INFINITY PHARMACEUTICALS, INC.
Form 10-Q
November 05, 2018
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q
(Mark One)
ý QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2018
OR
¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to .
Commission file number 000-31141
INFINITY PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

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

784 Memorial Drive, Cambridge, Massachusetts 02139
(Address of principal executive offices) (zip code)
(617) 453-1000
(Registrant's telephone number, including area code)
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ý No ¨
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes ý No ¨
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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	Smaller reporting company	Emerging growth company
¨	ý	¨	ý	¨

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No ý
Number of shares of the registrant's Common Stock, $0.001 par value, outstanding on October 31, 2018: 56,866,615

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FOR THE QUARTER ENDED SEPTEMBER 30, 2018

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PART I. FINANCIAL INFORMATION
Item 1. Unaudited Condensed Consolidated Financial Statements
INFINITY PHARMACEUTICALS, INC.
Condensed Consolidated Balance Sheets
(unaudited)
(in thousands, except share and per share amounts)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 32,216	$ 34,607
Available-for-sale securities	9,953	23,002
Receivable (note 8)	22,000	—
Prepaid expenses and other current assets	961	777
Total current assets	65,130	58,386
Property and equipment, net	58	219
Other assets	725	748
Total assets	$ 65,913	$ 59,353
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 491	$ 459
Accrued expenses	5,614	5,136
Note payable (note 8)	—	6,000
Total current liabilities	6,105	11,595
Other liabilities	36	28
Total liabilities	6,141	11,623
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, $0.001 par value; 1,000,000 shares authorized, no shares issued and outstanding at September 30, 2018 and December 31, 2017	—	—
Common Stock, $0.001 par value; 100,000,000 shares authorized; 56,855,548 and 50,761,039 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	57	51
Additional paid-in capital	730,272	715,213
Accumulated deficit	(670,552)	(667,519)
Accumulated other comprehensive loss	(5)	(15)
Total stockholders' equity	59,772	47,730
Total liabilities and stockholders' equity	$ 65,913	$ 59,353

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Collaboration revenue	$22,000	$ 6,000	$22,000	$ 6,000
Operating expenses:				
Research and development	5,379	9,338	15,039	17,278
General and administrative	3,442	4,505	10,435	17,147
Total operating expenses	8,821	13,843	25,474	34,425
Income (loss) from operations	13,179	(7,843)	(3,474)	(28,425)
Other income (expense):				
Investment and other income	202	1,026	534	1,663
Interest expense	—	(287)	(93)	(890)
Other expense (note 11)	—	—	—	(6,882)
Total other income (expense)	202	739	441	(6,109)
Net income (loss)	$13,381	$ (7,104)	$(3,033)	$ (34,534)
Earnings (loss) per common share:				
Basic	$0.23	$ (0.14)	$(0.06)	$ (0.68)
Diluted	$0.23	$ (0.14)	$(0.06)	$ (0.68)
Weighted average number of common shares outstanding:				
Basic	56,851,815	50,635,828	54,918,963	50,505,783
Diluted	57,638,666	50,635,828	54,918,963	50,505,783
Other comprehensive income (loss):				
Net unrealized holding gains (losses) on available-for-sale securities arising during the period	(5)	(2)	10	1
Comprehensive income (loss)	$13,376	$ (7,106)	$(3,023)	$ (34,533)

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

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INFINITY PHARMACEUTICALS, INC.
Condensed Consolidated Statements of Cash Flows
(unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2018	2017
Operating activities		
Net loss	$(3,033)	$(34,534)
Adjustments to reconcile net loss to net cash used in operating activities:		
Note payable	—	6,000
Depreciation	161	1,645
Stock-based compensation, including 401(k) match	2,584	5,391
Non-cash adjustment to financing obligation	—	1,882
Gain on sale of property and equipment	—	(772)
Other, net	159	(3)
Changes in operating assets and liabilities:		
Receivable	(22,000)	—
Prepaid expenses and other assets	(161)	997
Accounts payable, accrued expenses and other liabilities	1,218	(18,525)
Net cash used in operating activities	(21,072)	(37,919)
Investing activities		
Purchases of property and equipment	—	(26)
Purchases of available-for-sale securities	(15,686)	(21,987)
Proceeds from maturities of available-for-sale securities	28,790	18,000
Net cash provided by (used in) investing activities	13,104	(4,013)
Financing activities		
Proceeds from common stock sales facility, net of issuance costs	9,330	—
Proceeds from issuances of common stock, net	247	62
Repayment of note payable	(4,000)	—
Payments on financing obligation	—	(292)
Net cash provided by (used in) financing activities	5,577	(230)
Net decrease in cash, cash equivalents and restricted cash	(2,391)	(42,162)
Cash, cash equivalents and restricted cash at beginning of period	34,607	75,742
Cash and cash equivalents at end of period	$32,216	$33,580
Supplemental cash flow information		
Cash paid for interest	$—	$802
Supplemental schedule of noncash activities		
Issuance of common stock for repayment of note payable, including interest	$2,301	$—
Issuance of common stock for compensation	$493	$—

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

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

1. Organization

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

2. Basis of Presentation

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

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

The information presented in the condensed consolidated financial statements and related footnotes at September 30, 2018, and for the three and nine months ended September 30, 2018 and 2017, is unaudited, and the condensed consolidated balance sheet amounts and related footnotes at December 31, 2017 have been derived from our audited financial statements. For further information, please refer to the consolidated financial statements and accompanying footnotes included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 filed with the U.S. Securities and Exchange Commission, or SEC, on March 15, 2018, which we refer to as our 2017 Annual Report on Form 10-K.

Liquidity

As of September 30, 2018, we had cash, cash equivalents and available-for-sale securities of $42.2 million. We have primarily incurred operating losses since inception and have relied on our ability to fund our operations through collaboration and license arrangements and through the sale of stock. We expect to continue to spend significant resources to fund the development and potential commercialization of IPI-549, our sole clinical stage product candidate, an orally administered immuno-oncology product candidate that selectively inhibits the enzyme phosphoinositide-3 kinase gamma, or PI3K gamma, and to incur significant operating losses for the foreseeable future.

We believe that our existing cash, cash equivalents and available-for-sale securities at September 30, 2018, along with the $22.0 million earned from Verastem, Inc., or Verastem, in September 2018 as discussed further in Note 8, which we received in cash from Verastem on November 2, 2018, will be adequate to satisfy our forecasted operating needs into 2020. For more information, refer to the section titled "Liquidity and Capital Resources" in Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations.

3. Significant Accounting Policies

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

Segment Information

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

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Basic and Diluted Net Income (Loss) per Common Share

Basic net income (loss) per share is based upon the weighted average number of common shares outstanding during the period, excluding restricted stock that has been issued but has not yet vested. Diluted net income (loss) per share is based upon the weighted average number of common shares outstanding during the period plus the effect of additional weighted average common equivalent shares outstanding during the period when the effect of adding such shares is dilutive. Common equivalent shares result from the assumed exercise of outstanding stock options and the exercise of outstanding warrants (the proceeds of which are then assumed to have been used to repurchase outstanding stock using the treasury stock method) and the vesting of restricted shares of common stock. In addition, the assumed proceeds under the treasury stock method include the average unrecognized compensation expense of stock options that are in-the-money. This results in the "assumed" buyback of additional shares, thereby reducing the dilutive impact of stock options. The two-class method is used for outstanding warrants as such warrants are considered to be participating securities, and this method is more dilutive than the treasury stock method. The following outstanding shares of common stock equivalents were excluded from the computation of net income (loss) per share attributable to common stockholders for the periods presented because including them would have been antidilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Stock options	5,445,217	7,646,250	8,404,232	7,646,250
Warrants (excluded from treasury stock method)	1,000,000	1,000,000	1,000,000	1,000,000
Unvested restricted stock	—	457,822	—	457,822

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(in thousands, except share and per share amounts)			
Basic				
Net income (loss)	$13,381	$ (7,104)	$(3,033)	$(34,534)
Undistributed earnings allocated to warrants	(231)	—	—	—
Net income (loss)	$13,150	$ (7,104)	$(3,033)	$(34,534)
Weighted average common shares outstanding	56,851,815	50,635,828	54,918,963	50,505,783
Basic earnings (loss) per common share	$0.23	$ (0.14)	$(0.06)	$(0.68)
Diluted				
Net income (loss)	$13,381	$ (7,104)	$(3,033)	$(34,534)
Undistributed earnings allocated to warrants	(228)	—	—	—
Net income (loss)	$13,153	$ (7,104)	$(3,033)	$(34,534)
Weighted average common shares outstanding	56,851,815	50,635,828	54,918,963	50,505,783
Effect of dilutive options	786,849	—	—	—
Weighted average common shares outstanding assuming dilution	57,638,666	50,635,828	54,918,963	50,505,783
Diluted earnings (loss) per common share	$0.23	$ (0.14)	$(0.06)	$(0.68)

New Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2016-02, Leases, or ASU No. 2016-02, which requires lessees to recognize the assets and liabilities arising from leases on the balance sheet. ASU No. 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. In July 2018, the FASB issued ASU No. 2018-10, Codification Improvements to Topic 842, Leases, or ASU No. 2018-10, and ASU No. 2018-11, Leases (Topic 842) Targeted Improvements, or ASU No. 2018-11. ASU No. 2018-10 provides certain amendments that affect narrow aspects of the guidance issued in ASU No. 2016-02. ASU No. 2018-11 allows all entities adopting ASU No. 2016-02 to choose an additional (and optional) transition method of adoption, under which an entity initially applies

the new leases standard at the adoption date and recognizes a

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cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. We expect to adopt ASU No. 2016-02 using the optional transition method presented in ASU No. 2018-11 and are currently evaluating the potential impact that ASU No. 2016-02 may have on our financial position and results of operations.

Recently Adopted Accounting Pronouncements

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

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

We will recognize royalty revenue based upon net sales by the licensee of licensed products in licensed territories, and in the period the sales occur under the sales- and usage-based royalty exception when the sole or predominate item to which the royalty relates is a license to intellectual property.

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

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

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows, Restricted Cash, or ASU No. 2016-18, which provides guidance on the presentation of restricted cash and restricted cash equivalents in the statement of cash flows. Under the new standard, the statement of cash flows explains the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Amounts generally described as restricted cash and restricted cash equivalents are now included with cash and cash

equivalents when reconciling the beginning-of-period and end-of-period amounts shown in the statements of cash flows. We adopted ASU No. 2016-18 as of January 1, 2018 on a retrospective basis. We have no restricted cash equivalents.

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The cash, cash equivalents and restricted cash at the beginning and end of each period presented in our condensed consolidated statements of cash flows for the nine months ended September 30, 2018 and 2017 consisted of the following balances from our condensed consolidated balance sheets:

	Nine Months Ended September 30, 2018		Nine Months Ended September 30, 2017	
	Beginning of period	End of period	Beginning of period	End of period
	(in thousands)			
Cash and cash equivalents	$34,607	$32,216	$74,060	$33,580
Restricted cash	—	—	1,152	—
Restricted cash, less current portion	—	—	530	—
Cash, cash equivalents and restricted cash per statement of cash flows	$34,607	$32,216	$75,742	$33,580

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

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

In June 2018, the FASB issued ASU No. 2018-07, Compensation—Stock Compensation: Improvements to Nonemployee Share-Based Payment Accounting, or ASU No. 2018-07, which expands the scope of Accounting Standard Codification, or ASC, Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. ASU No. 2018-07 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. We adopted ASU No. 2018-07 as of July 1, 2018. The adoption of ASU No. 2018-07 did not have a material impact on our condensed consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement: Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement, or ASU No. 2018-13, which eliminates, adds and modifies certain disclosure requirements for fair value measurements as part of the FASB's disclosure framework project. ASU No. 2018-13 is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted. We adopted ASU No. 2018-13 as of September 30, 2018. The adoption of ASU No. 2018-13 did not have a material impact on our disclosure to our condensed consolidated financial statements.

4. Stock-Based Compensation

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

	Three Months Ended	Nine Months Ended September 30,

	September 30, 2018	2017	2018	2017
	(in thousands)			
Research and development	$141	$290	$400	$1,391
General and administrative	715	1,297	2,184	4,000
Total stock-based compensation expense	$856	$1,587	$2,584	$5,391

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As of September 30, 2018, we had approximately $2.6 million of total unrecognized compensation cost related to unvested common stock options and awards under our Employee Stock Purchase Plan which is expected to be recognized over a weighted-average period of 1.4 years.

Restricted Stock

We did not recognize any stock compensation expense for the nine months ended September 30, 2018 related to restricted stock. We recognized $0.3 million of stock compensation expense for the nine months ended September 30, 2017 related to restricted stock.

Stock Options

During the nine months ended September 30, 2018, we granted options to purchase 1,637,750 shares of our common stock at a weighted average fair value of $1.57 per share and a weighted average exercise price of $2.04 per share. 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. For the three and nine months ended September 30, 2018 and 2017, 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,	
	2018	2017	2018	2017
Risk-free interest rate	2.9 %	2.0 %	2.5 %	1.9 %
Expected annual dividend yield	—	—	—	—
Expected stock price volatility	95.9 %	88.6 %	96.9 %	90.0 %
Expected term of options	6.1 years	6.3 years	5.7 years	5.6 years

During the nine months ended September 30, 2018, options to purchase 135,000 shares of common stock were exercised, with a weighted-average exercise price of $1.47.

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, 2018			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	(in thousands)			
Cash and cash equivalents	$32,216	$ —	$ —	$ 32,216
Available-for-sale securities:				
U.S. Treasury securities due in one year or less	4,979	—	(3)	4,976
U.S. government-sponsored enterprise obligations due in one year or less	4,979	—	(2)	4,977
Total available-for-sale securities	9,958	—	(5)	9,953
Total cash, cash equivalents and available-for-sale securities	$42,174	$ —	$ (5)	$ 42,169

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

We held two debt securities at September 30, 2018 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 $10.0 million. There were no material unrealized losses from these securities. As of September 30, 2018, 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, 2018.

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

6. Fair Value

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

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

	Level 1	Level 2
	(in thousands)	
September 30, 2018		
Assets:		
Cash and cash equivalents	$32,216	$—
U.S. Treasury securities	—	4,976
U.S. government-sponsored enterprise obligations	—	4,977
Total	$32,216	$9,953
December 31, 2017		
Assets:		
Cash and cash equivalents	$34,607	$—
U.S. Treasury securities	—	3,494
U.S. government-sponsored enterprise obligations	—	19,508
Total	$34,607	$23,002

The carrying amounts reflected in the condensed consolidated balance sheets for prepaid expenses and other current assets, receivables, 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, 2018. We had no available-for-sale securities that were classified as Level 3 at any point during the nine months ended September 30, 2018 or during the year ended December 31, 2017.

7. Prepaid expenses and other current assets

Prepaid expenses and other current assets consist of the following:

	September 30, 2018	December 31, 2017
	(in thousands)	
Prepaid expenses	$818	$ 563
Other current assets	143	214
Total prepaid expenses and other current assets	$961	$ 777

8. Collaborations

Takeda

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

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

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

Verastem

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

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

On September 6, 2017, Verastem notified us that the DUO Study met certain pre-specified criteria at completion triggering a $6.0 million payment under the Verastem Agreement, which we received in cash on October 13, 2017. On September 24, 2018, we earned a $22.0 million payment from Verastem upon approval by the U.S. Food and Drug Administration of duvelisib for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma after at least two prior therapies, as well as adult patients with relapsed or refractory follicular lymphoma after at least two prior systemic therapies. We received the $22.0 million payment in cash on November 2, 2018. As of September 30, 2018, we recognized revenue and a corresponding receivable related to the $22.0 million payment as it is variable consideration that became unconstrained following regulatory approval.

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

In addition, Verastem is obligated to pay us a royalty of 4% on worldwide net sales of Licensed Products on a product-by-product and country-by-country basis, subject to specified conditions, to cover the reimbursement of research and development costs owed by us to Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products L.P., or Purdue. We refer to these royalty obligations as the Trailing Mundipharma Royalties. Once we have fully reimbursed Mundipharma and Purdue, the Trailing Mundipharma Royalties will be reduced to 1% of net sales in the United States.

PellePharm

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

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

Arcus

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

9. Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2018	December 31, 2017
	(in thousands)	
Accrued clinical and development	$2,654	$ 1,736
Accrued compensation and benefits	1,893	2,002
Other	1,067	1,398
Total accrued expenses	$5,614	$ 5,136

10. Stockholders' Equity

In May 2016, we entered into a controlled equity offering sales agreement, or Sales Agreement, with Cantor Fitzgerald & Co., or Cantor Fitzgerald, pursuant to which we may from time to time, at our option, offer and sell shares of our common stock having an aggregate offering price of up to $50.0 million through Cantor Fitzgerald, acting as our sales agent. Cantor Fitzgerald will be entitled to a commission of 3.0% of the aggregate gross proceeds from sales of shares of our common stock under the Sales Agreement. Sales of shares of our common stock under the Sales Agreement may be made by any method permitted by law that is deemed an "at the market" offering as defined in Rule 415 under the Securities Act of 1933, as amended, including sales made through the Nasdaq Global Select Market, on any other existing trading market for our common stock or to or through a market maker. We may also authorize Cantor Fitzgerald to sell shares in privately negotiated transactions. During the nine months ended September 30, 2018, we sold 4,461,893 shares of common stock at a weighted average price per share of $2.18 at-the-market pursuant to the Sales Agreement for $9.3 million in net proceeds. We have no obligation to sell shares of our common stock and cannot provide any assurances that we will issue any additional shares pursuant to the Sales Agreement. We may also suspend the offering of shares of our common stock upon notice to Cantor Fitzgerald and subject to other conditions.

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 was $19,796 per month. From September 1, 2018 until the expiration date, the base rent of the lease is $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.

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At September 30, 2018, future minimum payments under the lease are approximately $0.2 million.

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

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

During the 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 estimated carrying value of the building and building improvements and the related financing obligation and deferred rent at August 31, 2017; and (ii) the $5.0 million termination payment.

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

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

Business Overview

We are an innovative biopharmaceutical company dedicated to developing novel medicines for people with cancer. We combine proven scientific expertise with a passion for developing novel small molecule drugs that target disease pathways for potential applications in oncology. We are focusing our efforts on advancing IPI-549, an orally administered, clinical-stage, immuno-oncology product candidate that selectively inhibits the enzyme phosphoinositide-3-kinase-gamma, or PI3K-gamma. We believe IPI-549 is the only selective inhibitor of PI3K-gamma being investigated in clinical trials.

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On November 2, 2018, we and Bristol Myers Squibb, or BMS, entered into a clinical trial supply agreement to evaluate IPI-549 in combination with nivolumab, also known as Opdivo®, in patients with advanced urothelial cancer. Nivolumab is an immune checkpoint inhibitor therapy commercialized by BMS that targets a receptor in the human body called programmed death receptor 1, or PD-1. Under this agreement, we will operationalize MARIO-275: MAcrophage Reprogramming in Immuno-Oncology, a global, randomized Phase 2 study designed to evaluate the effect of adding IPI-549 to nivolumab in checkpoint-naïve advanced urothelial cancer patients who have progressed or recurred following treatment with platinum-based chemotherapy, and BMS has agreed to supply nivolumab for the study. Approximately 150 patients will be randomized between combination therapy and nivolumab monotherapy. The primary endpoint of the trial will be overall response rate, which will be assessed in the overall population as well as in subsets of patients with different baseline levels of myeloid derived suppressor cells, or MDSCs. In exploratory analyses of data from a BMS clinical study evaluating nivolumab monotherapy in patients with urothelial cancer, referred to as CheckMate-275, high levels of MDSCs were associated with shorter overall survival in patients treated with nivolumab. In our ongoing Phase 1/1b clinical study, MARIO-1, MDSCs were reduced in the majority of patients treated with IPI-549 monotherapy.

MARIO-1 is designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and activity for IPI-549 both as a monotherapy and in combination with nivolumab in approximately 200 patients with advanced solid tumors. The dose-escalation portions of MARIO-1 are complete, and enrollment is ongoing in seven combination therapy expansion cohorts to evaluate patients dosed at 40 mg daily, or QD, of IPI-549 in combination with the standard regimen of nivolumab. These cohorts are designed to evaluate IPI-549 in patients with specific types of cancer, including patients with non-small cell lung cancer, melanoma, or head and neck cancer whose tumors show initial resistance or initially respond to but subsequently develop resistance to immune checkpoint blockade therapy. The combination expansion component also includes a cohort of patients with triple negative breast cancer, or TNBC, who have not been previously treated with immune checkpoint blockade therapy, a cohort of patients with mesothelioma, a cohort of patients with adrenocortical carcinoma and a cohort of patients with high baseline blood levels of MDSCs. We expect to report data from the combination expansion component of the MARIO-1 trial in a late-breaking poster presentation at the 33rd Annual Meeting of the Society for Immunotherapy of Cancer on November 10, 2018.

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

At ASCO 2018, we also presented updated clinical and translational data from the fully enrolled monotherapy expansion portion of MARIO-1, which demonstrated that IPI-549 as a monotherapy continued to be well tolerated at all doses studied up to the recommended dose for expansion of 60 mg QD. IPI-549 demonstrated evidence of monotherapy clinical activity, with one durable partial response in peritoneal mesothelioma, where a patient remained on study after 20 months as of the ASCO 2018 data cutoff date of April 25, 2018. Further, IPI-549 monotherapy reduced immune suppression and increased immune activation, as indicated by analyses of peripheral blood and paired tumor biopsies.

On June 25, 2018, we entered into a clinical trial collaboration agreement with Arcus Biosciences, Inc., or Arcus. Under the terms of the agreement, which we refer to as the Arcus Agreement, we and Arcus will evaluate IPI-549 in

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

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On November 2, 2018, we received a $22.0 million cash payment from Verastem, Inc., or Verastem, paid pursuant to the Amended and Restated License Agreement effective October 29, 2016 between us and Verastem, which we refer to as the Verastem Agreement. The payment was earned upon the approval by the FDA on September 24, 2018 of duvelisib, the PI3K-delta,gamma inhibitor we licensed to Verastem under the Verastem Agreement, for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma after at least two prior therapies, as well as adult patients with relapsed or refractory follicular lymphoma after at least two prior systemic therapies. Verastem is obligated to pay us royalties on worldwide net sales of products containing duvelisib ranging from the mid-single digits to the high-single digits, which we expect to share equally with our PI3K licensor Takeda Pharmaceutical Company Limited, or Takeda.

We have primarily incurred operating losses since inception and will continue to fund our operations through collaboration and license arrangements and through the sale of securities until such time as we are able to generate significant revenue from product sales. To date, substantially all of our resources have been devoted to organizing and staffing our company, conducting preclinical research and clinical development, and otherwise raising capital and business planning. We expect to continue to spend significant resources to fund the development and potential commercialization of IPI-549 and will continue to incur significant operating losses for the foreseeable future. If we are unable to raise capital or enter into a collaboration or license arrangement on terms that ensure adequate funding, on terms favorable to us, we may have to delay or discontinue the development or commercialization of IPI-549.

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

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

Financial Overview

Revenue

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

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

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

We will recognize royalty revenue based upon net sales by the licensee of licensed products in licensed territories, and in the period the sales occur under the sales- and usage-based royalty exception when the sole or predominate item to which the royalty relates is a license to intellectual property.

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

Research and Development Expense

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

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

General and Administrative Expense

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

Other Income and Expense

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

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Critical Accounting Policies and Significant Judgments and Estimates

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

There have been no material changes to our critical accounting policies, other than as noted below under "New and Recently Adopted Accounting Pronouncements," during the nine months ended September 30, 2018. Please refer to Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our 2017 Annual Report on Form 10-K for a discussion of our critical accounting policies and significant judgments and estimates.

New and Recently Adopted Accounting Pronouncements

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

Results of Operations

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

	Three Months Ended September 30,		$ Change	% Change
	2018	2017		
	(in thousands)			
Collaboration revenue	$22,000	$6,000	$16,000	267 %
Research and development expense	5,379	9,338	(3,959)	(42)%
General and administrative expense	3,442	4,505	(1,063)	(24)%
Investment and other income	202	1,026	(824)	(80)%
Interest expense	—	(287)	287	(100)%

	Nine Months Ended September 30,		$ Change	% Change
	2018	2017		
	(in thousands)			
Collaboration revenue	$22,000	$6,000	$16,000	267 %
Research and development expense	15,039	17,278	(2,239)	(13)%
General and administrative expense	10,435	17,147	(6,712)	(39)%
Investment and other income	534	1,663	(1,129)	(68)%
Interest expense	(93)	(890)	797	(90)%
Other expense	—	(6,882)	6,882	(100)%

Collaboration Revenue

Collaboration revenue for the three and nine months ended September 30, 2018 and 2017 relates to the following payments earned under the Verastem Agreement: (i) $6.0 million upon notification on September 6, 2017 that the DUO Study, a randomized, Phase 3 monotherapy clinical study, met certain pre-specified criteria upon its completion, and (ii) $22.0 million earned on September 24, 2018 upon approval by the FDA of duvelisib for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma after at least two

prior therapies, as well as adult patients with relapsed or refractory follicular lymphoma after at least two prior systemic therapies.

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Research and Development Expense

Research and development expense for the three and nine months ended September 30, 2018 decreased as compared to the three and nine months ended September 30, 2017 primarily due to the execution of the $6.0 million Takeda Note in July 2017 (see Note 8 of the notes to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q). Compensation expense for the nine months ended September 30, 2018 decreased by $0.8 million compared to the nine months ended September 30, 2017 primarily related to stock compensation. This decrease was offset by an increase in clinical and development expenses for IPI-549 of $1.7 million and $5.2 million for the three and nine months ended September 30, 2018, respectively, as compared to the