INFINITY PHARMACEUTICALS, INC.
Form 10-Q
August 07, 2018
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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 June 30, 2018
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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer ý	Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨	Emerging growth company ¨

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨
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 August 1, 2018: 56,850,548

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INFINITY PHARMACEUTICALS, INC.
FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2018

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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)

	June 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$49,165	$ 34,607
Available-for-sale securities	—	23,002
Prepaid expenses and other current assets	1,273	777
Total current assets	50,438	58,386
Property and equipment, net	103	219
Other assets	725	748
Total assets	$51,266	$ 59,353
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$767	$ 459
Accrued expenses	4,912	5,136
Note payable (note 8)	—	6,000
Total current liabilities	5,679	11,595
Other liabilities	31	28
Total liabilities	5,710	11,623
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, $0.001 par value; 1,000,000 shares authorized, no shares issued and outstanding at June 30, 2018 and December 31, 2017	—	—
Common Stock, $0.001 par value; 100,000,000 shares authorized; 56,833,649 and 50,761,039 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	57	51
Additional paid-in capital	729,432	715,213
Accumulated deficit	(683,933)	(667,519)
Accumulated other comprehensive loss	—	(15)
Total stockholders' equity	45,556	47,730
Total liabilities and stockholders' equity	$51,266	$ 59,353

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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	$3,749	$3,901	$9,660	$7,940
General and administrative	3,386	6,205	6,992	12,642
Total operating expenses	7,135	10,106	16,652	20,582
Loss from operations	(7,135)	(10,106)	(16,652)	(20,582)
Other income (expense):				
Investment and other income	172	334	331	637
Interest expense	—	(300)	(93)	(602)
Other expense (note 11)	—	(6,882)	—	(6,882)
Total other income (expense)	172	(6,848)	238	(6,847)
Net loss	$(6,963)	$(16,954)	$(16,414)	$(27,429)
Basic and diluted loss per common share	$(0.12)	$(0.34)	$(0.30)	$(0.54)
Basic and diluted weighted average number of common shares outstanding	55,966,916	50,455,832	53,936,520	50,439,682
Other comprehensive loss:				
Net unrealized holding gains on available-for-sale securities arising during the period	11	—	15	3
Comprehensive loss	$(6,952)	$(16,954)	$(16,399)	$(27,426)

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)

	Six Months Ended June 30,	
	2018	2017
Operating activities		
Net loss	$(16,414)	$(27,429)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	116	1,384
Stock-based compensation, including 401(k) match	1,728	3,804
Non-cash adjustment to financing obligation	—	1,882
Other, net	176	8
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(473)	6,391
Accounts payable, accrued expenses and other liabilities	786	(12,922)
Net cash used in operating activities	(14,081)	(26,882)
Investing activities		
Purchases of available-for-sale securities	(5,744)	—
Proceeds from maturities of available-for-sale securities	28,790	18,000
Net cash provided by investing activities	23,046	18,000
Financing activities		
Proceeds from common stock sales facility, net of issuance costs	9,355	—
Proceeds from issuances of common stock, net	238	70
Repayment of note payable	(4,000)	—
Payments on financing obligation	—	(218)
Net cash provided by (used in) financing activities	5,593	(148)
Net increase (decrease) in cash, cash equivalents and restricted cash	14,558	(9,030)
Cash, cash equivalents and restricted cash at beginning of period	34,607	75,742
Cash, cash equivalents and restricted cash at end of period	$49,165	$66,712
Supplemental cash flow information		
Cash paid for interest	$—	$602
Supplemental schedule of noncash activities		
Issuance of common stock for repayment of note payable, including interest	$2,301	$—
Issuance of common stock for compensation	$493	$—

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

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Infinity Pharmaceuticals, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Organization

Infinity Pharmaceuticals, Inc., is an innovative biopharmaceutical company dedicated to developing novel medicines for people with cancer. As used throughout these unaudited, condensed consolidated financial statements, the terms "Infinity," "we," "us," and "our" refer to the business of Infinity Pharmaceuticals, Inc., and its wholly-owned subsidiaries.

2. Basis of Presentation

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

The accompanying condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring accruals and revisions of estimates, considered necessary for a fair presentation of the accompanying condensed consolidated financial statements have been included. Interim results for the three and six months ended June 30, 2018 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2018.

The information presented in the condensed consolidated financial statements and related footnotes at June 30, 2018, and for the three and six months ended June 30, 2018 and 2017, is unaudited, and the condensed consolidated balance sheet amounts and related footnotes at December 31, 2017 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, 2017 filed with the U.S. Securities and Exchange Commission, or SEC, on March 15, 2018, which we refer to as our 2017 Annual Report on Form 10-K.

Liquidity

As of June 30, 2018, we had cash and cash equivalents of $49.2 million. We have primarily incurred operating losses since inception and have relied on our ability to fund our operations through collaboration and license arrangements and through the sale of stock. We expect to continue to spend significant resources to fund the development and potential commercialization of IPI-549, our sole clinical stage product candidate, an orally administered immune-oncology product candidate that selectively inhibits the enzyme phosphoinositide-3 kinase gamma, or PI3K gamma, and to incur significant operating losses for the foreseeable future.

In the absence of additional funding or business development activities, we believe that our existing cash and cash equivalents will be adequate to satisfy our forecasted operating needs through the third quarter of 2019. This projected cash runway does not assume the receipt of the future potential $22.0 million contingent payment in cash or stock from Verastem, Inc., or Verastem (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

Our significant accounting policies are described in Note 2, "Summary of Significant Accounting Policies," in our 2017 Annual Report on Form 10-K, except as noted below with respect to our revenue recognition accounting policies within "Recently Adopted Accounting Pronouncements."

Segment Information

We operate in one business segment, which focuses on drug development. We make operating decisions based upon the performance of the enterprise as a whole and utilize our consolidated financial statements for decision making. All of our revenues since September 2006 have been generated under collaboration agreements.

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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, excluding restricted stock that has been issued but has not yet vested. 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) and the vesting of restricted shares of common stock. In addition, the assumed proceeds under the treasury stock method include the average unrecognized compensation expense of stock options that are in-the-money. This results in the "assumed" buyback of additional shares, thereby reducing the dilutive impact of stock options. The two-class method is used for outstanding warrants as such warrants are considered to be participating securities, and this method 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:

	At June 30,	
	2018	2017
Stock options	8,109,232	8,120,150
Warrants (excluded from treasury stock method)	1,000,000	1,000,000
Unvested restricted stock	—	663,811

New Accounting Pronouncements

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

In June 2018, the FASB issued ASU No. 2018-07, Compensation—Stock Compensation: Improvements to Nonemployee Share-Based Payment Accounting, or ASU No. 2018-07, which expands the scope of Accounting Standard Codification, or ASC, Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. ASU No. 2018-07 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 potential impact that ASU No. 2018-07 may have on our financial position and results of operations.

Recently Adopted Accounting Pronouncements

Effective January 1, 2018, we adopted FASB ASC Topic 606, Revenue from Contracts with Customers, or ASC 606. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. The standard allows for two transition methods - full retrospective, in which the standard is applied to each prior reporting period presented, or modified retrospective, in which the cumulative effect of initially applying the standard is recognized at the date of initial adoption. We elected the modified retrospective approach and applied it to contracts not completed at the date of adoption. Therefore, comparative prior periods have not been adjusted. The adoption of the standard did not have a material impact on our financial position and results of operations when applied to our two out-licensing arrangements. See Note 8 for additional details on these two arrangements. We did not recognize any revenue during the three and six months ended June 30, 2018 and 2017.

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The principles in the new standard are applied using a five-step model: 1) identify the customer contract; 2) identify the contract's performance obligations; 3) determine the transaction price; 4) allocate the transaction price to the performance obligations; and 5) recognize revenue when or as a performance obligation is satisfied. We evaluate all promised goods and services within a customer contract and determine which of those are separate performance obligations. This evaluation includes an assessment of whether the good or service is capable of being distinct and whether the good or service is separable from other promises in the contract. When a performance obligation is satisfied, we recognize as revenue the amount of the transaction price, excluding estimates of variable consideration that are constrained, that is allocated to that performance obligation. For contracts that contain variable consideration, such as milestone payments, we estimate the amount of variable consideration by using either the expected value method or the most likely amount method. In making this assessment, we evaluate factors such as the clinical, regulatory, commercial and other risks that must be overcome to achieve the milestone. We re-evaluate the probability of achievement of such milestones and any related constraint each reporting period. We will include variable consideration, without constraint, in the transaction price to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

We will recognize royalty revenue, if any, based upon actual and estimated net sales by the licensee of licensed products in licensed territories in the period the sales occur under the sales- and usage-based royalty exception when the sole or predominate item to which the royalty relates is a license to intellectual property. We have not recognized any royalty revenue to date.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments: Recognition and Measurement of Financial Assets and Financial Liabilities, or ASU No. 2016-01, which amends certain aspects of accounting and disclosure requirements for financial instruments, including the requirement that equity investments with readily determinable fair values be measured at fair value with any changes in fair value recognized in a company's results of operations. Equity investments that do not have readily determinable fair values may be measured at fair value or at cost minus impairment adjusted for changes in observable prices. We adopted ASU No. 2016-01 as of January 1, 2018. The adoption of ASU No. 2016-01 did not have an impact on our condensed consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments, or ASU No. 2016-15, which clarifies classification of certain cash receipts and cash payments on the statement of cash flows to reduce existing diversity in practice. We adopted ASU No. 2016-15 as of January 1, 2018. The adoption of ASU No. 2016-15 did not have a material impact on our condensed consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows, Restricted Cash, or ASU No. 2016-18, which provides guidance on the presentation of restricted cash and restricted cash equivalents in the statement of cash flows. Under the new standard, the statement of cash flows explains the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Amounts generally described as restricted cash and restricted cash equivalents are now included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period amounts shown in the statements of cash flows. We adopted ASU No. 2016-18 as of January 1, 2018 on a retrospective basis. We have no restricted cash equivalents. The cash, cash equivalents and restricted cash at the beginning and ending of each period presented in our condensed consolidated statements of cash flows for the six months ended June 30, 2018 and 2017 consisted of the following balances from our condensed consolidated balance sheets:

	Six Months Ended June 30, 2018		Six Months Ended June 30, 2017	
	Beginning of period	End of period	Beginning of period	End of period
	(in thousands)			
Cash and cash equivalents	$34,607	$49,165	$74,060	$66,197

Restricted cash	—	—	1,152	515
Restricted cash, less current portion	—	—	530	—
Cash, cash equivalents and restricted cash per statement of cash flows	$34,607	$49,165	$75,742	$66,712

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In May 2017, the FASB issued ASU No. 2017-09, Compensation—Stock Compensation: Scope of Modification Accounting, or ASU No. 2017-09, which clarifies when changes to the terms and conditions of a share-based payment award must be accounted for as modifications. The new guidance will result in fewer changes to the terms of an award being accounted for as modifications and reduce diversity in practice for when changes are accounted for as modifications. It does not change the accounting for modifications. We adopted ASU No. 2017-09 as of January 1, 2018, using a prospective approach to awards modified on or after the adoption date, and adoption did not have an impact on our financial statement presentation or disclosures.

In March 2018, the FASB issued ASU No. 2018-05, Income Taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118, which allowed SEC registrants to record provisional amounts in earnings for the year ended December 31, 2017 due to the complexities involved in accounting for the enactment of the Tax Cuts and Jobs Act of 2017, or the Act. We recognized the estimated income tax effects of the Act in our consolidated financial statements and accompanying footnotes included in our 2017 Annual Report on Form 10-K in accordance with SEC Staff Accounting Bulletin No. 118. The final impact may differ from the provisional amount due to, among other things, changes in interpretations and assumptions we have made thus far and the issuance of additional regulatory or other guidance.

4. Stock-Based Compensation

Total stock-based compensation expense related to all equity awards for the three and six months ended June 30, 2018 and 2017 was composed of the following:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(in thousands)			
Research and development	$124	$394	$259	$1,101
General and administrative	721	1,603	1,469	2,703
Total stock-based compensation expense	$845	$1,997	$1,728	$3,804

As of June 30, 2018, we had approximately $3.0 million of total unrecognized compensation cost related to unvested common stock options and awards under our Employee Stock Purchase Plan which is expected to be recognized over a weighted-average period of 1.2 years.

Restricted Stock

We did not recognize any stock compensation expense for the three and six months ended June 30, 2018 related to restricted stock. We recognized $0.3 million of stock compensation expense for the three and six months ended June 30, 2017 related to restricted stock, the vesting of which was determined to be probable as of June 30, 2017 and that vested on July 21, 2017 based on achievement of a specified performance condition.

Stock Options

During the six months ended June 30, 2018, we granted options to purchase 1,337,750 shares of our common stock at a weighted average fair value of $1.60 per share and a weighted average exercise price of $2.09 per share. During the six months ended June 30, 2017, we granted options to purchase 4,708,500 shares of our common stock at a weighted average fair value of $1.17 per share and a weighted average exercise price of $1.61 per share. For the three and six months ended June 30, 2018 and 2017, the fair values were estimated using the Black-Scholes valuation model using the following weighted-average assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Risk-free interest rate	2.8 %	1.8 %	2.4 %	1.9 %
Expected annual dividend yield	—	—	—	—
Expected stock price volatility	99.2 %	90.0 %	97.2 %	90.0 %
Expected term of options	5.4 years	5.7 years	5.6 years	

	5.6 years

During the six months ended June 30, 2018, options to purchase 130,000 shares of common stock were exercised, with a weighted-average exercise price of $1.46.

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

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

	June 30, 2018			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	(in thousands)			
Cash and cash equivalents	$49,165	$ —	$ —	$ 49,165
Total cash and cash equivalents	$49,165	$ —	$ —	$ 49,165

	December 31, 2017			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	(in thousands)			
Cash and cash equivalents	$34,607	$ —	$ —	$ 34,607
Available-for-sale securities:				
U.S. Treasury securities due in one year or less	3,497	—	(3)	3,494
U.S. government-sponsored enterprise obligations due in one year or less	19,520	—	(12)	19,508
Total available-for-sale securities	23,017	—	(15)	23,002
Total cash, cash equivalents and available-for-sale securities	$57,624	$ —	$ (15)	$ 57,609

During the six months ended June 30, 2018, all of our available-for-sale securities matured. We had no material realized gains or losses on our available-for-sale securities for the three and six months ended June 30, 2018 and 2017. There were no other-than-temporary impairments recognized for the three and six months ended June 30, 2018 and 2017.

6. Fair Value

We use a valuation hierarchy for disclosure of the inputs used to measure fair value. This hierarchy prioritizes the inputs into three broad levels. Level 1 inputs, which we consider the highest-level inputs, are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value. The classification of a financial asset or liability within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement. For our fixed income securities, we reference pricing data supplied by our custodial agent and nationally known pricing vendors, using a variety of daily data sources, largely readily-available market data and broker/dealer quotes. We validate the prices provided by our third-party pricing services by reviewing their pricing methods and obtaining market values from other pricing sources. After completing our validation procedures, we did not adjust or override any fair value measurements provided by our pricing services as of June 30, 2018 and December 31, 2017.

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The following table sets forth the assets carried at fair value measured on a recurring basis as of June 30, 2018 and December 31, 2017:

	Level 1	Level 2
	(in thousands)	
June 30, 2018		
Assets:		
Cash and cash equivalents	$49,165	$—
Total	$49,165	$—
December 31, 2017		
Assets:		
Cash and cash equivalents	$34,607	$—
U.S. Treasury securities	—	3,494
U.S. government-sponsored enterprise obligations	—	19,508
Total	$34,607	$23,002

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

There have been no changes to our valuation methods during the six months ended June 30, 2018. We evaluate transfers between levels at the end of each reporting period. There were no transfers of assets or liabilities between Level 1 and Level 2 during the six months ended June 30, 2018. We had no available-for-sale securities that were classified as Level 3 at any point during the six months ended June 30, 2018 or during the year ended December 31, 2017.

7. Prepaid expenses and other current assets

Prepaid expenses and other current assets consist of the following:

	June 30, 2018	December 31, 2017
	(in thousands)	
Prepaid expenses	$1,132	$ 563
Other current assets	141	214
Total prepaid expenses and other current assets	$1,273	$ 777

8. Collaborations

Takeda

In July 2010, we entered into a development and license agreement with Takeda Pharmaceutical Company Limited, which we refer to as Takeda, our PI3K inhibitor program licensor, under which we obtained rights to discover, develop and commercialize pharmaceutical products targeting the gamma and/or delta isoforms of PI3K, including IPI-549 and duvelisib, an oral, dual inhibitor of PI3K delta and gamma. We refer to the amended and restated development and license agreement, as amended, as the Takeda Agreement.

The July 2017 amendment to the Takeda Agreement terminated our obligations to pay royalties to Takeda with respect to worldwide net sales of products containing or comprised of a selective inhibitor of PI3K gamma, including but not limited to IPI-549. In consideration for such termination, we concurrently executed a convertible promissory note, which we refer to as the Takeda Note, which obligated us to pay Takeda, or its designated affiliate, the principal amount of $6.0 million together with interest accruing at a rate of 8% per annum on or before July 26, 2018 in cash or in shares of our common stock, at the election of Takeda. The $6.0 million has been included in our accompanying condensed consolidated balance sheets as a current liability titled Note Payable as of December 31, 2017. For the six months ended June 30, 2018, we recorded $0.1 million of interest expense related to the Takeda Note.

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On March 12, 2018, we exercised our right to prepay in full the Takeda Note in the principal amount of $6.0 million together with interest of approximately $0.3 million. Takeda elected to receive $4.0 million of such payment in cash and approximately $2.3 million of such payment in shares of our common stock. Pursuant to the terms of the Takeda Note, we issued 1,134,689 shares of common stock, calculated using an average price of $2.028 per share, to Takeda's designated subsidiary, Millennium Pharmaceuticals, Inc.

Verastem

On October 29, 2016, we and Verastem, Inc., or Verastem, entered into a license agreement, which we and Verastem amended and restated on November 1, 2016, effective as of October 29, 2016. We refer to the amended and restated license agreement as the Verastem Agreement. Under the Verastem Agreement, we granted to Verastem an exclusive worldwide license for the research, development, commercialization, and manufacture of duvelisib and products containing duvelisib, which we refer to as Licensed Products, in each case in oncology indications. Upon entry into the Verastem Agreement, Verastem assumed financial responsibility for activities that were part of our ongoing duvelisib program, including a randomized, Phase 3 monotherapy clinical study, which we refer to as the DUO Study, in patients with relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma. Following a transition period, which terminated December 31, 2016, Verastem assumed all financial and operational responsibility for the duvelisib program except for the clinical shutdown costs and certain clinical close-out activities that we agreed to retain.

We assessed this arrangement in accordance with ASC 606 and concluded that at the date of contract inception this arrangement contained two performance obligations, consisting of the license and transition activities. We satisfied the license at contract inception and transition activities over the transition period which ended in December 2016.

On September 6, 2017, Verastem notified us that the DUO Study met certain pre-specified criteria at completion triggering a $6.0 million payment under the Verastem Agreement, which we received in cash on October 13, 2017. On April 9, 2018, Verastem announced that the U.S. Food and Drug Administration, or FDA, had accepted, with priority review, Verastem's new drug application, or NDA, for approval of duvelisib for the treatment of patients with relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma and accelerated approval for the treatment of relapsed or refractory follicular lymphoma. The FDA target action date for response to the NDA is October 5, 2018. If Verastem receives approval of its NDA for duvelisib, Verastem is required to make a $22.0 million payment to us, in cash or, at Verastem's election, in whole or in part, in shares of Verastem common stock. As of June 30, 2018, we did not recognize revenue related to the $22.0 million payment as it is a variable consideration that is constrained as it depends on regulatory approval. Variable consideration associated with regulatory approvals are generally constrained until those approvals are received as it is outside of our control. As the performance obligations were previously satisfied, the milestone would be recognized as revenue in full in the period in which the milestone is achieved.

For any portion of the $22.0 million payment that Verastem elects to pay in shares of Verastem common stock in lieu of cash, the number of shares of Verastem common stock to be issued would be determined by multiplying (1) 1.025 by (2) the number of shares of common stock equal to (a) the amount of the payment to be paid in shares of common stock divided by (b) the average closing price of a share of common stock as quoted on Nasdaq for a 20-day period following the public announcement of the applicable event. The shares of common stock would be issued as unregistered securities, and Verastem would have an obligation to promptly file a registration statement with the SEC to register such shares for resale. Any issuance of shares would be subject to the satisfaction of standard closing conditions, including that all material authorizations, consents, and similar approvals necessary for such issuance shall have been obtained.

On a product-by-product and country-by-country basis, subject to specified conditions, Verastem is also obligated to pay us royalties on worldwide net sales of Licensed Products under the Verastem Agreement ranging from the mid-single digits to the high-single digits, which, if received, we expect to share equally with Takeda.

In addition, Verastem is obligated to pay us a royalty of 4% on worldwide net sales of Licensed Products on a product-by-product and country-by-country basis, subject to specified conditions, to cover the reimbursement of research and development costs owed by us to Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products L.P., or Purdue. We refer to these royalty obligations as the Trailing Mundipharma

Royalties. Once we have fully reimbursed Mundipharma and Purdue, the Trailing Mundipharma Royalties will be reduced to 1% of net sales in the United States.

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PellePharm

In June 2013, we entered into a license agreement with PellePharm, Inc., or PellePharm, under which we granted PellePharm exclusive global development and commercialization rights to our hedgehog inhibitor program, including IPI-926, a clinical-stage product candidate. We refer to our license agreement with PellePharm as the PellePharm Agreement and products covered by the PellePharm Agreement as Hedgehog Products. We assessed this arrangement in accordance with ASC 606 and concluded that at the date of contract inception there was only one performance obligation, consisting of the license, which was satisfied at contract inception.

Under the PellePharm Agreement, PellePharm is obligated to pay us up to $11.0 million in clinical, regulatory and commercial-based milestone payments through the first commercial sale of a Hedgehog Product. PellePharm is also obligated to pay us up to $37.5 million in success-based milestone payments upon the achievement of certain annual net sales thresholds, as well as a share of certain revenue received by PellePharm in the event that PellePharm sublicenses its rights under the PellePharm Agreement and tiered royalties on annual net sales of Hedgehog Products subject to specified conditions. As of June 30, 2018, we did not recognize revenue related to the milestones as they represent variable consideration that is constrained. In making this assessment, we considered numerous factors, including the fact that achievement of the milestones is outside our control and contingent upon the future success of clinical trials, PellePharm’s actions, and the receipt of regulatory approval. As the single performance obligation was previously satisfied, all clinical, regulatory and commercial-based milestones will be recognized as revenue in full in the period in which the constraint is removed. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as these amounts have been determined to relate predominantly to the license granted to PellePharm and therefore are recognized at the later of when the performance obligation is satisfied, or the related sales occur.

Arcus

On June 25, 2018, we entered into a clinical trial collaboration agreement with Arcus Biosciences, Inc., or Arcus. Under the terms of the agreement, which we refer to as the Arcus Agreement, we and Arcus will evaluate IPI-549 in combination with AB928, Arcus’s dual adenosine receptor antagonist, and AB122, Arcus’s anti-PD-1 antibody, as well as IPI-549 in combination with AB928 and chemotherapy, in patients with triple negative breast cancer or ovarian cancer in four separate cohorts. Expenses related to the four triple-combination cohorts will be split equally between us and Arcus.

9. Accrued Expenses

Accrued expenses consist of the following:

	June 30, 2018	December 31, 2017
	(in thousands)	
Accrued compensation and benefits	$1,568	$ 2,002
Accrued clinical and development	2,424	1,736
Other	920	1,398
Total accrued expenses	$4,912	$ 5,136

10. Stockholders' Equity

In May 2016, we entered into a controlled equity offering sales agreement, or Sales Agreement, with Cantor Fitzgerald & Co., or Cantor Fitzgerald, pursuant to which we may from time to time, at our option, offer and sell shares of our common stock having an aggregate offering price of up to $50.0 million through Cantor Fitzgerald, acting as our sales agent. Cantor Fitzgerald will be entitled to a commission of 3.0% of the aggregate gross proceeds from sales of shares of our common stock under the Sales Agreement. Sales of shares of our common stock under the Sales Agreement may be made by any method permitted by law that is deemed an “at the market” offering as defined in Rule 415 under the Securities Act of 1933, as amended, including sales made through the Nasdaq Global Select Market, on any other existing trading market for our common stock or to or through a market maker. We may also authorize Cantor Fitzgerald to sell shares in privately negotiated transactions. During the six months ended June 30, 2018, we sold 4,461,893 shares of common stock at a weighted average price per share of $2.18 at-the-market

pursuant to the Sales Agreement for $9.4 million in net proceeds. We have no obligation to sell shares of our common stock and cannot provide any assurances that we will issue any additional shares pursuant to the Sales Agreement. We may also suspend the offering of shares of our common stock upon notice to Cantor Fitzgerald and subject to other conditions.

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11. Commitments and Contingencies

We currently sublease 6,091 square feet of office space at 784 Memorial Drive, Cambridge, Massachusetts. The term of the lease commenced on September 1, 2017 and will expire on August 31, 2019. From September 1, 2017 through August 31, 2018, the base rent of the lease is $19,796 per month. From September 1, 2018 until the expiration date, the base rent of the lease will be $20,303 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.

At June 30, 2018, future minimum payments under the lease are approximately $0.3 million.

We previously leased approximately 61,000 square feet of office space in Cambridge, Massachusetts, under a lease agreement, or the Lease. We were deemed the owner of the building for accounting purposes, and we recorded the building in our property and equipment balance, although legal ownership remains with the landlord. Our balance sheet reflected a financing obligation related to the building.

In 2017, we and the landlord entered into amendments to the Lease to early terminate the Lease subject to the satisfaction of specified contingencies and a termination payment of $5.0 million. The contingencies were satisfied on June 15, 2017 and we paid the first installment of the termination payment to the landlord on June 19, 2017 of $4.5 million and the final installment on August 24, 2017 of $0.5 million. The Lease, as amended, terminated effective August 31, 2017.

During the three-month period ended June 30, 2017, we recorded other expense of $6.9 million which represents the loss incurred to terminate the financing obligation in connection with the August 31, 2017 lease termination. This loss was comprised of: (i) $1.9 million representing the difference between the estimated carrying value of the building and building improvements and the related financing obligation and deferred rent at August 31, 2017; and (ii) the $5.0 million termination payment.

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

The following discussion of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and related notes included elsewhere in this report. Some of the information contained in this discussion and analysis and set forth elsewhere in this report, including information with respect to our plans and strategy for our business, the possible achievement of development goals and milestones, our future 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,” “will,” “would,” “coul and other words and terms of similar meaning to help identify forward-looking statements, although not all forward-looking statements contain these identifying words. You also can identify these forward-looking statements by the fact that they do not relate strictly to historical or current facts. There are a number of important risks and uncertainties that could cause actual results or events to differ materially from those indicated by forward-looking statements made herein. These risks and uncertainties include those inherent in pharmaceutical research and development, such as adverse results in our drug discovery and clinical development activities, decisions made by the U.S. Food and Drug Administration, or FDA, and other regulatory authorities with respect to the development and commercialization of our product candidates, our ability to obtain, maintain and enforce intellectual property rights for our product candidates, our dependence on our alliance partners, competition, our ability to obtain any necessary financing to conduct our planned activities, our ability to implement our strategic plans, our ability to achieve cost-savings benefits from our restructuring and other risk factors described herein. We have included, and you should review, important factors in the cautionary statements included in this Quarterly Report on Form 10-Q, particularly in the section titled “Risk Factors” in Part II, that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis and elsewhere in this report. Unless required by law, we do not undertake any obligation to update any forward-looking statements.

Business Overview

We are an innovative biopharmaceutical company dedicated to developing novel medicines for people with cancer. We combine proven scientific expertise with a passion for developing novel small molecule drugs that target disease pathways for potential applications in oncology. We are focusing our efforts on advancing IPI-549, an orally administered, clinical-stage, immuno-oncology product candidate that selectively inhibits the enzyme

phosphoinositide-3-kinase-gamma, or PI3K-gamma. We believe IPI-549 is the only selective inhibitor of PI3K-gamma being investigated in clinical trials.

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We are conducting a Phase 1/1b clinical study designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and activity for IPI-549 — both as a monotherapy and in combination with nivolumab, also known as Opdivo® — in approximately 200 patients with advanced solid tumors. We refer to this study as MARIO-1: MAcrophage Reprogramming in Immuno-Oncology. Nivolumab is an immune checkpoint inhibitor therapy commercialized by Bristol-Myers Squibb, or BMS, that targets a receptor in the human body called programmed death receptor 1, or PD-1.

The dose-escalation portions of MARIO-1 are complete, and enrollment is ongoing in seven combination therapy expansion cohorts to evaluate patients dosed at 40 mg daily, or QD, of IPI-549 in combination with the standard regimen of nivolumab of 240 mg every two weeks. These cohorts are designed to evaluate IPI-549 in patients with specific types of cancer, including 20 to 25 patients each with non-small cell lung cancer, melanoma, and head and neck cancer whose tumors show initial resistance or initially respond to but subsequently develop resistance to immune checkpoint blockade therapy. The combination expansion component also includes a cohort of up to 29 patients with triple negative breast cancer, or TNBC, who have not been previously treated with immune checkpoint blockade therapy, a cohort of 10 patients with mesothelioma, a cohort of 10 patients with adrenocortical carcinoma and a cohort of 20 patients with high baseline blood levels of myeloid-derived suppressor cells, or MDSCs. We expect to report data from the combination expansion cohorts of the MARIO-1 trial in the second half of 2018.

On June 4, 2018, we presented clinical and translational data from the combination therapy dose-escalation portion of MARIO-1 during a poster session and poster discussion session at the American Society of Clinical Oncology Annual Meeting, or ASCO 2018, which demonstrated that IPI-549 combined with nivolumab was well tolerated at all doses tested, up to the recommended expansion dose of IPI-549 at 40 mg once daily plus nivolumab at 240 mg once every two weeks. No maximum tolerated dose was determined, and there were no treatment-related deaths. Of the 31 patients evaluable for safety as of the April 25, 2018 data cutoff date, the majority of adverse events were Grade 1 or 2, and the only treatment-related Grade 3 adverse events were uncomplicated rash (19%), increased liver enzymes AST or ALT (10%), and abdominal pain (3%). Additionally, the pharmacokinetic/pharmacodynamic profile of IPI-549 (up to 40 mg QD) was unaffected by nivolumab co-administration. Forty percent (12 of 30) of patients evaluable for efficacy demonstrated disease control with 10 patients with stable disease and two patients who achieved rapid, deep and durable partial responses, including one patient with adrenocortical cancer and one with microsatellite stable gallbladder cancer. In addition, IPI-549 reduced immune suppression and increased immune activation, as indicated by analyses of peripheral blood and paired tumor biopsies.

At ASCO 2018, we also presented updated clinical and translational data from the fully enrolled monotherapy expansion portion of MARIO-1, which demonstrated that IPI-549 as a monotherapy continued to be well tolerated at all doses studied up to the recommended dose for expansion of 60 mg QD. IPI-549 demonstrated evidence of monotherapy clinical activity, with one durable partial response in peritoneal mesothelioma, where a patient remained on study after 20 months as of the date of presentation at ASCO 2018.

On June 25, 2018, we entered into a clinical trial collaboration agreement with Arcus Biosciences, Inc., or Arcus. Under the terms of the agreement, which we refer to as the Arcus Agreement, we and Arcus will evaluate IPI-549 in combination with AB928, Arcus's dual adenosine receptor antagonist, and AB122, Arcus's anti-PD-1 antibody, as well as IPI-549 in combination with AB928 and chemotherapy, in patients with TNBC or ovarian cancer in four separate cohorts. As both macrophages and adenosine levels are believed to play critical roles in creating a highly immune-suppressive tumor microenvironment in TNBC and ovarian cancers, these triple-combination cohorts are designed to evaluate a potential treatment pathway for these difficult-to-treat cancers. The four triple-combination cohorts will be included in Arcus's ongoing Phase 1/1b trials evaluating AB928 combinations, with topline data from the Arcus Agreement cohorts expected in 2019. Expenses related to the four triple-combination cohorts will be split equally between us and Arcus.

We have primarily incurred operating losses since inception and will continue to fund our operations through collaboration and license arrangements and through the sale of securities until such time as we are able to generate significant revenue from product sales. To date, substantially all of our resources have been devoted to organizing and staffing our company, conducting preclinical research and clinical development, and otherwise raising capital and business planning. We expect to continue to spend significant resources to fund the development and potential

commercialization of IPI-549 and will continue to incur significant operating losses for the foreseeable future. If we are unable to raise capital or enter into a collaboration or license arrangement on terms that ensure adequate funding, on terms favorable to us, we may have to delay or discontinue the development or commercialization of IPI-549.

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Since our inception, corporate alliances have been integral to our strategy. These alliances have provided access to breakthrough science, significant research and development support and funding, and innovative drug development programs, all intended to help us realize the full potential of our product pipeline. All of our revenues since September 2006 have been generated under collaborative research agreements including our corporate alliances. For a further description of our strategic alliances, see Note 8 of the notes to our unaudited condensed, consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q and our prior disclosure included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 filed with the U.S. Securities and Exchange Commission on March 15, 2018, which we refer to as our 2017 Annual Report on Form 10-K.

Due to the risks and uncertainties inherent to product development and commercialization, as described in the section entitled “Risk Factors” in Part II of this Quarterly Report on Form 10-Q, we are unable to predict future expenses and future profitability. We may fail to obtain marketing approval for IPI-549 or to successfully commercialize IPI-549. If we are unable to create sustained profitability, we may be forced to reduce or terminate our operations.

Financial Overview

Revenue

To date, all our revenue has been generated under collaboration agreements. The terms of these collaboration agreements may include payment to us of upfront license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved, and/or royalties on product sales.

Effective January 1, 2018, we adopted Financial Accounting Standards Board Accounting Standard Codification Topic 606, Revenue from Contracts with Customers, or ASC 606. The standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. The standard allows for two transition methods - full retrospective, in which the standard is applied to each prior reporting period presented, or modified retrospective, in which the cumulative effect of initially applying the standard is recognized at the date of initial adoption. We elected the modified retrospective approach and applied it to contracts not completed at the date of adoption. Therefore, comparative prior periods have not been adjusted. The adoption of the standard did not have a material impact on our financial position and results of operations when applied to our two out-licensing arrangements. See Note 8 of the notes to our unaudited condensed, consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for additional details on these two arrangements.

The principles in the new standard are applied using a five-step model: 1) identify the customer contract; 2) identify the contract’s performance obligations; 3) determine the transaction price; 4) allocate the transaction price to the performance obligations; and 5) recognize revenue when or as a performance obligation is satisfied. We evaluate all promised goods and services within a customer contract and determine which of those are separate performance obligations. This evaluation includes an assessment of whether the good or service is capable of being distinct and whether the good or service is separable from other promises in the contract. When a performance obligation is satisfied, we recognize as revenue the amount of the transaction price, excluding estimates of variable consideration that are constrained, that is allocated to that performance obligation. For contracts that contain variable consideration, such as milestone payments, we estimate the amount of variable consideration by using either the expected value method or the most likely amount method. In making this assessment, we evaluate factors such as the clinical, regulatory, commercial and other risks that must be overcome to achieve the milestone. We re-evaluate the probability of achievement of such milestones and any related constraint each reporting period. We will include variable consideration, without constraint, in the transaction price to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

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 under the sales- and usage-based royalty exception when the sole or predominate item to which the royalty relates is a license to intellectual property. We have not recognized any royalty revenue to date.

In the event of an early termination of a collaboration agreement, any contract liabilities would be recognized in the period in which all our obligations under the agreement have been fulfilled.

Research and Development Expense

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

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- compensation of personnel associated with research and development activities;
- clinical testing costs, including payments made to contract research organizations;
- costs of combination and comparator drugs used in clinical studies;
- 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 and intellectual property, information technology infrastructure, corporate communications, corporate development and human resources. Other costs include facilities costs not otherwise included in research and development expense and professional fees for legal and accounting services.

Other Income and Expense

Other income and expense typically consists of interest earned on cash, cash equivalents and available-for-sale securities, gain or loss on sale of property and equipment and interest expense.

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 cumulative revenue related to variable consideration, 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, other than as noted below under “New and Recently Adopted Accounting Pronouncements,” during the six months ended June 30, 2018. Please refer to Part II, Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations” of our 2017 Annual Report on Form 10-K for a discussion of our critical accounting policies and significant judgments and estimates.

New and Recently Adopted Accounting Pronouncements

See Note 3 of the notes to our unaudited condensed, consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for a description of new and recently adopted accounting pronouncements applicable to our business.

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Results of Operations

The following table summarizes our results of operations for each of the three and six months ended June 30, 2018 and 2017, together with the change in these items in dollars and as a percentage:

	Three Months Ended June 30,		$ Change	% Change
	2018	2017		
	(in thousands)			
Research and development expense	$3,749	$3,901	$ (152)	(4)%
General and administrative expense	3,386	6,205	(2,819)	(45)%
Investment and other income	172	334	(162)	(49)%
Interest expense	—	(300)	300	(100)%
Other expense	—	(6,882)	6,882	(100)%

	Six Months Ended June 30,		$ Change	% Change
	2018	2017		
	(in thousands)			
Research and development expense	$9,660	$7,940	$ 1,720	22 %
General and administrative expense	6,992	12,642	(5,650)	(45)%
Investment and other income	331	637	(306)	(48)%
Interest expense	(93)	(602)	509	(85)%
Other expense	—	(6,882)	6,882	(100)%

Research and Development Expense

Research and development expense is comparable for the three months ended June 30, 2018 and June 30, 2017.

The increase in research and development expense for the six months ended June 30, 2018 as compared to the six months ended June 30, 2017 was primarily related to an increase in clinical and development expenses for IPI-549 of approximately $3.6 million which was partially offset by a decrease in compensation of approximately $1.6 million, which was primarily related to a reduction in bonus and stock compensation.

We began to track and accumulate expenses by major program starting on January 1, 2006. These expenses primarily relate to payroll and related expenses for personnel working on our programs, process development and manufacturing, preclinical toxicology studies, clinical trial costs and allocated costs of facilities. During the three and six months ended June 30, 2018, we estimate that we incurred $3.7 million and $9.7 million, respectively, on IPI-549. During the three and six months ended June 30, 2017, we estimate that we incurred $3.8 million and $7.7 million, respectively, on our PI3K inhibitor program, primarily related to IPI-549. From January 1, 2006 through June 30, 2018, we estimate that we incurred $619.4 million on our PI3K inhibitor program, including duvelisib and IPI-549.

We do not believe that the historical costs associated with our drug development programs are indicative of the future costs associated with these programs. Due to the variability in the length of time and scope of activities necessary to develop a product candidate and uncertainties related to our cost estimates and our ability to obtain marketing approval for our product candidates, accurate and meaningful estimates of the total costs required to bring our product candidates to market are not available.

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

- the nature, timing and estimated costs of the efforts necessary to complete the development of our programs;
- the completion dates of these programs; or
- the period in which material net cash inflows are expected to commence, if at all, from the programs described above and any potential future product candidates.

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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;
- clinical trial results;
- the cost of establishing clinical supplies of any product candidates;
- the cost and availability of comparator and combination drugs;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights relating to our programs under development;
- the terms and timing of any strategic alliance, licensing and other arrangements that we have or may establish in the future relating to our programs under development;
- the cost and timing of regulatory approvals; and
- the effect of competing technological and market developments.

General and Administrative Expense

The decrease in general and administrative expense for the three and six months ended June 30, 2018 as compared to the three and six months ended June 30, 2017 was primarily related to a decrease in compensation of $1.9 million and $3.4 million, respectively, related to a reduction in bonus and stock compensation and a decrease of $0.6 million and $1.3 million, respectively, related to the exit of our previous facility lease effective August 31, 2017.

Investment and Other Income

Investment and other income decreased for the three and six months ended June 30, 2018 as compared to the three and six months ended June 30, 2017 primarily as a result of decreased income from subleases at 784 Memorial Drive, which ended during the third quarter of 2017.

Interest Expense

Interest expense for the six months ended June 30, 2018 was due to the Takeda Note (see Note 8 of the notes to our unaudited condensed, consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q). There was no interest expense for the three months ended June 30, 2018.

Interest expense for the three and six months ended June 30, 2017 was due to the financing obligation related to our previous facility lease that was terminated effective August 31, 2017.

Other Expense

Other expense for the three and six months ended June 30, 2017 represents the loss incurred to terminate the financing obligation in connection with the August 31, 2017 termination of our previous lease. This loss was composed of: (i) $1.9 million representing the difference between the estimated carrying value of the building and building improvements and the related financing obligation and deferred rent at August 31, 2017; and (ii) a $5.0 million termination payment (see Note 11 of the notes to our unaudited condensed, consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q).

Liquidity and Capital Resources

We have not generated any revenue from product sales to date, and we do not expect to generate any such revenue for the foreseeable future, if at all. We have instead relied on the proceeds from sales of equity securities, debt, interest on investments, up-front license fees, expense reimbursement, milestones and cost sharing under our collaborations to fund our operations. Because IPI-549 is in clinical development, and the outcome of this effort is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidate or whether, or when, we may achieve profitability.

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Our significant capital resources are as follows:

	June 30, 2018	December 31, 2017
	(in thousands)	
Cash, cash equivalents and available-for-sale securities	$49,165	$ 57,609
Working capital	44,759	46,791

	Six Months Ended June 30,	
	2018	2017
	(in thousands)	
Cash provided by (used in):		
Operating activities	$(14,081)	$(26,882)
Investing activities	23,046	18,000
Financing activities	5,593	(148)

Cash Flows

For the six months ended June 30, 2018 compared to the six months ended June 30, 2017, our cash used in operating activities decreased primarily due to the completion of our 2016 restructuring payments in 2017. Our cash used in operating activities in future periods may vary significantly.

Net cash from investing activities for the six months ended June 30, 2018 included purchases of available-for-sale securities of $5.7 million and proceeds of $28.8 million from maturities of available-for-sale securities.

Net cash provided by financing activities for the six months ended June 30, 2018 included the net proceeds from our common stock sales facility of $9.4 million which was partially offset by the prepayment of the Takeda Note (see Note 8 of the notes to our unaudited condensed, consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q).

Common Stock Sales Facility

In May 2016, we entered into a controlled equity offering sales agreement, or Sales Agreement, with Cantor Fitzgerald & Co., or Cantor Fitzgerald, pursuant to which we may from time to time, at our option, offer and sell shares of our common stock having an aggregate offering price of up to $50.0 million through Cantor Fitzgerald, acting as our sales agent. Cantor Fitzgerald will be entitled to a commission of 3.0% of the aggregate gross proceeds from sales of shares of our common stock under the Sales Agreement. Sales of shares of our common stock under the Sales Agreement may be made by any method permitted by law that is deemed an “at the market” offering as defined in Rule 415 under the Securities Act of 1933, as amended, including sales made through the Nasdaq Global Select Market, on any other existing trading market for our common stock or to or through a market maker. We may also authorize Cantor Fitzgerald to sell shares in privately negotiated transactions. During the six months ended June 30, 2018, we sold 4,461,893 shares of common stock at a weighted average price per share of $2.18 at-the-market pursuant to the Sales Agreement for $9.4 million in net proceeds. We have no obligation to sell shares of our common stock and cannot provide any assurances that we will issue any additional shares pursuant to the Sales Agreement. We may also suspend the offering of shares of our common stock upon notice to Cantor Fitzgerald and subject to other conditions.

Operating Capital Requirements

As of June 30, 2018, we had cash and cash equivalents of $49.2 million. Excluding a potential $22.0 million contingent payment in cash or stock from Verastem, we believe that our current cash and cash equivalents will be adequate to satisfy our capital needs through the third quarter of 2019 based on our current operational plans.

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

- the scope, progress, results and costs of developing IPI-549, currently in clinical development;

- the timing of, and the costs involved in, obtaining regulatory approvals for IPI-549;

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- subject to receipt of marketing approval, revenue, if any, received from commercial sales of IPI-549;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- any breach, acceleration event or event of default under any agreements with third parties;
- the outcome of any lawsuits that could be brought against us;
- the cost of acquiring raw materials for, and of manufacturing, our product candidates is higher than anticipated;
- the cost or quantity required of comparator or combination drugs used in clinical studies increases;
- the effect of competing technological and market developments; and
- a loss in our investments due to general market conditions or other reasons.

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

Further, 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.

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.

Contractual Obligations

There have been no material changes to our contractual obligations during the six months ended June 30, 2018.

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. 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.

A hypothetical 100 basis point increase in interest rates would not result in a change in the fair value of our investments as of June 30, 2018 as compared to a change of less than $0.1 million as of December 31, 2017.

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Item 4. Controls and Procedures

Our management, with the participation of our principal executive and financial officers, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2018. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2018, our principal executive and financial officers concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal quarter ended June 30, 2018 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 us and our business. If any of the following risks occur, our business, financial condition, operating results and strategic plans could be materially and 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, 2017.

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, and may never become profitable, or if we become profitable, we may not remain profitable.

We have no approved products, have generated no product revenue from sales, and have primarily incurred operating losses. As of June 30, 2018, we had an accumulated deficit of $683.9 million. We expect to continue to spend significant resources to fund IPI-549, our selective inhibitor of phosphoinositide-3-kinase, or PI3K, gamma. While we may have net income in some periods as the result of non-recurring collaboration revenue, we expect to incur substantial operating losses over the next several years as our clinical trial and drug manufacturing activities continue. In addition, if we proceed to seek and possibly obtain regulatory approval of IPI-549, we would expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution, to the extent such sales, marketing, manufacturing and distribution are not the responsibility of a future collaborator. As a result, we expect that our accumulated deficit would also increase significantly.

IPI-549 is under clinical development and may never be approved for sale or generate any revenue. We will not be able to generate product revenue unless and until IPI-549 successfully completes clinical trials and receives regulatory approval. We do not expect to generate revenue from product sales for the foreseeable future. Even if we eventually generate revenues, we may never be profitable, and if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, and cause a decline in the value of our common stock.

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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 the development of IPI-549 or future efforts to commercialize IPI-549.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time consuming, expensive and uncertain process that takes years to complete. We will need substantial additional funds to support our planned operations. In the absence of additional funding or business development activities, we believe that our existing cash and cash equivalents at June 30, 2018 will be adequate to satisfy our capital needs through the third quarter of 2019 based on our current operating plans.

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

- the scope, progress, results and costs of developing IPI-549, currently in clinical development;
- the timing of, and the costs involved in, obtaining regulatory approvals for IPI-549;
- subject to receipt of marketing approval, revenue, if any, received from commercial sales of IPI-549;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- any breach, acceleration event or event of default under any agreements with third parties;
- the outcome of any lawsuits that could be brought against us;
- the cost of acquiring raw materials for, and of manufacturing, our product candidates is higher than anticipated;
- the cost or quantity required of comparator or combination drugs used in clinical studies increases;
- the effect of competing technological and market developments; and
- 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. For example, under our common stock sales facility, we sold 4,461,893 shares during the six months ended June 30, 2018. Additionally, we sold 1,134,689 shares of common stock to Millennium Pharmaceuticals, Inc., the designated subsidiary of Takeda Pharmaceutical Company Limited, as partial repayment for the convertible promissory note, or the Takeda Note, we issued on July 26, 2017. We refer to our PI3K inhibitor program licensor, including its several subsidiaries, as Takeda.

If we incur additional indebtedness, there could be significant adverse consequences, including:

- requiring us to dedicate a portion of our cash resources to the payment of interest and principal, and prepayment and repayment fees and penalties, thereby reducing money available to fund working capital, capital expenditures, product development and other general corporate purposes;
- requiring us to grant security interests on our assets;
- subjecting us to restrictive covenants that may reduce 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;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete;
- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options; and
- increasing our vulnerability to adverse changes in general economic, industry and market conditions.

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We may not have sufficient funds, and may be unable to arrange for additional financing, to pay the amounts due under any debt that we may incur. Failure to make payments or comply with other covenants under these debt instruments could result in an event of default and acceleration of amounts due. If an event of default occurs and the lenders accelerate the amounts due, we may not be able to make accelerated payments.

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 valuable rights to our technologies, future revenue streams, or product candidates, and we may not be able to enter into such agreements on acceptable terms, if at all.

If we are unable to obtain additional funding on a timely basis, we may be required to curtail, terminate, sell or license rights to develop and market IPI-549 that we would otherwise prefer to develop and market ourselves, or to scale back, suspend, or terminate our business operations.

We have broad discretion in the use of our available cash and other sources of funding and may not use them effectively.

Our management has broad discretion in the use of our available cash and other sources of funding and could spend those resources in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could cause the price of our common stock to decline and delay the development of IPI-549 or any future product candidate. We may invest our available cash pending its use in a manner that does not produce income or that loses value.

Risks Related to the Development and Commercialization of IPI-549 and Any Future Product Candidate

We are dependent on the success of IPI-549, our only product candidate.

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

We currently have no products approved for sale and are investing substantially all of our efforts and financial resources in the development of IPI-549.

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

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

We also expect that the success of IPI-549 will depend primarily on its therapeutic potential in combination with other therapeutics, such as checkpoint inhibitor therapies, and not as a monotherapy.

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

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

To date, we have not obtained approval from the FDA or any foreign regulatory authority to market or sell any of our product candidates. IPI-549 and any future product candidates that we seek to advance will be subject to extensive governmental regulations relating to development, clinical trials, manufacturing and commercialization. Rigorous preclinical testing, testing in clinical trials, and an extensive regulatory approval process are required in the United States and in many foreign jurisdictions prior to the commercial sale of medicinal products like our product candidates.

For example, we are evaluating IPI-549, our only product candidate, in clinical development. If MARIO-1: MAcrophage Reprogramming in Immuno-Oncology, or MARIO-1, our Phase 1/1b clinical trial of IPI-549, is successful, we will need to conduct further clinical trials and will need to apply for regulatory approval before we may market or sell any products based on IPI-549. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that IPI-549 will not obtain marketing approval. Even if IPI-549 has a beneficial effect, that effect may not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of IPI-549 that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity of or intolerability caused by IPI-549 or mistakenly believe that IPI-549 is toxic or not well tolerated when that is not in fact the case.

We may conduct clinical trials for IPI-549 or future product candidates at sites outside the United States. The FDA may not accept data from trials conducted in such locations and the conduct of trials outside the United States could subject us to additional delays and expense.

In the future we may conduct one or more of our clinical trials with one or more trial sites that are located outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with GCP. The FDA must be able to validate the data from the trial through an onsite inspection if necessary. The trial population must also have a similar profile to the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful, except to the extent the disease being studied does not typically occur in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt our development of IPI-549 or any future product candidates.

In addition, the conduct of clinical trials outside the United States could have a significant adverse impact on us. Risks inherent in conducting international clinical trials include:

- clinical practice patterns and standards of care that vary widely among countries;
- non-U.S. regulatory authority requirements that could restrict or limit our ability to conduct our clinical trials;
- administrative burdens of conducting clinical trials under multiple non-U.S. regulatory authority schema;
- foreign exchange fluctuations; and
- diminished protection of intellectual property in some countries.

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

We cannot predict whether we will encounter problems with any of our ongoing or planned clinical trials that will cause us or regulatory authorities to delay, suspend, or discontinue clinical trials or to delay the analysis of data from ongoing clinical trials. Any of the following could delay or disrupt the clinical development of IPI-549:

- unfavorable results of discussions with the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;

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

We may suspend, or the FDA or other applicable regulatory authorities may require us to suspend, clinical trials of IPI-549 at any time if we or they believe the patients participating in such clinical trials, or in independent third-party clinical trials for drugs based on similar technologies, are being exposed to unacceptable health risks or for other reasons.

The delay, suspension or discontinuation of any of our clinical trials, or a delay in the analysis of clinical data for IPI-549, for any of the foregoing reasons, could adversely affect our ability to obtain regulatory approval for and to commercialize IPI-549, increase our operating expenses and have a material adverse effect on our financial results.

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

Adverse events or undesirable side effects caused by, or other unexpected properties of, IPI-549, alone or in combination with other agents, could cause us, any collaborators, an institutional review board or regulatory authorities to interrupt, delay or halt clinical trials of IPI-549 and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities. If IPI-549 is associated with adverse events or undesirable side effects or has properties that are unexpected, we, or any collaborators, may need to abandon development or limit development of IPI-549 to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause undesirable or unexpected side effects that prevented further development of the compound.

If the market opportunities for our product candidates are smaller than we believe they are, even assuming approval of a drug candidate, our business may suffer.

Our projections of both the number of people who are affected by disease within our target indications, as well as the subset of these people who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, healthcare utilization databases and market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Likewise, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business.

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

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

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

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

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

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

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

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

Our inability to enroll sufficient numbers of patients in our clinical trials, or any delays in patient enrollment, could result in increased costs and longer development periods for our product candidates.

Clinical trials require sufficient patient enrollment, which is a function of many factors, including:

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

Our failure to enroll patients in a clinical trial could delay the initiation or completion of the clinical trial beyond current expectations. In addition, the FDA or other foreign regulatory authorities could require us to conduct clinical trials with a larger number of patients than has been projected for any of our product candidates. As a result of these factors, we may not be able to enroll a sufficient number of patients in a timely or cost-effective manner.

Furthermore, enrolled patients may drop out of a clinical trial, which could impair the validity or statistical significance of the clinical trial. A number of factors can influence the patient discontinuation rate, including, but not limited to:

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

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

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

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 may in the future submit for any product candidate or may conclude after review of our data that our application is insufficient to obtain marketing approval. If the FDA does not accept or approve any future NDAs we may submit, 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 application that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional trials or studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDAs.

Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing any 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 one or more product candidates, which could significantly harm our business.

Even if a product candidate receives marketing approval in the future, 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 future collaborator, to market such product candidate, and we could become subject to costly and damaging product liability claims.

Even if we receive regulatory approval for a product candidate, we will have tested it in only a small number of patients in carefully defined subsets and over a limited period of time during our clinical trials, such as is the case for IPI-549. If any future applications for marketing are approved and more patients begin to use our products, or patients use such products for a longer period of time, such products might be less effective than indicated by our clinical trials. Furthermore, new risks and side effects associated with such products may be discovered or previously observed risks and side effects may become more prevalent and/or clinically significant.

In addition, supplemental clinical trials that may be conducted on a drug following its initial approval may produce findings that are inconsistent with the trial results previously submitted to regulatory authorities. As a result, regulatory authorities may revoke their approvals, or we may be required to conduct additional clinical trials, make changes in labeling of a product (including a “black box” warning or a contraindication) or the manner in which it is administered, reformulate such product or make changes to and obtain new approvals for our and our suppliers’ manufacturing facilities. We also might have to withdraw or recall such product from the marketplace, and regulators might seize such product. We might be subject to fines, injunctions, or the imposition of civil or criminal penalties. Any safety concerns with respect to such product may also result in a significant drop in the potential sales of such 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 a product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, in which case we may not be able to generate significant revenues from product sales to become profitable.

Even if a product candidate obtains regulatory approval, it 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 it is designated under physician treatment guidelines as a first, second or third line therapy;

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- changes in the standard of care for targeted indications;
- 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 product candidate we develop, such as IPI-549, received marketing approval but fails to achieve market acceptance, we would not be able to generate significant revenue, which may adversely impact our ability to become profitable.

If we obtain approval to commercialize a product candidate outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

We expect that we will be subject to additional risks in commercializing any product candidate outside the United States, including:

- different regulatory requirements for approval of drugs and biologics in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods and fires.

Even if we receive regulatory approvals for marketing any product candidates we may develop, 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 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 any product candidates and our ability to conduct our business.

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If we are unable to establish sales, marketing and distribution capabilities or enter into sales, marketing and distribution arrangements with third parties, we may not be successful in commercializing any product candidates if approved.

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

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

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

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

Immuno-oncology, or IO, 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.

IPI-549 is an inhibitor of the gamma isoform of PI3K, and we believe it is the only PI3K-gamma selective inhibitor in clinical development. However, there are many competitors developing or commercializing therapies targeting macrophage biology, including the following competitors, which we believe to be conducting clinical studies of product candidates targeting one or more aspects of macrophage biology: Array Biopharma, Inc., Deciphera Pharmaceuticals, Inc., Incyte Corporation (through its collaboration with Calithera Inc.), Bristol-Myers Squibb Company (through its collaboration with Five Prime Therapeutics, Inc.), Plexxikon Inc., Eli Lilly and Company, Amgen Inc., F. Hoffmann-La Roche Ltd, Janssen Research & Development, LLC, a subsidiary of Johnson & Johnson, Forty Seven Inc., Surface Oncology, Inc., Celgene Corporation, Trillium Therapeutics Inc., Pfizer Inc., XBiotech, Inc., AbbVie Inc., Takeda Pharmaceuticals International, Inc., Novartis AG, Efranat Ltd., Seattle Genetics, Inc., AstraZeneca PLC, Apexigen Inc., X4 Pharmaceuticals, Inc., Syndax Pharmaceuticals, Inc., Syntrix Biosystems, Inc., Eisai Co., Ltd., and Alligator Bioscience AB.

Further, the broader field of IO is crowded with innovative therapies that may compete with IPI-549, including checkpoint inhibitor therapies such as PD-1 inhibitors nivolumab and pembrolizumab; PDL-1 inhibitors atezolizumab, avelumab, and durvalumab; and CTLA-4 inhibitors ipilimumab, and tremelimumab. Many of these checkpoint inhibitor therapies are being evaluated in combination with other non-checkpoint inhibitor IO product candidates. For example, nivolumab, which we are currently testing in combination with IPI-549, is being evaluated in multiple clinical trials in combination with non-checkpoint inhibitor candidates such as BMS-986016, an anti-LAG3 antibody; elotuzumab, a CD319 antibody; urelumab, a CD137 antibody; cabiralizumab, an anti-CSF1R antibody; and NKTR-214, an IL-2R agonist. The success of competing IO therapies may limit the number of patients available for

enrollment in our clinical trials.

Our competitors may commence and complete clinical testing of their product candidates, obtain regulatory approvals and begin commercialization of their products sooner than we and/or our collaborators may for IPI-549. These competitive products may have superior safety or efficacy, have more attractive pharmacologic properties, or be manufactured less expensively than IPI-549. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to

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be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, the development of our product candidates.

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

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

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

The extent to which patients have third-party payor coverage that could in principle cover treatment with IPI-549 may be affected by legislative and regulatory changes relating to the Patient Protection and Affordable Care Act, or ACA. For instance, the so-called “individual mandate” provisions of the ACA require most individuals to carry acceptable insurance for themselves and their family, whether through the government or a private insurer, or else incur a penalty. However, the tax reform legislation signed into law on December 22, 2017, eliminated the penalty for failure to comply with the individual mandate, effective for periods beginning after December 31, 2018. This change and other legislative or regulatory actions in relation to the ACA may increase the pool of patients lacking third-party payor coverage. 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, or prevent it altogether, which may negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability or the ability of any future collaborators to recoup our or their investment in IPI-549, even if IPI-549 obtains marketing approval.

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

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

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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 IPI-549 could significantly harm our operating results, our ability to raise capital needed to commercialize IPI-549 and our overall financial condition.

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

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

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

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

We could face exposure to significant product liability or other claims if IPI-549 is alleged to have caused harm. These risks are inherent in the testing, manufacturing and marketing of human medicinal products. Although we do not currently commercialize any products, claims could be made against us based on the use of IPI-549 or duvelisib, an oral, dual inhibitor of the delta and gamma isoforms of PI3K, in clinical trials. We currently have clinical trial insurance and will seek to obtain product liability insurance prior to the commercial launch of IPI-549. Our insurance may not, however, provide adequate coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain current amounts of

insurance coverage or obtain additional or sufficient insurance at a reasonable cost. If we are sued for any injury caused by IPI-549, our liability could exceed our insurance coverage and our total assets, and we would need to divert management attention to our defense. Claims against us, regardless of their merit or potential outcome, may also generate negative publicity or hurt our ability to recruit investigators and patients to our clinical trials, obtain physician acceptance of IPI-549, or expand our business.

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Risks Related to Our Dependence on Third Parties

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

We currently have worldwide development and commercialization rights to IPI-549. We license certain patent and other intellectual property rights under our agreement with Takeda, which we refer to as the Takeda Agreement, to discover, develop and commercialize pharmaceutical products targeting the delta and/or gamma isoforms of PI3K, including IPI-549 and duvelisib. We have also licensed or sublicensed certain of our intellectual property rights to third parties, including our exclusive license of worldwide rights to develop and commercialize duvelisib to Verastem, Inc., or Verastem, pursuant to an agreement we entered into with Verastem in November 2016 and which we refer to as the Verastem Agreement. We may in the future seek other third-party collaborators. The success of a strategic alliance with any partner is largely dependent on the resources, efforts, technology and skills brought to such alliance by such partner. The benefits of such alliances will be reduced or eliminated if any such partner:

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

If such partner were to terminate its arrangements with us, or breach such arrangements, or fail to maintain the financial resources necessary to continue financing its portion of development, manufacturing, and commercialization costs, as applicable, we may not have the financial resources or capabilities necessary to continue development and commercialization of the product candidate on our own. Consequently, the development and commercialization of the affected product candidate could be delayed, curtailed or terminated, and we may find it difficult to attract a new collaborator for such product candidate.

Disputes and difficulties in these types of relationships are common, often due to priorities changing over time, conflicting priorities or conflicting interests. Merger and acquisition activity may exacerbate these conflicts. Much of the potential revenue from alliances consists of payments contingent upon the achievement of specified milestones and royalties payable on sales of any successfully developed drugs. Any such contingent revenue will depend upon our, and our collaborators', ability to successfully develop, launch, market and sell new drugs. In some cases, we will not be involved in some or all of these processes, and we will depend entirely on our collaborators.

If any future collaborator fails to develop or effectively commercialize a product candidate that is the subject of our strategic alliance with them, we may not be able to develop and commercialize such product candidate independently, and our financial condition and operations would be negatively impacted.

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

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

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

Any collaboration agreements that we enter into in the future may contain restrictions on our ability to enter into potential collaborations or to otherwise develop IPI-549 or any product candidate that we may develop in the future. 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 a given product candidate, reduce or delay its development, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

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

We rely on third parties such as contract research organizations, medical institutions and external investigators to enroll qualified patients, conduct our clinical trials and provide services in connection with such clinical trials, and we intend to rely on these and other similar entities in the future. Our reliance on these third parties for clinical development activities reduces our control over these activities. Accordingly, these third-party contractors may not complete activities on schedule or conduct our clinical trials in accordance with regulatory requirements or the trial design. If these third parties do not successfully carry out their contractual obligations or meet expected deadlines, we may be required to replace them. Replacing a third-party contractor may result in a delay of the affected trial and unplanned costs. If this were to occur, our ability to obtain regulatory approval for and to commercialize IPI-549 or any product candidate that we may develop in the future could be delayed.

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

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

IPI-549 requires precise, high quality manufacturing. The third-party manufacturers on which we rely may not be able to comply with cGMPs, and other applicable government regulations and corresponding foreign standards. These regulations govern manufacturing processes and procedures and the implementation and operation of systems to control and assure the quality of products. The FDA and foreign regulatory authorities may, at any time, audit or inspect a manufacturing facility to ensure compliance with cGMPs and other quality standards. Any failure by our contract manufacturers to achieve and maintain high manufacturing and quality control standards could result in the inability of IPI-549 to be released for use in one or more countries. In addition, such a failure could result in, among other things, patient injury or death, product liability claims, penalties or other monetary sanctions, the failure of regulatory authorities to grant marketing approval of IPI-549, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of IPI-549, operating restrictions and/or criminal prosecution, any of which could significantly and adversely affect supply of IPI-549 and seriously hurt our business.

Contract manufacturers may also encounter difficulties involving production yields or delays in performing their services. We do not have control over third-party manufacturers' performance and compliance with applicable regulations and standards. If, for any reason, our manufacturers cannot perform as agreed, we may be unable to replace such third-party manufacturers in a timely manner, and the production of IPI-549 would be interrupted, resulting in delays in clinical trials and additional costs. Switching manufacturers may be difficult because the number of potential manufacturers is limited, the 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 quickly find a replacement manufacturer on acceptable terms, or at all.

To date, IPI-549 has been manufactured for preclinical testing and clinical trials primarily by third-party manufacturers. If the FDA or other regulatory agencies approve IPI-549 for commercial sale, we expect that we would continue to rely, at least initially, on third-party manufacturers to produce commercial quantities of IPI-549. These manufacturers may not be able to successfully increase the manufacturing capacity for IPI-549 in a timely or economical manner, or at all. Significant scale-up of manufacturing might entail changes in the manufacturing process that would have to be submitted to or approved by the FDA or other regulatory agencies. If contract manufacturers engaged by us are unable to successfully increase the manufacturing capacity for IPI-549, or we are unable to establish our own manufacturing capabilities, the commercial launch of any approved products may be delayed or there may be a shortage in supply.

Risks Related to Our Intellectual Property

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

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

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

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If we do not obtain or maintain these intellectual property rights which we require, we could encounter substantial delays in developing and commercializing IPI-549 or any other potential product candidate 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 our 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 the Takeda Agreement, under which we obtained rights to discover, develop and commercialize pharmaceutical products targeting the delta and/or gamma isoforms of PI3K, including IPI-549 and duvelisib. We may enter into additional license agreements in the future. Our license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under these licenses, our licensors may have the right to terminate these license agreements, in which event we might not be able to market IPI-549 that is covered by these agreements, or our licensors may convert the license to a non-exclusive license, which could adversely affect the value of IPI-549 being developed under the license agreement. Termination of these license agreements or reduction or elimination of our licensed rights may also result in our having to negotiate new or reinstated licenses with less favorable terms. For example, if we fail to use diligent efforts to develop and commercialize products licensed under the Takeda Agreement, or if Verastem materially breaches the Verastem Agreement, we could lose our license rights under the Takeda Agreement, including rights to IPI-549.

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

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

Our success depends substantially upon our ability to obtain and maintain intellectual property protection for IPI-549. We own or hold exclusive licenses to a number of U.S. and foreign patents and patent applications directed to IPI-549. Our success depends on our ability to obtain patent protection both in the United States and in other countries for IPI-549, our methods of manufacture and our methods of use. Our ability to protect IPI-549 from unauthorized or infringing use by third parties depends substantially on our ability to obtain and enforce our patents.

Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and molecular diagnostics and the claim scope of these patents, our ability to obtain and enforce patents that may issue from any pending or future patent applications is uncertain and involves complex legal, scientific and factual questions. The standards that the United States Patent and Trademark Office, or USPTO, 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 Leahy-Smith America Invents Act, or 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.

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

In the absence of adequate patent protection in other countries, competitors may similarly be able to obtain regulatory approval in those countries for products that duplicate IPI-549. The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States. Many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. Some of our development efforts may be performed in China, India and other countries outside of the United States through third-party contractors. We may not be able to monitor and assess intellectual property developed by these contractors effectively; therefore, we may not be able to appropriately protect this intellectual property and could lose valuable intellectual property rights. In addition, the legal protection afforded to inventors and owners of intellectual property in countries outside of the United States may not be as protective of intellectual property rights as in the United States, and we may, therefore, be unable to acquire and protect intellectual property developed by these contractors to the same extent as if these development activities were being conducted in the United States. If we encounter difficulties in protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

In addition, we rely on intellectual property assignment agreements with our collaborators, vendors, employees, consultants, clinical investigators, scientific advisors and other collaborators to grant us ownership of new intellectual property that is developed by them. These agreements may not result in the effective assignment to us of that intellectual property.

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

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

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

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

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

remedy in the event of unauthorized disclosure or misuse of confidential information or other breaches of the agreements.

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In addition, we may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. Trade secrets are, however, difficult to protect. Others may independently discover our trade secrets and proprietary information, and in such case we could not assert any trade secret rights against such party. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside of the United States may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to seek to enforce and determine the scope of our proprietary rights and could result in a diversion of management's attention, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

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

Patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the USPTO for the entire time prior to issuance as a U.S. patent. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Consequently, we cannot be certain that we were the first to invent, or the first to file patent applications on, IPI-549 or its therapeutic use. In the event that a third party has also filed a U.S. patent application relating to IPI-549 or a similar invention, we may have to participate in interference or derivation proceedings declared by the USPTO or the third party to determine priority of invention in the United States. An adverse decision in an interference or derivation proceeding may result in the loss of rights under a patent or patent application. In addition, the cost of interference proceedings could be substantial.

Claims by third parties of intellectual property infringement are costly and distracting, and could deprive us of valuable rights we need to develop or commercialize IPI-549 and any product candidate that we might develop in the future.

Our commercial success will depend on whether there are third-party patents or other intellectual property relevant to our potential products that may block or hinder our ability to develop and commercialize IPI-549. We may not have identified all U.S. and foreign patents or published applications that may adversely affect our business either by blocking our ability to manufacture or commercialize our drugs or by covering similar technologies that adversely affect the applicable market. In addition, we may undertake research and development with respect to IPI-549, even when we are aware of third-party patents that may be relevant to IPI-549, on the basis that we may challenge or license such patents. There are no assurances that such licenses will be available on commercially reasonable terms, or at all. If such licenses are not available, we may become subject to patent litigation and, while we cannot predict the outcome of any litigation, it may be expensive and time consuming. If we are unsuccessful in litigation concerning patents owned by third parties, we may be precluded from selling IPI-549.

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

- pay substantial damages;
- stop developing, manufacturing and/or commercializing IPI-549;
- develop non-infringing product candidates, technologies and methods; and
- obtain one or more licenses from other parties, which could result in our paying substantial royalties or the granting of cross-licenses to our technologies.

If any of the foregoing were to occur, we may be unable to commercialize IPI-549, or we may elect to cease certain of our business operations, either of which could severely harm our business.

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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 USPTO 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 we or our employees 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 our senior management and scientific personnel.

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

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If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We have not yet registered trademarks in our potential markets. Any registered trademarks or trade names may be challenged, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

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 USPTO 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 or our sublicensees 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.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our product candidates but that are not covered by the claims of the patents that we own or license or may own in the future;
- we, or any partners or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, or any partners or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our pending licensed patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of IPI-549. If

we or our collaborators are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we or they will not be able to commercialize IPI-549, and our ability to generate revenue will be materially impaired.

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

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

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of IPI-549. Any marketing approval we or our collaborators ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

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

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

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

Additionally, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. On March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, Brexit could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the European Union. For example, the British government has begun negotiating the terms of the UK's withdrawal from the EU. It is

unclear what impact Brexit may have, if any, on the development and commercialization of IPI-549, although the first practical effects of Brexit on healthcare were felt in November 2017 when EU member states voted to move the European Medicines Agency, or the EMA, the EU's regulatory body, from London to Amsterdam. Operations in Amsterdam are slated to commence by March 30, 2019, although the move itself could cause significant disruption to the regulatory approval process in Europe.

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Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for our product candidates, which could significantly and materially harm our business.

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

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

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs applicable to drug manufacturers or quality assurance standards applicable to medical device manufacturers, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, any contract manufacturers we may engage in the future, our current or future collaborators and their contract manufacturers will also be subject to other regulatory requirements, including submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements regarding the distribution of samples to physicians, recordkeeping, and costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product such as the requirement to implement a risk evaluation and mitigation strategy.

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

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

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

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

The FDA and other agencies, including the Department of Justice, or the DOJ, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the

FDCA 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.

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

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

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

Under the CURES Act and the Trump Administration's regulatory reform initiatives, the FDA's policies, regulations and guidance may be revised or revoked and that could prevent, limit or delay regulatory approval of our product candidates, which would impact our ability to generate revenue.

In December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but its ultimate implementation is unclear. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. An under-staffed FDA could result in delays in the FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Moreover, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, which requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within the Office of Management and Budget on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but

also to significant agency guidance documents. In addition, on February 24, 2017, President Trump issued an executive order directing each affected agency to designate an agency official as a “Regulatory Reform Officer” and establish a “Regulatory Reform Task Force” to implement the two-for-one provisions and other previously issued executive orders relating to the review of federal regulations, however it is difficult to predict how these requirements will be implemented, and the extent to which they will

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impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

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. As we move toward potential commercialization of IPI-549, any corporate compliance program we design would be intended 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. However, if implemented, we cannot guarantee that such program would 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.

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

Recently enacted and future legislation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of and commercialize our 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 product candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any future 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 future collaborators, may receive for any approved products.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

In March 2010, then-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 ACA. Among the provisions of the ACA of potential importance to our business and IPI-549, including, without limitation, our ability to commercialize and the prices we may obtain for any of our product candidates and that are approved for sale, are the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of federal healthcare fraud and abuse laws, including the False Claims Act and the 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;
- extension of manufacturers' Medicaid rebate liability;
- 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 financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2024 unless additional Congressional action is taken. 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.

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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 we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Since enactment of the ACA, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the law. In May 2017, the U.S. House of Representatives passed legislation known as the American Health Care Act of 2017. Thereafter, the Senate Republicans introduced and then updated a bill to replace the ACA known as the Better Care Reconciliation Act of 2017. The Senate Republicans also introduced legislation to repeal the ACA without companion legislation to replace it, and a “skinny” version of the Better Care Reconciliation Act of 2017. In addition, the Senate considered proposed healthcare reform legislation known as the Graham-Cassidy bill. None of these measures was passed by the U.S. Senate.

The Trump Administration has also taken executive actions to undermine or delay implementation of the ACA. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In October 2017, the President signed a second Executive Order allowing for the use of association health plans and short-term health insurance, which may provide fewer health benefits than the plans sold through the ACA exchanges. At the same time, the Administration announced that it will discontinue the payment of cost-sharing reduction, or CSR, payments to insurance companies until Congress approves the appropriation of funds for such CSR payments. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. A bipartisan bill to appropriate funds for CSR payments was introduced in the Senate, but the future of that bill is uncertain.

More recently, with enactment of the Tax Cuts and Jobs Act of 2017, which was signed by the President on December 22, 2017, Congress repealed the “individual mandate.” The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, will become effective in 2019. According to the Congressional Budget Office, the repeal of the individual mandate will cause 13 million fewer Americans to be insured in 2027 and premiums in insurance markets may rise. Further, each chamber of the Congress has put forth multiple bills designed to repeal or repeal and replace portions of the ACA. Although none of these measures has been enacted by Congress to date, Congress may consider other legislation to repeal and replace elements of the ACA. The Congress will likely consider other legislation to replace elements of the ACA during the next Congressional session.

We will continue to evaluate the effect that the ACA and its possible repeal and replacement could have on our business. It is possible that repeal and replacement initiatives, if enacted into law, could ultimately result in fewer individuals having health insurance coverage or in individuals having insurance coverage with less generous benefits. While the timing and scope of any potential future legislation to repeal and replace ACA provisions is highly uncertain in many respects, it is also possible that some of the ACA provisions that generally are not favorable for the research-based pharmaceutical industry could also be repealed along with ACA coverage expansion provisions. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop commercialize product candidates.

The costs of prescription pharmaceuticals in the United States has also been the subject of considerable discussion in the United States, and members of Congress and the Administration have stated that they will address such costs through new legislative and administrative measures. The pricing of prescription pharmaceuticals is also subject to governmental control outside the United States. In these countries, pricing negotiations with governmental authorities

can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of our product candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired. In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs.

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Moreover, legislative and regulatory proposals have also been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical drugs. 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 drug 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 future collaborators to more stringent drug labeling and post-marketing testing and other requirements.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, such as the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we, or any current or future collaborators, may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

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.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. The FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

We cannot ensure 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.

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In addition, changes in our products or solutions or changes in applicable export or import laws and regulations may create delays in the introduction, provision, or sale of our products and solutions in international markets, prevent customers from using our products and solutions or, in some cases, prevent the export or import of our products and solutions to certain countries, governments or persons altogether. Any limitation on our ability to export, provide, or sell our products and solutions could adversely affect our business, financial condition and results of operations.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

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, as well as other work-related injuries, 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 2008 global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as that in 2008, 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. 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.

We rely significantly upon information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cyber-security incidents, could harm our ability to operate our business effectively.

Despite the implementation of security measures and certain data recovery measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber attacks, computer viruses, unauthorized access, sabotage, natural disasters, terrorism, war, telecommunication and electrical failures and other disruptions. System failures, accidents or security breaches could cause interruptions in operations for us or those third parties with which we contract, and could result in a material disruption of our clinical and commercialization activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate public disclosure of confidential or proprietary information, we could incur liability and our product development and commercialization efforts could be delayed. Such delay could have a material adverse impact on our business, operating results and financial condition.

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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 Potential Future Growth

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

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

Retaining qualified scientific and business personnel is also critical to our success. Our industry has experienced a high rate of turnover of management personnel in recent years. If we lose one or more of our executive officers or other key employees, our ability to implement our business strategy successfully could be seriously harmed. This competition is particularly intense near our headquarters in Cambridge, Massachusetts. We may not be able to attract or retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. In addition, we may face additional challenges in retaining our existing senior management and key employees for our company as our business needs change.

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

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

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

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

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

Risks Related to Our Common Stock

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

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

- the results of our current and any future clinical trials of IPI-549;
- future sales of, and the trading volume in, our common stock;
- announcements of strategic transactions relating to our programs or our company;
- our entry into key agreements, including those related to the acquisition or in-licensing of new programs, or the termination of key agreements, including the Takeda Agreement or the Verastem Agreement;
- the results and timing of regulatory reviews relating to the approval of IPI-549;
- the initiation of, material developments in, or conclusion of litigation, including but not limited to litigation to enforce or defend any of our intellectual property rights or to defend product liability claims;
- the failure of IPI-549, if approved, to achieve commercial success;
- the results of clinical trials conducted by others on drugs that would compete with IPI-549;
- the regulatory approval of drugs that would compete with IPI-549;
- issues in manufacturing IPI-549;
- the loss of executive officers or other 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.

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

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

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

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

Our condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses. Such estimates and judgments include those related to revenue recognition, impairment of long-lived assets, 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, which could be impacted by our restructuring or employee turnover, as such requirements exist today or may be modified, supplemented or amended in the future, could have a material adverse effect on our business, operating results and stock price.

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

We have incurred significant net losses since our inception and cannot guarantee when, if ever, we will become profitable. To the extent that we continue to generate federal and state taxable losses, unused net operating loss and tax credit carryforwards will carry forward to offset future taxable income, subject to applicable limitations on the use of those losses. Losses incurred in taxable years ending on or before December 31, 2017, are eligible to be carried

forward for up to 20 years, and to be deducted in full against income for the years to which they may be carried. Losses incurred in taxable years ending after December 31, 2017, are eligible to be carried forward indefinitely, but may offset no more than 80% of the taxable income for the years to which they are carried (computed without regard to the deduction for carryovers of net operating losses). Net operating loss carryovers from periods ending on or before December 31, 2017, and tax credit carryovers from all periods, could expire unused and be unavailable to offset future income tax liabilities.

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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 and credit carryovers to reduce its tax liability for post-change periods may be limited. We may experience ownership changes 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 credits currently claimed as a carryover. A detailed study could result in adjustment to our research and development credit carryovers. If we determine that an ownership change has occurred and our ability to use our historical net operating loss and tax credit carryovers is materially limited, or if our research and development carryforwards are adjusted, our use of those attributes to offset future income tax liabilities would be limited.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation that significantly revised the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain how various states will respond to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts.

Our effective tax rate may be different than experienced in the past due to numerous factors, including passage of the newly enacted federal income tax law, changes in the mix of our profitability apportioned to tax jurisdictions in which we may operate, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

Because we do not anticipate paying cash dividends, stock price appreciation, if any, will be our stockholders' sole return on investment.

We anticipate retaining any future earnings for reinvestment in the infrastructure and personnel necessary to support our development and potential 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 August 1, 2018, stockholders beneficially owning 5% or more of our common stock, as well as our executive officers, directors, and their respective affiliates, beneficially owned in the aggregate approximately 33% 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 our company;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

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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 June 30, 2018, we had $49.2 million in cash and cash equivalents. 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 5. Other Information

Amendment to Executive Severance Benefits Plan

On August 3, 2018, the Compensation Committee of our Board of Directors approved Amendment No. 1, or the Amendment, to our Executive Severance Benefits Plan, or the Plan. The Amendment replaces the original definition of an eligible participant to provide that only employees appointed by the board of directors as an “executive officer” of our company within the meaning of Rule 3b-7 under the Securities Exchange Act of 1934 would be eligible for benefits under the Plan. The Amendment did not change the benefits provided to eligible participants under the Plan, a description of which may be found in the Compensation Discussion and Analysis section of our definitive proxy statement filed with the U.S. Securities and Exchange Commission on April 25, 2018, under the heading Components of Our Compensation Program and Relationship to Performance - Severance Benefits.
The foregoing description of the terms of the Amendment does not purport to be complete and is qualified in its entirety by reference to the full text of the Amendment, which we intend to file as an exhibit to our Quarterly Report on Form 10-Q for the period ending September 30, 2018.

Appointment of Chief Medical Officer

On August 6, 2018, Samuel Agresta, M.D., M.P.H., joined us as Senior Vice President, Chief Medical Officer. Prior to joining us, Dr. Agresta served as Vice President and Head of Clinical Development at Agios Pharmaceuticals, Inc., or Agios, where he was responsible for the development and approval of enasidineb and ivosidenib for the treatment

of patients with acute myeloid leukemia that harbor isocitrate dehydrogenase, or IDH, mutations. Before joining Agios, Dr. Agresta held positions of responsibility in oncology clinical development at Merrimack Pharmaceuticals and Genentech, Inc. Prior to his indust

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ry experience, Dr. Agresta served on the oncology faculty at the Moffitt Cancer Center where he specialized in adolescent sarcoma care and participated in numerous industry trials.

Dr. Agresta received his medical degree, internal medicine training, and served as chief resident at Tulane University School of Medicine in New Orleans. While in medical school, he also received a Master's in Public Health and Tropical Medicine from Tulane University School of Public Health. He completed his medical oncology fellowship at the University of South Florida and Moffitt Cancer Center Cancer where he also received a Master's in Clinical Investigation from the University of South Florida.

Item 6. Exhibits

		Incorporated by Reference			
Exhibit No.	Description	Form	SEC Filing date	Exhibit Number	Filed with this 10-Q
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	
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.				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.				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.				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.				X
101	The following materials from the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, 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

SIGNATURES

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

INFINITY PHARMACEUTICALS, INC.

Date: August 7, 2018 By: /s/ LAWRENCE E. BLOCH, M.D., J.D.
Lawrence E. Bloch, M.D., J.D.
President
(Principal Financial Officer & Principal Accounting Officer)