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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2017

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 ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 ☒	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 ☒

Number of shares of the registrant's Common Stock, $0.001 par value, outstanding on November 2, 2017: 50,711,433

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INFINITY PHARMACEUTICALS, INC.

FORM 10-Q

FOR THE QUARTER ENDED SEPTEMBER 30, 2017

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PART I. FINANCIAL INFORMATION

Item 1. Unaudited Condensed Consolidated Financial Statements

INFINITY PHARMACEUTICALS, INC.

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

	September 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 33,580	$ 74,060
Available-for-sale securities	21,995	18,004
Restricted cash	—	1,152
Prepaid expenses and other current assets	8,364	8,444
Total current assets	63,939	101,660
Property and equipment, net (note 8)	309	23,424
Restricted cash, less current portion	—	530
Other assets	23	41
Total assets	$ 64,271	$ 125,655
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 354	$ 2,413
Accrued expenses	4,517	21,008
Financing obligation, current (note 8)	—	442
Note payable (note 9)	6,000	—
Total current liabilities	10,871	23,863
Deferred rent (note 8)	—	183
Financing obligation, less current portion (note 8)	—	19,149
Other liabilities	26	6
Total liabilities	10,897	43,201
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, $0.001 par value; 1,000,000 shares authorized, no shares issued and outstanding at September 30, 2017 and December 31, 2016	—	—
Common Stock, $0.001 par value; 100,000,000 shares authorized; 50,689,512 and 50,374,871 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	51	50
Additional paid-in capital	713,548	708,096
Accumulated deficit	(660,223)	(625,689)
Accumulated other comprehensive loss	(2)	(3)
Total stockholders' equity	53,374	82,454
Total liabilities and stockholders' equity	$ 64,271	$ 125,655

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

INFINITY PHARMACEUTICALS, INC.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Collaboration revenue	$ 6,000	$ —	$ 6,000	$ 18,723
Operating expenses:				
Research and development	9,338	12,814	17,278	104,949
General and administrative	4,505	7,120	17,147	33,648
Total operating expenses	13,843	19,934	34,425	138,597
Gain on AbbVie Opt-Out (note 9)	—	—	—	112,216
Loss from operations	(7,843)	(19,934)	(28,425)	(7,658)
Other income (expense):				
Interest expense	(287)	(305)	(890)	(921)
Other expense (note 8)	—	—	(6,882)	—
Investment and other income	1,026	741	1,663	1,408
Total other income (expense)	739	436	(6,109)	487
Net loss	$ (7,104)	$ (19,498)	$ (34,534)	$ (7,171)
Basic and diluted loss per common share:	$ (0.14)	$ (0.39)	$ (0.68)	$ (0.15)
Basic and diluted weighted average number of common shares outstanding:	50,635,828	49,583,776	50,505,783	49,448,725
Other comprehensive loss:				
Net unrealized holding gains (losses) on available-for-sale securities arising during the period	(2)	(1)	1	(44)
Comprehensive loss	$ (7,106)	$ (19,499)	$ (34,533)	$ (7,215)

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

INFINITY PHARMACEUTICALS, INC.

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

	Nine Months Ended September 30,	
	2017	**2016**
Operating activities		
Net loss	$ (34,534)	$ (7,171)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash gain on AbbVie Opt-Out	—	(112,216)
Note payable	6,000	—
Depreciation	1,645	2,566
Stock-based compensation, including 401(k) match	5,391	10,317
Non-cash adjustment to financing obligation	1,882	—
Impairment of property and equipment	—	771
Gain on sale of property and equipment	(772)	(488)
Other, net	(3)	137
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	997	654
Accounts payable, accrued expenses and other liabilities	(18,525)	(9,235)
Deferred revenue	—	(18,723)
Net cash used in operating activities	(37,919)	(133,388)
Investing activities		
Purchases of property and equipment	(26)	(661)
Proceeds from sale of assets	—	1,146
Purchases of available-for-sale securities	(21,987)	(52,490)
Proceeds from maturities of available-for-sale securities	18,000	83,625
Proceeds from sales of available-for-sale securities	—	11,953
Net cash (used in) provided by investing activities	(4,013)	43,573
Financing activities		
Proceeds from issuances of common stock related to stock incentive plans and awards	62	444
Proceeds from issuances of common stock related to employee stock purchase plan	—	18
Release of restricted cash	1,682	—
Payments on financing obligation	(292)	(310)
Net cash provided by financing activities	1,452	152
Net decrease in cash and cash equivalents	(40,480)	(89,663)
Cash and cash equivalents at beginning of period	74,060	188,170
Cash and cash equivalents at end of period	$ 33,580	$ 98,507
Supplemental cash flow information		
Cash paid for interest	$ 802	$ 921

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

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 nine months ended September 30, 2017 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2017.

The information presented in the condensed consolidated financial statements and related footnotes at September 30, 2017, and for the three and nine months ended September 30, 2017 and 2016, is unaudited, and the condensed consolidated balance sheet amounts and related footnotes at December 31, 2016 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, 2016 filed with the U.S. Securities and Exchange Commission, or SEC, on March 14, 2017, which we refer to as our 2016 Annual Report on Form 10-K.

Liquidity

We have generated an accumulated deficit of $660.2 million and will require substantial additional capital to fund operations. Our success is dependent on our ability to develop our sole clinical stage product candidate, IPI-549, an orally administered immuno-oncology product candidate that selectively inhibits the enzyme phosphoinositide-3-kinase-gamma, or PI3K-gamma, and ultimately upon our ability to attain profitable operations. We are subject to a number of risks similar to other life science companies seeking to develop and commercialize pharmaceuticals, including, but not limited to, risks relating to the successful development of IPI-549 and our need for additional funding, which may not be available.

As of September 30, 2017, we had cash and cash equivalents and available-for-sale securities of $55.6 million. Excluding the potential $22.0 million contingent payment in cash or stock from Verastem Inc., or Verastem (see Note 9), we believe that our current cash and cash equivalents will be adequate to satisfy our capital needs into the first quarter of 2019 based on our current operational plan. 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.

Reclassifications

Certain amounts in the prior years' financial statements have been reclassified to conform with the current year presentation. These reclassifications have no impact on previously reported net income, net loss or cash flows.

3. Significant Accounting Policies

Our significant accounting policies are described in Note 2, "Summary of Significant Accounting Policies," in our 2016 Annual Report on Form 10-K.

Segment Information

We operate in one business segment, which focuses on drug development. We make operating decisions based upon 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.

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 such 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 September 30,	
	2017	2016
Stock options	7,646,250	7,795,707
Warrants (excluded from treasury stock method)	1,000,000	1,000,000
Unvested restricted stock	457,822	1,341,600

New Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update, or ASU, No. 2014-9, *Revenue from Contracts with Customers*, or ASU No. 2014-9, which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. ASU No. 2014-9 was originally effective for interim and annual periods beginning after December 15, 2016. In August 2015, the FASB issued a one-year deferral of the effective date of this standard to annual reporting periods, and interim reporting periods within those years, beginning after December 15, 2017. Entities are allowed to adopt the standard as of the original effective date. 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 expect to elect the modified retrospective approach and are continuing to evaluate the impact that ASU No. 2014-09 may have on our consolidated financial statements in connection with collaboration and license agreements.

In November 2016, FASB issued ASU No. 2016-18, *Statement of Cash Flows, Restricted Cash,* or ASU No. 2016-18. ASU No. 2016-18 provides guidance on the presentation of restricted cash and restricted cash equivalents in the statement of cash flows. Under ASU No. 2016-18, the statement of cash flows shall explain 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 cash equivalents should now be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period amounts shown on the statements of cash flows. The amendments of this ASU are effective for reporting periods beginning after December 15, 2017, with early adoption permitted. Other than the revised statement of cash flows presentation, the adoption of ASU No. 2016-18 is not expected to have an impact on our condensed consolidated financial statements.

Recently Adopted Accounting Pronouncements

In March 2016, the FASB issued ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting*, or ASU No. 2016-09, which simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification of cash flows. We adopted ASU No. 2016-09 as of January 1, 2017. Under the new standard, all excess tax benefits and tax deficiencies are recognized as income tax expense or benefit in the statement of operations. The tax effects of exercised or vested awards are treated as discrete items in the reporting period in which they occur. We applied the modified retrospective adoption approach upon adoption of the standard, and prior periods have not been adjusted. As a result, we established a net operating loss deferred tax asset of $7.5 million to account for prior period excess tax benefits through retained earnings and an offsetting valuation allowance of $7.5 million through retained earnings because it is not more likely than not that the deferred tax asset will be realized due to historical and expected future losses. We elected to recognize forfeitures related to employee share-based payments as they occur. There was no material impact on our financial statements as a result of the adoption of this guidance.

4. Stock-Based Compensation

Total stock-based compensation expense related to all equity awards for the three and nine months ended September 30, 2017 and 2016 was comprised of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(in thousands)			
Research and development	$ 290	$ 1,075	$ 1,391	$ 5,041
General and administrative	1,297	1,714	4,000	5,276
Total stock-based compensation expense	$ 1,587	$ 2,789	$ 5,391	$ 10,317

As of September 30, 2017, we had approximately $5.7 million of total unrecognized compensation cost related to unvested common stock options, restricted common stock and awards under our Employee Stock Purchase Plan, or ESPP, which are expected to be recognized over a weighted-average period of 1.2 years.

Restricted Stock

During the nine months ended September 30, 2017, no restricted stock was granted, 148,300 shares of restricted stock were forfeited and 190,989 shares of restricted stock vested. As of September 30, 2017, 457,822 shares of restricted stock are issued and unvested. During the nine months ended September 30, 2016, 1,521,600 shares of restricted stock were granted, 180,000 shares of restricted stock were forfeited, and no restricted stock vested. As of September 30, 2016, 1,341,600 shares of restricted stock are issued and unvested. The restricted stock vests, if at all, based on the achievement of specified performance conditions.

We recognized $0.3 million of stock compensation expense for the nine months ended September 30, 2017 related to restricted stock. We did not recognize any stock compensation expense related to restricted stock for the nine months ended September 30, 2016.

Stock Options

During the nine months ended September 30, 2017, we granted options to purchase 4,726,500 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. During the nine months ended September 30, 2016, we granted options to purchase 1,617,472 shares of our common stock at a weighted average fair value of $3.75 per share and a weighted average exercise price of $6.14 per share. For the three and nine months ended September 30, 2017 and 2016, the fair values were estimated using the Black-Scholes valuation model using the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Risk-free interest rate	2.0%	—	1.9%	1.8%
Expected annual dividend yield	—	—	—	—
Expected stock price volatility	88.6%	—	90.0%	73.0%
Expected term of options	6.3 years	—	5.6 years	5.4 years

During the nine months ended September 30, 2017, no options to purchase shares of common stock were exercised.

Employee Stock Purchase Plan

We temporarily suspended the ESPP program on June 24, 2016, and our Board of Directors approved the commencement of a new offering period in June 2017. The weighted-average fair value of each purchase right granted during the nine months ended September 30, 2017 and 2016 was $0.98 and $2.91, respectively. For the nine months ended September 30, 2017 and 2016, the fair values were estimated using the Black-Scholes valuation model using the following weighted-average assumptions:

	Nine Months Ended September 30,	
	2017	2016
Risk-free interest rate	1.2%	0.8%
Expected annual dividend yield	—	—
Expected stock price volatility	101.8%	63.5%
Expected term	1.3 years	1.3 years

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

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

	September 30, 2017			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	(in thousands)			
Cash and cash equivalents	$ 33,580	$ —	$ —	$ 33,580
Available-for-sale securities:				
U.S. Treasury securities due in one year or less	1,496	—	—	1,496
U.S. government-sponsored enterprise obligations due in one year or less	20,501	1	(3)	20,499
Total available-for-sale securities	21,997	1	(3)	21,995
Total cash and cash equivalents	$ 55,577	$ 1	$ (3)	$ 55,575

	December 31, 2016			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	(in thousands)			
Cash and cash equivalents	$ 74,060	$ —	$ —	$ 74,060
Available-for-sale securities:				
U.S. Treasury securities due in one year or less	6,753	—	(1)	6,752
U.S. government-sponsored enterprise obligations due in one year or less	11,254	—	(2)	11,252
Total available-for-sale securities	18,007	—	(3)	18,004
Total cash, cash equivalents and available-for-sale securities	$ 92,067	$ —	$ (3)	$ 92,064

We held seven debt securities at September 30, 2017 that had been in an unrealized loss position for less than 12 months and no debt securities that had been in an unrealized loss position for 12 months or greater. The fair value of these securities was $13.6 million. There were no material unrealized losses from these securities. As of September 30, 2017, we held no securities in foreign financial institutions. We evaluated our securities for other-than-temporary impairments based on quantitative and qualitative factors. We considered the decline in market value for these securities to be primarily attributable to current economic and market conditions. It is not more likely than not that we will be required to sell these securities, and we do not intend to sell these securities before the recovery of their amortized cost basis. Based on our analysis, we do not consider these investments to be other-than-temporarily impaired as of September 30, 2017.

We had no material realized gains or losses on our available-for-sale securities for the three and nine months ended September 30, 2017 and 2016. There were no other-than-temporary impairments recognized for the three and nine months ended September 30, 2017 and 2016.

6. Fair Value

We use a valuation hierarchy for disclosure of the inputs used to measure fair value. This hierarchy prioritizes the inputs into three broad levels. Level 1 inputs, which we consider the highest level inputs, are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value. The classification of a financial asset or liability within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement. For our fixed income securities, we reference pricing data supplied by our custodial agent and nationally known pricing vendors, using a variety of daily data sources, largely readily-available market data and broker/dealer quotes. We validate the prices provided by our third party pricing services by reviewing their pricing methods and obtaining market values from other pricing sources. After completing our validation procedures, we did not adjust or override any fair value measurements provided by our pricing services as of September 30, 2017 and December 31, 2016.

The following table provides the assets carried at fair value measured on a recurring basis as of September 30, 2017 and December 31, 2016:

	Level 1	Level 2
	(in thousands)	
September 30, 2017		
Assets:		
Cash and cash equivalents	$ 31,581	$ 1,999
U.S. Treasury securities	—	1,496
U.S. government-sponsored enterprise obligations	—	20,499
Total	$ 31,581	$ 23,994
December 31, 2016		
Assets:		
Cash and cash equivalents	$ 61,008	$ 13,052
U.S. Treasury securities	—	6,752
U.S. government-sponsored enterprise obligations	—	11,252
Total	$ 61,008	$ 31,056

The fair value of the available-for-sale securities and cash and cash equivalents (including asset types listed above with maturities of three months or less at the time of purchase) is based on the following inputs for both U.S. Treasury securities and U.S, government-sponsored enterprise obligations: benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data including TRACE® reported trades.

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

There have been no changes to our valuation methods during the nine months ended September 30, 2017. We evaluate transfers between levels at the end of each reporting period. There were no transfers of assets or liabilities between Level 1 and Level 2 during the nine months ended September 30, 2017. We had no available-for-sale securities that were classified as Level 3 at any point during the nine months ended September 30, 2017 or during the year ended December 31, 2016.

7. Prepaid expenses and other current assets

Prepaid expenses and other current assets consist of the following:

	September 30, 2017	December 31, 2016
	(in thousands)	
Prepaid expenses	$ 1,107	$ 3,336
Other current assets	1,257	5,108
Verastem receivable (note 9)	6,000	—
Total prepaid expenses and other current assets	$ 8,364	$ 8,444

8. Property and Equipment

Property and equipment consist of the following:

	September 30, 2017	December 31, 2016
	(in thousands)	
Computer equipment and software	$ 4,019	$ 4,411
Furniture and fixtures	—	918
Building and building improvements	—	23,586
Leasehold improvements	—	431
	4,019	29,346
Less accumulated depreciation	(3,710)	(5,922)
	$ 309	$ 23,424

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

On the Commencement Date, building construction was initiated to suit our then-anticipated future needs. We were responsible for the construction project, including having responsibility to pay for a portion of the structural elements of the building and bearing the risk of cost overruns. As such, we were deemed the owner of the building for accounting purposes, and we recorded the building in our property and equipment balance, although legal ownership remained with the Landlord. Our balance sheet also reflected a financing obligation related to this building. Depreciation on the building and building improvements commenced in June 2015. At December 31, 2016, the accompanying condensed consolidated balance sheet reflects the building and building improvements, net of accumulated depreciation, of approximately $22.0 million and a financing obligation of approximately $19.6 million.

On March 27, 2017, we and the Landlord entered into an amendment to the Lease under which we and the Landlord agreed to the early termination of the Lease subject to the satisfaction of specified contingencies, which we refer to as Lease Termination Contingencies, and a termination payment of $5.0 million, which we refer to as the Termination Payment and describe further below. The Lease amendment was extended by entry into a second lease amendment dated May 1, 2017 and a third lease amendment dated May 31, 2017. We refer to the Lease amendment and its extensions as the Lease Amendments.

The Lease Termination Contingencies were satisfied on June 15, 2017 and, pursuant to the Lease Amendments, we paid the first installment of the Termination Payment to the Landlord on June 19, 2017 of $4.5 million and the final installment of the Termination Payment on August 24, 2017 of $0.5 million. The Lease, as amended, terminated effective August 31, 2017. Upon lease termination, the net carrying value of the building and building improvements, leasehold improvements, and the related financing obligation and deferred rent at August 31, 2017 were removed from our consolidated balance sheet.

We provided a security deposit to the Landlord in the form of a letter of credit in the initial amount of $1.0 million, which was reduced by $0.5 million in April 2017. The remaining $0.5 million was returned to us in September 2017 following the payment of the final installment of the Termination Payment.

During the nine-month period ended September 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 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.

During the three and nine months ended September 30, 2017, we sold certain personal property, fixtures and equipment that had a net book value of approximately $0.1 million for proceeds of $0.9 million resulting in a net gain of $0.8 million. The proceeds were received in October 2017.

9. Collaborations

Takeda

In July 2010, we entered into a development and license agreement with Intellikine, Inc., or Intellikine, under which we obtained rights to discover, develop and commercialize pharmaceutical products targeting the gamma and/or delta isoforms of PI3K, including IPI-549 and duvelisib, an oral, dual inhibitor of PI3K delta and gamma. In January 2012, Intellikine was acquired by Takeda Pharmaceuticals Company Limited. We refer to our PI3K inhibitor program licensor as Takeda. In

December 2012, we amended and restated our development and license agreement with Takeda and further amended the agreement in July 2014, September 2016 and July 2017. We refer to the amended and restated development and license agreement, as amended, as the Takeda Agreement.

Under the terms of the Takeda Agreement, we are obligated to pay Takeda an aggregate of up to $5.0 million in remaining success-based milestone payments for the development of a product candidate other than duvelisib, which could include IPI-549. We are also obligated to pay Takeda up to an aggregate of $165 million in remaining success-based milestone payments related to the approval and commercialization of one product candidate other than duvelisib, which could be IPI-549.

Under the September 2016 amendment to the Takeda Agreement, and in connection with our entry into the Verastem Agreement described below, we are no longer obligated to pay Takeda any remaining milestone payments for the development, approval or commercialization of duvelisib. In return, we are obligated to pay Takeda 50% of all revenue arising from certain qualifying transactions for duvelisib, including those under the Verastem Agreement, described in more detail below, subject to certain exceptions including revenue we receive as reimbursement for duvelisib research and development expenses.

Except for duvelisib in oncology indications, IPI-549, and other products containing a selective inhibitor of PI3K-gamma, we are obligated to pay Takeda tiered royalties ranging from 7% to 11% on worldwide net sales of products described in the agreement. Such royalties are payable until the later to occur of the expiration of specified patent rights and the expiration of non-patent regulatory exclusivities in a country, subject to reduction of the royalties and, in certain circumstances, limits on the number of products subject to a royalty obligation.

The 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, pursuant to which we are obligated 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 share payment price would be equal to the average closing price of our common stock for the 20 days prior to the payment date. We have the right to prepay the Takeda Note, in whole or in part, without penalty and any amounts owed under the Takeda Note would become immediately due and payable in the event of a change of control of Infinity, as defined in the Takeda Note. Additionally, any unpaid amounts may become immediately due and payable upon customary events of default, as defined in the Takeda Note. The $6.0 million has been included in our accompanying condensed consolidated balance sheets as a current liability titled Note Payable. For the three months ended September 30, 2017, we recorded the $6.0 million in research and development expense and $0.1 million of interest expense related to the Takeda Note.

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

Verastem

On October 29, 2016, we and Verastem entered into a license agreement, which we and Verastem amended and restated on November 1, 2016, effective as of October 29, 2016. We refer to the amended and restated license agreement as the Verastem Agreement. Under the Verastem Agreement, we granted to Verastem an exclusive worldwide license for the research, development, commercialization, and manufacture of duvelisib and products containing duvelisib, which we refer to as the 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 in patients with relapsed/refractory chronic lymphocytic leukemia, which we refer to as the DUO Study. Verastem is obligated to use diligent efforts, as defined in the Verastem Agreement, to develop and commercialize one Licensed Product. During the term of the Verastem Agreement, we have agreed not to research, develop, manufacture or commercialize duvelisib in any indication in humans or animals.

Under the Verastem Agreement, we have financial responsibility for up to $4.5 million of costs related to the shutdown of certain specified clinical studies. We have incurred the $4.5 million maximum for clinical study shutdown costs through September 30, 2017. Following a short transition period, which terminated December 31, 2016, Verastem has 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. Verastem will reimburse us for costs incurred by us during the transition period associated with the clinical studies assumed by Verastem.

Pursuant to the terms of the Verastem Agreement, Verastem is required to make the following payments to us in cash or, at Verastem's election, in whole or in part, in shares of Verastem common stock: (i) $6.0 million upon the completion of the DUO Study if the results of the DUO Study meet certain pre-specified criteria and (ii) $22.0 million upon the approval for a Licensed Product of a new drug application, or NDA, in the United States or approval of an application for marketing authorization with a regulatory authority outside of the United States. On September 6, 2017, Verastem notified us that the DUO Study met the pre-specified criteria and we had earned the $6.0 million payment. Verastem elected to pay cash for the required payment. During the three months ended September 30, 2017, we recorded revenue of $6.0 million for the achievement of this payment. Additionally, we recorded a receivable of $6.0 million in prepaid expenses and other current assets as of September 30, 2017, and payment was received in October 2017.

For any portion of the remaining 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 twenty 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.

Verastem is also obligated to pay us royalties on worldwide net sales of Licensed Products ranging from the mid-single digits to the high-single digits. The royalty obligation will continue on a product-by-product and country-by-country basis until the latest to occur of (i) the last-to-expire patent right covering the applicable Licensed Product in the applicable country, (ii) the last-to-expire patent right covering the manufacture of the applicable Licensed Product in the country of manufacture of such Licensed Product, (iii) the expiration of non-patent regulatory exclusivity for such Licensed Product in the applicable country and (iv) ten years following the first commercial sale of a Licensed Product in the applicable country, provided that upon the expiration of the last-to-expire patent right covering the Licensed Product in the United States, the applicable royalty on net sales for such Licensed Product in the United States will be reduced by 50%. The royalties are also subject to reduction by 50% of certain third-party royalty payments or patent litigation damages or settlements which might be required to be paid by Verastem if litigation were to arise, with any such reductions capped at 50% of the amounts otherwise payable during the applicable royalty payment period.

In addition to the foregoing, Verastem is obligated to pay us a royalty of 4% on worldwide net sales of Licensed Products to cover the reimbursement of research and development costs owed by us to Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products L.P., or Purdue. We refer to this royalty obligation 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. The Trailing Mundipharma Royalties are payable on a product-by-product basis until the latest to occur of (i) the last-to-expire patent right covering the applicable Licensed Product in the United States, (ii) the last-to-expire patent right covering the manufacture of the applicable Licensed Product in the country of manufacture of such Licensed Product, (iii) the expiration of non-patent regulatory exclusivity for such Licensed Product in the United States and (iv) ten years following the first commercial sale of such Licensed Product in the United States, provided that, upon the expiration of the last-to-expire patent right covering a Licensed Product in the United States, the applicable royalty on net sales for such Licensed Product in the United States will be reduced by 50%. In addition, the Trailing Mundipharma Royalties are subject to reduction by 50% of certain third-party royalty payments or patent litigation damages or settlements which might be required to be paid by Verastem if litigation were to arise, with any such reductions capped at 50% of the amounts otherwise payable during the applicable royalty payment period.

The Verastem Agreement expires when each party no longer has any obligations to the other party under the Verastem Agreement. Verastem has the right to terminate the Verastem Agreement upon at least 180 days' prior written notice to us at any time. Either party may terminate the Verastem Agreement if the other party materially breaches or defaults in the performance of its obligations. If we terminate the Verastem Agreement for Verastem's material breach, patent challenge, or insolvency, or if Verastem terminates for convenience, then, at our request and subject to our execution of a waiver of certain types of damages, Verastem will transition the duvelisib program back to us at Verastem's cost. If Verastem terminates for our breach or insolvency, Verastem will effect a more limited transition of the duvelisib program to us at our request and cost, subject to our

execution of a waiver of certain types of damages, and we will thereafter pay to Verastem a low single-digit royalty on net sales of Licensed Products.

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

AbbVie

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

The AbbVie Opt-Out was irrevocable, and we had no obligation to continue to provide AbbVie any services related to Duvelisib Products after June 24, 2016. We recognized revenue of $18.7 million during the nine months ended September 30, 2016 related to the development and committee services provided through June 24, 2016. We recorded the remaining amounts already received from AbbVie and allocated to development and committee services of $112.2 million as a gain during the nine months ended September 30, 2016, reflecting the fact that we are no longer obligated to provide any such services and have no obligation to refund any of the payments received to date.

Under the terms of the AbbVie Agreement, we and AbbVie agreed to share equally commercial profits or losses of Duvelisib Products in the United States, and AbbVie agreed to pay us tiered royalties on net sales of Duvelisib Products outside the United States.

We and AbbVie shared oversight of development and agreed to use diligent efforts, as defined in the AbbVie Agreement, to carry out our development activities under an agreed upon development plan. We had primary responsibility for the conduct of development of Duvelisib Products and had the initial responsibility to manufacture Duvelisib Products. AbbVie had responsibility for the conduct of certain contemplated combination clinical studies, which we refer to as the AbbVie Studies. Excluding the AbbVie Studies, we were responsible for all costs to develop and manufacture Duvelisib Products up to a maximum amount of $667 million. The development and manufacturing costs for the AbbVie Studies were shared equally. During the three and nine months ended September 30, 2017, we did not recognize any expense related to shared costs with AbbVie. During the three and nine months ended September 30, 2016, we recognized an expense of $1.9 million and $9.5 million, respectively, in research and development expense related to our portion of the shared costs.

We and AbbVie shared operational responsibility and decision making authority for commercialization of Duvelisib Products in the United States. Prior to commercialization and regulatory approval, we recognized the cost of manufacturing as a component of research and development and the cost of commercialization as a component of general and administrative expenses. During the three and nine months ended September 30, 2016, we accounted for AbbVie's share of the costs as a reduction of the related expense or as additional expense. We recognized credits of approximately $0.9 million and $1.0 million during the three and nine months ended September 30, 2016, respectively, in research and development expense related to these costs. During the three and nine months ended September 30, 2016, we recognized credits of $1.8 million and $4.4 million, respectively, in general and administrative expense related to these costs.

Under the AbbVie Agreement, AbbVie paid us a non-refundable $275 million upfront payment in 2014 and a $130 million milestone payment in November 2015 associated with the completion of enrollment of DYNAMO, our Phase 2 clinical study evaluating the efficacy and safety of duvelisib in patients with refractory indolent non-Hodgkin lymphoma, or iNHL. Of the total $405 million received from AbbVie, we allocated $234.3 million to the license which was recognized as revenue upon receipt of the upfront payment and achievement of the milestone payment. Revenue related to development services and committee services was recognized using the proportionate performance method.

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

Neither party has any ongoing financial obligation to the other party under the AbbVie Agreement.

10. Accrued Expenses

Accrued expenses consisted of the following:

	September 30, 2017	December 31, 2016
	(in thousands)	
Accrued restructuring	$ —	$ 6,920
Accrued compensation and benefits	1,057	5,445
Accrued drug manufacturing costs	543	311
Accrued clinical studies	1,123	7,054
Accrued preclinical studies	282	2
Other	1,512	1,276

Total accrued expenses	$ 4,517	$ 21,008

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 September 30, 2017, future minimum payments under the lease are approximately $0.3 million, which is comprised of $0.2 million for the calendar year 2018 and $0.1 million for the calendar year 2019.

We terminated our previous lease for office space effective August 31, 2017. See Note 8 for details of the previous lease.

12. Restructuring Activities

In June 2016, we reported the top line data from DYNAMO, a registration-focused Phase 2 monotherapy study evaluating the efficacy and safety of duvelisib in patients with refractory indolent non-Hodgkin lymphoma, or iNHL. The study met its primary endpoint with an overall response rate of 46%, all of which were partial responses, among 129 patients with iNHL. As a result, we commenced the first of four restructurings that were approved by our Board of Directors in order to preserve our resources as we determined future strategic plans. We undertook the second restructuring following the AbbVie Opt-Out and undertook the third and fourth restructurings in connection with progress on our strategic plans to divest duvelisib, ultimately culminating with our entry into the Verastem Agreement. See Note 9 for additional detail on the AbbVie Opt-Out and the Verastem Agreement.

We reduced our employee headcount by approximately 75% compared to our employee headcount as of December 31, 2015 due to these four restructurings. We have existing severance plans that outline contractual termination benefits. We recognized all contractual severance and benefits outlined in the plan when termination was probable and reasonably estimable in accordance with FASB Accounting Standards Codification Topic 712, *Compensation - Nonretirement Postemployment Benefits,* during 2016 at the time of each restructuring.

In addition to the employee-related costs, during the year ended December 31, 2016, we recorded approximately $1.9 million of expense related to the write-off of prepaid expenses that were not expected to continue and other payments that were due as a result of early terminations.

During the year ended December 31, 2016, we also identified and recorded the impairment of approximately $0.4 million in furniture and fixtures and $0.8 million related to a facility lease that was terminated in 2016.

The following table summarizes the impact of the 2016 restructuring activities on our operating expenses and payments for the nine months ended September 30, 2017 and the current liability remaining on our balance sheet as of September 30, 2017:

	Amounts accrued at December 31, 2016	Charges incurred during the nine months ended September 30, 2017	Amounts paid during the nine months ended September 30, 2017	Less non-cash charges during the nine months ended September 30, 2017	Amounts accrued at September 30, 2017
			(in thousands)		
Employee severance, benefits and related costs for work force reduction	$ 6,892	$ —	$ 6,627	$ 265	$ —
Contract termination, prepaid expense write-offs and other related costs	28	15	43	—	—
Total restructuring	$ 6,920	$ 15	$ 6,670	$ 265	$ —

During the nine months ended September 30, 2016, we recorded $16.9 million of expense related to restructuring activities of which $11.2 million is recorded in research and development expense and $5.7 million is recorded in general and administrative expense.

During the year ended December 31, 2016, we recorded $21.2 million of expense related to restructuring activities of which $13.6 million is recorded in research and development expense and $7.6 million is recorded in general and administrative expense. As of September 30, 2017, we do not have any future payments or expect to incur any additional costs.

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," "could," "should," "continue," and other words and terms of similar meaning to help identify forward-looking statements, although not all forward-looking statements contain these identifying words. You also can identify these forward-looking statements by the fact that they do not relate strictly to historical or current facts. There are a number of important risks and uncertainties that could cause actual results or events to differ materially from those indicated by forward-looking statements made herein. These risks and uncertainties include those inherent in pharmaceutical research and development, such as adverse results in our drug discovery and clinical development activities, decisions made by the U.S. Food and Drug Administration, or FDA, and other regulatory authorities with respect to the development and commercialization of our product candidates, our ability to obtain, maintain and enforce intellectual property rights for our product candidates, our dependence on our alliance partners, competition, our ability to obtain any necessary financing to conduct our planned activities, our ability to implement our strategic plans, our ability to achieve cost-savings benefits from our restructuring and other risk factors described herein. We have included, and you should review, important factors in the cautionary statements included in this Quarterly Report on Form 10-Q, particularly in the section titled "Risk Factors" in Part II, that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis 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 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.

Preclinical research has demonstrated that PI3K-gamma is highly expressed in tumor-associated macrophages and that inhibition of PI3K-gamma signaling by treatment with IPI-549 results in a reprogramming of macrophages in the tumor microenvironment from the M2, or pro-tumor, phenotype to the M1, or anti-tumor, phenotype. This shift increases the number and activity of anti-tumor T cells while also increasing the production of pro-inflammatory cytokines, which can further stimulate an anti-tumor immune response. Preclinical data from multiple solid tumor in vivo models demonstrated that IPI-549 was active as a monotherapy and that IPI-549 administered in combination with checkpoint inhibition led to enhanced activity compared to either treatment alone. Additionally, preclinical in vivo tumor model data demonstrated that M2 pro-tumor macrophages are associated with resistance to treatment by immune checkpoint inhibition and that treatment with IPI-549 in combination with immune checkpoint inhibition is able to overcome this resistance. These preclinical data further elucidate the mechanism of action for IPI-549 by demonstrating that PI3K-gamma plays a key role in the immuno-suppressive tumor microenvironment.

Based on our preclinical data, we are conducting a Phase 1/1b clinical study designed to evaluate the safety, tolerability, pharmacokinetics, or PK, pharmacodynamics, or PD, 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. 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.

Our Phase 1/1b study consists of four components: a monotherapy dose-escalation component; a monotherapy expansion component; a combination therapy dose-escalation component designed to evaluate IPI-549 in combination with the standard regimen of nivolumab; and a combination therapy expansion component in patients with specific cancers. The combination therapy expansion component is designed to evaluate IPI-549 in combination with nivolumab in patients with selected solid tumors, including non-small cell lung cancer, melanoma, and squamous cell carcinoma of the head and neck, whose tumors have shown initial resistance or subsequently have developed resistance to immune checkpoint therapy and is intended to directly test whether IPI-549 is able to overcome resistance to checkpoint inhibitors as demonstrated in preclinical models. Additionally, the combination therapy expansion component includes a cohort of patients with a difficult-to-treat form of breast cancer commonly referred to as "triple negative breast cancer," or TNBC, who have not previously been exposed to anti-PD-1 or anti-PD-L1 therapy.

Patient enrollment is complete in all monotherapy dose escalation cohorts ranging from 10 mg once daily, or QD, to 60 mg QD, and we have initiated the monotherapy expansion component evaluating IPI-549 dosed at 60 mg QD in approximately 25 patients with a variety of advanced solid tumors. The monotherapy expansion component dose was selected

based on safety and an analysis of PK and PD that demonstrated that IPI-549 maintained near-complete suppression of PI3K-gamma across the full 24-hour dosing interval at this dose level. Patient enrollment is complete in cohorts evaluating IPI-549 dosed at 20 mg QD, 30 mg QD, and 40 mg QD, each in combination with the standard regimen of nivolumab. We expect to initiate the combination therapy expansion component in the fourth quarter of 2017.

We have entered into a clinical supply agreement with BMS under which BMS has agreed to provide nivolumab at no cost to us for use in our Phase 1/1b study of IPI-549. Under the agreement with BMS, we have agreed to provide BMS with clinical data from the study. In September 2017, we announced the expansion of our clinical collaboration with BMS to include our cohort investigating IPI-549 in combination with nivolumab in patients with TNBC.

In April 2017, we reported updated clinical data from our Phase 1/1b study of IPI-549 in a poster session at the American Association for Cancer Research, or AACR, Annual Meeting. Of the 15 evaluable patients from the monotherapy dose escalation component, preliminary data showed no dose-limiting toxicities or serious drug-related side effects and showed no side effects that led to treatment discontinuation or dose reduction. As of the March 20, 2017 data cutoff date, 6 of the 15 evaluable patients, or 40%, remained on treatment for at least 16 weeks, and three had remained on treatment for more than 32 weeks. Of the six evaluable patients from the combination therapy dose escalation component, all of whom were in the cohort evaluating IPI-549 at 20 mg QD in combination with nivolumab, preliminary data showed no dose-limiting toxicities or serious drug-related side effects and no side effects that led to treatment discontinuation. We are evaluating patients from the combination therapy dose escalation cohort assessing IPI-549 at 40 mg QD in combination with nivolumab. On November 10, 2017, we will present updated clinical and translational data from the monotherapy dose escalation component during an oral session and a poster session at the Society for Immunotherapy of Cancer Annual Meeting, or SITC 2017. We will also present an abstract entitled “Phase 1/1b, first-in-human study of the PI3K-gamma inhibitor IPI-549 as monotherapy and combined with nivolumab in patients with advanced solid tumors” during the clinical-trials-in-progress session of SITC 2017.

We have worldwide development and commercialization rights to IPI-549, subject to certain success-based milestone payment obligations to our licensor, Takeda, as described in more detail under the heading Strategic Alliances - Takeda. Additionally, we are obligated to pay our former strategic collaborators Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products L.P., or Purdue, a 4% royalty in the aggregate on worldwide net sales of products that were previously subject to the strategic alliance, including IPI-549, until such time as Mundipharma and Purdue have recovered approximately $260 million in royalty payments from all products that were previously subject to the strategic alliance. After this cost recovery, which represents the funding paid to us for research and development services performed by us under our strategic alliance, our royalty obligations to Mundipharma and Purdue will be reduced to a 1% royalty on net sales in the United States of products that were previously subject to the strategic alliance, including IPI-549.

On October 13, 2017, we received a $6.0 million payment from Verastem, Inc., or Verastem, pursuant to the Verastem Agreement. The payment was made following the determination that the Phase 3 DUO clinical study evaluating the efficacy and safety of duvelisib in patients with relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma met certain pre-specified criteria at completion. Please see the section entitled Strategic Alliances - Verastem for more information regarding the Verastem Agreement.

Lease Termination and Current Lease

On August 31, 2017, our lease agreement, or Lease, for approximately 61,000 square feet of office space at 784 Memorial Drive, Cambridge, Massachusetts, terminated pursuant to a Lease amendment between us and our landlord, BHX, LLC, as Trustee of 784 Realty Trust on March 27, 2017. In connection with the early termination of the Lease, we paid our Landlord a $5.0 million termination payment.

We currently sublease 6,091 square feet of office space at 784 Memorial Drive, Cambridge, Massachusetts from the new tenant. The term of the lease commenced on September 1, 2017 and will expire on August 31, 2019.

Strategic Alliances

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

Takeda

In July 2010, we entered into a development and license agreement with Intellikine, Inc., or Intellikine, under which we obtained rights to discover, develop and commercialize pharmaceutical products targeting the gamma and/or delta isoforms of PI3K, including IPI-549 and duvelisib, an oral, dual inhibitor of PI3K delta and gamma. In January 2012, Intellikine was acquired by Takeda Pharmaceutical Company Limited. We refer to our PI3K inhibitor program licensor as Takeda. In December 2012, we amended and restated our development and license agreement with Takeda and further amended the agreement in July 2014, September 2016 and July 2017. We refer to the amended and restated development and license agreement, as amended, as the Takeda Agreement.

Under the terms of the Takeda Agreement, we are obligated to pay Takeda up to $5.0 million in remaining success-based milestone payments for the development of a product candidate other than duvelisib, which could include IPI-549. We are also obligated to pay Takeda up to $165 million in remaining success-based milestone payments related to the approval and commercialization of one product candidate other than duvelisib, which could be IPI-549.

Under the September 2016 amendment to the Takeda Agreement, and in connection with our entry into the Verastem Agreement, we are no longer obligated to pay Takeda any remaining milestone payments for the development, approval or commercialization of duvelisib. In return, we are obligated to pay Takeda 50% of all revenue arising from certain qualifying transactions for duvelisib, including those under the Verastem Agreement, subject to certain exceptions including revenue we receive as reimbursement for duvelisib research and development expenses.

Except for duvelisib in oncology indications, IPI-549, and other products containing a selective inhibitor of PI3K-gamma, we are obligated to pay Takeda tiered royalties ranging from 7% to 11% on worldwide net sales of products described in the agreement. Such royalties are payable until the later to occur of the expiration of specified patent rights and the expiration of non-patent regulatory exclusivities in a country, subject to reduction of the royalties and, in certain circumstances, limits on the number of products subject to a royalty obligation.

The 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, pursuant to which we are obligated 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 share payment price would be equal to the average closing price of our common stock for the 20 days prior to the payment date. We have the right to prepay the Takeda Note, in whole or in part, without penalty and any amounts owed under the Takeda Note would become immediately due and payable in the event of a change of control of Infinity, as defined in the Takeda Note. Additionally, any unpaid amounts may become immediately due and payable upon customary events of default, as defined in the Takeda Note.

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

Verastem

On October 29, 2016, we and Verastem entered into a license agreement, which we and Verastem amended and restated on November 1, 2016, effective as of October 29, 2016. We refer to the amended and restated license agreement as the Verastem Agreement. Under the Verastem Agreement, we granted to Verastem an exclusive worldwide license for the research, development, commercialization, and manufacture of duvelisib and products containing duvelisib, which we refer to as the 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 in patients with relapsed/refractory chronic lymphocytic leukemia, which we refer to as the DUO Study. Verastem is obligated to use diligent efforts, as defined in the Verastem Agreement, to develop and commercialize one Licensed Product. During the term of the Verastem Agreement, we have agreed not to research, develop, manufacture or commercialize duvelisib in any indication in humans or animals.

Under the Verastem Agreement, we have financial responsibility for up to $4.5 million of costs related to the shutdown of certain specified clinical studies. We have incurred the $4.5 million maximum for clinical study shutdown costs through September 30, 2017. Following a short transition period, which terminated December 31, 2016, Verastem has 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. Verastem will reimburse us for costs incurred by us during the transition period associated with the clinical studies assumed by Verastem.

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. Verastem is required to make a remaining $22.0 million payment to us, in cash, or at Verastem's election, in whole or in part, in shares of Verastem common stock, upon the approval for a Licensed Product of a new drug application, or NDA, in the United States or approval of an application for marketing authorization with a regulatory authority outside of the United States. For any portion of the remaining 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 twenty 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 Securities and Exchange Commission, or 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.

Verastem is also obligated to pay us royalties on worldwide net sales of Licensed Products ranging from the mid-single digits to the high-single digits. The royalty obligation will continue on a product-by-product and country-by-country basis until the latest to occur of (i) the last-to-expire patent right covering the applicable Licensed Product in the applicable country, (ii) the last-to-expire patent right covering the manufacture of the applicable Licensed Product in the country of manufacture of such Licensed Product, (iii) the expiration of non-patent regulatory exclusivity for such Licensed Product in the applicable country and (iv) ten years following the first commercial sale of a Licensed Product in the applicable country, provided that upon the expiration of the last-to-expire patent right covering the Licensed Product in the United States, the applicable royalty on net sales for such Licensed Product in the United States will be reduced by 50%. The royalties are also subject to reduction by 50% of certain third-party royalty payments or patent litigation damages or settlements which might be required to be paid by Verastem if litigation were to arise, with any such reductions capped at 50% of the amounts otherwise payable during the applicable royalty payment period.

In addition to the foregoing, Verastem is obligated to pay us a royalty of 4% on worldwide net sales of Licensed Products to cover the reimbursement of research and development costs owed by us to Mundipharma and Purdue. We refer to this royalty obligation 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. The Trailing Mundipharma Royalties are payable on a product-by-product basis until the latest to occur of (i) the last-to-expire patent right covering the applicable Licensed Product in the United States, (ii) the last-to-expire patent right covering the manufacture of the applicable Licensed Product in the country of manufacture of such Licensed Product, (iii) the expiration of non-patent regulatory exclusivity for such Licensed Product in the United States and (iv) ten years following the first commercial sale of such Licensed Product in the United States, provided that, upon the expiration of the last-to-expire patent right covering a Licensed Product in the United States, the applicable royalty on net sales for such Licensed Product in the United States will be reduced by 50%. In addition, the Trailing Mundipharma Royalties are subject to reduction by 50% of certain third-party royalty payments or patent litigation damages or settlements which might be required to be paid by Verastem if litigation were to arise, with any such reductions capped at 50% of the amounts otherwise payable during the applicable royalty payment period.

The Verastem Agreement expires when each party no longer has any obligations to the other party under the Verastem Agreement. Verastem has the right to terminate the Verastem Agreement upon at least 180 days' prior written notice to us at any time. Either party may terminate the Verastem Agreement if the other party materially breaches or defaults in the performance of its obligations. If we terminate the Verastem Agreement for Verastem's material breach, patent challenge, or insolvency, or if Verastem terminates for convenience, then, at our request and subject to our execution of a waiver of certain types of damages, Verastem will transition the duvelisib program back to us at Verastem's cost. If Verastem terminates for our breach or insolvency, Verastem will effect a more limited transition of the duvelisib program to us at our request and cost, subject to our execution of a waiver of certain types of damages, and we will thereafter pay to Verastem a low single-digit royalty on net sales of Licensed Products.

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

AbbVie

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

Under the AbbVie Agreement, AbbVie paid us a non-refundable $275 million upfront payment in 2014 and a $130 million milestone payment in November 2015 associated with the completion of enrollment of DYNAMO, our Phase 2 clinical study evaluating the efficacy and safety of duvelisib in patients with refractory indolent non-Hodgkin lymphoma, or iNHL.

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

Neither party has any ongoing financial obligation to the other party under the AbbVie Agreement.

Financial Overview

Revenue

To date, all our revenue has been generated under research collaboration agreements. The terms of these research 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. We evaluate all deliverables within an arrangement to determine whether or not they provide value on a stand-alone basis. Based on this evaluation, the deliverables are separated into units of accounting. For each unit of accounting identified within an arrangement, we determine the period over which the performance obligation occurs. Revenue is then recognized using the proportional performance method if the level of effort to complete the performance obligations under an arrangement can be reasonably estimated. We recognize revenue based upon our best estimate of the selling price for each element when there is no other means to determine the fair value of that item and allocate the consideration based on the relative values. The process for determining the best estimate of the selling price involves significant judgment and estimates.

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

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

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

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

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

Research and Development Expense

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

- compensation of personnel associated with research and development activities;
- clinical testing costs, including payments made to contract research organizations;
- costs of combination and comparator drugs used in clinical studies;
- costs of purchasing laboratory supplies and materials;
- costs of manufacturing product candidates for preclinical testing and clinical studies;
- costs associated with the licensing of research and development programs;
- preclinical testing costs, including costs of toxicology studies;
- fees paid to external consultants;
- fees paid to professional service providers for independent monitoring and analysis of our clinical trials;
- costs for collaboration partners to perform research activities, including development milestones for which a payment is due when achieved;
- depreciation of equipment; and
- allocated costs of facilities.

General and Administrative Expense

General and administrative expense primarily consists of compensation of personnel in executive, finance, accounting, legal 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 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 nine months ended September 30, 2017. Please refer to Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our annual report on Form 10-K for the fiscal year ended December 31, 2016 for a discussion of our critical accounting policies and significant judgments and estimates.

New and Recently Adopted Accounting Pronouncements

See Note 3 to our condensed consolidated financial statements included in Item 1, "Unaudited Condensed Consolidated Financial Statements," of this Form 10-Q for a description of new and recently adopted accounting pronouncements applicable to our business.

Results of Operations

The following table summarizes our results of operations for each of the three and nine months ended September 30, 2017 and 2016, together with the change in these items in dollars and as a percentage:

	Three Months Ended September 30,			
	2017	2016	$ Change	% Change
	(in thousands)			
Collaboration revenue	$ 6,000	$ —	$ 6,000	— %
Research and development expense	9,338	12,814	(3,476)	(27)%
General and administrative expense	4,505	7,120	(2,615)	(37)%
Interest expense	(287)	(305)	18	(6)%
Investment and other income	1,026	741	285	38 %

	Nine Months Ended September 30,			
	2017	2016	$ Change	% Change
	(in thousands)			
Collaboration revenue	$ 6,000	$ 18,723	$ (12,723)	(68)%
Research and development expense	17,278	104,949	(87,671)	(84)%
General and administrative expense	17,147	33,648	(16,501)	(49)%
Gain on AbbVie Opt-Out (note 9)	—	112,216	(112,216)	(100)%
Interest expense	(890)	(921)	31	(3)%
Other expense (note 8)	(6,882)	—	(6,882)	— %
Investment and other income	1,663	1,408	255	18 %

Collaboration Revenue

Collaboration revenue for the three and nine months ended September 30, 2017 relates to the payment from Verastem following the determination by Verastem that the DUO Study met certain pre-specified criteria at completion.

Collaboration revenue for the three and nine months ended September 30, 2016 relates to research and development revenue from the AbbVie Agreement. Revenue related to development services and committee services related to the AbbVie Agreement was recognized using the proportionate performance method as services were provided through the AbbVie Opt-Out on June 24, 2016.

Research and Development Expense

The $3.5 million decrease in research and development expense for the three months ended September 30, 2017 as compared to the three months ended September 30, 2016 was primarily due to a decrease in compensation expense of approximately $4.8 million primarily attributable to the restructuring activities in 2016, as well as a decrease in clinical and development expenses for duvelisib of approximately $3.5 million. Further information regarding restructuring activities is described below under the heading “Liquidity and Capital Resources—Organizational Restructuring.” These decreases are partially offset by an increase in expense related to the execution of the $6.0 million Takeda Note.

The $87.7 million decrease in research and development expense for the nine months ended September 30, 2017 as compared to the nine months ended September 30, 2016 was primarily due to a decrease of $48.7 million related to clinical and development expenses for duvelisib. In addition, compensation expense decreased by approximately $29.5 million primarily attributable to the restructuring activities in 2016. These decreases are partially offset by an increase in expense related to the execution of the $6.0 million Takeda Note.

We began to track and accumulate expenses by major program starting on January 1, 2006. These expenses primarily relate to payroll and related expenses for personnel working on our programs, process development and manufacturing, preclinical toxicology studies, clinical trial costs and allocated costs of facilities. During the three and nine months ended September 30, 2017 and 2016, and from January 1, 2006 through September 30, 2017, we estimate that we incurred the following expenses by program:

Program	Three Months Ended September 30, 2017	Three Months Ended September 30, 2016	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016	January 1, 2006 to September 30, 2017
			(in millions)		
PI3K inhibitor (1)	$ 9.5	$ 14.5	$ 17.2	$ 102.8	$ 606.2
Hsp90 inhibitor	—	—	—	—	137.8
Hedgehog pathway inhibitor	—	—	—	—	164.1

(1) Includes both duvelisib and IPI-549. Includes expense related to the $6.0 million Takeda Note.

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

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

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

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

- 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 drugs;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights relating to our programs under development;
- the terms and timing of any strategic alliance, licensing and other arrangements that we have or may establish in the future relating to our programs under development;
- the cost and timing of regulatory approvals;
- the scope and rate of progress of our preclinical studies and other research and development activities; and
- the effect of competing technological and market developments.

General and Administrative Expense

The $2.6 million decrease in general and administrative expense for the three months ended September 30, 2017 as compared to the three months ended September 30, 2016 was primarily attributable to a decrease in compensation due to restructuring activities in 2016.

The $16.5 million decrease in general and administrative expense for the nine months ended September 30, 2017 as compared to the nine months ended September 30, 2016 was primarily attributable to a decrease of $9.4 million in compensation due to restructuring activities in 2016, a decrease of $2.1 million related to professional service fees and a decrease of $1.6 million related to early duvelisib commercial activities.

Gain on AbbVie Opt-Out

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

Interest Expense

Interest expense for the three and nine months ended September 30, 2017 and 2016 was due to the financing obligation related to our 784 Memorial Drive lease (see Note 8) and the Takeda Note (see Note 9).

Other Expense

Other expense for the three and nine months ended September 30, 2017 represents the loss incurred to terminate the financing obligation in connection with the August 31, 2017 termination of the Lease at 784 Memorial Drive, Cambridge, Massachusetts. 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. Further information regarding the lease termination is described in Note 8.

Investment and Other Income

Investment and other income increased for the three and nine months ended September 30, 2017 as compared to the three and nine months ended September 30, 2016 primarily as a result of a gain on the sale of personal property, fixtures and equipment.

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.

Our significant capital resources are as follows:

	September 30, 2017	December 31, 2016
	(in thousands)	
Cash, cash equivalents and available-for-sale securities	$ 55,575	$ 92,064
Working capital	53,068	77,797

	Nine Months Ended September 30,	
	2017	2016
	(in thousands)	
Cash provided by (used in):		
Operating activities	$ (37,919)	$ (133,388)
Investing activities	(4,013)	43,573
Capital expenditures (included in investing activities above)	(26)	(661)
Financing activities	1,452	152

Cash Flows

For the nine months ended September 30, 2017 compared to the nine months ended September 30, 2016, our cash used in operating activities decreased primarily due to lower research and development expenses following the license of duvelisib to Verastem. Our cash used in operating activities during the nine months ended September 30, 2017 included $6.7 million of payments for restructuring activities incurred in 2016 as well as $5.0 million for the Termination Payment related to our 784 Memorial Drive Lease termination. Our cash used in operating activities in future periods may vary significantly.

Net cash from investing activities for the nine months ended September 30, 2017 included purchases of available-for-sale securities of $22.0 million and proceeds of $18.0 million from maturities of available-for-sale securities.

Net cash from financing activities for the nine months ended September 30, 2017 included the release of approximately $1.7 million of restricted cash related to the termination of our lease at 780/790 Memorial Drive and 784 Memorial Drive, which was partially offset by $0.3 million of payments on the financing obligation related to our 784 Memorial Drive Lease (see Note 8).

At-the-Market Facility

In May 2016, we entered into an at-the-market sales agreement, or Sales Agreement, with Cantor Fitzgerald & Co., or Cantor Fitzgerald, as agent, pursuant to which we may from time to time, at our option, offer and sell shares of our common stock having an aggregate offering price of up to $50.0 million through Cantor Fitzgerald, acting as our sales agent. Cantor Fitzgerald will be entitled to a commission of up to 3.0% of the gross proceeds from sales of shares of our common stock under the Sales Agreement. Sales of shares of our common stock under the Sales Agreement may be made by any method permitted by law that is deemed an "at the market" offering as defined in Rule 415 under the Securities Act of 1933. We may also authorize Cantor Fitzgerald to sell shares in negotiated transactions. As of September 30, 2017, we had not used the at-the-market facility. We have no obligation to sell shares of our common stock and cannot provide any assurances that we will issue any shares pursuant to the Sales Agreement. We may also suspend the offering of shares of our common stock upon notice and subject to other conditions.

Organizational Restructuring

In June 2016, we reported the top line data from DYNAMO, a registration-focused Phase 2 monotherapy study evaluating the efficacy and safety of duvelisib in patients with refractory indolent non-Hodgkin lymphoma, or iNHL. The study met its primary endpoint with an overall response rate of 46%, all of which were partial responses, among 129 patients with iNHL. As a result, we commenced the first of four restructurings that were approved by our Board of Directors in order to preserve our resources as we determined future strategic plans. We undertook the second restructuring following the AbbVie Opt-Out and undertook the third and fourth restructurings in connection with progress on our strategic plans to divest duvelisib, ultimately culminating with our entry into the Verastem Agreement. See Note 9 for additional detail on the AbbVie Opt-Out and the Verastem Agreement.

We reduced our employee headcount by approximately 75% compared to our employee headcount as of December 31, 2015 due to these four restructurings. We have existing severance plans that outline contractual termination benefits. We recognized all contractual severance and benefits outlined in the plan when termination was probable and reasonably estimable in accordance with FASB Accounting Standards Codification Topic 712, *Compensation - Nonretirement Postemployment Benefits,* during 2016 at the time of each restructuring.

In addition to the employee-related costs, during the year ended December 31, 2016, we recorded approximately $1.9 million of expense related to the write-off of prepaid expenses that were not expected to continue and other payments that were due as a result of early terminations.

During the year ended December 31, 2016, we also identified and recorded the impairment of approximately $0.4 million in furniture and fixtures and $0.8 million related to a facility lease that was terminated in 2016.

The following table summarizes the impact of the 2016 restructuring activities on our operating expenses and payments for the nine months ended September 30, 2017 and the current liability remaining on our balance sheet as of September 30, 2017:

	Amounts accrued at December 31, 2016	Charges incurred during the nine months ended September 30, 2017	Amounts paid during the nine months ended September 30, 2017	Less non-cash charges during the nine months ended September 30, 2017	Amounts accrued at September 30, 2017
			(in thousands)		
Employee severance, benefits and related costs for work force reduction	$ 6,892	$ —	$ 6,627	$ 265	$ —
Contract termination, prepaid expense write-offs and other related costs	28	15	43	—	—
Total restructuring	$ 6,920	$ 15	$ 6,670	$ 265	$ —

During the nine months ended September 30, 2016, we recorded $16.9 million of expense related to restructuring activities of which $11.2 million is recorded in research and development expense and $5.7 million is recorded in general and administrative expense.

During the year ended December 31, 2016, we recorded $21.2 million of expense related to restructuring activities of which $13.6 million is recorded in research and development expense and $7.6 million is recorded in general and administrative expense. As of September 30, 2017, we do not have any future payments or expect to incur any additional costs.

Operating Capital Requirements

As of September 30, 2017, we had cash and cash equivalents of $55.6 million. Excluding the 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 into the first quarter of 2019 based on our current operational plans, which do not include duvelisib expenses going forward.

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

- the scope, progress, results and costs of developing IPI-549, currently in clinical development;
- the timing of, and the costs involved in, obtaining regulatory approvals for IPI-549;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- any breach, acceleration event or event of default under any agreements with third parties;
- whether Takeda elects to receive repayment of the principal of the convertible promissory Note and the interest accrued thereon in cash or in shares of our common stock;
- the outcome of any lawsuits that could be brought against us;
- the cost of acquiring raw materials for, and of manufacturing, our product candidates is higher than anticipated;
- the cost or quantity required of comparator drugs used in clinical studies increases; and
- a loss in our investments due to general market conditions or other reasons.

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

The following is a summary of our long-term contractual cash obligations as of September 30, 2017. Other than as set forth below, there were no material changes, outside the ordinary course of business, in our outstanding contractual obligations from those disclosed in our annual report on Form 10-K for the year ended December 31, 2016:

	Payments Due by Period			
	(in thousands)			
Contractual Obligations	**Total**	**2017 (1)**	**2018**	**2019**
784 facility	$ 331	$ —	$ 169	$ 162

(1) Reflects remaining three months of 2017.

Under the terms of the agreement with Mundipharma and Purdue, we are obligated to pay Mundipharma and Purdue a 4% royalty in the aggregate, subject to reduction as described below, on worldwide net sales of products that were covered by the alliance until such time as Mundipharma and Purdue have recovered approximately $260 million in royalty payment from all products that were covered by the alliance, representing the research and development funding paid for research and development services performed by us through the termination of the strategic alliance. After this cost recovery, our royalty obligations to Mundipharma and Purdue will be reduced to a 1% royalty on net sales in the United States of products that were previously subject to the strategic alliance. All payments are contingent upon the successful commercialization of products that were subject to the alliance, which products require significant further development. As such, there is significant uncertainty about whether any such products will ever be approved or commercialized. If no products are commercialized, no payments will be due by us to Mundipharma and Purdue; therefore, such contingencies have not been recorded in our financial statements.

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our interest income is sensitive to changes in the general level of U.S. interest rates, particularly since a significant portion of our investments are in money market funds. 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 result in an approximate $0.1 million decrease in the fair value of our investments as of September 30, 2017, as compared to an approximate $25,000 decrease as of December 31, 2016.

Item 4. Controls and Procedures

Our management, with the participation of our principal executive and financial officers, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2017. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal

financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2017, our principal executive and financial officers concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal quarter ended September 30, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1A. Risk Factors

You should carefully consider the following risk factors, in addition to other information included in this quarterly report on Form 10-Q, in evaluating Infinity and our business. If any of the following risks occur, our business, financial condition, operating results and strategic plans could be materially adversely affected. These risk factors restate and supersede the risk factors set forth under the heading "Risk Factors" in our annual report on Form 10-K for the fiscal year ended December 31, 2016.

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 September 30, 2017, we had an accumulated deficit of $660.2 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. 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.

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 and available-for-sale securities at September 30, 2017 will be adequate to satisfy our capital needs into the first 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. 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;
- 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;
- whether Takeda Pharmaceuticals Company Limited, or Takeda, our PI3K licensor, elects to receive repayment of the principal of the convertible promissory note that we issued on July 26, 2017, or the Takeda Note, and the interest accrued thereon, in cash or in shares of our common stock;
- the outcome of any lawsuits that could be brought against us;
- the cost of acquiring raw materials for, and of manufacturing, our product candidates is higher than anticipated;
- the cost or quantity required of comparator drugs used in clinical studies increases; and
- a loss in our investments due to general market conditions or other reasons.

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, or if Takeda elects to receive our common stock as repayment of the Takeda Note, it could result in dilution to our existing stockholders, increased fixed payment obligations and the existence of securities with rights that may adversely affect the rights of our existing stockholders including liquidation or other preferences and anti-dilution protections. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our

competitiveness, such as limitations on our ability to incur additional debt, make capital expenditures, create liens, redeem stock, declare dividends, and acquire, sell or license intellectual property rights, or other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects. In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

We may also seek additional funds through arrangements with collaborators or other third parties, or through project financing. These arrangements would generally require us to relinquish or encumber rights to some of our technologies or product candidates, and we may not be able to enter into such agreements on acceptable terms, if at all.

If we are unable to obtain additional funding on a timely basis, we may be required to curtail, terminate, sell or license IPI-549 or to scale back, suspend or terminate our business operations.

Risks Related to the Development and Commercialization of IPI-549

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:

- 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.

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

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

To date, we have not obtained approval from the FDA or any foreign regulatory authority to market or sell any of our product candidates. Any 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 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.

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

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

- unfavorable results of discussions with the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- delays in receiving, or the inability to obtain, required approvals from institutional review boards or other reviewing entities at clinical sites selected for participation in our clinical trials;
- delays in enrolling patients into clinical trials;
- a lower than anticipated retention rate of patients in clinical trials;
- the need to repeat or discontinue clinical trials as a result of inconclusive or negative results or unforeseen complications in testing or because the results of later trials may not confirm positive results from earlier preclinical studies or clinical trials;
- inadequate supply, delays in distribution or deficient quality of, or inability to purchase or manufacture drug product, comparator drugs or other materials necessary to conduct our clinical trials;
- unfavorable FDA or other foreign regulatory inspection and review of a clinical trial site, Infinity, or an Infinity vendor, or records of any clinical or preclinical investigation;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials, which may occur even if they were not observed in earlier trials or only observed in a limited number of participants;
- a finding that the trial participants are being exposed to unacceptable health risks;
- the placement by the FDA or a foreign regulatory authority of a clinical hold on a trial; or
- any restrictions on, or post-approval commitments with regard to, any regulatory approval we ultimately obtain that render the product candidate not commercially viable.

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

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

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

Adverse events or undesirable side effects caused by, or other unexpected properties of, IPI-549 could cause us, any collaborators, an institutional review board or regulatory authorities to interrupt, delay or halt clinical trials of IPI-549 and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities. If IPI-549 is associated with adverse events or undesirable side effects or has properties that are unexpected, we, or any collaborators, may need to abandon development or limit development of IPI-549 to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable

from a risk-benefit perspective. Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause undesirable or unexpected side effects that prevented further development of the compound.

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.

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 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.

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

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

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

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

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

In addition, supplemental clinical trials that may be conducted on a drug following its initial approval may produce findings that are inconsistent with the trial results previously submitted to regulatory authorities. As a result, regulatory authorities may revoke their approvals, or we may be required to conduct additional clinical trials, make changes in labeling of IPI-549 (including a “black box” warning or a contraindication) or the manner in which it is administered, reformulate IPI-549 or make changes to and obtain new approvals for our and our suppliers’ manufacturing facilities. We also might have to withdraw or recall IPI-549 from the marketplace, and regulators might seize IPI-549. We might be subject to fines, injunctions, or the imposition of civil or criminal penalties. Any safety concerns with respect to IPI-549 may also result in a significant drop in the potential sales of IPI-549, damage to our reputation in the marketplace, or result in our and our collaborators’ becoming subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales of our approved product or substantially increase the costs and expenses of commercializing and marketing our product and could negatively impact our stock price.

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

Even if IPI-549 obtains regulatory approval, 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;
- 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 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.

Even if we receive regulatory approvals for marketing IPI-549 or other product candidates we may develop in the future, we could lose our regulatory approvals and our business would be adversely affected if we, our collaborators, or our contract manufacturers fail to comply with continuing regulatory requirements.

The FDA and other regulatory agencies continue to review products even after they receive initial approval. If we receive approval to commercialize any 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.

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 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 (through its collaboration with Five Prime Therapeutics, Inc.), Plexxikon Inc., Eli Lilly and Company, Amgen Inc., F. Hoffmann-La Roche Ltd, Forty Seven Inc., Celgene Corporation, Trillium Therapeutics Inc., Pfizer, XBiotech, Inc., AbbVie Inc., Takeda Pharmaceuticals International, Inc., Novartis AG, Efranat Ltd., Seattle Genetics, Inc., Apexigen Inc., X4 Pharmaceuticals, Inc., Syntrix Biosystems, and Alligator Bioscience AB.

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

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

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

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

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

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

There may also be delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Reimbursement rates may vary, by way of example, according to the use of the product and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost drugs or may be incorporated into existing payments for other services.

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

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

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

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

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

We face exposure to significant product liability or other claims if IPI-549 is alleged to have caused harm. These risks are inherent in the testing, manufacturing and marketing of human medicinal products. Although we do not currently commercialize any products, claims could be made against us based on the use of IPI-549 or duvelisib, 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.

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 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, as was the case in 2016 with AbbVie Inc., or AbbVie, or breach such arrangements, or fail to maintain the financial resources necessary to continue financing its portion of development, manufacturing, and commercialization costs, as applicable, we may not have the financial resources or capabilities necessary to continue development and commercialization of the product candidate on our own. Consequently, the development and commercialization of the affected product candidate could be delayed, curtailed or terminated, and we may find it difficult to attract a new collaborator for such product candidate.

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.

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

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

We would face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for an additional collaboration will depend, among other things, upon our assessment of the collaborator's resources 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 IPI-549 from competing product candidates, design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities and the regulatory pathway for any such approval, the potential market for IPI-549, the costs and complexities of manufacturing and delivering the product to patients and the potential of competing products. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for IPI-549.

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

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

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

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

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

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

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 find a replacement manufacturer on acceptable terms quickly, or at all.

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

Risks Related to Our Intellectual Property

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

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

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

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

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

We are party to several license agreements under which we license patent rights and other intellectual property related to our business including 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 U.S. Congress passed the Leahy-Smith America Invents Act, or the America Invents Act, which became effective in March 2013. The America Invents Act reforms United States patent law in part by changing the standard for patent approval for certain patents from a “first to invent” standard to a “first to file” standard and developing a post-grant review system. This new law changes United States patent law in a way that may severely weaken our ability to obtain patent protection in the United States. Additionally, recent judicial decisions establishing new case law and a reinterpretation of past case law, as well as regulatory initiatives, may make it more difficult for us to protect our intellectual property.

Issued patents that we have or may obtain or license may not provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

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

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

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

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

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

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

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

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

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

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

Patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the 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.

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.

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.

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 fail to comply with these requirements, competitors might be able to enter the market earlier than would otherwise have been the case, which could decrease our revenue from that product.

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

Even if we complete the necessary preclinical studies and clinical trials, the 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.

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.

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 fail to comply with regulatory requirements or if we experience unanticipated problems with IPI-549, when and if it is approved.

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

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

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

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on distribution or use of a product;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;

- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure;
- injunctions or the imposition of civil or criminal penalties; and
- litigation involving patients using our products.

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

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

Healthcare providers, physicians and third party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with healthcare providers, physicians and third party payors may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

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

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

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our financial results. We are developing and implementing a corporate compliance program designed to ensure that we will market and sell any future products that we successfully develop from our product candidates in compliance with all applicable laws and regulations, but we cannot guarantee that this program will protect us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

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

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

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

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

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription products and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for products that are inhaled, infused, instilled, implanted or injected;
- expansion of healthcare fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand products to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient products to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report product samples that manufacturers and distributors provide to physicians;

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- a new Independent Payment Advisory Board, or IPAB, which has authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription products; and
- established the Center for Medicare and Medicaid Innovation within the Center for Medicare and Medicaid Services to test innovative payment and service delivery models.

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. 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.

With the new Administration and Congress, there will likely be additional administrative or legislative changes, including modification, repeal, or replacement of all, or certain provisions of, the ACA. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. The Budget Resolution is not a law, however, it is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the ACA. Further, on January 20, 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.

At the same time, Congress has focused on additional legislative changes, including in particular repeal and replacement of certain provisions of the ACA. To those ends, on May 4, 2017, the US House of Representatives passed the American Health Care Act and the Senate is currently considering legislative proposals leading to new healthcare reform legislation. It remains to be seen, however, whether new legislation repealing and replacing the ACA is enacted and, if so, precisely what the new legislation will provide, when it will be enacted and what impact it will have on the availability of healthcare and containing or lowering the cost of healthcare. It is possible that these 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. It is also possible that some ACA provisions that generally are not favorable for the research-based pharmaceutical industry could also be repealed along with ACA coverage expansion provisions. At this point, healthcare reform and its impacts on the Company are highly uncertain in many respects.

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.

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.

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

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

Our products and solutions are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls. Exports of our products and solutions outside of the United States must be made in compliance with these laws and regulations. If we fail to comply with these laws and regulations, we and certain of our employees could be subject to substantial civil or criminal penalties, including the possible loss of export or import privileges; fines, which may be imposed on us and responsible employees or managers; and, in extreme cases, the incarceration of responsible employees or managers.

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Employee Matters and Managing Growth

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

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

Retaining qualified scientific and business personnel is also critical to our success. Our industry has experienced a high rate of turnover of management personnel in recent years. If we lose one or more of our executive officers or other key employees, our ability to implement our business strategy successfully could be seriously harmed. This competition is particularly intense near our headquarters in Cambridge, Massachusetts. We may not be able to attract or retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. In addition, as a result of our restructurings throughout 2016, we may face additional challenges in retaining our existing senior management and key employees for our company as our business needs change.

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

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

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

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

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

Risks Related to Our Common Stock

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

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

- the results of our current and any future clinical trials of IPI-549;
- 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;
- our indebtedness, including our issuance of the Takeda Note, and any potential dilution from the repayment of such debt and interest accrued thereon in shares of our common stock at Takeda's election;
- 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.

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. Since June 2016, our bid price has often been under $2.00 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 consolidated financial statements could prove inaccurate.

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

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

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

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

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

We do not anticipate paying cash dividends, so you must rely on stock price appreciation for any return on your investment.

We anticipate retaining any future earnings for reinvestment in the infrastructure and personnel necessary to support our development and eventual 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 November 2, 2017, 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 40% of our common stock. These stockholders have the ability to influence our company through this ownership position. For example, as a result of this concentration of ownership, these stockholders, if acting together, may have the ability to affect the outcome of matters submitted to our stockholders for approval, including the election and removal of directors, changes to our equity compensation plans and any merger or similar transaction. This concentration of ownership may, therefore, harm the market price of our common stock by:

- delaying, deferring or preventing a change in control of Infinity;
- impeding a merger, consolidation, takeover or other business combination involving Infinity; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of Infinity.

Anti-takeover provisions in our organizational documents and Delaware law may make an acquisition of us difficult.

We are incorporated in Delaware. Anti-takeover provisions of Delaware law and our organizational documents may make a change in control more difficult. Also, under Delaware law, our Board of Directors may adopt additional anti-takeover measures. For example, our charter authorizes our Board of Directors to issue up to 1,000,000 shares of undesignated preferred stock and to determine the terms of those shares of stock without any further action by our stockholders. If our Board of Directors exercises this power, it could be more difficult for a third party to acquire a majority of our outstanding voting stock. Our charter and bylaws also contain provisions limiting the ability of stockholders to call special meetings of stockholders.

Our stock incentive plan generally permits our Board of Directors to provide for acceleration of vesting of options granted under that plan in the event of certain transactions that result in a change of control. If our Board of Directors uses its authority to accelerate vesting of options, this action could make an acquisition more costly, and it could prevent an acquisition from going forward.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law statute, which generally prohibits a person who owns in excess of 15% of our outstanding voting stock from engaging in a transaction with us for a period of three years after the date on which such person acquired in excess of 15% of our outstanding voting common stock, unless the transaction is approved by our Board of Directors and holders of at least two-thirds of our outstanding voting stock, excluding shares held by such person. The prohibition against such transactions does not apply if, among other things, prior to the time that such person became an interested stockholder, our Board of Directors approved the transaction in which such person acquired 15% or more of our outstanding voting stock. The existence of the foregoing provisions could limit the price that investors might be willing to pay in the future for shares of our common stock.

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

As of September 30, 2017, we had $55.6 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 6. Exhibits

(a) Exhibits.

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

EXHIBIT INDEX

Exhibit No.	Description	Incorporated by Reference			Filed with this 10-Q
		Form	SEC Filing date	Exhibit Number	
3.1	Restated Certificate of Incorporation of the Registrant.	10-Q	8/9/2007	3.1	
3.2	Amended and Restated Bylaws of the Registrant.	8-K	3/17/2009	3.1	
4.1	Form of Common Stock Certificate.	10-K	3/14/2008	4.1	
10.1	Third Amendment to Amended and Restated Development and License Agreement, dated July 26, 2017, by and between the Registrant and Intellikine LLC.				X
10.2	Convertible Promissory Note, dated July 26, 2017, by and between Registrant and Intellikine LLC.				X
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.				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 September 30, 2017, 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: November 7, 2017

By: /s/ LAWRENCE E. BLOCH, M.D., J.D.

Lawrence E. Bloch, M.D., J.D.

President

(Principal Financial Officer & Principal Accounting Officer)

AMENDMENT No. 3 TO

AMENDED AND RESTATED DEVELOPMENT AND LICENSE AGREEMENT

This Amendment No. 3 to Amended and Restated Development and License Agreement (" **Amendment No. 3**") is made as of this 26th day of July, 2017 (the "**Amendment No. 3 Effective Date**") by and between Intellikine LLC, a limited liability company organized and existing under the laws of the State of Delaware and successor to Intellikine, Inc. ("**Intellikine**"), and Infinity Pharmaceuticals, Inc., a company organized and existing under the laws of the State of Delaware ("**Infinity**"). Intellikine and Infinity are each referred to individually as a "**Party**" and together as the "**Parties**".

RECITALS

WHEREAS, Intellikine and Infinity are parties to the Amended and Restated Development and License Agreement, effective as of December 24, 2012, as amended on July 29, 2014 and on September 27, 2016 (the "***Agreement***");

WHEREAS, the Parties wish to terminate Infinity's obligations to pay Royalties with respect to PI3K-Gamma Product(s) (as defined below);

WHEREAS, the Parties wish to amend the Agreement, in accordance with Section 18.8 thereof, as set forth below;

NOW THEREFORE, in consideration of the mutual covenants and agreements contained herein, the Parties agree as follows:

1. Definitions.

1.1 "***PI3K-Gamma Product***" means a Product which is, or which contains or comprises, the compound known as IPI-549 or a compound with PI3Kγ/PI3Kδ IC50 ratio that is < 0.10 and a PI3Kγ/PI3Ka ratio that is < 0.10 (or any of the various chemical forms of any of the foregoing compounds, including acids, bases, salts, metabolites, esters, isomers, enantiomers, pro-drug forms, hydrates, solvates, polymorphs and degradants thereof in crystal, powder or other form). For purposes of this definition, IC50 values shall be determined using the Promega assay as described in Exhibits 4 and 4-A of the Agreement

1.2 All terms used, but not defined, in this Amendment No. 3 shall have the meaning set forth in the Agreement.

2. Royalty Termination Consideration. In consideration for the termination of Infinity's obligation to pay Royalties with respect to the PI3K-Gamma Product(s) as described herein, Infinity shall execute the convertible promissory note attached hereto as Exhibit A (the ***"Promissory Note"***) concurrently with the execution of this Amendment No. 3.

3. Royalty Termination. Effective upon Infinity's execution of the Promissory Note, Infinity's obligation to pay Royalties with respect to PI3K-Gamma Product(s) shall terminate. Notwithstanding the foregoing, (a) the Royalty Term(s) for Royalty-Bearing Product(s) will, for the avoidance of doubt, continue, on a Royalty-Bearing Product-by-Royalty-Bearing Product and country-by-country basis, except for Infinity's obligation to pay Royalties with respect to (i) the PI3K-Gamma Product(s) and (ii) the IPI-145 Product(s) in oncology, (b) the PI3K-Gamma Product(s) and the IPI-145 Product(s) will continue to constitute a Royalty-Bearing Product(s), as defined in Article 1 of the Agreement, and for all other purposes in the Agreement, except for Infinity's obligation to pay Royalties with respect to (i) PI3K-Gamma Product(s) and (ii) the IPI-145 Product(s) in oncology, and (c) the provisions of Section 9.2(b) shall continue to apply to PI3K-Gamma Product(s) and the IPI-145 Product(s) on a Royalty-Bearing Product-by-Royalty-Bearing Product and country-by-country basis.

4. Press Release. In the event that either Party wishes to issue a press release or other public statement relating to the terms and conditions of this Amendment No. 3, it shall comply with the obligations set forth in Section 13.2 of the Agreement with respect thereto.

5. Entire Agreement/Amendments. Except as amended by this Amendment No. 3, the Agreement, and the Parties' respective rights and obligations thereunder, shall remain in full force and effect. After the Amendment No. 3 Effective Date, every reference in the Agreement to the "Agreement" shall mean the Agreement as amended by this Amendment.

6. Counterparts. This Amendment No. 3 may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Signatures provided by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail shall be deemed to be original signatures.

[THIS SPACE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Amendment No. 3 to be executed by their duly authorized representatives

SIGNED for and on behalf of	)	/s/Christophe Bianchi
INTELLIKINE LLC	)	Christophe Bianchi
	)	President of Intellikine LLC and Millennium Pharmaceuticals, Inc.

SIGNED for and on behalf of	)	/s/Adelene Q. Perkins
INFINITY PHARMACEUTICALS, INC.	)	Adelene Q. Perkins
	)	Chief Executive Officer

Exhibit A

Promissory Note

THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED. NO SALE OR DISPOSITION MAY BE EFFECTED EXCEPT IN COMPLIANCE WITH RULE 144 UNDER SAID ACT OR AN EFFECTIVE REGISTRATION STATEMENT RELATED THERETO OR AN OPINION OF COUNSEL FOR THE HOLDER SATISFACTORY TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED UNDER THE ACT OR RECEIPT OF A NO-ACTION LETTER FROM THE SECURITIES AND EXCHANGE COMMISSION.

CONVERTIBLE PROMISSORY NOTE

$6,000,000.00 July 26, 2017

Cambridge, MA

For value received **INFINITY PHARMACEUTICALS, INC.**, a Delaware corporation (the "***Company***"), by means of this Convertible Promissory Note (this "**Note**") promises to pay to **Intellikine LLC** or its assigns ("***Holder***") the principal sum of $6,000,000.00 together with accrued and unpaid interest thereon, each due and payable on the date and in the manner set forth below.

1. Repayment. Unless converted in accordance with Section 3 below, all payments of interest and principal shall be in lawful money of the United States of America. All payments shall be applied first to accrued interest, and thereafter to principal. Unless this Note has been previously converted in accordance with the terms of Section 3 below, the entire outstanding principal balance and all unpaid accrued interest shall become fully due and payable on July 26, 2018 (the "***Maturity Date***").

2. Interest Rate. The Company promises to pay simple interest on the outstanding principal amount hereof from the date hereof until payment in full, which interest shall be payable at the rate of 8.0% per annum or the maximum rate permissible by law, whichever is less. Interest shall be due and payable on the Maturity Date and shall be calculated on the basis of a 365-day year for the actual number of days elapsed.

3. Conversion.

(a) At the election of the Holder (which election shall be made in the sole and absolute discretion of the Holder), any payment (whether on account of principal, interest or any other amount) hereunder, whether made upon the occurrence of the Maturity Date, the occurrence of an Event of Default, the occurrence of a Change of Control, an optional prepayment by the Company of any amount outstanding hereunder or otherwise, may be made, in whole or in part, by delivery to the Holder of a number of shares of common stock of the Company, par value $0.001 per share (the "C***ommon Stock***") calculated by dividing the amount to be paid by the Company pursuant to this Section 3(a) by the Share Payment Price. The **Share Payment Price** means the average closing price per share of Common Stock of the Company for the twenty (20) trading days prior to (and not including) the Payment Date. The shares of Common Stock of the Company issued pursuant to this Section 3(a) shall be referred to herein as the "**Repayment Shares**." To the extent any such calculation results in a number of shares which includes a fractional share, the number of

Repayment Shares to be delivered shall be rounded down to the nearest whole share, and the fractional amount shall be paid in cash.

In order to make the election under this Section 3(a), the Holder shall deliver written notice indicating the maximum number of Repayment Shares to be issued in full or partial satisfaction of such payment and the calculation of the Share Payment Price (the "**Share Payment Notice**"), which Share Payment Notice shall be irrevocable (except to the extent that, after exercising its good faith efforts, the Company is unable to obtain any necessary shareholder approvals or to comply with all applicable regulations, including obtaining all applicable regulatory approvals, in which case the Company may pay the applicable amount in cash), to the Company of its election to receive such payment under this Section 3(a): (i) at least twenty (20) days prior to the Maturity Date; or (ii) in the case of a prepayment by the Company, within fifteen (15) days following receipt of a Prepayment Notice from the Company; or (iii) in the case of a Change of Control, within fifteen (15) days following receipt of a Change of Control Notice from the Company (the date such notice of election is sent to the Company being the "**Share Payment Notice Date**"). On the applicable Payment Date, the Company shall deliver or cause to be delivered to the Holder, in accordance with the Share Payment Notice from such Holder, the appropriate number of shares of Common Stock and, if applicable, any additional cash amount payable and a certificate of an authorized officer of the Company certifying the final calculation of the Share Payment Price. The **Payment Date** means the Maturity Date, the date of an occurrence of an Event of Default or Change of Control, or, in the case of a prepayment pursuant to Section 6, the payment date specified by the Company in the Prepayment Notice.

(b) Assuming that the Holder has elected to exercise its rights pursuant to Section 3(a), the Company represents and warrants to the Holder that on the Payment Date the shares of Common Stock being issued on the Payment Date will have been duly authorized by all necessary corporate action on the part of the Company, and on such date the Common Stock subject to the cancellation of indebtedness will have been validly issued and will be fully paid and nonassessable, free and clear of all liens. The issuance of such Repayment Shares will not be subject to preemptive rights of any other shareholder of the Company. The Repayment Shares will be eligible for listing on the NASDAQ Global Market (or such other stock exchange on which the Common Stock is then listed) and issued in accordance with the terms of this Note.

(c) Assuming that the Holder has elected to exercise its rights pursuant to Section 3(a), the Holder represents and warrants to the Company that: (i) it is acquiring the Repayment Shares for its own account for investment and not with a view to, or for sale in connection with, any distribution thereof, nor with any present intention of distributing or selling the same, and such Holder has no present or contemplated agreement, undertaking, arrangement, obligation, indebtedness or commitment providing for the disposition thereof; and (ii) such Holder has made such inquiry concerning the Company and its business and personnel as it has deemed appropriate; and the Holder has sufficient knowledge and experience in finance and business that it is capable of evaluating the risks and merits of its investment in the Company. Such Holder is an "accredited investor" as defined in Rule 501(a) under the Securities Act of 1933, as amended ("**Securities Act**");

(d) The Company agrees to (i) at all times make available adequate current public information with respect to the Company, as those terms are understood and defined in Rule 144 under the Securities Act ("***Rule 144***"); (ii) use its best efforts to file with the Securities and Exchange Commission in a timely manner all reports and other documents required of the Company under the Securities Act and the Securities Exchange Act of 1934, as amended ("**Exchange Act**"); and (iii) furnish to the Holder upon request (A) a written statement by the Company as to its compliance with the current public information requirements of Rule 144 and the reporting requirements of the Exchange Act, (B) a copy of the most recent annual or quarterly report of the Company, and (C) such other reports and documents of the Company as the Holder may reasonably request to avail itself of any similar rule or regulation of the Commission allowing it to sell Repayment Shares without registration.

(e) Upon conversion of this Note, the Company will be forever released from all of its obligations and liabilities under this Note with regard to that portion of the principal amount and accrued interest being converted, including without limitation the obligation to pay such portion of the principal amount and accrued interest.

1. Change of Control. In the event of a Change of Control (as defined below) prior to repayment of the Note in full pursuant to Section 1 or conversion of the Note pursuant to Section 3, immediately prior to such Change of Control, the entire outstanding principal balance and all unpaid accrued interest shall become fully due and payable immediately prior to the closing of such Change of Control. The term "**Change of Control**" means (i) a sale of all or substantially all of the Company's assets other than to an Excluded Entity (as defined below), (ii) a merger, consolidation or business combination transaction of the Company with or into another corporation, limited liability company or other entity other than an Excluded Entity, in each case pursuant to which stockholders of the Company prior to such merger, consolidation or business combination transaction own less than fifty percent (50%) of the voting interests in the surviving or resulting entity, or (iii) the consummation of a transaction, or series of related transactions, in which any "person" (as such term is used in Sections 13(d) and 14(d) of the Exchange Act) becomes the "beneficial owner" (as defined in Rule 13d-3 of the Exchange Act), directly or indirectly, of at least fifty percent (50%) of the Company's then outstanding voting securities. Notwithstanding the foregoing, a transaction shall not constitute a Change of Control if its purpose is to (A) change the jurisdiction of the Company's incorporation, (B) create a holding company that will be owned in substantially the same proportions by the persons who hold the Company's securities immediately before such transaction, or (C) obtain funding for the Company in a financing that is approved by the Company's Board of Directors. An "**Excluded Entity**" means a corporation or other entity of which the holders of voting capital stock of the Company outstanding immediately prior to such transaction are the direct or indirect holders of voting securities representing at least a majority of the votes entitled to be cast by all of such corporation's or other entity's voting securities outstanding immediately after such transaction. The Company shall provide to Holder written notice (the "**Change of Control Notice**") of a Change of Control at least twenty five (25) days prior to the anticipated closing date of the Change of Control.

2. Expenses. In the event of any default hereunder, the Company shall pay all reasonable attorneys' fees and court costs incurred by Holder in enforcing and collecting this Note.

3. Prepayment. The Company may prepay this Note (whether or not due) in whole or in part, and any other amount owing hereunder (whether as principal, interest or otherwise), and may do so on one or more occasions, prior to the Maturity Date. In the event the Company desires to make a prepayment, the Company shall provide to Holder written notice (the "**Prepayment Notice**") of its intent to make a prepayment, which notice shall include the amount and date of such payment and shall be provided at least twenty five (25) days prior to the payment date specified in such notice.

4. Default. If there shall be any Event of Default hereunder, at the option and upon the declaration of the Holder and upon written notice to the Company (which election and notice shall not be required in the case of an Event of Default under Section 7(b) or 7(c)), this Note shall accelerate and all principal and unpaid accrued interest shall become due and payable. The occurrence of any one or more of the following shall constitute an Event of Default:

(a) The Company fails to pay timely any of the principal amount due under this Note on the date the same becomes due and payable or any accrued interest or other amounts due under this Note on the date the same becomes due and payable;

(b) The Company files any petition or action for relief under any bankruptcy, reorganization, insolvency or moratorium law or any other law for the relief of, or relating to, debtors, now or hereafter in effect, or makes any assignment for the benefit of creditors or takes any corporate action in furtherance of any of the foregoing; or

(c) An involuntary petition is filed against the Company (unless such petition is dismissed or discharged within 60 days under any bankruptcy statute now or hereafter in effect, or a custodian, receiver, trustee, assignee for the benefit of creditors (or other similar official) is appointed to take possession, custody or control of any property of the Company; or

(d) The Company shall default in its performance of any covenant under this Note.

5. Waiver. The Company hereby waives demand, notice, presentment, protest and notice of dishonor.

6. Governing Law. This Note shall be governed by and construed under the laws of the Commonwealth of Massachusetts, without giving effect to conflicts of laws principles.

7. Modification; Waiver. Any term of this Note may be amended or waived with the written consent of the Company and the Holder. Any amendment or waiver effected in accordance with this Section 10 shall be binding upon the Company, the Holder and each transferee of any Note.

8. Assignment. The terms and conditions of this Note shall inure to the benefit of and be binding upon the respective successors and assigns of the Company and the Holder. Notwithstanding the foregoing, except in the event of a transfer by the Holder to an Affiliate (as defined below), the Holder may not assign, pledge, or otherwise transfer this Note without the prior

written consent of the Company. Subject to the preceding sentence, this Note may be transferred only upon its surrender to the Company for registration of transfer, duly endorsed, or accompanied by a duly executed written instrument of transfer in form satisfactory to the Company. Thereupon, this Note shall be reissued to, and registered in the name of, the transferee, or a new Note for like principal amount and interest shall be issued to, and registered in the name of, the transferee. Interest and principal shall be paid solely to the registered holder of this Note. Such payment shall constitute full discharge of the Company's obligation to pay such interest and principal. For purposes of this Section 11, the term "Affiliate" as it relates to a transfer by the Holder, shall mean any entity that directly or indirectly through one or more intermediaries, controls, in controlled by, or is under common control with the Holder and, with respect to the foregoing, the term "control" (including the terms "controlled by" and "under common control with") means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of the Holder, whether through ownership of voting securities, by contract or otherwise.

9. Notices. Any notice required or permitted by this Note shall be in writing and shall be deemed sufficient when delivered personally or by overnight courier or sent by email or fax (upon customary confirmation of receipt), or forty-eight (48) hours after being deposited in the U.S. mail as certified or registered mail with postage prepaid, addressed to the party to be notified at such party's address or fax number as set forth on the signature page, as subsequently modified by written notice, or if no address is specified on the signature page, at the most recent address set forth in the Company's books and records.

10. Entire Agreement. This Note constitutes the entire agreement between the Company and the Holder pertaining to the subject matter hereof, and any and all other written or oral agreements existing between the Company and the Holder pertaining to the subject matter hereof are expressly canceled.

11. Counterparts. This Note may be executed in counterparts, each of which will be deemed to be an original and both of which together will constitute a single agreement.

12. Stockholders, Officers and Directors Not Liable. In no event shall any, stockholder, officer or director of the Company be liable for any amounts due or payable pursuant to this Note.

13. Loss of Note. Upon receipt by the Company of evidence satisfactory to it of the loss, theft, destruction or mutilation of this Note or any Note exchanged for it, and indemnity satisfactory to the Company (in case of loss, theft or destruction) or surrender and cancellation of such Note (in the case of mutilation), the Company will make and deliver in lieu of such Note a new Note of like tenor.

14. Registration Rights.

(a) Defined Terms. As used in this Section 17, the following terms shall have the following meanings:

(i) "**Prospectus**" means (i) the prospectus included in any Registration Statement contemplated by this Section 17, as amended or supplemented by any prospectus supplement, with respect to the terms of the offering of any portion of the Registrable Securities covered by such Registration Statement and by all other amendments and supplements to the prospectus, including post-effective amendments and all material incorporated by reference in such prospectus, and (ii) any "free writing prospectus" as defined in Rule 405 promulgated under the Securities Act.

(ii) "**Registrable Securities**" means (a) the Repayment Shares, and (b) any shares of Common Stock issued or issuable with respect to the Repayment Shares by way of a stock dividend or stock split or in connection with a combination of shares, recapitalization, merger, consolidation or other reorganization. As to any particular Registrable Securities, such securities shall cease to be Registrable Securities when (i) a Registration Statement covering such securities has been declared effective by the SEC and such securities have been disposed of pursuant to such effective Registration Statement, (ii) such securities are sold under circumstances in which all of the applicable conditions of Rule 144 (or any similar provisions then in force) are met, (iii) such securities are otherwise transferred and such securities may be resold without subsequent registration under the Securities Act, or (iv) such securities shall have ceased to be outstanding.

(iii) "**Registration Statement**" means any registration statement of the Company which covers any of the Registrable Securities pursuant to the provisions of this Section 17, including the Prospectus, amendments and supplements to such Registration Statement, including post-effective amendments, all exhibits and all materials incorporated by reference in such Registration Statement.

(iv) "**SEC**" means the U.S. Securities and Exchange Commission.

(b) Registration Statements.

(i) Demand Registration.

A. At any time after a Payment Date, the Holder may request registration under the Securities Act of all of its Registrable Securities the held on a Form S-3 registration statement (or any successor to such form) (or, if Form S-3 is not then available, on such form of registration statement as is then available to effect a registration of the Registrable Securities pursuant to this subsection (b)(i)(A) (each a "**Demand Registration**"). Each request for a Demand Registration shall specify the approximate number of Registrable Securities required to be registered. Upon receipt of a Demand Registration request, the Company shall cause a Form S-3 registration statement (or any successor to such form) (or, if Form S-3 is not then available, on such form of registration statement as is then available to effect a registration of the Registrable Securities pursuant to this subsection (b)(i)(A) to be filed within forty-five (45) days after the date on which such request was received by the Company. The Company shall not be required to effect a Demand Registration (i) more than the greater of (x) two (2) times and (y) the number of Payment Dates that occur pursuant to this Agreement plus one (1), for the Holder; provided, however, that a Registration Statement shall not count as a Demand Registration requested under this subsection (b)(i)(A) unless and until it has become effective, or (ii) if the Company furnishes to the Holder a

certificate signed by an authorized officer of the Company stating that (a) within sixty (60) days of receipt of the Demand Registration request under this subsection (b)(i), the Company expects to file a registration statement for the public offering of securities for the account of the Company (other than a registration of securities (x) issuable pursuant to an employee stock option, stock purchase or similar plan, (y) issuable pursuant to a merger, exchange offer or a transaction of the type specified in Rule 145(a) under the Securities Act or (z) in which the only securities being registered are securities issuable upon conversion of debt securities which are also being registered), provided, that the Company is actively employing good faith efforts to cause such registration statement to become effective, or (b) the Company is engaged in a material transaction or has an undisclosed material corporate development, in either case, which would be required to be disclosed in the Registration Statement, and in the good faith judgment of the Company's Board of Directors, such disclosure would be materially detrimental to the Company and its stockholders at such time (in which case, the Company shall disclose the matter as promptly as reasonably practicable and thereafter file the Registration Statement, and the Holder agrees not to disclose any information about such material transaction to third parties until such disclosure has occurred or such information has entered the public domain other than through breach of this provision by such Holder), provided, however, that the Company shall have the right to defer the filing of the Registration Statement pursuant to this subsection only twice in any twelve (12) month period and such deferral may not exceed a period of more than sixty (60) days in the aggregate during such twelve-month period.

B. If the Holder requests a Demand Registration and elects to distribute the Registrable Securities covered by its request in an underwritten offering, the Holder shall so advise the Company as a part of its request made pursuant to subsection (b)(i)(A). The Holder shall select the investment banking firm or firms to act as the managing underwriter or underwriters in connection with such offering; provided, however, that such selection shall be subject to the consent of the Company, which consent shall not be unreasonably withheld, delayed or conditioned.

(c) Piggyback Registration.

(i) At any time after a Payment Date, if the Company proposes to register any shares of its Common Stock under the Securities Act (other than a registration effected solely to implement an employee benefit plan or a transaction to which Rule 145 is applicable, or a registration statement on Form S-4, S-8 or any successor form thereto or another form not available for registering the Registrable Securities for sale to the public), whether for its own account or for the account of one or more stockholders of the Company, and the form of Registration Statement to be used may be used for the registration of Registrable Securities (each a "Piggyback Registration"), then the Company shall give prompt written notice (in any event no later than fifteen (15) days prior to the filing of such Registration Statement) to the Holder of its intention to effect such a registration and, subject to subsection (c)(i) and subsection (c)(ii) shall include in such registration all Registrable Securities with respect to which the Company has received, within ten (10) days after the Company's notice has been given to the Holder, a written request from the Holder for inclusion. A Piggyback Registration shall not be considered a Demand Registration for purposes of subsection (b)(i).

(ii) If a Piggyback Registration is initiated as a primary underwritten offering on behalf of the Company and the managing underwriter advises the Company and the Holder (if

the Holder has elected to include Registrable Securities in such Piggyback Registration) in writing that in its opinion the number of shares of Common Stock proposed to be included in such registration, including all Registrable Securities and all other shares of Common Stock proposed to be included in such underwritten offering, exceeds the number of shares of Common Stock which can be sold in such offering and/or that the number of shares of Common Stock proposed to be included in any such registration would adversely affect the price per share of the Common Stock to be sold in such offering, and/or any other marketing or other factors dictate that a limitation be imposed with respect to the number of shares of Common Stock proposed to be included in such registration, the Company shall include in such registration (i) first, the number of shares of Common Stock that the Company proposes to sell; (ii) second, the number of shares of Common Stock requested to be included therein by the Holder; and (iii) third, the number of shares of Common Stock requested to be included therein by holders of Common Stock (other than the Holder), allocated among such holders in such manner as they may agree.

(iii) If a Piggyback Registration is initiated as an underwritten offering on behalf of a holder of Common Stock other than the Holder, and the managing underwriter advises the Company in writing that in its opinion the number of shares of Common Stock proposed to be included in such registration, including all Registrable Securities and all other shares of Common Stock proposed to be included in such underwritten offering, exceeds the number of shares of Common Stock which can be sold in such offering and/or that the number of shares of Common Stock proposed to be included in any such registration would adversely affect the price per share of the Common Stock to be sold in such offering, and/or any other marketing or other factors dictate that a limitation be imposed with respect to the number of shares of Common Stock proposed to be included in such registration, the Company shall include in such registration (i) first, the number of shares of Common Stock requested to be included therein by the holder(s) requesting such registration and by the Holder, allocated pro rata among such holders on the basis of the number of shares of Common Stock (on a fully diluted, as converted basis) and the number of Registrable Securities, as applicable, owned by all such holders or in such manner as they may otherwise agree; and (ii) second, the number of shares of Common Stock requested to be included therein by other holders of Common Stock, allocated among such holders in such manner as they may agree.

(iv) The Company shall select the investment banking firm or firms to act as the managing underwriter or underwriters in connection with any offering relating to any Piggyback Registration.

(d) Requirements of the Company.

(i) In connection with the filing by the Company of any Registration Statement, the Company shall furnish to the Holder (i) a copy of the Prospectus, including a preliminary prospectus, in conformity with the requirements of the Securities Act, and (ii) such other documents as the Holder may reasonably request, in order to facilitate the public sale or other disposition of the Registrable Securities.

(ii) The Company shall use its reasonable best efforts to cause each Registration Statement contemplated by this Section 17 to be declared effective or become effective as soon as

practicable following the filing thereof with the SEC. The Company shall notify the Holder in writing after any Registration Statement is declared effective.

(iii) In the event of any stock split, stock dividend or transaction with respect to the Registrable Securities that increases the number of Registrable Securities, if a then-effective Registration Statement does not cover the resale of such additional number of Registrable Securities, the Company shall amend or supplement any Registration Statement to cover such additional number of Registrable Securities.

(iv) The Company shall use its best efforts to register or qualify the Registrable Securities covered by any Registration Statement under the securities laws of each state of the United States; provided, however, that the Company shall not be required in connection with this subsection (d)(iv) to qualify as a foreign corporation or execute a general consent to service of process in any jurisdiction.

(v) If the Company has delivered preliminary or final Prospectuses to the Holder and, after having done so, the Prospectus is amended or supplemented to comply with the requirements of the Securities Act, the Company shall promptly notify the Holder and, if requested by the Company, the Holder shall immediately cease making offers or sales of shares under the applicable Registration Statement and return all Prospectuses to the Company. The Company shall promptly provide the Holder with revised or supplemented Prospectuses and, following receipt of the revised or supplemented Prospectuses, the Holder shall be free to resume making offers and sales under the applicable Registration Statement.

(vi) The Company shall advise the Holder promptly after it shall receive notice or obtain knowledge of the issuance of any stop order by the SEC delaying or suspending the effectiveness of any Registration Statement or of the initiation or threat of any proceeding for that purpose, and it will promptly use commercially reasonable efforts to prevent the issuance of any stop order or to obtain its withdrawal at the earliest possible moment if such stop order should be issued.

(e) Requirements of the Holder. The Company shall not be required to include any Registrable Securities in any Registration Statement contemplated by this Section 17 unless the Holder furnishes to the Company, in writing, such information regarding the Holder and the proposed sale of the Registrable Securities by the Holder as the Company may reasonably request in writing in connection with such Registration Statement or as shall be required in connection therewith by the SEC or any state securities law authorities.

(f) Suspension. The Company may suspend the use of any Registration Statement or Prospectus (a "**Suspension**") by the Holder if the Company determines in good faith that such Suspension is necessary to (A) delay the disclosure of material non-public information concerning the Company, the disclosure of which at the time, in the good faith opinion of the Company's Board of Directors, would be materially detrimental to the Company or its stockholders for a registration to be effected at such time; (B) amend or supplement the affected Registration Statement or the related Prospectus so that such Registration Statement or Prospectus shall not include an untrue statement of a material fact or omit to state a material fact

required to be stated therein; or (C) amend or supplement the affected Registration Statement or Prospectus in order to make the statements therein, in light of the circumstances under which they were made, not misleading; provided, however, in each case of clauses (A) through (C), that the Company shall (a) promptly notify the Holder in writing of such Suspension and the reasons therefor, but shall not disclose to the Holder any material non-public information giving rise to a Suspension under clause (A); (b) advise the Holder in writing to cease all sales under the Registration Statement or Prospectus until the end of the Suspension; and (c) use its reasonable best efforts to terminate such Suspension as promptly as practicable. The Company may not exercise its rights pursuant to this Section 1(f) for more than sixty (60) days in the aggregate in any twelve (12) month period.

(g) Expenses. Except as set forth below, the Company will pay all of the expenses incurred in connection with complying with this Section 17 (whether or not any Registration Statement or Prospectus becomes final or effective), including, without limitation: all registration, filing and printing fees, the Company's counsel and accounting fees and expenses, costs and expenses associated with clearing the Registrable Securities for sale under applicable state securities laws (including, without limitation, fees, charges and disbursements of counsel in connection with such clearance), all listing fees, expenses incurred by the Company (but not the Holder) in connection with any "road show," and reasonable fees, charges and disbursements of counsel to the Holder. The Company shall not be required to pay or reimburse the Holder for any underwriting discounts or commissions and fees of underwriters, selling brokers, dealer managers or similar securities industry professionals with respect to the Registrable Securities being sold.

(h) Indemnification. The Company agrees to indemnify and hold harmless the Holder and its Affiliates from and against any losses, claims, damages or liabilities to which such Holder and its Affiliates (under the Securities Act, the Exchange Act, state securities or Blue Sky laws or otherwise) insofar as such losses, claims, damages or liabilities (or actions or proceedings in respect thereof) arise out of, or are based upon any untrue statement of a material fact contained in any Registration Statement covering the Repayment Shares or in any preliminary prospectus or Prospectus contained in such Registration Statement, or any amendment or supplement to such Registration Statement, or the omission or alleged omission to state a material fact required to be stated therein or necessary to make the statements therein not misleading, and the Company will promptly reimburse the Holder and its Affiliates for any reasonable legal or other expenses reasonably incurred in investigating, defending or preparing to defend any such action, proceeding or claim, or preparing to defend any such action, proceeding or claim; provided, however, that the Company shall not be liable in any such case to the extent that such loss, claim, damage or liability arises out of, or is based upon, an untrue statement made in such Registration Statement, preliminary prospectus or Prospectus, or any amendment or supplement in reliance upon and in conformity with written information furnished to the Company by or at the request of such Holder or its Affiliates specifically for use in the preparation thereof or any statement or omission in any Prospectus that is corrected in any subsequent prospectus that was delivered to such Holder prior to the pertinent sale or sales by such Holder.

The Holder agrees to indemnify and hold harmless the Company, each underwriter and each person, if any, who controls the Company within the meaning of Section 15 of the Securities Act, each officer of the Company who signs the Registration Statement and each director of the Company, from and against any losses, claims, damages or liabilities to which the Company or any such underwriter, officer, director or controlling person may become subject (under the Securities Act, the Exchange Act, state securities or Blue Sky laws or otherwise), insofar as such losses, claims, damages or liabilities (or actions or proceedings in respect thereof) arise out of, or are based upon any untrue statement of a material fact contained in any Registration Statement covering the Repayment Shares or in any preliminary prospectus, Prospectus contained in such Registration Statement, or any amendment or supplement to such Registration Statement or the omission or alleged omission to state a material fact required to be stated therein or necessary to make the statements therein not misleading, if such untrue statement or omission was made in reliance upon and in conformity with written information furnished by or on behalf of the Holder specifically for use in preparation of the Registration Statement, Prospectus, amendment or supplement and the Holder will promptly reimburse the Company, or such underwriter, officer, director or controlling person, as the case may be, for any legal or other expenses reasonably incurred in investigating, defending or preparing to defend any such action, proceeding or claim; provided, however, that the Holder's obligation to indemnify the Company shall be limited to the net amount received by the Holder from the sale of the Repayment Shares.

Promptly after receipt by any indemnified person of a notice of a claim or the beginning of any action in respect of which indemnity is to be sought against an indemnifying person pursuant to this subsection 17(h), such indemnified person shall notify the indemnifying person in writing of such claim or of the commencement of such action, but the omission to so notify the indemnifying party will not relieve it from any liability which it may have to any indemnified party under this subsection 17(h) (except to the extent that such omission materially and adversely affects the indemnifying party's ability to defend such action). Subject to the provisions hereinafter stated, in case any such action shall be brought against an indemnified person, the indemnifying person shall be entitled to participate therein, and, to the extent that it shall elect by written notice delivered to the indemnified party promptly (and in any even within five (5) days) after receiving the aforesaid notice from such indemnified party, shall be entitled to assume the defense thereof, with counsel reasonably satisfactory to such indemnified person. After notice from the indemnifying person to such indemnified person of its election to assume the defense thereof, such indemnifying person shall not be liable to such indemnified person for any legal expenses subsequently incurred by such indemnified person in connection with the defense thereof; provided, however, that if (i) the claim involves remedies other than monetary damages or (ii) there exists or shall exist a conflict of interest that would make it inappropriate, in the opinion of counsel to the indemnified person, for the same counsel to represent both the indemnified person and such indemnifying person or any affiliate or associate thereof, the indemnified person shall be entitled to retain its own counsel at the expense of such indemnifying person; provided, however, that no indemnifying person shall be responsible for the fees and expenses of more than one separate counsel (together with appropriate local counsel) for all indemnified parties. In no event shall any indemnifying person be liable in respect of any amounts paid in settlement of any action unless the indemnifying person shall have approved the terms of such settlement; provided, however, that such consent shall not be unreasonably withheld. No indemnifying person shall, without the prior written consent of the indemnified person, effect

any settlement of any pending or threatened proceeding in respect of which any indemnified person is or could have been a party and indemnification could have been sought hereunder by such indemnified person, unless such settlement includes an unconditional release of such indemnified person from all liability on claims that are the subject matter of such proceeding.

If the indemnification provided for in this subsection 17(h) is unavailable to or insufficient to hold harmless an indemnified party under paragraph (i) or (ii) above in respect of any losses, claims, damages or liabilities (or actions or proceedings in respect thereof) referred to therein, then each indemnifying party shall contribute to the amount paid or payable by such indemnified party as a result of such losses, claims, damages or liabilities (or actions in respect thereof) in such proportion as is appropriate to reflect the relative fault of the Company on the one hand and the Holder, as well as any other holders under such Registration Statement on the other hand, in connection with the statements or omissions or other matters which resulted in such losses, claims, damages or liabilities (or actions in respect thereof), as well as any other relevant equitable considerations. The relative fault shall be determined by reference to, among either things, in the case of an untrue statement, whether the untrue statement relates to information supplied by the Company on the one hand or a Holder or other holder on the other hand and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such untrue statement. The Company and the Holder agree that it would not be just and equitable if contribution pursuant to this paragraph (iv) were determined by pro rata allocation (even if the Holder and any other holders were treated as one entity for such purpose) or by any other method of allocation which does not take into account the equitable considerations referred to above in this paragraph (iv). The amount paid or payable by an indemnified party as a result of the losses, claims, damages or liabilities (or actions in respect thereof) referred to above in this paragraph (iv) shall be deemed to include any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim. Notwithstanding the provisions of this paragraph (iv), the Holder shall not be required to contribute any amount in excess of the amount by which the net amount received by the Holder from the sale of the Repayment Shares to which such loss relates exceeds the amount of any damages which the Holder has otherwise been required to pay by reason of such untrue statement. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation.

The rights and obligation of the Company and the Holder under this subsection 17(h) shall survive the cancellation of this Note.

[signature page follows]

INFINITY PHARMACEUTICALS, INC.

By: /s/Adelene Q. Perkins
Name: Adelene Q. Perkins
Title: Chair and CEO
Address: 784 Memorial Drive, Cambridge, MA

HOLDER

Intellikine LLC

By: /s/Christophe Bianchi
Name: Christophe Bianchi
Title: President of Intellikine LLC
Address: 40 Landsdowne Street, Cambridge, MA 02139

Exhibit 31.1

CERTIFICATION PURSUANT TO RULES 13A-14(A) AND 15D-14(A)
UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Adelene Q. Perkins, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Infinity Pharmaceuticals, Inc. (the "Registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;

4. The Registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

5. The Registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: November 7, 2017

/s/Adelene Q. Perkins
Adelene Q. Perkins
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO RULES 13A-14(A) AND 15D-14(A)
UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Lawrence E. Bloch, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Infinity Pharmaceuticals, Inc. (the "Registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;

4. The Registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

5. The Registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: November 7, 2017

/s/Lawrence E. Bloch, M.D., J.D.
Lawrence E. Bloch, M.D., J.D.
President
(Principal Financial Officer & Principal Accounting Officer)

Exhibit 32.1

STATEMENT PURSUANT TO 18 U.S.C. §1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. §1350, the undersigned certifies that, to her knowledge, this Quarterly Report on Form 10-Q for the period ended September 30, 2017 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in this report fairly presents, in all material respects, the financial condition and results of operations of Infinity Pharmaceuticals, Inc.

Date: November 7, 2017

/s/Adelene Q. Perkins
Adelene Q. Perkins
Chief Executive Officer
(Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to Infinity Pharmaceuticals, Inc. and will be retained by Infinity Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

STATEMENT PURSUANT TO 18 U.S.C. §1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. §1350, the undersigned certifies that, to his knowledge, this Quarterly Report on Form 10-Q for the period ended September 30, 2017 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in this report fairly presents, in all material respects, the financial condition and results of operations of Infinity Pharmaceuticals, Inc.

Date: November 7, 2017

/s/Lawrence E. Bloch, M.D., J.D.
Lawrence E. Bloch, M.D., J.D.
President
(Principal Financial Officer & Principal Accounting Officer)

A signed original of this written statement required by Section 906 has been provided to Infinity Pharmaceuticals, Inc. and will be retained by Infinity Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.