to obtain marketing approval of our other product candidates and affect the prices 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 our other product candidates, 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 our product candidates 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

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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 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

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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.

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

We are highly dependent on our executive leadership team. All of these individuals are employees-at-will, which means that neither Infinity nor the employee is obligated to a fixed term of service and that the employment relationship may

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be terminated by either Infinity or the employee at any time, without notice and whether or not cause or good reason exists for such termination. The loss of the services of any of these individuals might impede the achievement of our research, development and commercialization objectives. We do not maintain “key person” insurance on any of our employees.

Recruiting and retaining qualified scientific and business personnel is also critical to our success. 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 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. 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 encounter difficulties in managing organizational change, which could adversely affect our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug manufacturing, regulatory affairs and sales, marketing and distribution. To manage these growth activities, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Our management may need to devote a significant amount of its attention to managing these growth activities. Due to limited experience with commercialization including sales and marketing, we may not be able to effectively manage the expansion of our operations, retain key employees, or identify, recruit and train additional qualified personnel. Our inability to manage the expansion of our operations effectively may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy, including the successful commercialization of our product candidates.

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

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

We may acquire additional businesses, products, product candidates, or technologies that complement or augment our existing business. We may not be able to integrate any acquired 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,

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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 our product candidates;
- the results of preclinical studies and planned clinical trials of our discovery-stage programs;
- product portfolio decisions resulting in the delay or termination of our product development programs;
- future sales of, and the trading volume in, our common stock;
- our entry into key agreements, including those related to the acquisition or in-licensing of new programs, or the termination of key agreements, including our collaboration and license agreement with AbbVie, or our amended and restated development and license agreement with Takeda;
- the results and timing of regulatory reviews relating to the approval of our product candidates;
- the initiation of, material developments in, or conclusion of litigation, including but not limited to litigation to enforce or defend any of our intellectual property rights or to defend product liability claims;
- the failure of any of our product candidates, if approved, to achieve commercial success;
- the results of clinical trials conducted by others on drugs that would compete with our product candidates;
- the regulatory approval of drugs that would compete with our product candidates;
- issues in manufacturing our product candidates or any approved products;
- the loss of key employees;
- changes in estimates or recommendations, or publication of inaccurate or unfavorable research about our business, by securities analysts who cover our common stock;
- future financings through the issuance of equity or debt securities or otherwise;
- healthcare reform measures, including changes in the structure of healthcare payment systems;
- our cash position and period-to-period fluctuations in our financial results; and
- general and industry-specific economic and/or capital market conditions.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock.

In the past, when the market price of a stock has been volatile, as our stock price may be, holders of that stock have occasionally brought securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit is without merit, negative publicity could be generated, and we could incur substantial costs defending the lawsuit. A stockholder lawsuit could also divert the time and attention of our management.

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

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related to revenue recognition, accrued expenses, assumptions in the valuation of stock-based compensation and income taxes. We base our estimates and judgments on historical experience, facts and circumstances known to us and on various assumptions that we believe to be reasonable under the circumstances. These estimates and judgments, or the assumptions underlying them, may change over time or prove inaccurate. If this is the case, we may be required to restate our financial statements, which could in turn subject us to securities class action litigation. Defending against such potential litigation relating to a restatement of our financial statements would be expensive and would require significant attention and resources of our management. Moreover, our insurance to cover our obligations with respect to the ultimate resolution of any such litigation may be inadequate. As a result of these factors, any such potential litigation could have a material adverse effect on our financial results and cause our stock price to decline.

If we are not able to maintain effective internal control under Section 404 of the Sarbanes-Oxley Act, our business and stock price could be adversely affected.

Section 404 of the Sarbanes-Oxley Act of 2002 requires us, on an annual basis, to review and evaluate our internal control and requires our independent auditors to attest to the effectiveness of our internal control over financial reporting. Any failure by us to maintain the effectiveness of our internal control in accordance with the requirements of Section 404 of the Sarbanes-Oxley Act, as such requirements exist today or may be modified, supplemented or amended in the future, could have a material adverse effect on our business, operating results and stock price.

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 April 29, 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 55% 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.

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Anti-takeover provisions in our organizational documents and Delaware law may make an acquisition of us difficult.
We are incorporated in Delaware. Anti-takeover provisions of Delaware law and our organizational documents may make a change in control more difficult. Also, under Delaware law, our board of directors may adopt additional anti-takeover measures. For example, our charter authorizes our board of directors to issue up to 1,000,000 shares of undesignated preferred stock and to determine the terms of those shares of stock without any further action by our stockholders. If our board of directors exercises this power, it could be more difficult for a third party to acquire a majority of our outstanding voting stock. Our charter and bylaws also contain provisions limiting the ability of stockholders to call special meetings of stockholders.
Our stock incentive plan generally permits our board of directors to provide for acceleration of vesting of options granted under that plan in the event of certain transactions that result in a change of control. If our board of directors uses its authority to accelerate vesting of options, this action could make an acquisition more costly, and it could prevent an acquisition from going forward.
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 March 31, 2016, we had $193.0 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.

Item 6. Exhibits
(a) Exhibits.
The exhibits listed in the Exhibit Index are included in this report.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

INFINITY PHARMACEUTICALS, INC.

Date: May 4, 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)

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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	Amendment No. 6 to 2010 Stock Incentive Plan. Filed herewith.				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 March, 31, 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