INFINITY PHARMACEUTICALS, INC.
Form 10-Q
November 09, 2009
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2009

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.

(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.)**

780 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 x 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, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

Number of shares of the registrant s Common Stock, $0.001 par value, outstanding on September 30, 2009: 26,198,513

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INFINITY PHARMACEUTICALS, INC.

FORM 10-Q

FOR THE QUARTER ENDED SEPTEMBER 30, 2009

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PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

INFINITY PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

(unaudited)

	September 30, 2009	December 31, 2008
Assets		
Current assets:		
Cash and cash equivalents	$ 33,974,419	$ 16,574,549
Available-for-sale securities	105,805,656	110,197,138
Unbilled accounts receivable		7,414,570
Notes receivable from employees	41,672	42,198
Prepaid expenses and other current assets	3,264,418	2,389,411
Total current assets	143,086,165	136,617,866
Property and equipment, net	5,584,099	5,320,439
Loan commitment asset from Purdue entities, net	16,453,050	17,319,000
Long-term available-for-sale securities	702,709	
Notes receivable from employees	47,577	28,780
Restricted cash	1,146,368	1,138,161
Other assets	155,980	193,262
Total assets	$ 167,175,948	$ 160,617,508
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 2,494,398	$ 2,759,288
Accrued expenses	9,853,894	11,562,641
Deferred revenue from Purdue entities	3,227,030	1,702,860
Current portion of capital lease obligations	6,329	5,953
Total current liabilities	15,581,651	16,030,742
Deferred revenue from Purdue entities, less current portion	36,602,451	21,939,251
Other liabilities	2,286,661	2,340,099
Capital lease obligations, less current portion	7,154	11,949
Total liabilities	54,477,917	40,322,041
Commitments and contingencies		
Stockholders equity:		
Preferred Stock, $.001 par value; 1,000,000 shares authorized; no shares issued and outstanding at September 30, 2009 and December 31, 2008		
Common Stock, $.001 par value; 100,000,000 shares authorized; 26,198,513 and 24,064,857 shares issued and outstanding at September 30, 2009 and December 31, 2008, respectively	26,199	24,065
Additional paid-in capital	285,947,863	268,447,955
Accumulated deficit	(173,492,956)	(148,891,909)
Accumulated other comprehensive income	216,925	715,356

Total stockholders equity	112,698,031	120,295,467
Total liabilities and stockholders equity	$ 167,175,948	$ 160,617,508

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

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	**2008**	**2009**	**2008**
Collaborative research and development revenue:				
From Purdue entities	$ 13,775,745	$	$ 36,370,000	$
Other		2,500,000		16,391,458
Operating expenses:				
Research and development	18,499,060	11,732,206	60,453,361	31,029,091
General and administrative	4,570,282	3,780,740	15,581,871	11,234,423
Total operating expenses	23,069,342	15,512,946	76,035,232	42,263,514
Loss from operations	(9,293,597)	(13,012,946)	(39,665,232)	(25,872,056)
Other income (expense):				
Interest expense	(433,272)	(2,113)	(866,943)	(19,800)
Income from residual funding after reacquisition of Hsp90 program			12,450,000	
Income from NIH reimbursement			1,745,386	
Interest and investment income	401,264	623,543	1,735,742	2,774,366
Net other income (expense)	(32,008)	621,430	15,064,185	2,754,566
Net loss	$ (9,325,605)	$ (12,391,516)	$ (24,601,047)	$ (23,117,490)
Basic and diluted loss per common share	$ (0.36)	$ (0.63)	$ (0.94)	$ (1.17)
Basic and diluted weighted average number of common shares outstanding	26,154,557	19,759,766	26,062,217	19,722,255

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)

	Nine Months Ended September 30, 2009	Nine Months Ended September 30, 2008
Operating activities		
Net loss	$ (24,601,047)	$ (23,117,490)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation	1,591,335	1,520,018
Stock-based compensation	5,444,847	4,271,516
Gain on sales of property and equipment	(62,171)	(29,000)
Gain on sales of available-for-sale securities	(28,052)	(107,313)
Impairment of available-for-sale security	15,666	49,428
Amortization of loan commitment asset from Purdue	865,950	
Net accretion of available-for-sale securities	(242,801)	(1,497,121)
Other, net	36,767	49,084
Changes in operating assets and liabilities:		
Accounts receivable and unbilled accounts receivable	7,414,570	800,190
Prepaid expenses and other assets	(860,930)	238,171
Accounts payable, accrued expenses and other liabilities	(1,968,844)	(1,066,313)
Deferred revenue	16,187,370	(15,625,000)
Net cash provided by (used in) operating activities	3,792,660	(34,513,830)
Investing activities		
Purchases of property and equipment	(1,854,995)	(601,594)
Proceeds from sales of property and equipment	62,171	29,000
Purchases of available-for-sale securities	(134,813,291)	(91,180,122)
Proceeds from sales of available-for-sale securities	36,141,736	28,540,158
Proceeds from maturities of available-for-sale securities	102,117,084	93,122,409
Net cash provided by investing activities	1,652,705	29,909,851
Financing activities		
Proceeds from issuances of common stock	168,924	93,901
Proceeds from issuance of common stock and warrants to Purdue entities	11,830,000	
Release of restricted cash		564,986
Payments on equipment loan and other debt		(360,660)
Capital lease payments	(4,419)	(8,699)
New employee loans	(40,000)	(30,000)
Net cash provided by financing activities	11,954,505	259,528
Net increase (decrease) in cash and cash equivalents	17,399,870	(4,344,451)
Cash and cash equivalents at beginning of period	16,574,549	23,164,721
Cash and cash equivalents at end of period	$ 33,974,419	$ 18,820,270
Supplemental cash flow disclosure		
Interest paid	$ 982	$ 13,738

Income taxes paid	$ 30,000	$ 92,000

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 a drug discovery and development company that is utilizing its strength in small molecule drug technologies to discover and develop medicines for the treatment of cancer and related conditions. 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 subsidiary.

2. Basis of Presentation

These condensed consolidated financial statements include the accounts of Infinity and its wholly-owned subsidiary. 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 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, 2009 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2009. We have evaluated our condensed consolidated financial statements through November 9, 2009, the date these financial statements were issued.

The information presented in the condensed consolidated financial statements and related footnotes at September 30, 2009, and for the three and nine months ended September 30, 2009 and 2008, is unaudited and the condensed consolidated balance sheet amounts and related footnotes at December 31, 2008 have been derived from our audited financial statements. For further information, 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, 2008, which was filed with the U.S. Securities and Exchange Commission (SEC) on March 13, 2009.

3. Significant Accounting Policies

Financial Accounting Standards Board (FASB) Codification

In June 2009, the FASB issued Financial Accounting Standards Board Statement (SFAS) No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles a Replacement of FASB Statement No. 162* (SFAS No. 168). The FASB Accounting Standards Codification (the Codification) is intended to be the single source of authoritative nongovernmental U.S. generally accepted accounting principles. Rules and interpretive releases of the SEC under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. SFAS No. 168 is effective for interim and annual periods ending after September 15, 2009. All existing accounting standards have been superseded as described in SFAS No. 168. All other accounting literature not included in the Codification is non-authoritative. The adoption of SFAS No. 168 during the three months ended September 30, 2009 did not impact our financial position or results of operations. All references on authoritative nongovernmental U.S. generally accepted accounting principles throughout this quarterly report on Form 10-Q relate to the Codification.

Cash Equivalents and Available-For-Sale Securities

Cash equivalents and available-for-sale securities primarily consist of money market funds, U.S. government-sponsored enterprise obligations, corporate obligations, U.S. Treasury obligations and asset-backed securities. We consider all highly liquid investments with maturities of three months or less at the time of purchase to be cash equivalents. Cash equivalents, which consist primarily of a money market fund and a U.S. government-sponsored enterprise obligation, are stated at market value and are both readily convertible to known amounts of cash and close enough to maturity that each presents insignificant risk of change in value due to changes in interest rates. Our classification of cash equivalents

is consistent with prior periods.

We determine the appropriate classification of available-for-sale securities at the time of purchase and reevaluate such designation at each balance sheet date. We have classified all of our marketable securities at September 30, 2009 and December 31, 2008 as available-for-sale. We carry available-for-sale securities at fair value, with the unrealized gains and losses reported in accumulated other comprehensive income, which is a separate component of stockholders equity. We adjust the cost of

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available-for-sale debt securities for amortization of premiums and accretion of discounts to maturity. We include such amortization and accretion in interest and investment income. The cost of securities sold is based on the specific identification method. We include interest and dividends on securities classified as available-for-sale in interest and investment income. Realized gains and losses and certain other-than-temporary impairments on available-for-sale securities are reported in interest and investment income.

Other-than-temporary impairments must be recognized through earnings if we have the intent to sell the debt security or if it is more likely than not that we will be required to sell the debt security before recovery of our amortized cost basis. Even if we do not expect to sell a debt security, we must also evaluate expected cash flows to be received and determine if a credit loss has occurred. In the event of a credit loss, only the amount associated with the credit loss is recognized through earnings. The amount of loss relating to other factors is recorded in accumulated other comprehensive income.

Segment Information

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

All of our revenues to date have been generated under research collaboration agreements. Revenue associated with the amortization of the deferred revenue associated with the grant of licenses to, and reimbursed research and development services provided for, Mundipharma International Corporation Limited (Mundipharma) and Purdue Pharmaceutical Products L.P. (Purdue) accounted for all of our revenue for the three and nine months ended September 30, 2009. Revenues associated with the up-front license fee we received from MedImmune, Inc., a division of AstraZeneca plc (MedImmune/AZ), accounted for 100% of our revenue for the three months ended September 30, 2008 and 46% of our revenue for the nine months ended September 30, 2008. Revenue associated with the up-front license fee and reimbursable research and development services we received from the Novartis Institutes for BioMedical Research, Inc. (Novartis) accounted for the remaining 54% of our revenue for the nine months ended September 30, 2008.

Payments due from MedImmune/AZ represented 64% of our unbilled accounts receivable balance as of December 31, 2008. Payments due from Mundipharma and Purdue represented the remaining 36% of our unbilled accounts receivable balance at December 31, 2008.

Basic and Diluted Loss per Common Share

Basic 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 is not yet vested. Diluted 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 (the proceeds of which are then assumed to have been used to repurchase outstanding stock using the treasury stock method), the exercise of outstanding warrants 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. Common equivalent shares have not been included in the loss per share calculations for the periods presented because the effect of including them would have been anti-dilutive. Total potential gross common equivalent shares consisted of the following:

	At September 30,	
	2009	2008
Stock options	5,051,643	4,026,680
Warrants	6,246,629	246,629
Unvested restricted shares	22,164	14,435

Stock-Based Compensation Expense

We expense the fair value of employee stock options and other equity compensation. We use our judgment in determining the fair value of our equity instruments, including in selecting the inputs we use for the Black-Scholes valuation model. Equity instrument valuation models are by their nature highly subjective. Any significant changes in any of our judgments, including those used to select the inputs for the Black-Scholes valuation model, could have a significant impact on the fair value of the equity instruments granted and the associated compensation charge we record in our financial statements.

Revenue Recognition

To date, all of our revenue has been generated under research collaboration agreements. The terms of these research collaboration agreements may include payment to us of non-refundable, up-front license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved, and/or royalties on product sales. We divide agreements containing multiple elements into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the collaborative partner and whether there is objective and reliable evidence of fair value of the undelivered obligation(s). For these agreements, we allocate the consideration we receive among the separate units based on their respective fair values or, in some cases, the residual method, and we apply the applicable revenue recognition criteria to each of the separate units.

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We recognize revenues from non-refundable, up-front license fees on a straight-line basis over the contracted or estimated period of performance, which is typically the research or development term. We recognize research and development funding as earned over the period of effort.

We recognize milestone payments as revenue upon achievement of the milestone only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone and (4) the milestone is at risk for both parties. If any of these conditions is not met, we defer the milestone payment and recognize it as revenue over the estimated period of performance under the contract as we complete our performance obligations.

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 revenues to date.

Research and Development Expense

Research and development expense consists of expenses incurred in performing research and development activities, including salaries and benefits, facilities expenses, overhead expenses, materials and supplies, preclinical expenses, clinical trial and related clinical manufacturing expenses, stock-based compensation expense, contract services, and other outside expenses. We expense research and development costs as they are incurred. We have entered into certain collaboration agreements in which expenses are shared with the collaborator, and others in which we are reimbursed for work performed on behalf of the collaborator. We record all of our expenses as research and development expense. If the arrangement is a cost-sharing arrangement and there is a period during which we receive payments from the collaborator, we record payments from the collaborator for its share of the development effort as a reduction of research and development expense. If the arrangement is a cost-sharing arrangement and there is a period during which we make payments to the collaborator, we record our payments to the collaborator for its share of the development effort as additional research and development expense. If the arrangement provides for reimbursement of research and development expenses, we record the reimbursement as revenue. Our collaboration with MedImmune/AZ was a cost-sharing arrangement; our alliance with Mundipharma and Purdue provides for, and our collaboration with Novartis provided for, the reimbursement of our research and development expenses.

Income Taxes

We use the liability method to account for income taxes. Deferred tax assets and liabilities are determined based on differences between financial reporting and income tax basis of assets and liabilities, as well as net operating loss carryforwards, and are measured using the enacted tax rates and laws that will be in effect when the differences reverse. Deferred tax assets are reduced by a valuation allowance to reflect the uncertainty associated with their ultimate realization. The effect on deferred taxes of a change in tax rate is recognized in income or loss in the period that includes the enactment date.

We use our judgment for the recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return.

Due to the uncertainty surrounding the realization of favorable tax attributes in future tax returns, we have recorded a full valuation allowance against our otherwise recognizable net deferred tax assets as of September 30, 2009 and December 31, 2008.

Fair Value Measurements

We define fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. We determine fair value based on the assumptions market participants use when pricing the asset or liability. We also use the fair value hierarchy that prioritizes the information used to develop these assumptions.

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

Property and Equipment

Property and equipment are stated at cost. Application development costs incurred for computer software developed or obtained for internal use are capitalized. Depreciation is recorded using the straight-line method over the estimated useful lives of the applicable assets. Upon sale or retirement, the cost and related accumulated depreciation are eliminated from the respective account and the resulting gain or loss, if any, is

included in current operations. Amortization of leasehold improvements and capital leases are included in depreciation expense. Repairs and maintenance charges that do not increase the useful life of the assets are charged to operations as incurred. Property and equipment are depreciated over the following periods:

Laboratory equipment	5 years
Computer equipment and software	3 years
Leasehold improvements	Shorter of life of lease or useful life of asset
Furniture and fixtures	7 years

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New Accounting Pronouncements

In October 2009, the FASB issued Accounting Standard Update No. 2009-13, *Multiple-Element Revenue Arrangements* (ASU No. 2009-13), which updates the existing multiple-element revenue arrangements guidance currently included in Accounting Standards Codification No. 605-25, in two ways. The first change relates to the determination of when the individual deliverables included in a multiple-element arrangement may be treated as separate units of accounting. This is significant as it will likely result in the requirement to separate more deliverables within an arrangement, ultimately leading to less revenue deferral. The second change modifies the manner in which the transaction consideration is allocated across the separately identified deliverables. ASU No. 2009-13 also significantly expands the disclosures required for multiple-element revenue arrangements. ASU No. 2009-13 will be effective for the first annual reporting period beginning on or after June 15, 2010, and may be applied retrospectively for all periods presented or prospectively to arrangements entered into or materially modified after the adoption date. We do not expect ASU No. 2009-13 to have a material impact on our financial statements or results of operations.

4. Stock-Based Compensation

We measure share-based compensation cost at the grant date based on the estimated fair value of the award, and recognize it as expense over the employee s requisite service period. We have no awards with market or performance conditions. We use the Black-Scholes valuation model in determining the fair value of equity awards. Total stock-based compensation expense, related to all equity awards, for the three and nine months ended September 30, 2009 and 2008 comprised the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Effect of stock-based compensation on net loss by line item:				
Research and development	$ 879,723	$ 719,594	$ 2,621,461	$ 2,012,391
General and administrative	898,312	743,226	2,823,386	2,259,125

As of September 30, 2009, there was approximately $9.6 million of total unrecognized compensation cost, net of estimated forfeitures, related to unvested stock options, which are expected to be recognized over a weighted-average period of 2.7 years.

During the nine months ended September 30, 2009, we granted options to purchase 534,260 shares of our common stock at a weighted average fair value of $3.71. During the nine months ended September 30, 2008, we granted options to purchase 357,070 shares of our common stock at a weighted-average fair value of $3.70. 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,	
	2009	2008	2009	2008
Risk-free interest rate	2.89%	3.25%	2.23%	2.87%
Expected annual dividend yield				
Expected stock price volatility	58.65%	53.57%	56.64%	55.25%
Expected term of options	5.53 years	5.08 years	5.42 years	5.24 years

5. Comprehensive Loss

The components of our comprehensive loss include our net loss and the change in unrealized gains and losses on our available-for-sale securities. For the three and nine months ended September 30, 2009 and 2008, comprehensive loss was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Net loss	$ (9,325,605)	$ (12,391,516)	$ (24,601,047)	$ (23,117,490)

Net unrealized holding losses on available-for-sale securities (1)	(228,493)	(9,953)	(498,431)	(112,901)
Total comprehensive loss	$ (9,554,098)	$ (12,401,469)	$ (25,099,478)	$ (23,230,391)

(1) For the three and nine months ended September 30, 2009, net realized gains on available-for-sale securities included in net loss totaled $19,273 and $12,386, respectively. For the nine months ended September 30, 2008, the net realized gains on available-for-sale securities included in net loss totaled $57,885. There were no realized gains or losses during the three months ended September 30, 2008.

Accumulated other comprehensive income consists of unrealized net gains on available-for-sale securities.

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

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

	September 30, 2009			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash and cash equivalents due in 90 days or less	$ 33,974,394	$ 25	$	$ 33,974,419
Available-for-sale securities:				
Corporate bonds due in one year or less	20,393,047	100,113		20,493,160
U.S. Treasury securities due in one year or less	2,279,922	5,066		2,284,988
Asset backed securities due after ten years	708,094		(5,385)	702,709
U.S. government-sponsored enterprise obligations due in one year or less	82,910,402	117,442	(336)	83,027,508
Total available-for-sale securities	106,291,465	222,621	(5,721)	106,508,365
Total cash, cash equivalents and available-for-sale securities	$ 140,265,859	$ 222,646	$ (5,721)	$ 140,482,784

	December 31, 2008			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash and cash equivalents due in 90 days or less	$ 16,566,285	$ 8,264	$	$ 16,574,549
Available-for-sale securities:				
Corporate bonds due in one year or less	40,888,605	320,025		41,208,630
U.S. Treasury securities due in one year or less	1,520,153	1,057		1,521,210
Asset backed securities due after ten years	765,845	345	(16,633)	749,557
U.S. government-sponsored enterprise obligations due in one year or less	66,315,443	402,298		66,717,741
Total available-for-sale securities	109,490,046	723,725	(16,633)	110,197,138
Total cash, cash equivalents and available-for-sale securities	$ 126,056,331	$ 731,989	$ (16,633)	$ 126,771,687

We had three debt securities in an unrealized loss position at September 30, 2009. These securities have been in such a position for less than 12 months. The unrealized loss on those securities was $5,721 and their fair value was $2,215,834. An other-than-temporary impairment must be recognized through earnings if we have the intent to sell the debt security or if it is more likely than not that we will be required to sell the debt security before recovery of our amortized cost basis. Even if we do not expect to sell a debt security, we must also evaluate expected cash flows to be received and determine if a credit loss has occurred. In the event of a credit loss, only the amount associated with the credit loss is recognized through earnings. We record the amount of loss relating to other factors in accumulated other comprehensive income. We do not consider the investments comprising our unrealized loss of $5,721 as of September 30, 2009 to be other-than temporarily impaired.

During the nine months ended September 30, 2009, we determined that one debt security was other-than-temporarily impaired and accordingly recorded a loss of $15,666 in our condensed consolidated statement of operations. During the nine months ended September 30, 2008, we determined that one debt security was other-than-temporarily impaired and accordingly recorded a loss of $49,428 in our condensed consolidated statement of operations. We determined that we did not have any securities that were other-than-temporarily impaired for the three months ended September 30, 2009 or 2008. We did not recognize any cumulative effect as an adjustment to the opening balance of accumulated deficit with a corresponding adjustment to accumulated other comprehensive income.

Realized gains on our available-for-sale securities were $19,273 and $28,052 for the three and nine months ended September 30, 2009, respectively. Realized gains on our available-for-securities were $107,313 for the nine months ended September 30, 2008. There were no

realized gains for the three months ended September 30, 2008.

7. 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 are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value. The classification of a financial asset or liability within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement. For our fixed income securities, we reference pricing data supplied by our custodial agent and nationally known pricing vendors, using a variety of daily data sources, largely readily-available market data and broker quotes.

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The following table provides the assets carried at fair value measured on a recurring basis as of September 30, 2009:

	Level 1	Level 2
Cash and cash equivalents	$ 32,468,329	$ 1,506,090
Corporate obligations (including commercial paper)		20,493,160
Asset-backed securities		702,709
U.S. Treasury securities		2,284,988
U.S. government-sponsored enterprise obligations		83,027,508
Total	$ 32,468,329	$ 108,014,455

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

Corporate Obligations:

Commercial Paper: calculations by custodian based on three month Treasury bill published on last business day of the month.

Other: benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data.

Asset-backed securities: benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data, new issue data, monthly payment information and collateral performance.

U.S. Treasury securities: benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data and vendor trading platform data.

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.

There have been no changes to the valuation methods during the nine months ended September 30, 2009.

8. Collaborations

Purdue and Mundipharma

In November 2008, we entered into strategic alliance agreements with each of Purdue and Mundipharma to develop and commercialize pharmaceutical products. The alliance includes product candidates that inhibit or target the Hedgehog pathway and fatty acid amide hydrolase, or FAAH, and product candidates arising out of all our discovery projects in all disease fields that achieve development candidate status on or before December 31, 2011 (with Mundipharma having the right, through the exercise of two consecutive one-year options, to extend such period through December 31, 2013). We refer to such three to five year period as the funded discovery period. Our heat shock protein 90, or Hsp90, and Bcl-2 programs are expressly excluded from the alliance. The agreement with Purdue is focused on the development and U.S. commercialization of products targeting FAAH. The agreement with Mundipharma is focused on the development and commercialization outside of the United States of all products and product candidates covered by the alliance, including those targeting FAAH.

Under the strategic alliance agreements, we have responsibility and decision-making authority for the performance of early discovery projects and the development of all product candidates on a worldwide basis. There are no joint steering or similar committees for the alliance. Mundipharma is obligated to pay 100% of our contractually budgeted amounts for research and development expenses incurred by us for early discovery projects and product candidates included in the alliance until the later of December 31, 2013 and the commencement of the first Phase 3 clinical study of such product candidate. We refer to such date as the transition date. After the transition date for each product candidate other than those arising out of the FAAH project, we will share with Mundipharma all research and development costs for such product candidate equally. Upon completion of the first Phase 1 clinical study of the first product developed under the research program that inhibits or targets FAAH, Purdue and Mundipharma may elect to assume responsibility, at their own expense, for the future development of FAAH products and their sale in and outside of the United States, respectively. We are recording revenue for reimbursed research and development services we perform for Mundipharma and Purdue. We recorded $13.1 million and $34.2 million in such revenue in the three and nine month periods ended September 30, 2009, respectively. In the first month of each quarter, Purdue and Mundipharma each prepay a quarterly research and development service amount, which we record as deferred revenue and amortize to revenue as earned over the period of effort.

In connection with the entry into the strategic alliance agreements in November 2008, we also entered into a securities purchase agreement and line of credit agreement with Purdue and its independent associated company, Purdue Pharma L.P. (PPLP). In March 2009, Purdue assigned its interest under the line of credit agreement to PPLP. Under the securities purchase agreement we issued and sold in a first equity closing in November 2008 an aggregate of four million shares of our common stock at a purchase price of $11.25 per share, for an aggregate purchase price of $45 million. Of such shares, two million shares of our common stock were purchased by

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each purchaser. In January 2009, we conducted a second equity closing where we issued and sold an aggregate of two million shares of our common stock and warrants to purchase up to an aggregate of six million shares of our common stock, for an aggregate purchase price of $30 million. An equal number of shares and warrants were purchased by each purchaser.

These warrants are exercisable for:

- 1,000,000 shares of our common stock at any time up to July 1, 2010, with an initial exercise price of $15.00 per share, with such exercise price increasing over time depending on when such warrants are exercised, up to a maximum exercise price of $20.00 per share;

- 2,000,000 shares of our common stock at any time up to July 1, 2011, with an initial exercise price of $20.00 per share, with such exercise price increasing over time depending on when such warrants are exercised, up to a maximum exercise price of $30.00 per share; and

- 3,000,000 shares of our common stock at any time up to July 2, 2012, with an initial exercise price of $30.00 per share, with such exercise price increasing over time depending on when such warrants are exercised, up to a maximum exercise price of $40.00 per share.

The fair value of these warrants was estimated as of November 2008 using a binomial valuation model assuming no expected dividends, a volatility of 58%, contractual lives ranging from 1.6 years to 3.6 years and risk-free interest rates ranging from of 1.0% to 1.5%. The aggregate fair value of these warrants of approximately $1.3 million was recorded as additional paid-in capital in the nine months ended September 30, 2009.

In November 2008 for financial statement purposes, we recorded $23.8 million as deferred revenue associated with the grant of licenses to Mundipharma and Purdue. This amount represented the excess of the amount paid by Purdue and PPLP for the four million shares of our common stock ($11.25 per share) over the closing market price on the day before the first equity closing ($5.29 per share). In 2008, we considered our obligation, absent material adverse changes, to issue Purdue and PPLP the second closing securities to be a forward contract with immaterial intrinsic value, which was recorded in stockholders equity. This forward contract closed in January 2009 upon the issuance of the second closing securities. In January 2009 for financial statement purposes, we recorded $18.2 million as deferred revenue associated with the grant of licenses to Mundipharma and Purdue representing the excess of the $30 million paid by Purdue and PPLP for the second closing securities over the fair market value of these securities ($5.29 per share for the common stock and approximately $1.3 million for the warrants) as of the day before the first equity closing. All deferred revenue related to this strategic alliance is currently recognized as revenue ratably over 14 years, which is our estimated period of performance under the alliance agreements. We will periodically review this estimate and make adjustments as facts and circumstances dictate. We recognized $0.7 million and $2.2 million in such revenue in the three and nine months ended September 30, 2009, respectively.

The line of credit agreement provides for the borrowing by us of one or more unsecured loans up to an aggregate maximum principal amount of $50 million. The loans may be drawn by us through March 31, 2012. The loans, which may be used by us for any proper corporate purpose, mature on April 1, 2019 and will be subordinate to any senior indebtedness that we may incur. Borrowings made under the line of credit agreement will bear interest, payable on the maturity date, at a fluctuating rate set at the prime rate on the business day prior to the funding of each loan and will be reset on the last business day of each month ending thereafter. Interest will be compounded on each successive three-month anniversary of the funding of each loan. Outstanding loans may be prepaid without penalty or premium prior to the maturity date. Amounts borrowed under the credit agreement, once borrowed, may not be borrowed again. We have certain rights to repay outstanding amounts under the line of credit agreement in shares of our common stock.

The extension of the line of credit at an interest rate below our incremental borrowing rate represented the transfer of additional value to us in the arrangement. As such, we recorded the fair value of the line of credit of $17.3 million as a loan commitment asset on our balance sheet in 2008. Because Purdue and its associated companies became significant related parties as a result of the equity issuances, we recorded the offset to this loan commitment asset as additional paid-in capital in 2008. Beginning on April 1, 2009, when the line of credit was first available for our use, we started amortizing this asset on a straight line basis to interest expense over the life of the loan arrangement, or 10 years. During the three and nine months ended September 30, 2009, we recognized $0.4 million and $0.9 million, respectively, in such expense. As of September 30, 2009, no amounts have been borrowed under this line of credit.

MedImmune/AZ

In August 2006, we entered into a product development and commercialization agreement with MedImmune/AZ to jointly develop and commercialize cancer drugs targeting Hsp90 and the Hedgehog pathway. Under the terms of this agreement, we shared equally with MedImmune/AZ all development costs, as well as potential profits and losses, from any future marketed products. In November 2007, we regained from MedImmune/AZ worldwide development and commercialization rights under our Hedgehog pathway program on a royalty-free basis. In December 2008, we regained from MedImmune/AZ worldwide development and commercialization rights under our Hsp90 chaperone inhibitor program. Following the reacquisition of the Hsp90 chaperone inhibitor

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program in December 2008 we had no more substantial performance obligations to MedImmune/AZ and as such, we recognized the remaining portion of the up-front license fee as revenue in the year ended December 31, 2008. We also recorded reimbursable amounts from MedImmune/AZ through December 31, 2008 as income from residual funding, a component of other income in our statement of operations. MedImmune/AZ s funding obligation under the Hsp90 chaperone inhibitor program was to continue until June 2009. In January 2009, we reached an agreement with MedImmune/AZ to settle the residual funding obligation remaining for 2009 through lump-sum payments totaling $12.5 million, which were recorded as income from residual funding after reacquisition of Hsp90 program in the nine months ended September 30, 2009. We received $12.5 million in cash from MedImmune/AZ in the nine months ended September 30, 2009.

Since the MedImmune/AZ collaboration was a cost-sharing arrangement, we recorded reimbursable amounts for MedImmune/AZ s share of the development effort up through the date of our reacquisition of the Hsp90 chaperone inhibitor program in December 2008 as a reduction of research and development expense. We reduced research and development expense for MedImmune/AZ reimbursable amounts by $4.2 million and $13.2 million for the three and nine months ended September 30, 2008. The entirety of our deferred revenue at September 30, 2008 was attributable to the up-front license fee we received from MedImmune/AZ upon entry into this collaboration. We recognized $2.5 million and $7.5 million in revenue in connection with the amortization of the deferred revenue in the three and nine months ended September 30, 2008. In the three and nine months ended September 30, 2009, we did not recognize any up-front license fee revenue nor did we record a reduction of research and development expense associated with the MedImmune/AZ collaboration. We will not recognize any revenue from the up-front license fee nor record any reduction of research and development expense or any income from residual funding after reacquisition of Hsp90 program related to the MedImmune/AZ collaboration in future periods.

9. Income from NIH Reimbursement

During the nine months ended September 30, 2009, we received $1.7 million from the National Institutes of Health relating to contract work performed by Discovery Partners International, Inc. from August 2004 through June 2006. As the amount received is not related to our ordinary operations, we have recorded the amount as other income.

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

Forward-Looking Information

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, includes forward-looking statements that involve risks and uncertainties. You should review the section titled Risk Factors in Part II of this report for a discussion of important factors 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.

Business Overview

We are a drug discovery and development company that is utilizing our strength in small molecule drug technologies to discover and develop medicines for the treatment of cancer and related conditions.

Our lead product candidate, IPI-504 (retaspimycin hydrochloride), is an intravenously-administered small molecule inhibitor of heat shock protein 90, or Hsp90. Hsp90 is a central component of the cellular chaperone system a system that supports and stabilizes cancer-causing proteins such as c-Kit, EGFR, and HER2, enabling multiple forms of cancer to thrive. Inhibition of the Hsp90 chaperone knocks out this critical source of support for cancer cells, leading to tumor growth inhibition and cancer cell death. Thus, Hsp90 chaperone inhibition may represent a significant yet currently unaddressed strategy for treating patients with cancer.

We are evaluating IPI-504 in multiple clinical trials, including an international Phase 2 clinical trial of IPI-504 in combination with Herceptin® (trastuzumab) in patients with HER2-positive metastatic breast cancer, the Phase 2 portion of a Phase 1/2 clinical trial of IPI-504 in patients with advanced non-small cell lung cancer, or NSCLC, and a Phase 1 clinical trial of IPI-504 in combination with Taxotere® (docetaxel) in patients with advanced solid tumors. The clinical trials of IPI-504 in combination with Herceptin and Taxotere are both actively enrolling patients; patient enrollment in the NSCLC study is complete and data analysis is ongoing. Additionally, we expect to commence a trial of IPI-504 in patients with advanced, dedifferentiated liposarcoma in early 2010. In May 2009, we presented preliminary data from the NSCLC and Taxotere combination trials at the 2009 American Society for Clinical Oncology Annual Meeting demonstrating a generally well-tolerated safety profile

in both trials and, in the NSCLC trial, anti-tumor activity evidenced by a 14% overall response rate. We are currently researching genetic biomarkers that could be related to response to IPI-504 in patients with NSCLC. Based on the results of this research, we plan to conduct further clinical investigation of IPI-504 in patients with NSCLC.

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We are also enrolling patients in a Phase 1 clinical trial of IPI-493, an orally-delivered inhibitor of Hsp90, in patients with advanced solid tumors. This trial is designed to assess the safety and tolerability of IPI-493 and to identify a dose and schedule for subsequent studies. We plan to conduct further clinical evaluation of IPI-493 in 2010.

In April 2009, we elected to close our international Phase 3 registration trial of IPI-504 in patients with refractory gastrointestinal stromal tumors (GIST) following the recommendation of our independent data monitoring committee, or IDMC. The IDMC s recommendation to close this study followed an early review of safety data that showed a higher than anticipated mortality rate among patients enrolled in the treatment arm. We expect to report data from this trial in early 2010.

In December 2008, we reacquired from MedImmune, Inc., an affiliate of AstraZeneca plc, all worldwide development and commercialization rights for our Hsp90 chaperone inhibitor program, which includes IPI-504 and IPI-493. We refer to MedImmune in this report as MedImmune/AZ.

Our next most advanced program is directed against the Hedgehog signaling pathway, or Hedgehog pathway. The Hedgehog pathway is highly active in regulating tissue and organ formation during embryonic development. When abnormally activated, the Hedgehog pathway is believed to play a central role in allowing the proliferation and survival of several types of cancers, including pancreatic, prostate, lung, breast, blood, skin and certain brain cancers. The lead candidate in our Hedgehog pathway program, IPI-926, has shown potent and selective inhibition of the Hedgehog pathway as well as anti-tumor activity in preclinical models. In October 2008, we commenced a Phase 1 clinical trial evaluating IPI-926 in patients with advanced and/or metastatic solid tumors. The primary objectives of this study are to evaluate the safety and tolerability of IPI-926 and to identify a dose and schedule for subsequent studies. We expect to initiate Phase 2 development of IPI-926 beginning in 2010. We are pursuing our Hedgehog pathway program in collaboration with Mundipharma International Corporation Limited, or Mundipharma.

We also have a discovery program directed to fatty acid amide hydrolase, or FAAH, an emerging target for neuropathic pain. The enzyme FAAH degrades anandamide, which is a neurotransmitter that produces a pain relieving effect in response to pain and nerve injury. FAAH inhibition is believed to increase the duration of anandamide s effect, prolonging pain relief at the site of release. In early 2009, we selected IPI-940 as our clinical candidate for this program and we are conducting studies directed to the filing of an investigational new drug application for IPI-940 with the FDA. We expect to start a Phase 1 clinical trial of IPI-940 in early 2010. We are pursuing our FAAH program in collaboration with Mundipharma and an independent associated company, Purdue Pharmaceutical Products L.P., or Purdue.

We have spent, and expect to continue to spend, significant resources to fund the research and development of IPI-504, IPI-493, IPI-926, IPI-940 and our other drug candidates. While we may have net income in future periods as a result of non-recurring collaboration income, we expect to incur substantial and increasing operating losses over the next several years as our clinical trial and drug manufacturing activities increase.

Our Internet website is http://www.infi.com. We regularly use our website to post information regarding our business, product development programs and governance, and we encourage investors to use our website, particularly the information in the section entitled Investors/Media, as a source of information about us. The foregoing references to our website are not intended to, nor shall they be deemed to, incorporate information on our website into this document by reference.

Collaboration Agreements

Purdue and Mundipharma. In November 2008, we entered into strategic alliance agreements with each of Purdue and Mundipharma to develop and commercialize pharmaceutical products. The alliance includes product candidates that inhibit or target the Hedgehog pathway and FAAH, and product candidates arising out of all our discovery projects in all disease fields that achieve development candidate status on or before December 31, 2011 (with Mundipharma having the right, through the exercise of two consecutive one-year options, to extend such period through December 31, 2013). We refer to such three to five year period as the funded discovery period. Our Hsp90 and Bcl-2 programs are expressly excluded from the alliance. The agreement with Purdue is focused on the development and U.S. commercialization of products targeting FAAH. The agreement with Mundipharma is focused on the development and commercialization outside of the United States of all products and product candidates covered by the alliance, including those targeting FAAH.

Under the strategic alliance agreements, we have responsibility and decision-making authority for the performance of early discovery projects and the development of all product candidates on a worldwide basis. There are no joint steering or similar committees for the alliance. Mundipharma is obligated to pay 100% of our contractually budgeted amounts for research and development expenses incurred by us for early discovery projects and product candidates included in the alliance until the later of December 31, 2013 and the commencement of the first Phase 3 clinical study of such product candidate. We refer to such date as the transition date. After the transition date for each product candidate other than those arising out of the FAAH project, we will share with Mundipharma all research and development costs for such product candidate equally. Upon completion of the first Phase 1 clinical study of the first product developed under the research program that inhibits or targets

FAAH, Purdue and Mundipharma may elect to assume responsibility, at their own expense, for the future development of FAAH products and their sale in and outside of the

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United States, respectively. We are recording revenue for reimbursed research and development services we perform for Mundipharma and Purdue. We recorded $13.1 million and $34.2 million in such revenue in the three and nine month periods ended September 30, 2009, respectively.

Mundipharma has the right to opt out of any early discovery project or any preclinical or clinical development program on an annual basis in November of each year. In the event of an opt-out decision, Mundipharma, together with Purdue with respect to the FAAH project, will continue to provide funding for, in the aggregate, 100% of our contractually budgeted research and development expenses for the applicable project or program for one year after the date of such opt out. Purdue has a comparable opt out right with respect to the FAAH project. In addition, we and Mundipharma each have the right to opt out of continued development of a product candidate after it has reached the transition date, with a one year tail funding obligation for its 50% of post-transition date research and development expenses. If a party exercises its right to opt out of the development of a product or product candidate after the transition date, the other party may elect to continue the development and assume responsibility for the worldwide commercialization of such product or product candidate, subject to the payment of a royalty.

Except as set forth above with respect to FAAH products and opt-out products, we will have the right and responsibility to market and sell products arising from the research program in the United States and Mundipharma will have the right and responsibility to market and sell products arising from the research program outside of the United States. Other than pursuant to the strategic alliance agreements, neither we, Purdue nor Mundipharma may develop, manufacture or commercialize products that arise out of the research program or products that are directed to the same target or pathway as a product included in the research program, unless and until a party terminates its rights with respect to such products.

If we in-license any product or product candidate during the funded discovery period for which commercialization rights outside of the United States are available for grant by us to Mundipharma, Mundipharma will have the option to include such in-licensed product or product candidate in the alliance by paying us a prescribed percentage of the up-front license fee or other acquisition cost, which percentage could be up to 60% of such fee or cost, in order for Mundipharma to obtain commercialization rights for such in-licensed product or product candidate in all countries outside of the United States, and by funding research and development costs in the same manner as products or product candidates arising out of our internal discovery programs. The agreement with Mundipharma provides for the agreed-upon research and development budgets to be updated to reflect the inclusion of any in-licensed products or product candidates. There will be no royalties paid between the parties on in-licensed candidates.

Except with respect to products that have been in-licensed by us, for which no royalties will be payable between the parties, we are obligated to pay Mundipharma a 5% royalty on net sales of the commercialized products until such time as Mundipharma has recovered all research and development expenses paid to us under the research program prior to the applicable transition date. After such cost recovery, we are obligated to pay a tiered, 1% to 3% royalty on U.S. net sales of those products. For products in which Mundipharma has opted-out of development prior to the transition date, we are obligated to pay royalties of 1% to 5% of worldwide net sales as a function of the stage of development of the applicable product candidate at the time of opt-out. For products in which either party has opted-out of development following the transition date, the commercializing party is obligated to pay the other party a 5% royalty on net sales. Mundipharma is obligated to pay us a tiered, 10% to 20% royalty on annual net sales outside of the United States of each product arising out of the alliance, and Purdue is obligated to pay us a tiered, 10% to 20% royalty on annual net sales of FAAH products in the United States. Royalties are payable until the later to occur of the last-to-expire of specified patent rights and the expiration of non-patent regulatory exclusivities in a country, provided that if royalties are payable solely on the basis of non-patent regulatory exclusivity, each of the rates above is reduced by one-half. In addition, all royalties payable under the strategic alliance agreements, whether by us, Purdue or Mundipharma, are subject to reduction on account of third party royalty payments or patent litigation damages or settlements, with any such reductions capped at 50% of the amounts otherwise payable during the applicable royalty payment period.

In connection with the entry into the strategic alliance agreements, we also entered into a securities purchase agreement and line of credit agreement with Purdue and its independent associated company, Purdue Pharma L.P., or PPLP. In March 2009, Purdue assigned its interest under the line of credit agreement to PPLP. Under the securities purchase agreement we issued and sold in a first equity closing in November 2008 an aggregate of four million shares of our common stock at a purchase price of $11.25 per share, for an aggregate purchase price of $45 million. Of such shares, two million shares of our common stock were purchased by each purchaser. In January 2009, we conducted a second equity closing where we issued and sold an aggregate of two million shares of our common stock, and warrants to purchase up to an aggregate of six million shares of our common stock, for an aggregate purchase price of $30 million. Of the second closing securities, an equal number were purchased by each purchaser.

In 2008, we recorded $23.8 million as deferred revenue associated with the grant of licenses to Mundipharma and Purdue. This amount represented the excess of the amount paid by Purdue and PPLP for our common stock ($11.25 per share) over the closing market price on the day before the first equity closing ($5.29 per share). In 2008, we considered our obligation, absent material adverse changes, to issue Purdue and PPLP the second closing securities to be a forward contract with immaterial intrinsic value, which was recorded in stockholders equity. This

forward contract closed in January 2009 upon the issuance of the second closing securities. In January 2009, we recorded $18.2 million as deferred revenue associated with the grant of licenses to Mundipharma and Purdue,

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representing the excess of the $30 million paid by Purdue and PPLP for the second closing securities over the fair market value of these securities ($5.29 per share for the common stock and approximately $1.3 million for the warrants) as of the day before the first equity closing. All deferred revenue related to the strategic alliance with Mundipharma and Purdue will be recognized as revenue ratably over 14 years, which is our estimated period of performance under the arrangement. We will periodically review this estimate and make adjustments as facts and circumstances dictate. We recognized $0.7 million and $2.2 million in such revenue in the three and nine months ended September 30, 2009, respectively.

The line of credit agreement provides for the borrowing by us of one or more unsecured loans up to an aggregate maximum principal amount of $50 million. The loans may be drawn by us through March 31, 2012. The loans, which may be used by us for any proper corporate purpose, mature on April 1, 2019, which we refer to as the maturity date, and will be subordinate to any senior indebtedness that we may incur. Borrowings made under the line of credit agreement will bear interest, payable on the maturity date, at a fluctuating rate set at the prime rate on the business day prior to the funding of each loan and will be reset on the last business day of each month ending thereafter. Interest will be compounded on each successive three-month anniversary of the funding of each loan. Outstanding loans may be prepaid without penalty or premium prior to the maturity date. Amounts borrowed under the credit agreement, once borrowed, may not be borrowed again. We have certain rights to repay outstanding amounts under the line of credit agreement in shares of our common stock.

The extension of the line of credit at an interest rate below our incremental borrowing rate represents the transfer of additional value to us in the arrangement. As such, we recorded the fair value of the line of credit of $17.3 million as a loan commitment asset on our balance sheet in 2008. We are amortizing this asset to interest expense over the life of the loan arrangement, or 10 years commencing on April 1, 2009. Because Purdue and its associated companies became significant related parties as a result of the equity issuances, we recorded the offset to this asset as additional paid-in capital in 2008. As of September 30, 2009, no amounts have been borrowed under this line of credit.

MedImmune/AZ. In August 2006, we entered into a product development and commercialization agreement with MedImmune/AZ to jointly develop and commercialize cancer drugs targeting Hsp90 and the Hedgehog pathway. In November 2007, we regained from MedImmune/AZ worldwide development and commercialization rights under our Hedgehog pathway program and in December 2008, we reacquired from MedImmune/AZ worldwide development and commercialization rights to our Hsp90 chaperone inhibitor program.

Under the terms of this agreement, we shared equally with MedImmune/AZ all development costs, as well as potential profits and losses, from any future marketed products. MedImmune/AZ made non-refundable, up-front payments totaling $70 million to us in order to obtain co-exclusive rights to the Hsp90 and Hedgehog pathway development programs, and paid a $15 million milestone to us in 2008 upon initiation of the phase 3 clinical trial of IPI-504 in patients with GIST that we elected to close in April 2009. Upon the reacquisition of rights to the Hsp90 chaperone inhibitor program, we recognized all of the remaining deferred revenue related to the up-front license fee from MedImmune/AZ, as we had no further performance obligations to MedImmune/AZ. Following the reacquisition of the Hsp90 chaperone inhibitor program in December 2008, MedImmune/AZ remained obligated to fund an amount equivalent to its share of Hsp90 program costs for the ensuing six-month period, and we recorded these reimbursable amounts from the reacquisition date through December 31, 2008 as income from residual funding, a component of other income in our statement of operations. In January 2009, however, we agreed with MedImmune/AZ to settle the residual funding obligation remaining for 2009 through lump-sum payments totaling $12.5 million, which were recorded as income from residual funding after reacquisition of Hsp90 program in the nine months ended September 30, 2009. We received $12.5 million in cash from MedImmune/AZ in the nine months ended September 30, 2009.

The profit and cost-sharing provisions of our arrangement with MedImmune/AZ are no longer applicable, and we have full control over all future development and commercialization activities under our Hsp90 and Hedgehog pathway programs, subject to the payment of single-digit royalties to MedImmune/AZ on worldwide net sales, if any, of each of IPI-504 and IPI-493. We do not have a royalty obligation to MedImmune/AZ on any future sales of IPI-926.

Novartis. In February 2006, we entered into a collaboration agreement with Novartis Institute for BioMedical Research, Inc., or Novartis, to discover, develop and commercialize drugs targeting Bcl protein family members for the treatment of a broad range of cancers. Under the terms of this agreement, we granted to Novartis an exclusive, worldwide license to research, develop and commercialize pharmaceutical products that are based upon our proprietary Bcl inhibitors. Novartis paid us a $15 million up-front license fee, which we originally recognized over an estimated period of performance of four years, an affiliate of Novartis made a $5 million equity investment in us, and Novartis committed to provide us research funding of approximately $10 million over the initial two-year research term, which expired in February 2008. Novartis had the right to extend the research term for up to two additional one-year terms, under which Novartis could have obligated us to provide up to five full-time equivalents, at Novartis expense, to enable the full transition of the Bcl inhibitor program to Novartis. Novartis chose not to exercise its right for the one-year extensions; thus, the research term ended in February 2008 and we have no further performance obligations to Novartis. As a result, we recognized $8.1 million of the up-front license fee as revenue in the three months ended March 31, 2008. We may request to participate in clinical development of any products arising from this collaboration and, if such request is agreed upon by Novartis,

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Novartis will fund agreed-upon development costs that are incurred by us. We also have a non-exclusive right to detail Bcl-2 family inhibitor products in the United States, with our detailing costs to be reimbursed by Novartis. Novartis has agreed to make milestone payments totaling over $370 million if certain specified research, development and commercialization milestones are achieved for multiple products for multiple indications, such that total payments to us could exceed $400 million. Novartis has also agreed to pay us royalties upon successful commercialization of any products developed under the alliance.

Financial Overview

Revenue

All of our revenue to date has been derived from license fees, the reimbursement of research and development costs, contract service revenue and milestones payments received from our collaboration partners. Where the agreement with a collaboration partner, such as our agreements with Mundipharma, Purdue and Novartis, provides for the partner to provide research funding for our research and development efforts, we recognize this cost reimbursement as revenue in the period earned. In the future, we may generate revenue from a combination of product sales, research and development support services and milestone payments in connection with strategic relationships, and royalties resulting from the sales of products developed under licenses of our intellectual property. We expect that any revenue we generate will fluctuate from year to year as a result of the timing and amount of license fees, research and development reimbursement, milestone and other payments earned under our collaborative or strategic relationships, and the amount and timing of payments that we earn upon the sale of our products, to the extent any are successfully commercialized. If we fail to complete the development of our drug candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

Research and Development Expense

We are a drug discovery and development company that has focused its efforts in the field of cancer and related conditions. Our research and development expense primarily consists of the following:

- compensation of personnel associated with research activities, including consultants;
- clinical testing costs, including payments made to contract research organizations;
- laboratory supplies and materials;
- manufacturing drug candidates for preclinical testing and clinical studies;
- preclinical testing costs, including costs of toxicology studies;
- fees paid to professional service providers for independent monitoring and analysis of our clinical trials;
- depreciation of equipment; and
- allocated costs of facilities.

Under our collaboration with MedImmune/AZ, we shared research and development expenses equally with MedImmune/AZ. In December 2008, we reacquired from MedImmune/AZ worldwide development and commercialization rights to our Hsp90 chaperone inhibitor program. Amounts reimbursed by MedImmune/AZ under the cost-sharing provisions of the parties collaboration agreement incurred prior to our reacquisition of the Hsp90 chaperone inhibitor program were recorded as a reduction of research and development expense in our statements of

operations. Amounts reimbursed by MedImmune/AZ incurred following the reacquisition of the Hsp90 chaperone inhibitor program were recorded as income from residual funding after reacquisition of Hsp90 program in our statements of operations. This cost-sharing arrangement also applied to our Hedgehog pathway inhibitor program through May 31, 2008.

General and Administrative Expense

General and administrative expense primarily consists of salaries and other related costs for personnel in executive, finance, accounting, legal, information technology infrastructure, corporate communications and human resources functions. Other costs include facilities costs not otherwise included in research and development expense, professional fees for legal and accounting services and early commercial development costs. General and administrative expense also consists of the costs of maintaining our intellectual property portfolio.

Other Income and Expense

Interest expense and other interest and investment income typically consists of interest earned on cash, cash equivalents and available-for-sale securities, net of interest expense, and amortization of warrants. Interest expense includes amortization of the loan commitment asset from PPLP. Reimbursable amounts from MedImmune/AZ incurred following the reacquisition of the Hsp90 program in December 2008 are recorded as income from residual funding, which is included in other income and expense.

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Critical Accounting Policies and Significant Judgments and Estimates

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

Financial Accounting Standards Board (FASB) Codification

In June 2009, the FASB issued Financial Accounting Standards Board Statement (SFAS) No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles a Replacement of FASB Statement No. 162* (SFAS No. 168). The FASB Accounting Standards Codification (the Codification) is intended to be the single source of authoritative nongovernmental U.S. generally accepted accounting principles. Rules and interpretive releases of the SEC under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. SFAS No. 168 is effective for interim and annual periods ending after September 15, 2009. All existing accounting standards have been superseded as described in SFAS No. 168. All other accounting literature not included in the Codification is non-authoritative. The adoption of SFAS No. 168 during the three months ended September 30, 2009 did not impact our financial position or results of operations. All references on authoritative nongovernmental U.S. generally accepted accounting principles throughout this quarterly report on Form 10-Q relate to the Codification.

Revenue Recognition

To date, all of our revenue has been generated under research collaboration agreements. The terms of these research collaboration agreements may include payment to us of non-refundable, up-front license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved, and/or royalties on product sales. We divide agreements containing multiple elements into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the collaborative partner and whether there is objective and reliable evidence of fair value of the undelivered obligation(s). For these agreements, we allocate the consideration that we receive among the separate units based on their respective fair values or the residual method, and we apply the applicable revenue recognition criteria to each of the separate units.

We recognize revenue from non-refundable, up-front license fees on a straight-line basis over the contracted or estimated period of performance, which is typically the research or development term. We recognize research and development funding as earned over the period of effort. We regularly consider whether events warrant a change in the estimated period of performance under an agreement. Such a change would cause us to modify the period of time over which we recognize revenue from the up-front license fees paid to us under that agreement and would, in turn, result in changes in our quarterly and annual results.

We recognize milestone payments as revenue upon achievement of the milestone only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone and (4) the milestone is at risk for both parties. If any of these conditions is not met, we defer the milestone payment and recognize it as revenue over the estimated period of performance under the contract as we complete our performance obligations.

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.

We exercise our judgment in determining whether an agreement contains multiple elements and, if so, how much revenue is allocable to each element. In addition, we exercise our judgment in determining when our significant obligations have been met under such agreements and the specific time periods over which we recognize revenue, such as non-refundable, up-front license fees. To the extent that actual facts and circumstances differ from our initial judgments, our revenue recognition with respect to such transactions would change accordingly and any such change could affect our reported operating results.

Research and Development Expense

Research and development expense consists of expenses incurred in performing research and development activities. We expense research and development costs as they are incurred. We have entered into certain collaboration agreements in which expenses are shared with the collaborator, and others in which we are reimbursed for work performed on behalf of the collaborator. We record all of these expenses as research and development expense. If the arrangement is a cost-sharing arrangement and there is a period during which we receive payments from the collaborator, we record payments from the collaborator for its share of the development effort as a reduction of research and development expense. If the arrangement is a cost-sharing arrangement and there is a period during which we make payments to the collaborator, we record our payments to the collaborator for its share of the development effort as additional research and development expense. If the arrangement provides for reimbursement of research and development expenses, we record the reimbursement as revenue. Our collaboration with MedImmune/AZ was a cost-sharing arrangement; our alliance with Mundipharma and Purdue provides for, and our collaboration with Novartis provided for, the reimbursement of our research and development expenses.

Accrued Expenses

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves identifying services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date. Examples of services for which we must estimate accrued expenses include contract service fees paid to contract manufacturers in conjunction with pharmaceutical development work and to contract research

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organizations in connection with clinical trials and preclinical studies. In connection with these service fees, our estimates are most affected by our understanding of the status and timing of services provided. The majority of our service providers invoice us in arrears for services performed. In the event that we do not identify certain costs that have been incurred by our service providers, or if we over- or under-estimate the level of services performed or the costs of such services in any given period, our reported expenses for such period would be too low or too high. We often rely on subjective judgments to determine the date on which certain services commence, the level of services performed on or before a given date, and the cost of such services. We make these judgments based upon the facts and circumstances known to us. Our estimates of expenses in future periods may be over- or under-accrued.

Stock-Based Compensation

We expense the fair value of employee stock options and other equity compensation. We use our judgment in determining the fair value of our equity instruments, including in selecting the inputs we use for the Black-Scholes valuation model. Equity instrument valuation models are by their nature highly subjective. Any significant changes in any of our judgments, including those used to select the inputs for the Black-Scholes valuation model, could have a significant impact on the fair value of the equity instruments granted and the associated compensation charge we record in our financial statements.

Income Taxes

We use the liability method to account for income taxes. Deferred tax assets and liabilities are determined based on differences between financial reporting and income tax basis of assets and liabilities, as well as net operating loss carryforwards, and are measured using the enacted tax rates and laws that will be in effect when the differences reverse. Deferred tax assets are reduced by a valuation allowance to reflect the uncertainty associated with their ultimate realization. The effect on deferred taxes of a change in tax rate is recognized in income or loss in the period that includes the enactment date.

We use our judgment for the recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return.

Fair Value Measurements

We define fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. We determine fair value based on the assumptions market participants use when pricing the asset or liability. We also use the fair value hierarchy that prioritizes the information used to develop these assumptions.

New Accounting Pronouncements

In October 2009, the FASB issued Accounting Standard Update No. 2009-13, *Multiple-Element Revenue Arrangements* (ASU No. 2009-13), which updates the existing multiple-element revenue arrangements guidance currently included in Accounting Standards Codification No. 605-25, in two ways. The first change relates to the determination of when the individual deliverables included in a multiple-element arrangement may be treated as separate units of accounting. This is significant as it will likely result in the requirement to separate more deliverables within an arrangement, ultimately leading to less revenue deferral. The second change modifies the manner in which the transaction consideration is allocated across the separately identified deliverables. ASU No. 2009-13 also significantly expands the disclosures required for multiple-element revenue arrangements. ASU No. 2009-13 will be effective for the first annual reporting period beginning on or after June 15, 2010, and may be applied retrospectively for all periods presented or prospectively to arrangements entered into or materially modified after the adoption date. We do not expect ASU No. 2009-13 to have a material impact on our financial statements or results of operations.

Results of Operations

The following tables summarize our results of operations for each of the three and nine months ended September 30, 2009 and 2008, in thousands, together with the change in these items in dollars and as a percentage:

	For the Three Months Ended September 30,			
	2009	2008	$ Change	% Change
Revenue	$ 13,776	$ 2,500	$ 11,276	451%
Research and development expense	(18,499)	(11,732)	(6,767)	58%
General and administrative expense	(4,570)	(3,781)	(789)	21%

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	For the Three Months Ended September 30, 2009	2008	$ Change	% Change
Interest expense	(433)	(2)	(431)	21,550%
Interest and investment income	401	624	(223)	(36)%

	For the Nine Months Ended September 30, 2009	2008	$ Change	% Change
Revenue	$ 36,370	$ 16,391	$ 19,979	122%
Research and development expense	(60,453)	(31,029)	(29,424)	95%
General and administrative expense	(15,582)	(11,234)	(4,348)	39%
Interest expense	(867)	(20)	(847)	4,235%
Income from residual funding after reacquisition of Hsp90 program	12,450		12,450	
Income from NIH reimbursement	1,745		1,745	
Interest and investment income	1,736	2,774	(1,038)	(38)%

Revenue

Our revenue during the three and nine months ended September 30, 2009 consisted of approximately $13.1 million and $34.2 million, respectively, for reimbursed research and development services, and $0.7 million and $2.2 million, respectively, from the amortization of the deferred revenue associated with the grant of licenses, under our strategic alliance with Mundipharma and Purdue.

Our revenue during the three-month period ended September 30, 2008 was entirely attributable to the amortization of the up-front license fee we received from MedImmune/AZ upon entry into our collaboration in August 2006.

Our revenue during the nine-month period ended September 30, 2008 consisted of approximately:

- $7.5 million associated with the amortization of the up-front license fee we received from MedImmune/AZ; and
- $8.1 million related to the amortization of the non-refundable license fee, and $0.8 million in revenue related to the reimbursable research and development services we performed, under our Bcl-2 collaboration with Novartis.

Research and Development Expense

Research and development expense represented approximately 80% and 76% of our total operating expenses for the three months ended September 30, 2009 and 2008, respectively. Research and development expense represented approximately 80% and 73% of our total operating expenses for the nine months ended September 30, 2009 and 2008, respectively. The increase in research and development expense as a percentage of total operating expenses was primarily due to our treatment of the cost-sharing provisions of our collaboration with MedImmune/AZ following our reacquisition of the worldwide development and commercialization rights to our Hsp90 chaperone inhibitor program in December 2008.

Research and development expense in the three months ended September 30, 2008 included a credit of $4.2 million for research and development amounts reimbursed by MedImmune/AZ under the cost-sharing provisions of the collaboration agreement. In addition to the effect of the MedImmune/AZ reimbursed amounts, the increase in research and development expense in the three months ended September 30, 2009 as compared to the same period in 2008 is primarily attributable to:

- an increase of $1.4 million in compensation and benefits, including stock-based compensation expense, for our research and development personnel, which was primarily driven by the hiring of new research and development personnel and annual base salary increases; and

an increase of $0.8 million in pharmaceutical development expenses and $0.5 million in preclinical expenses as we advance our pipeline of drug candidates.

Research and development expense in the nine months ended September 30, 2008 included a credit of $13.2 million for research and development amounts reimbursed by MedImmune/AZ under the cost-sharing provisions of the collaboration agreement. In addition to the effect of the MedImmune/AZ reimbursed amounts, the increase in research and development expense in the nine months ended September 30, 2009 as compared to the same period in 2008 is primarily attributable to:

an increase of $4.7 million in compensation and benefits, including stock-based compensation expense, for our research and development personnel, which was primarily driven by the hiring of new research and development personnel and annual base salary increases;

an increase of $4.1 million in pharmaceutical development expenses and $1.1 million in preclinical expenses as we advance our pipeline of drug candidates;

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an increase of $3.1 million for clinical trials of IPI-504, IPI-493 and IPI-926, including costs related to our phase 3 clinical trial of IPI-504 in patients with GIST that we stopped in April 2009; and

an increase of $1.2 million in consulting expenses.

During the three and nine months ended September 30, 2009 and 2008, we estimate that we incurred the following expenses by program. These expenses relate primarily to payroll and related expenses for personnel working on the programs, drug development and manufacturing, preclinical toxicology studies and clinical trial costs. In addition, for the Hsp90 chaperone and Hedgehog pathway inhibitor programs, these expenses for the nine months ended September 30, 2008 include credits of approximately $13.2 million attributable to amounts reimbursed by MedImmune/AZ under the cost-sharing provisions of our collaboration agreement. For the Hsp90 chaperone inhibitor program, these expenses for the three months ended September 30, 2008 include credits of approximately $4.2 million attributable to amounts reimbursed by MedImmune/AZ under the cost-sharing provisions of our collaboration agreement.

Program	Three Months Ended September 30, 2009	Three Months Ended September 30, 2008
Hsp90 Chaperone Inhibitors	$ 6.4 million	$ 3.9 million
Hedgehog Pathway Inhibitors	6.4 million	3.7 million
FAAH	2.1 million	

Program	Nine Months Ended September 30, 2009	Nine Months Ended September 30, 2008
Hsp90 Chaperone Inhibitors	$ 28.0 million	$ 12.8 million
Hedgehog Pathway Inhibitors	16.4 million	6.8 million
FAAH	6.9 million	
Bcl-2		0.6 million

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

We expect expenses for our Hedgehog pathway inhibitor program to increase as we make progress in the clinical development of IPI-926. In addition, we expect expenses for FAAH to increase as we perform IND-enabling studies and commence clinical development of IPI-940. We do not expect to incur any future research and development expenses for the Bcl-2 program because our research obligations under our collaboration with Novartis ended in February 2008.

General and Administrative Expense

The increase in general and administrative expense for the three months ended September 30, 2009 as compared to the three months ended September 30, 2008 is primarily attributable to an increase of $0.6 million in compensation and benefits, including stock-based compensation expense, for our general and administrative personnel, which was primarily driven by the hiring of new general and administrative personnel and annual base salary increases, and an increase of $0.2 million in patent expenses.

The increase in general and administrative expense for the nine months ended September 30, 2009 as compared to the nine months ended September 30, 2008 is primarily attributable to an increase of $2.0 million in compensation and benefits, including stock-based compensation expense, for our general and administrative personnel, which was primarily driven by the hiring of new general and administrative personnel and annual base salary increases, an increase of $1.0 million in consulting expenses, principally related to early commercial development, an increase of $0.4 million in patent expenses, and an increase of $0.4 million in corporate communications expenses.

Interest Expense

Interest expense increased for the three and nine months ended September 30, 2009 as compared to the three and nine months ended September 30, 2008 primarily as a result of amortizing the loan commitment asset from Purdue.

Income from Residual Funding After Reacquisition of Hsp90 Program

MedImmune/AZ s funding obligations under the Hsp90 chaperone inhibitor program were to continue from our reacquisition of that program in December 2008 until June 2009. In January 2009, we reached an agreement with MedImmune/AZ to settle the residual funding obligations remaining for 2009 through lump sum payments totaling approximately $12.5 million, which were recorded as income from residual funding after reacquisition of Hsp90 program in the nine months ended September 30, 2009. We do not expect any such income in future periods.

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Income from NIH Reimbursement

During the nine months ended September 30, 2009, we received $1.7 million from the National Institutes of Health related to contract work performed by Discovery Partners International, Inc. from August 2004 through June 2006. We do not expect any such income in future periods.

Interest and Investment Income

Interest and investment income decreased in the three and nine months ended September 30, 2009 as compared to the three and nine months ended September 30, 2008 primarily as a result of the lower yields on our cash equivalents and available-for-sale securities. We expect interest and investment income to continue to be lower in 2009 as compared to 2008 primarily due to lower expected yields, partially offset by higher average balances due to the Purdue transaction.

Liquidity and Capital Resources

We have not generated any revenue from the sale of drugs to date, and we do not expect to generate any such revenue for the next several years, if at all. We have instead relied on the proceeds from sales of equity securities, interest on investments, license fees, expense reimbursement under our collaborations, milestone payments, contract service payments and debt to fund our operations. Our available-for-sale debt securities primarily trade in liquid markets, and the average days to maturity of our portfolio as of September 30, 2009 is less than six months. Because our product candidates are in various stages of clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability.

Our significant capital resources are as follows:

	September 30, 2009	December 31, 2008
Cash, cash equivalents and available-for-sale securities	$ 140,482,784	$ 126,771,687
Working capital	127,504,514	120,587,124

	Nine Months Ended September 30,	
	2009	2008
Cash provided by (used in):		
Operating activities	$ 3,792,660	$ (34,513,830)
Investing activities	1,652,705	29,909,851
Capital expenditures (included in investing activities above)	(1,854,995)	(601,594)
Financing activities	11,954,505	259,528

Cash Flows

The principal use of cash in operating activities in all of the periods presented was the funding of our research and development expenses, which increase as our drug development programs advance. Cash flows from operations can vary significantly due to various factors, including changes in accounts receivable and unbilled accounts receivable, as well as changes in accounts payable, accrued expenses and deferred revenue. During January 2009, we issued to Purdue and PPLP an aggregate of two million shares of our common stock and warrants to purchase up to six million shares of our common stock for cash proceeds of $30 million. These securities were recorded at their fair value of $11.8 million and reflected as cash flows from financing activities. The balance of $18.2 million was accounted for as an up-front license fee in deferred revenue and recorded in our cash flows from operating activities. During the nine months ended September 30, 2008, we recognized the remaining portion of our deferred revenue, or $8.1 million, related to the up-front license fee from Novartis upon conclusion of the research term of our Bcl-2 collaboration. During the nine months ended September 30, 2009, we collected all of our unbilled receivables from Purdue, Mundipharma and MedImmune/AZ.

Net cash used in investing activities for the period ended September 30, 2009 included $134.8 million in purchases of available-for-sale securities, proceeds of $102.1 million from maturities of available-for-sale securities, and proceeds of $36.1 million from sales of available-for-sale securities. Capital expenditures in the nine months ended September 30, 2009 primarily consisted of laboratory equipment and capitalized software costs. Capital expenditures for the nine months ended September 30, 2008 primarily consisted of laboratory equipment along with leasehold improvements and office equipment related to our additional office space.

We will need substantial additional funds to support our planned operations. In the absence of additional funding or business development activities and based on our current operating plans, we expect that our current cash, cash equivalents and available-for-sale securities, together with the $50 million line of credit that has been made available to us by Purdue, are sufficient to fund our planned operations into 2013. We may, however, need to raise additional funds before that date if our research and development expenses exceed our current expectations, if we do not receive the payments we expect to receive from Mundipharma and Purdue or if we acquire or license rights to additional drug candidates or new technologies from one or more third parties. This could occur for many reasons, including:

some or all of our drug candidates fail in clinical or preclinical studies and we are forced to seek additional drug candidates;

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our drug candidates require more extensive clinical or preclinical testing than we currently expect;

we advance more of our drug candidates than expected into costly later stage clinical trials;

we advance more preclinical drug candidates than expected into early stage clinical trials;

the cost of acquiring raw materials for, and of manufacturing, our drug candidates is higher than anticipated;

we are required, or consider it advisable, to acquire or license intellectual property rights from one or more third parties;

Mundipharma or Purdue elects to discontinue its participation in a partnered program; or

we experience a loss in our investments due to general market conditions or other reasons.

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, or at all, particularly in light of current market conditions. In addition, the terms of our financings may be dilutive to, or otherwise adversely affect, holders of our common stock, and such terms may impact our ability to make capital expenditures or incur additional debt. 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 drug candidates, and we may not be able to enter into such agreements on acceptable terms, if at all. If we are unable to obtain additional funding on a timely basis, we may be required to curtail or terminate some or all of our development programs, including some or all of our drug candidates.

Contractual Obligations and Off-Balance Sheet Arrangements

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

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, U.S. government-sponsored enterprise obligations, corporate obligations, U.S. Treasury obligations and asset-backed securities. We do not enter into investments for trading or speculative purposes. Our cash is deposited in and invested through highly rated financial institutions in North America. Our marketable securities are subject to interest rate risk and will fall in value if market interest rates increase.

A hypothetical 100 basis point increase in interest rates would result in an approximate $518,000 decrease in the fair value of our investments as of September 30, 2009, as compared to an approximate $418,000 decrease as of December 31, 2008. We generally hold our fixed income investments until maturity and, therefore, we do not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments.

Item 4. Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2009. 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 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, or persons performing similar functions, 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, 2009, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

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No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended September 30, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1A. Risk Factors

You should carefully consider the following risk factors, in addition to other information included in this quarterly report on Form 10-Q, in evaluating Infinity and our business. If any of the following risks occur, our business, financial condition and operating results could be materially adversely affected.

Risks Related to Our Stage of Development as a Company

We have a history of operating losses, expect to incur significant and increasing operating losses in the future, and may never be consistently profitable.

We have a limited operating history for you to evaluate our business. We have no approved products and have generated no product revenue. We have primarily incurred operating losses. As of September 30, 2009, we had an accumulated deficit of $173.5 million. We have spent, and expect to continue to spend, significant resources to fund the research and development of IPI-504, IPI-493, IPI-926, IPI-940 and our other drug candidates. While we may have net income in future periods as the result of non-recurring collaboration income, as we did in the year ended December 31, 2008, we expect to incur substantial and increasing operating losses over the next several years as our clinical trial and drug manufacturing activities increase. As a result, we expect that our accumulated deficit will also increase significantly.

Our drug candidates are in varying stages of preclinical and clinical development and may never be approved for sale or generate any revenue. We will not be able to generate product revenue unless and until one of our drug candidates successfully completes clinical trials and receives regulatory approval. Since even our most advanced drug candidate requires substantial additional clinical development, we do not expect to receive revenue from our drug candidates for several years, if at all. 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.

We may be unable to raise the substantial additional capital that we will need to sustain our operations.

We will need substantial additional funds to support our planned operations. In the absence of additional funding or business development activities and based on our current operating plans, we expect that our current cash, cash equivalents and available-for-sale securities, together with the $50 million line of credit that has been made available to us by Purdue Pharmaceutical Products L.P., or Purdue, are sufficient to fund our planned operations into 2013. We may, however, need to raise additional funds before that date if our research and development expenses exceed our current expectations, if we do not receive the payments we expect to receive from Mundipharma International Corporation Limited, or Mundipharma, and Purdue or if we acquire or license rights to additional drug candidates or new technologies from one or more third parties. This could occur for many reasons, including:

- some or all of our drug candidates fail in clinical or preclinical studies and we are forced to seek additional drug candidates;
- our drug candidates require more extensive clinical or preclinical testing than we currently expect;
- we advance more of our drug candidates than expected into costly later stage clinical trials;
- we advance more preclinical drug candidates than expected into early stage clinical trials;

the cost of acquiring raw materials for, and of manufacturing, our drug candidates is higher than anticipated;

we are required, or consider it advisable, to acquire or license intellectual property rights from one or more third parties;

Mundipharma or Purdue elects to discontinue its participation in a partnered program; or

we experience a loss in our investments due to general market conditions or other reasons.

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, or at all, particularly in light of current market conditions. In addition, the terms of such financings may be dilutive to, or otherwise adversely affect, holders of our common stock, and such terms may impact our ability to make capital expenditures or incur additional debt. 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 drug candidates, and we may not be able to enter into such arrangements on acceptable terms, if at all. If we are unable to obtain additional funding on a timely basis, we may be required to curtail or terminate some or all of our product development programs.

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Our investments in cash equivalents and available-for-sale securities are subject to risks that may cause losses and affect the liquidity of these investments.

As of September 30, 2009, we had approximately $140 million in cash, cash equivalents and available-for-sale securities. We historically have invested these amounts in money market funds, corporate obligations, U.S. government-sponsored enterprise obligations, U.S. Treasury securities and asset-backed securities meeting the criteria of our investment policy, which is focused on the preservation of our capital. These investments are subject to general credit, liquidity, market and interest rate risks, which may be affected by U.S. sub-prime mortgage defaults that have affected various sectors of the financial markets and caused credit and liquidity issues. 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 condition and results of operations.

Our results to date do not guarantee that any of our product candidates will be safe or effective, or receive regulatory approval.

The risk of failure of our current clinical candidates is high. To date, the data supporting our clinical development strategy for IPI-504, IPI-493, IPI-926, and IPI-940 are derived solely from laboratory and preclinical studies and, in the case of IPI-504, limited early-stage clinical trials. Later clinical trials may not yield data consistent with earlier clinical trials, as was the case in our Phase 3 clinical trial of IPI-504 in patients with gastrointestinal stromal tumors, or GIST, which we elected to close in April 2009 when an early review of safety data showed a higher than anticipated mortality rate among patients enrolled in the treatment arm. In such a case, it may be necessary for us to change our development strategy or abandon development of that drug candidate, either of which would result in delays and additional costs. It is impossible to predict when or if IPI-504, IPI-493, IPI-926, IPI-940 or any of our other drug candidates will prove safe or effective in humans or receive regulatory approval. These drug candidates may not demonstrate in patients the chemical and pharmacological properties ascribed to them in laboratory studies or early-stage clinical trials, and they may interact with human biological systems or other drugs in unforeseen, ineffective or harmful ways. If we are unable to discover or successfully develop drugs that are safe and effective in humans, we will not have a viable business.

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

We have a global strategic alliance with Mundipharma to research, develop and jointly commercialize IPI-926, IPI-940 and product candidates arising out of our Hedgehog signaling pathway, or Hedgehog pathway, fatty acid amide hydrolase, or FAAH, and early discovery programs, and with Purdue to commercialize product candidates arising out of our FAAH program in the United States. Under the strategic alliance agreements, Mundipharma and Purdue have committed to provide substantial funding, significant capabilities in the field of pain and, in the case of Mundipharma, significant capabilities in marketing and sales outside of the United States. The success of this alliance is largely dependent on the resources, efforts, technology and skills brought to such alliance by Mundipharma and Purdue. Disputes and difficulties in these types of relationships are common, often due to conflicting priorities or conflicts of interest. Merger and acquisition activity may exacerbate these conflicts. The benefits of this alliance will be reduced or eliminated if Mundipharma and/or Purdue:

- terminates either or both of the strategic alliance agreements;
- fails to devote financial or other resources to the applicable alliance, thereby hindering or delaying development, manufacturing or commercialization activities;
- fails to successfully develop or manufacture any products arising out of our FAAH program or to commercialize any drug candidate under the applicable alliance; or
- fails to maintain the financial resources necessary to continue financing its portion of development, manufacturing, and commercialization costs or its own operations.

Under our agreements with Mundipharma and Purdue, each agreement may be terminated on 60 days prior written notice if we were to materially breach such agreement and fail to cure such breach within the 60-day notice period. In addition, each of these strategic alliance agreements may be terminated in the event we experience a change in control or in the event that, during the funded research period, either

Julian Adams is no longer a full-time executive of Infinity or both Steven Holtzman and Adelene Perkins are no longer full-time executives of Infinity. In addition, Mundipharma has the right to opt out of participation in the Hedgehog pathway and/or FAAH programs in November of each calendar year, subject to 12 months of continued funding, and Purdue has a similar right with respect to the FAAH program. If Mundipharma and/or Purdue were to exercise its right to opt out of a program or to terminate its respective agreement, we may not have sufficient financial resources or capabilities to continue development and commercialization of products from the affected program, and our ability to attract a new alliance partner would be made more difficult.

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Much of the potential revenue from our alliance with Mundipharma and Purdue, and any alliances we may enter into in the future, will consist of contingent payments, such as royalties payable on sales of any successfully developed drugs. Any such contingent revenue will depend upon our, and our alliance partners , ability to successfully develop, introduce, market and sell new products. In some cases, we will not be involved in these processes and will depend entirely on our alliance partners. For example, Mundipharma will be responsible for all of the commercialization efforts outside of the United States for any products that are successfully developed from our Hedgehog pathway program and our early stage development programs, and Purdue and Mundipharma will be jointly responsible for all development and commercialization activities for products arising out of the FAAH program following Phase 1 clinical trials. Any of our current or future alliance partners may fail to develop or effectively commercialize products using our products or technologies because it:

- decides not to devote the necessary resources because of internal constraints, such as limited personnel with the requisite scientific expertise, limited cash resources or specialized equipment limitations, or the belief that other drug development programs may have a higher likelihood of obtaining regulatory approval or may potentially generate a greater return on investment;
- does not have sufficient resources necessary to carry the drug candidate through clinical development, regulatory approval and commercialization; or
- cannot obtain the necessary regulatory approvals.

If any current or future alliance partner fails to develop or effectively commercialize our drug candidates, we may not be able to develop and commercialize that drug independently, and our financial condition and operations would be negatively impacted.

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

We are highly dependent on our management team, particularly Steven Holtzman, Adelene Perkins, Julian Adams and the other members of 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. For example, Purdue and Mundipharma each have the right to terminate its strategic alliance with us if, during the funded research period, either Julian Adams is no longer a full-time executive of Infinity or both Steven Holtzman and Adelene Perkins are no longer full-time executives of Infinity. We do not maintain key person insurance on any of our employees.

Recruiting and retaining qualified scientific and business personnel is also critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. This competition is particularly intense near our headquarters in Cambridge, Massachusetts. We also experience competition for the hiring of scientific personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development strategy. Our consultants and advisors may be employed by other entities, have commitments under consulting or advisory contracts with third parties that limit their availability to us, or both.

We may encounter difficulties in managing our growth, which could adversely affect our operations.

We have experienced a period of rapid organizational growth. Our ability to manage our growth effectively depends upon the continual improvement of our processes and procedures, and the preservation of our corporate culture. We may not be able to implement improvements in an efficient or timely manner, or maintain our corporate culture through organizational change. If we do not meet these challenges, we may be unable to take advantage of market opportunities, execute our business strategies or respond to competitive pressures, which in turn may slow our growth or give rise to inefficiencies that would increase our losses or delay our programs.

We may acquire additional technology and complementary businesses in the future. Acquisitions involve many risks, any one of which could materially harm our business, including the diversion of management s attention from core business concerns, failure to exploit acquired technologies, or the loss of key employees from either our business or the acquired business.

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

Our condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these condensed 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 the accrual of research and development expenses and revenue recognition. 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.

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If we are not able to maintain effective internal controls 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 controls, and requires our independent auditors to attest to the effectiveness of our internal controls. Any failure by us to maintain the effectiveness of our internal controls in accordance with the requirements of Section 404 of the Sarbanes-Oxley Act, as such requirements exist today or may be modified, supplemented or amended in the future, could have a material adverse effect on our business, operating results and stock price.

Risks Related to the Development and Commercialization of Our Drug Candidates

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

To date, we have not obtained approval from the U.S. Food and Drug Administration, or FDA, or any foreign regulatory authority to market or sell any of our drug candidates. Our success depends primarily upon our, and our strategic alliance partners , ability to develop and commercialize our drug candidates successfully. Our most advanced drug candidate is IPI-504, which is currently in several early-to-mid-stage clinical trials, and our next most advanced drug candidate is IPI-493, for which we commenced our first clinical trial in July 2008. We also commenced our first clinical trial of IPI-926 in October 2008 and have other drug candidates in various stages of preclinical development and discovery research.

Our drug candidates are subject to extensive governmental regulations relating to development, clinical trials, manufacturing and commercialization. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process are required in the United States and in many foreign jurisdictions prior to the commercial sale of medicinal products like our drug candidates. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that none of the drug candidates we are developing, or may in the future develop, either alone or in collaboration with strategic alliance partners, will obtain marketing approval. In connection with the clinical trials of IPI-504, IPI-493, IPI-926 and any other drug candidate we may seek to develop in the future, we face, among other risks, risks that:

- the drug candidate may not prove to be safe or effective;
- the results of later trials may not confirm positive results from earlier preclinical studies or clinical trials, as was the case with our Phase 3 clinical trial of IPI-504 in GIST; and
- the results may not meet the level of statistical significance required by the FDA or other regulatory authorities.

We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA and comparable foreign regulatory agencies. The time required to complete clinical trials and for regulatory review by the FDA and other countries regulatory agencies is uncertain and typically takes many years. Some of our drug candidates may be eligible for the FDA s programs that are designed to facilitate the development and expedite the review of certain drugs, but we cannot provide any assurance that any of our drug candidates will qualify for one or more of these programs. Even if a drug candidate qualifies for one or more of these programs, the FDA may later decide that the drug candidate no longer meets the conditions for qualification.

Our analysis of data obtained from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unanticipated delays or increased costs due to changes in government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. For example, the Food and Drug Administration Amendments Act of 2007, or FDAAA, may make it more difficult and costly for us to obtain regulatory approval of our drug candidates and to produce, market and distribute products after approval. The FDAAA granted a variety of new powers to the FDA, many of which are aimed at improving the safety of drug products before and after approval. In particular, it authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information, and require risk evaluation and mitigation strategies for certain drugs. In addition, it significantly expanded the federal government s clinical trial registry and results databank and creates new restrictions on the advertising and promotion of drug products. Under the FDAAA, companies that violate the new law are subject to substantial civil monetary penalties.

Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability to generate revenues from the particular drug candidate. Furthermore, the uses for which any regulatory authority may grant approval to market a product may be limited, thus placing limitations on the manner in which we may market the product and limiting its market potential.

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

We cannot predict whether we will encounter problems with any of our ongoing or planned clinical trials that will cause us or regulatory authorities to delay or suspend clinical trials, as was the case with our decision to close our Phase 3 clinical trial of IPI-504 in GIST, or to delay the analysis of data from ongoing clinical trials. Any of the following could delay the clinical development of our drug candidates:

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

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delays in receiving, or the inability to obtain, required approvals from institutional review boards or other reviewing entities at clinical sites selected for participation in our clinical trials;

delays in enrolling patients into clinical trials;

a lower than anticipated retention rate of patients in clinical trials;

the need to repeat clinical trials as a result of inconclusive or negative results or unforeseen complications in testing;

inadequate supply or deficient quality of drug product or other materials necessary to conduct our clinical trials;

unfavorable FDA inspection and review of a clinical trial site or records of any clinical or preclinical investigation;

serious and unexpected drug-related side effects experienced by participants in our clinical trials;

a finding that the trial participants are being exposed to unacceptable health risks;

the placement by the FDA 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 drug candidate not commercially viable.

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

the size of the patient population;

the nature of the trial protocol;

the number of clinical trial sites and the proximity of patients to those sites;

the availability of effective treatments for the relevant disease;

the eligibility criteria for the trial;

the commitment of clinical investigators to identify eligible patients; and

competing studies or trials.

Delays in patient enrollment can result in increased costs and longer development times. Our failure to enroll patients in our clinical trials could delay the completion of the clinical trial beyond current expectations. In addition, the FDA could require us to conduct clinical trials with a larger number of subjects than has been projected for any of our drug 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 drug 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 drug candidate; and

the availability of numerous alternative treatment options that may induce patients to discontinue their participation in the trial.

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

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

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

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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 duties or meet expected deadlines, we may be required to replace them. Replacing a third party contractor may result in a delay of the affected trial and unplanned costs. If this were to occur, our efforts to obtain regulatory approval for and to commercialize our drug candidates may be delayed.

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

Manufacturing difficulties could delay or preclude commercialization of our drug candidates and substantially increase our expenses.

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

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

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

A natural product is utilized in the production of IPI-926. This product is currently supplied from naturally available plant material. Our ability to acquire and process sufficient amounts of plant material to meet our manufacturing requirements is subject to a number of risks, including the receipt of permits from federal and state authorities, adverse weather conditions or natural disasters that may impact plant availability or our ability to harvest it. In addition, we may be unsuccessful in identifying other locations where this plant naturally occurs or establishing a sustainable method for growing this plant in a controlled environment. A material shortage of this plant could adversely impact or disrupt the manufacture of IPI-926, thus impacting our clinical trial activities and, if IPI-926 is successfully developed, our ability to satisfy commercial demand for the product, thus adversely affecting our financial position and results of operations.

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We have certain commercialization rights to our oncology product portfolio, but we currently have limited marketing and sales experience and capabilities.

We currently have commercialization rights in the United States for products arising out of our all of our programs, except the FAAH program, and worldwide commercialization rights for our Hsp90 chaperone inhibitor program, including IPI-504 and IPI-493. Additionally, we have the right to co-detail in the United States any products arising from our Bcl-2 collaboration with Novartis. In order to successfully commercialize our drug candidates, we will need to establish adequate marketing and sales capabilities. We may not successfully establish these capabilities or have sufficient resources to do so. If we do not establish adequate marketing and sales capabilities, our ability to successfully commercialize any drug candidates that we successfully develop will be adversely affected, as will our financial condition and results of operations. Even if we do develop such capabilities, we will compete with other companies that have experienced and well-funded marketing and sales operations, and we will incur additional expenses.

If physicians and patients do not accept our future drugs, we may not be able to generate significant revenues from product sales.

Even if any of our drug candidates obtains regulatory approval, that product may not gain market acceptance among physicians, patients 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 drugs;
- lower demonstrated clinical safety and efficacy compared to other drugs;
- lack of cost-effectiveness;
- lack of reimbursement from managed care plans and other third-party payors;
- inconvenient or difficult administration;
- prevalence and severity of side effects;
- potential advantages of alternative treatment methods;
- safety concerns with similar drugs marketed by others;
- the reluctance of the target population to try new therapies and of physicians to prescribe those therapies;
- the success of our physician education programs; and

ineffective sales, marketing and distribution support.

If any of our approved drugs fails to achieve market acceptance, we would not be able to generate significant revenue from those drugs or achieve profitability.

Even if we receive regulatory approvals for marketing our drug candidates, we could lose our regulatory approvals and our business would be adversely affected if we, our collaborators, or our contract manufacturers fail to comply with continuing regulatory requirements.

The FDA continues to review products even after they receive initial approval. If we receive approval to commercialize any of our drug candidates, the manufacturing, marketing and sale of these drugs will be subject to continuing regulation, including compliance with quality systems regulations, good manufacturing practices, adverse event requirements, and prohibitions on promoting a product for unapproved uses. Enforcement actions resulting from our failure to comply with government and regulatory requirements could result in fines, suspension of approvals, withdrawal of approvals, product recalls, product seizures, mandatory operating restrictions, criminal prosecution, civil penalties and other actions that could impair the manufacturing, marketing and sale of our drug candidates and our ability to conduct our business.

If our drug candidates exhibit harmful side effects after approval, our regulatory approvals could be revoked or otherwise negatively impacted, and we could become subject to costly and damaging product liability claims.

Even if we receive regulatory approval for any of our drug candidates, we will have tested them in only a small number of patients during our clinical trials. If our applications for marketing are approved and more patients begin to use our products, new risks and side effects associated with our products may be discovered. In addition, supplemental clinical trials that may be conducted on a drug following its initial approval may produce findings that are inconsistent with the trial results previously submitted to regulatory authorities. As a result, regulatory authorities may revoke their approvals, or we may be required to conduct additional clinical trials, make changes in labeling of our product, reformulate our product or make changes and obtain new approvals for our and our suppliers manufacturing facilities. We also might have to withdraw or recall our products from the marketplace. Any safety concerns with respect to a product may also result in a significant drop in the potential sales of that product, damage to our reputation in the marketplace, or result in us 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.

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Any drugs we develop may become subject to unfavorable pricing regulations or third-party reimbursement practices, thereby harming our business.

Our ability to commercialize any products successfully also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. In the United States and in foreign jurisdictions, there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the healthcare system. For example, in some countries other than the United States, pricing of prescription drugs is subject to government control, and we expect proposals to implement similar controls in the United States to continue. The pendency or approval of such proposals could result in a decrease in our stock price or limit our ability to raise capital or to enter into collaborations or license rights to our drug candidates.

Even if we succeed in bringing one or more products to the market, these products may not be considered cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis. Because our programs are in the early stages of development, we are unable at this time to determine their cost effectiveness or the likely level or method of reimbursement. Increasingly, the third-party payors who reimburse patients, such as government and private insurance plans, are requiring that drug companies provide them with predetermined discounts from list prices, and are seeking to reduce the prices charged for pharmaceutical products. If the price we are able to charge for any products we develop is inadequate in light of our development and other costs, our profitability could be adversely affected.

There may be significant delays in obtaining coverage for newly-approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA. Moreover, eligibility for coverage does not imply that any drug will be reimbursed in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement may be based on payments allowed for lower-cost drugs that are already reimbursed, may be incorporated into existing payments for other services and may reflect budgetary constraints or imperfections in Medicare data. Net prices for drugs may be reduced by mandatory discounts or rebates required by government health care programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for new drugs that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

Federal legislation may increase the pressure to reduce prices of pharmaceutical products paid for by Medicare, which could adversely affect our revenues, if any.

The Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA, expanded Medicare coverage for drug purchases by the elderly and disabled beginning in 2006. The legislation provides for the use of formularies, preferred drug lists and similar mechanisms that may limit the number of drugs that will be covered in any therapeutic class or reduce the reimbursement for some of the drugs in a class. As a result of the expansion of legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce healthcare-related costs. Indeed, legislation that would permit the federal government to negotiate drug prices directly with manufacturers under the Medicare prescription drug programs is a major policy priority for many members of Congress and may be passed in the future. These cost reduction initiatives could decrease the coverage and price that we receive for any products that we may develop in the future and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement systems, and any limits on or reductions in reimbursement that occur in the Medicare programs may result in similar limits on or reductions in payments from private payors.

New federal laws or regulations on drug importation could make lower cost versions of our future products available, which could adversely affect our revenues, if any.

The prices of some drugs are lower in other countries than in the United States because of government price regulation and market conditions. Under current law, importation of drugs into the United States is generally not permitted unless the drugs are approved in the United States and the entity that holds that approval consents to the importation. Various proposals have been advanced to permit the importation of drugs from other countries to provide lower cost alternatives to the products available in the United States. If the laws or regulations are changed to permit more widespread importation of drugs into the United States than is currently permitted, such a change could have an adverse effect on our business by making available lower priced alternatives to our future products.

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Failure to obtain regulatory and pricing approvals in foreign jurisdictions could delay or prevent commercialization of our products abroad.

In order for us or our strategic alliance partners to market our drug candidates outside of the United States, separate regulatory approvals must be obtained and we or our alliance partners will need to comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval abroad may differ from and be longer than that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval and additional risks associated with requirements particular to those foreign jurisdictions where we will seek regulatory approval of our products. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We and our alliance partners may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market outside the United States. The failure to obtain these approvals could materially adversely affect our business, financial condition and results of operations.

Our business could be harmed if we are unable to comply with applicable fraud and abuse and other laws and regulations where our drug candidates may ultimately be sold.

As our pipeline of drug candidates matures, we are becoming increasingly subject to extensive and complex laws and regulations, including but not limited to health care fraud and abuse laws, such as the federal false claims act, the federal anti-kickback statute, and other state and federal laws and regulations. A number of states, most notably Massachusetts and Vermont, have also passed legislation relating to interactions between biopharmaceutical companies and healthcare providers. We are developing and implementing a corporate compliance program designed to ensure that we will market and sell any drug candidates that we successfully develop in compliance with all applicable U.S. 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.

Risks Related to Our Field

Our competitors and potential competitors may develop products that make ours less attractive or obsolete.

We seek to develop new drugs for cancer and related conditions. The cancer therapeutic segment of the pharmaceutical industry is highly competitive and rapidly changing. 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 forms of cancer. We currently face, and expect to continue to face, intense and increasing competition as new products enter the market and advanced technologies become available. Moreover, there are a number of large pharmaceutical companies currently marketing and selling products to treat cancer, including Bristol-Myers Squibb Company, F. Hoffmann-La Roche Ltd. and its subsidiary Genentech, Novartis Pharma AG and Pfizer, Inc. In addition to currently approved drugs, there are a significant number of drugs that are currently under development and may become available in the future for the treatment of various forms of cancer. We are also aware of a number of companies seeking to develop drug candidates directed to the same biological targets that our own drug candidates are designed to inhibit. Specifically, we are aware of numerous companies that have clinical development programs for compounds targeting Hsp90, which is the target of IPI-504 and IPI-493. These companies include, without limitation, Bristol-Myers Squibb, Biogen Idec Inc., Pfizer, Vernalis plc (in collaboration with Novartis), Synta Pharmaceuticals Corp., Exelixis, Inc., Astex Therapeutics Limited and Myriad Pharmaceuticals, Inc. In addition, Genentech (in collaboration with Curis, Inc.), Bristol-Myers Squibb (through its collaboration with Exelixis, Inc.), Pfizer and Novartis are developing drugs targeting the Hedgehog signaling pathway, which is also being targeted by IPI-926. Finally, we believe that each of Pfizer, and sanofi-aventis llc are developing inhibitors of FAAH.

Many of our competitors have:

- significantly greater financial, technical and human resources than us, and may be better equipped to discover, develop, manufacture and commercialize drug candidates;

- more extensive experience in preclinical testing and clinical trials, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products; and/or

drug candidates that have been approved or are in later-stage clinical development than our own drug candidates.

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 strategic alliance partners may for our own drug candidates. These competitive products may have superior safety or efficacy, have more attractive pharmacologic properties, or may be manufactured less expensively than our drug candidates. If we are unable to compete effectively against these companies on the basis of safety, efficacy or cost, then we may not be able to commercialize our drug candidates or achieve a competitive position in the market. This would adversely affect our ability to generate revenues.

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

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

We work with hazardous materials that may expose us to liability.

Our activities involve the controlled storage, use and disposal of hazardous materials, including infectious agents, corrosive, explosive and flammable chemicals, various radioactive compounds, and compounds known to cause birth defects. We are subject to certain federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. We incur significant costs to comply with these laws and regulations. In addition, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, regulatory authorities may curtail our use of these materials, and we could be liable for any civil damages that result. These damages may exceed our financial resources or insurance coverage, and may seriously harm our business. Additionally, an accident could damage, or force us to shut down, our operations.

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.

Risks Related to Intellectual Property

Our success depends substantially upon our ability to obtain and maintain intellectual property protection for our drug candidates.

We own or hold exclusive licenses to a number of U.S. and foreign patents and patent applications directed to our drug candidates. Our success depends on our ability to obtain patent protection both in the United States and in other countries for our drug candidates, their methods of manufacture and methods of their use. Our ability to protect our drug candidates from unauthorized or infringing use by third parties depends substantially on our ability to obtain and enforce our patents. Our lead oral Hsp90 candidate, IPI-493, contains an active pharmaceutical ingredient for which we believe composition of matter protection is unavailable. Consequently, we have filed patent applications directed to IPI-493 and other novel formulations of this active pharmaceutical ingredient, as well as methods of their use, which may not provide the same level of protection as composition of matter patent protection on the active pharmaceutical ingredient itself.

Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions 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 which the United States Patent and Trademark Office, or PTO, and its foreign counterparts use to grant patents are not always applied predictably or uniformly and are subject to change. To date, no consistent policy has emerged regarding the breadth of claims allowed in pharmaceutical 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. In addition, the U.S. Congress has considered, and may consider in the future, legislation that could change United States law regarding, among other things, post-grant review of issued patents and the calculation of damages once patent infringement has been determined by a court of law. If enacted into law, these provisions could severely weaken patent protection in the United States.

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If we do not obtain adequate intellectual property protection for our products in the United States, competitors could duplicate them without repeating the extensive testing that we had been required to undertake to obtain approval of the products 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 at least 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 of products that duplicate our products.

The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States. Many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. Some of our development efforts are 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 appropriately protect this intellectual property and could thus 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 strategic alliance partners, vendors, employees, consultants, 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. As a result, our ownership of key intellectual property could be compromised.

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

Patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the PTO for the entire time prior to issuance as a U.S. patent. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Consequently, we cannot be certain that we were the first to invent, or the first to file patent applications on, our drug candidates or their therapeutic use. In the event that a third party has also filed a U.S. patent application relating to our drug candidates or a similar invention, we may have to participate in interference proceedings declared by the PTO or the third party to determine priority of invention in the United States. For example, we are aware of third parties who are actively researching ansamycin analogs that are similar to IPI-504. These third parties have pending applications related to these analogs, but we have the first published application covering IPI-504. Notwithstanding the fact that we filed the first patent application related to these analogs, it is possible that an interference proceeding could be declared between our application covering IPI-504 and one or more of these third party applications, even the one of those applications for which we have secured a license. An adverse decision in an interference proceeding may result in the loss of rights under a patent or patent application. In addition, the cost of interference proceedings could be substantial.

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

Our commercial success will depend on whether there are third party patents or other intellectual property relevant to our potential products that may block or hinder our ability to develop and commercialize our drug candidates. We may not have identified all U.S. and foreign patents or published applications that may affect our business either by blocking our ability to manufacture or commercialize our drugs or by covering similar technologies that affect the applicable market. In addition, we may undertake research and development with respect to potential products, even when we are aware of third party patents that may be relevant to such potential products, on the basis that we may challenge or license such patents. For example, in our Hsp90 chaperone inhibitor program, we have initiated clinical trials evaluating the administration of IPI-504 in combination with each of trastuzumab and docetaxel, and we may conduct additional trials with IPI-504 in combination with other therapeutic agents. We are aware of issued patents and published applications directed to combinations of Hsp90 chaperone inhibitors with a variety of other therapeutic agents. We are also aware of patents and patent applications directed to methods of treating various disorders using a variety of Hsp90 chaperone inhibitors. We are in the process of evaluating the scope and validity of these patents and applications to determine whether we need to obtain one or more licenses.

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

- pay substantial damages;
- stop developing, manufacturing and/or commercializing the infringing drug candidates or approved products;
- develop non-infringing products, 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 this were to occur, we may be unable to commercialize the affected products, or we may elect to cease certain of our business operations, either of which could severely harm our business.

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

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

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

In order to protect our proprietary technology, we rely in part on confidentiality agreements with our vendors, strategic alliance partners, 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 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.

If we fail to obtain necessary or useful licenses to intellectual property, we could encounter substantial delays in the research, development and commercialization of our drug candidates.

We may decide to license third-party technology that we deem necessary or useful for our business. We may not be able to obtain these licenses at a reasonable cost, or at all. If we do not obtain necessary licenses, we could encounter substantial delays in developing and commercializing our drug candidates while we attempt to develop alternative technologies, methods and drug candidates, which we may not be able to accomplish. Furthermore, if we fail to comply with our obligations under our third party license agreements, we could lose license rights that are important to our business.

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Risks Associated with Our Common Stock

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

The market price of our common stock could 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-504, IPI-493 and IPI-926 and our other drug candidates;
- the results of preclinical studies and planned clinical trials of our other discovery-stage programs;
- future sales of, and the trading volume in, our common stock;
- the entry into key agreements, including those related to the acquisition or in-licensing of new programs, or the termination of key agreements;
- the results and timing of regulatory reviews relating to the approval of our drug candidates;
- the initiation of, material developments in, or conclusion of litigation to enforce or defend any of our intellectual property rights;
- the initiation of, material developments in, or conclusion of litigation to defend product liability claims;
- the failure of any of our drug candidates, if approved, to achieve commercial success;
- the results of clinical trials conducted by others on drugs that would compete with our drug candidates;
- issues in manufacturing our drug candidates or any approved products;
- the loss of key employees;
- changes in estimates or recommendations by securities analysts who cover our common stock;
- future financings through the issuance of equity or debt securities or otherwise;
- changes in the structure of health care payment systems;

our cash position and period-to-period fluctuations in our financial results; and

general and industry-specific economic 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.

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

We anticipate retaining any future earnings for reinvestment in our research and development programs. 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 stockholder rights plan, anti-takeover provisions in our organizational documents, and Delaware law may make an acquisition of us difficult.

We are a party to a stockholder rights plan, also referred to as a poison pill, which is intended to deter a hostile takeover by making any proposed acquisition of us more expensive and less desirable to the potential acquirer.

In addition, 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 901,000 shares of currently 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 by-laws 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.

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Under Section 203 of the Delaware General Corporation Law, a corporation may not engage in a business combination with any holder of 15% or more of its capital stock until the holder has held the stock for three years unless, among other possibilities, the board of directors approves the transaction. Our board of directors could use this provision to vote against any such transaction. 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 officers, directors and major shareholders may be able to exert significant control over the company, which may make an acquisition of us difficult.

Our executive officers, directors, certain affiliates and other major shareholders control approximately 40% of our outstanding common stock and have the ability to influence the 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 determine the outcome of matters submitted to our stockholders for approval, including the election and removal of directors 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.

Item 6. Exhibits

(a) Exhibits.

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

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

INFINITY PHARMACEUTICALS, INC.

Date: November 9, 2009

By: /s/ ADELENE Q. PERKINS
Adelene Q. Perkins
President & Chief Business Officer
(Principal Financial Officer)

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EXHIBIT INDEX

Exhibit	Description
3.1	Restated Certificate of Incorporation of the Registrant. Previously filed as Exhibit 3.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (File No. 000-31141) and incorporated herein by reference.
3.2	Amended and Restated Bylaws of the Registrant. Previously filed as Exhibit 3.1 to the Registrant s Current Report on Form 8-K filed on March 17, 2009 (File No. 000-31141) and incorporated herein by reference.
4.1	Form of Common Stock Certificate. Previously filed as Exhibit 4.1 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2007 (File No. 000-31141) and incorporated herein by reference.
4.2	Rights Agreement between the Registrant and American Stock Transfer & Trust Company dated February 13, 2003, which includes the form of Certificate of Designation for the Series A junior participating preferred stock as Exhibit A, the form of Rights Certificate as Exhibit B and the Summary of Rights to Purchase Series A junior participating preferred stock as Exhibit C. Previously filed as Exhibit 4.2 to the Registrant s Current Report on Form 8-K filed on February 24, 2003 (File No. 000-31141) and incorporated herein by reference.
4.3	First Amendment to the Rights Agreement between the Registrant and American Stock Transfer & Trust Company dated April 11, 2006. Previously filed as Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed on April 12, 2006 (File No. 000-31141) and incorporated herein by reference.
4.4	Second Amendment to the Rights Agreement between the Registrant and American Stock Transfer & Trust Company, LLC dated November 19, 2008. Previously filed as Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed on November 20, 2008 (File No. 000-31141) and incorporated herein by reference.
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended. Filed herewith.
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended. Filed herewith.
32.1	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Filed herewith.
32.2	Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Filed herewith.