

INFINITY PHARMACEUTICALS, INC.

Form 10-Q

August 09, 2007

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2007

OR

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

For the transition period from _____ to _____.

Commission file number 000-31141

INFINITY PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of

incorporation or organization)

780 Memorial Drive, Cambridge, Massachusetts 02139

33-0655706
(I.R.S. Employer

Identification No.)

(Address of principal executive offices) (zip code)

Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

(617) 453-1000

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer

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

Number of shares of the registrant's Common Stock, \$0.001 par value, outstanding on June 30, 2007: 19,671,121

Table of Contents

INFINITY PHARMACEUTICALS, INC.

FORM 10-Q

FOR THE QUARTER ENDED JUNE 30, 2007

TABLE OF CONTENTS

	Page No.
PART I	
<u>FINANCIAL INFORMATION</u>	3
Item 1.	
<u>Condensed Consolidated Financial Statements</u>	3
<u>Condensed Consolidated Balance Sheets as of June 30, 2007 and December 31, 2006</u>	3
<u>Condensed Consolidated Statements of Operations for the Three and Six Months Ended June 30, 2007 and 2006</u>	4
<u>Condensed Consolidated Statements of Cash Flows for the Three and Six Months ended June 30, 2007 and 2006</u>	5
<u>Notes to Condensed Consolidated Financial Statements</u>	6
Item 2.	
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	13
Item 3.	
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	21
Item 4.	
<u>Controls and Procedures</u>	22
PART II	
<u>OTHER INFORMATION</u>	23
Item 1A.	
<u>Risk Factors</u>	23
Item 2.	
<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	34
Item 4.	
<u>Submission of Matters to a Vote of Security Holders</u>	34
Item 6.	
<u>Exhibits</u>	35
<u>Signatures</u>	36

Table of Contents**PART I. FINANCIAL INFORMATION**

Item 1. Condensed Consolidated Financial Statements
INFINITY PHARMACEUTICALS, INC.
Condensed Consolidated Balance Sheets

	June 30, 2007 (unaudited)	December 31, 2006
Assets		
Current assets:		
Cash and cash equivalents	\$ 16,754,384	\$ 74,147,479
Available-for-sale securities	105,585,492	27,549,305
Accounts receivable	434,034	1,409,646
Unbilled accounts receivable	4,884,188	40,725,164
Notes receivable from employees	73,457	87,257
Prepaid expenses and other current assets	2,206,388	2,179,702
Total current assets	129,937,943	146,098,553
Property and equipment, net	7,142,354	6,539,930
Notes receivable from employees	69,928	104,642
Restricted cash	1,619,179	1,578,699
Other assets	226,253	326,058
Total assets	\$ 138,995,657	\$ 154,647,882
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	\$ 643,739	\$ 892,184
Accrued expenses	5,804,284	8,829,206
Deferred revenue	13,750,000	13,750,000
Current portion of long-term debt and capital leases	846,795	1,362,930
Total current liabilities	21,044,818	24,834,320
Deferred revenue, less current portion	57,916,667	64,791,667
Other liabilities	2,160,625	2,222,735
Long-term debt and capital leases, less current portion	52,357	374,205
Total liabilities	81,174,467	92,222,927
Stockholders equity:		
Preferred Stock, \$.001 par value; 1,000,000 shares authorized, no shares issued and outstanding at June 30, 2007 and December 31, 2006		
Common Stock, \$.001 par value; 100,000,000 shares authorized, and 19,671,121 shares issued and outstanding, at June 30, 2007; 100,000,000 shares authorized, and 19,523,243 shares issued and outstanding, at December 31, 2006		
	19,671	19,523
Additional paid-in capital	220,452,627	219,110,907
Accumulated deficit	(162,697,910)	(155,305,106)
Treasury stock, at cost		(1,323,810)

Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

Accumulated other comprehensive gain (loss)	46,802	(76,559)
Total stockholders' equity	57,821,190	62,424,955
Total liabilities and stockholders' equity	\$ 138,995,657	\$ 154,647,882

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

Table of Contents**INFINITY PHARMACEUTICALS, INC.****Condensed Consolidated Statements of Operations***(unaudited)*

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2007	2006	2007	2006
Collaborative research and development revenue	\$ 5,654,170	\$ 2,818,695	\$ 11,769,920	\$ 3,537,445
Operating expenses:				
Research and development	8,186,976	8,824,946	15,663,379	18,502,965
General and administrative	3,237,390	1,385,653	6,530,421	3,358,353
Total operating expenses	11,424,366	10,210,599	22,193,800	21,861,318
Loss from operations	(5,770,196)	(7,391,904)	(10,423,880)	(18,323,873)
Other (expense) income:				
Interest expense	(29,222)	(212,173)	(131,688)	(354,053)
Interest and investment income	1,639,595	208,407	3,506,037	402,651
Net other income (expense)	1,610,373	(3,766)	3,374,349	48,598
Net loss	\$ (4,159,823)	\$ (7,395,670)	\$ (7,049,531)	\$ (18,275,275)
Basic and diluted net loss per common share	\$ (0.21)	\$ (3.04)	\$ (0.36)	\$ (7.57)
Basic and diluted weighted average number of common shares outstanding	19,505,672	2,435,095	19,438,731	2,413,245

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

Table of Contents**INFINITY PHARMACEUTICALS, INC.****Condensed Consolidated Statements of Cash Flows***(unaudited)*

	Six Months Ended June 30, 2007	Six Months Ended June 30, 2006
Operating activities		
Net loss	\$ (7,049,531)	\$ (18,275,275)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	1,403,615	1,706,552
Stock-based compensation	2,332,284	825,374
Loan forgiveness	52,229	62,652
Gain on sale of property and equipment	(11,107)	
Net accretion of available-for-sale securities	(1,653,160)	(48,088)
Amortization of warrants	29,712	52,633
Interest income on restricted cash	(40,480)	(31,380)
Interest income on employee loans	(2,061)	(3,662)
Changes in operating assets and liabilities:		
Accounts receivable and unbilled accounts receivable	36,816,588	(1,881,195)
Prepaid expenses and other assets	57,649	(1,629,397)
Accounts payable	(248,445)	417,684
Accrued expenses and other liabilities	(3,359,544)	(530,086)
Deferred revenue	(6,875,000)	13,750,000
Net cash provided by (used in) operating activities	21,452,749	(5,584,188)
Investing activities		
Purchases of property and equipment	(2,009,932)	(470,648)
Proceeds from sale of property and equipment	15,000	
Purchases of available-for-sale securities	(121,791,942)	(1,697,286)
Sales and maturities of available-for-sale securities	45,532,276	1,499,998
Net cash used in investing activities	(78,254,598)	(667,936)
Financing activities		
Proceeds from sale of Series D Convertible Preferred Stock		5,000,000
Proceeds from issuances of common stock	262,633	65,992
Repurchase of common stock		(4,986)
Proceeds from equipment loan and other debt		15,000,000
Payments on equipment loan and other debt	(821,014)	(2,040,570)
Capital lease payments	(31,213)	(70,626)
Repayment of employee loans	8,348	2,133
New employee loans	(10,000)	(95,000)
Net cash (used in) provided by financing activities	(591,246)	17,856,943
Net (decrease) increase in cash and cash equivalents	(57,393,095)	11,604,819
Cash and cash equivalents at beginning of period	74,147,479	9,442,756
Cash and cash equivalents at end of period	\$ 16,754,384	\$ 21,047,575
Supplemental cash flow disclosure		
Interest paid	\$ 119,764	\$ 316,892

Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

Income taxes paid \$ 1,100,000 \$

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

Table of Contents

Infinity Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Organization

On September 12, 2006, we completed our reverse merger in which a wholly-owned subsidiary of Discovery Partners International, Inc., or DPI, merged with Infinity Pharmaceuticals, Inc., or IPI, such that IPI became a wholly-owned subsidiary of DPI. We refer to this transaction as the merger. Immediately following the merger, IPI changed its name to Infinity Discovery, Inc., which we refer to as Old Infinity. In addition, DPI changed its name to Infinity Pharmaceuticals, Inc., or Infinity, and its ticker symbol on the NASDAQ Global Market to INFI. As used throughout these unaudited, condensed consolidated financial statements, Infinity, we, us, or our refers to the business of the combined company after the merger and the business of Old Infinity prior to the merger. As used throughout these unaudited, condensed consolidated financial statements, DPI refers to the business of Discovery Partners International, Inc. prior to completion of the merger.

Upon completion of the merger, Infinity common stock was issued to Old Infinity stockholders, and Infinity assumed all of the stock options, stock warrants and restricted stock of Old Infinity outstanding as of September 12, 2006. Immediately following the closing of the merger, former Old Infinity stockholders, option holders and warrant holders owned approximately 69% of the combined company on a fully-diluted basis and former DPI stockholders, option holders and warrant holders owned approximately 31% of the combined company on a fully-diluted basis. In addition, after completion of the merger, the business conducted by the combined company became the one operated by Old Infinity prior to completion of the merger.

Since former Old Infinity security holders owned, immediately following the merger, approximately 69% of the combined company on a fully-diluted basis and as a result of certain other factors, including that former Old Infinity directors constituted a majority of the combined company's board of directors and all members of the combined company's executive management were from Old Infinity, Old Infinity was deemed to be the acquiring company for accounting purposes and the transaction was accounted for as a reverse acquisition of assets and a recapitalization in accordance with accounting principles generally accepted in the United States. These financial statements reflect the historical results of Old Infinity prior to the merger and that of the combined company following the merger, and do not include the historical financial results of DPI prior to the completion of the merger. Stockholders' equity has been retroactively restated to reflect the number of shares of common stock received by former Old Infinity security holders in the merger, after giving effect to the difference between the par values of the capital stock of Old Infinity and Infinity common stock, with the offset to additional paid-in capital. In addition, the pre-merger financial information has been restated to reflect the 1-for-4 reverse split of DPI common stock that became effective immediately prior to the closing of the merger, the closing of the merger, and the related conversion of all of the capital stock of Old Infinity into Infinity common stock.

Infinity 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.

2. Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring accruals and revisions of estimates, considered necessary for a fair presentation of the accompanying condensed consolidated financial statements have been included. Interim results for the three and six months ended June 30, 2007 are not necessarily indicative of the results that may be expected for the year ending December 31, 2007. 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, 2006, which was filed with the U.S. Securities and Exchange Commission (SEC) on March 14, 2007.

The information presented in the condensed consolidated financial statements and related footnotes at June 30, 2007, and for the three and six months ended June 30, 2007 and 2006, is unaudited and the condensed consolidated balance sheet amounts and related footnotes at December 31, 2006 have been derived from our audited financial statements.

3. Significant Accounting Policies

Cash Equivalents and Available-For-Sale Securities

Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

Cash equivalents and available-for-sale securities primarily consist of money market funds, asset-backed securities, corporate obligations and U.S. government agency obligations. 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 money market funds, are stated at cost, which approximates market value.

Table of Contents

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 June 30, 2007 and December 31, 2006 as available-for-sale. We carry available-for-sale securities at fair value, with the unrealized gains and losses reported in a separate component of stockholders' equity. The fair value of these securities is based on quoted market prices.

We adjust the cost of 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. Realized gains and losses and declines in value, if any, that we judge to be other-than-temporary on available-for-sale securities are reported 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 investment income. There are no realized gains or losses for the three and six months ended June 30, 2007 and 2006.

Reclassifications

Certain prior year amounts in net cash provided by operating activities and net cash used in investing activities have been reclassified to conform to the current year presentation. This reclassification has no impact on previously reported financial position or net loss.

Segment Information

Statement of Financial Accounting Standards (SFAS) No. 131, *Disclosures About Segments of an Enterprise and Related Information* (SFAS 131), establishes standards for the way that companies report information about operating segments in their financial statements. SFAS No. 131 also establishes standards for related disclosures about products and services. 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. During the periods presented:

revenues associated with the up-front license fees, reimbursable research and development services and compound delivery fees we received from Novartis Institutes for BioMedical Research, Inc. (Novartis) and Novartis International Pharmaceutical Ltd. (Novartis International) accounted for approximately 56% and 100% of our revenue for the three months ended June 30, 2007 and 2006, respectively, and 58% and 100% of our revenue for the six months ended June 30, 2007 and 2006, respectively, and

revenues associated with the up-front license fee we received from MedImmune, Inc. (MedImmune) accounted for approximately 44% of our revenue for the three months ended June 30, 2007 and 42% of our revenue for the six months ended June 30, 2007.

Further, payments due from Novartis represented 100% of our accounts receivable balance as of June 30, 2007. Payments from MedImmune and Novartis represented 68% and 32%, respectively, of our accounts receivable balance as of December 31, 2006. Payments from MedImmune and Novartis represented 69% and 31%, respectively, of our unbilled accounts receivable balance as of June 30, 2007. Payments from MedImmune and Novartis represented 93% and 7%, respectively, of our unbilled accounts receivable balance as of December 31, 2006.

Basic and Diluted Net Loss per Common Share

Basic net loss per share is based upon the weighted average number of common shares outstanding during the period, excluding restricted stock that has been issued but is not yet vested. Diluted net loss per share is based upon the weighted average number of common shares outstanding during the period, plus the effect of additional weighted average common equivalent shares outstanding during the period when the effect of adding such shares is dilutive. Common equivalent shares result from the assumed exercise of outstanding stock options (the proceeds of which are then assumed to have been used to repurchase outstanding stock using the treasury stock method), the assumed conversion of preferred stock, the exercise of outstanding warrants and the vesting of restricted shares of common stock. Common equivalent shares have not been included in the net loss per share calculations because the effect of including them would have been anti-dilutive. Total potential gross common equivalent shares consisted of the following:

At June 30,

Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

	2007	2006
Preferred stock		10,038,222
Stock options	3,079,059	1,206,754
Warrants to purchase common stock	246,629	260,376
Unvested restricted shares	115,594	294,149

Table of Contents

Stock-Based Compensation Expense

We adopted SFAS No. 123(R), *Share-Based Payment* (SFAS No. 123(R)), as of January 1, 2006. SFAS No. 123(R) requires companies to expense the fair value of employee stock options and other equity compensation. We apply the recognition provisions of SFAS No. 123(R) and Emerging Issues Task Force (EITF) No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring or in Connection with Selling Goods or Services* (EITF No. 96-18) for all stock option grants to non-employees.

Revenue Recognition

To date, all of our revenue has been generated under research collaboration agreements and, accordingly, we recognize revenue in accordance with the SEC's Staff Accounting Bulletin (SAB) No. 101, *Revenue Recognition in Financial Statements*, as amended by SAB No. 104, *Revenue Recognition*, and EITF No. 00-21, *Revenue Arrangements With Multiple Deliverables*.

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 the residual method, and we apply the applicable revenue recognition criteria to each of the separate units.

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 and (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone. 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 of licensed products in licensed territories as provided by the licensee 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 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 related to these collaboration arrangements 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 will 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 is a cost-sharing arrangement; our collaboration with Novartis provides for the reimbursement of our research and development expenses.

Table of Contents***Accounting for Sabbatical Leave***

We adopted EITF 06-2, *Accounting for Sabbatical Leave and Other Similar Benefits Pursuant to FASB Statement No. 43* (EITF 06-2), on January 1, 2007. Under EITF 06-2, an employee's right to a compensated absence under a sabbatical or other similar benefit arrangement (a) that requires the completion of a minimum service period and (b) in which the benefit does not increase with additional years of service, accumulates pursuant to paragraph 6(b) of SFAS No. 43, *Accounting for Compensated Absences*, for arrangements in which the individual continues to be a compensated employee and is not required to perform duties for the entity during the absence. Therefore, the compensation cost associated with a sabbatical or other similar benefit arrangement should be accrued over the requisite service period. We applied EITF 06-2 as a change in accounting principle through a cumulative-effect adjustment to accumulated deficit.

Income Taxes

We adopted Financial Accounting Standards Board (FASB) Interpretation No. 48, *Accounting for Uncertainty in Income Taxes-an Interpretation of FASB Statement No. 109* (FIN 48), on January 1, 2007. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS No. 109, *Accounting for Income Taxes*. FIN 48 prescribes a 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. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. In accordance with FIN 48, we will recognize any interest and penalties related to unrecognized tax benefits in income tax expense.

New Accounting Pronouncements

In February 2007, FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS No. 159). SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The objective of SFAS No. 159 is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. We have not completed our evaluation of SFAS No. 159, but we do not currently believe that it will have a material impact on our financial position or results of operations.

In February 2007, the Emerging Issues Task Force of the FASB issued EITF 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (EITF 07-3). In EITF 07-3, the task force reached a consensus that nonrefundable advance payments for goods or services to be received in the future for use in research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services are performed. EITF 07-3 is effective for new contracts entered into during fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. We have not completed our evaluation of EITF 07-3, but we do not currently believe it will have a material impact on our results of operations or financial position.

4. Stock-Based Compensation***SFAS No. 123(R) Compensation Expense***

Under SFAS No. 123(R), share-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the employee's requisite service period. We have no awards with market or performance conditions. We adopted the provisions of SFAS No. 123(R) on January 1, 2006, using the modified prospective method. The provisions of SFAS No. 123(R) apply to new awards, unvested awards that were outstanding on the effective date, and awards subsequently modified or cancelled. Estimated compensation expense for unvested awards outstanding at the date of adoption will be recognized over the remaining service period on a straight-line basis using the compensation cost previously calculated for pro forma disclosure purposes under SFAS No. 123. Upon the adoption of SFAS No. 123(R), we elected to continue using the Black-Scholes valuation model to determine the fair value of equity awards.

In March 2006, we forgave certain outstanding nonrecourse loans that were given to certain of our employees in previous years in order for these employees to exercise stock options. This forgiveness constituted a modification of the awards under SFAS No. 123(R), and resulted in compensation expense of \$510,000, of which \$347,000 was recognized immediately since portions of the awards were vested. We recognized \$12,456 and \$26,054 of compensation expense related to these nonrecourse loans for the three months ended June 30, 2007 and 2006, respectively, and \$38,510 and \$373,054 of compensation expense for the six months ended June 30, 2007 and 2006, respectively.

Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

Total stock-based compensation expense, related to all equity awards, recognized under SFAS No. 123(R) for the three and six months ended June 30, 2007 and 2006 comprised the following (unaudited):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2007	2006	2007	2006
<i>Effect of stock-based compensation on net loss by line item:</i>				
Research and development	\$ 625,160	\$ 213,138	\$ 1,173,975	\$ 452,320
General and administrative	571,918	129,750	1,158,309	373,054

Table of Contents

As of June 30, 2007, there was approximately \$13.6 million of total unrecognized compensation cost, net of estimated forfeitures, related to unvested options and restricted stock granted, including \$46,328 of unrecognized compensation expense associated with the forgiveness of the nonrecourse loans. Total cost for all unrecognized compensation is expected to be recognized over a weighted-average period of 3.2 years.

As a result of the adoption of SFAS No. 123(R), our basic and diluted loss per share for the three months ended June 30, 2007 and 2006 is greater by \$0.06 and \$0.14, respectively, and for the six months ended June 30, 2007 and 2006 is greater by \$0.12 and \$0.34, respectively.

SFAS No. 123(R) Valuation Assumptions

The fair value of the options under SFAS No. 123(R) at June 30, 2007 and 2006 was estimated using the Black-Scholes valuation model using the following assumptions:

	For the Three Months Ended June 30, 2007	For the Three Months Ended June 30, 2006
Risk-free interest rate	4.88%	4.92%
Expected annual dividend yield		
Expected stock price volatility	60.43%	63.53%
Expected term of options	5.05 years	5.02 years
	For the Six Months Ended June 30, 2007	For the Six Months Ended June 30, 2006
Risk-free interest rate	4.82%	4.82%
Expected annual dividend yield		
Expected stock price volatility	61.28%	64.90%
Expected term of options	5.05 years	5.05 years

The valuation assumptions were determined as follows:

Risk-free interest rate: The yield on zero-coupon U.S. Treasury securities for a period that is commensurate with the expected term of the awards.

Expected annual dividend yield: The estimate for annual dividends is zero, because we have not historically paid a dividend and do not intend to do so in the foreseeable future.

Expected stock price volatility: We determine the expected volatility by using an average historical volatility from comparable public companies having volatility data covering a period equivalent to the expected term of our options.

Expected term of options: The expected term of the awards represents the period of time that the awards are expected to be outstanding. We use historical data and expectations for the future to estimate employee exercise and post-vest termination behavior. We believe that all groups of employees exhibit similar exercise and post-vest termination behavior and therefore do not stratify employees into multiple groups.

SFAS No. 123(R) requires the application of an estimated forfeiture rate to current period expense to recognize compensation expense only for those awards expected to vest. We estimate forfeitures based upon historical data, adjusted for known trends, and will adjust the estimate of forfeitures if actual forfeitures differ or are expected to differ from such estimates. Subsequent changes in estimated forfeitures will be recognized through a cumulative adjustment in the period of change and will also impact the amount of stock-based compensation expense in future periods. As of June 30, 2007 and 2006, the forfeiture rate was estimated to be 3.4% and 16.4%, respectively.

Table of Contents

A summary of our stock option activity for the six months ended June 30, 2007 is as follows:

	Stock Options	Weighted-Average Exercise Price	Weighted-Average Contractual Life (years)	Aggregate Intrinsic Value (in millions)
Outstanding at January 1, 2007	1,889,572	\$ 7.47		
Granted	1,367,288	13.25		
Exercised	(131,188)	2.00		
Forfeited	(46,613)	8.41		
Outstanding at June 30, 2007	3,079,059	\$ 10.27	8.83	\$ 1.9
Vested or expected to vest at June 30, 2007	929,714	\$ 6.47	7.79	\$ 4.1
Exercisable at June 30, 2007 (1)	1,414,953	\$ 6.33	8.03	\$ 6.4

(1) Options exercisable at June 30, 2007 include: (a) vested or expected to vest options from the Infinity Pharmaceuticals, Inc. 2000 Stock Incentive Plan; and (b) both unvested and vested or expected to vest options from the Infinity Pharmaceuticals, Inc. Pre-Merger Stock Incentive Plan (the 2001 Plan), which allowed early exercises of options into restricted stock. The 2001 Plan was not assumed by us following the DPI merger; therefore, no further grants may be made under the 2001 Plan.

The aggregate intrinsic value was calculated based on the positive difference between the closing fair market value of our common stock on June 30, 2007 and the exercise price of the underlying options. The aggregate intrinsic value of options exercised during the six months ended June 30, 2007 was \$1,381,613. The total cash received from employees and non-employees as a result of stock option exercises during the six months ended June 30, 2007 was approximately \$262,633.

The weighted-average fair value per share of options granted during the six months ended June 30, 2007 was \$7.51.

All options granted to employees during the three and six months ended June 30, 2007 were granted with exercise prices equal to the fair market value of our common stock on the date of grant.

No related income tax benefits were recorded during the three months ended June 30, 2007 and 2006.

We settle employee stock option exercises with newly issued common shares.

5. Comprehensive Loss

SFAS No. 130, *Reporting Comprehensive Income*, establishes rules for the reporting and display of comprehensive income (loss) and its components. 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 six months ended June 30, 2007 and 2006, comprehensive loss was as follows:

	Three Months Ended		Six Months Ended	
	June 30, 2007	June 30, 2006	June 30, 2007	June 30, 2006
Net loss	\$ (4,159,823)	\$ (7,395,670)	\$ (7,049,531)	\$ (18,275,275)
Unrealized holding gains (losses) on available-for-sale securities	71,296	(140)	123,361	1,644
Total comprehensive loss	\$ (4,088,527)	\$ (7,395,810)	\$ (6,926,170)	\$ (18,273,631)

Accumulated other comprehensive loss consists of unrealized gains and losses on available-for-sale securities.

6. Accounting for Sabbatical Leave

On January 1, 2007, we adopted EITF 06-2 to account for sabbatical leaves. All of our full-time employees are eligible to receive four paid weeks of sabbatical leave after five years of continuous employment. The cumulative effect of a change in accounting principle as a result of the adoption of EITF 06-2 was \$343,273, which was recorded to accumulated deficit and accrued expenses as of January 1, 2007. We recorded additional compensation expense of \$52,838 and \$60,935 for the three and six months ended June 30, 2007, respectively. Prior to the adoption of EITF 06-2, we did not accrue for the sabbatical leaves.

Table of Contents

7. Income Taxes

On January 1, 2007, we adopted FIN 48 to account for uncertainty in income taxes. In connection with the adoption of FIN 48, interest expense and penalties associated with unrecognized tax benefits will be accrued when appropriate, and reported in the income tax expense line on our statement of operations. We will calculate interest by applying the applicable tax jurisdiction statutory rate of interest in effect at the time the exposure arose and adjusted accordingly as the interest rates change. We filed income tax returns in the U.S. federal, Massachusetts and other state jurisdictions and are subject to examinations by those authorities for all tax years from 1993 to the present. We have not recorded a liability for unrecognized tax benefits prior to the adoption of FIN 48, as a result of adopting FIN 48, or during the three or six months ended June 30, 2007. Accordingly, we have not recognized any corresponding interest or penalties for the three or six months ended June 30, 2007.

Table of Contents

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 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.

DPI Merger

On September 12, 2006, Discovery Partners International, Inc., or DPI, completed a merger with Infinity Pharmaceuticals, Inc., or IPI, pursuant to which a wholly-owned subsidiary of DPI merged with and into IPI. IPI was the surviving corporation in the merger, changed its name to Infinity Discovery, Inc., or Old Infinity, and became a wholly-owned subsidiary of DPI. In addition, we changed our name from Discovery Partners International, Inc. to Infinity Pharmaceuticals, Inc. and our ticker symbol on the NASDAQ Global Market to INFI.

Upon completion of the merger, our common stock was issued to Old Infinity stockholders, and we assumed all of the stock options, stock warrants and restricted stock of Old Infinity outstanding as of September 12, 2006. Immediately following the closing of the merger, former Old Infinity stockholders, option holders and warrant holders owned approximately 69% of the combined company on a fully-diluted basis and former DPI stockholders, option holders and warrant holders owned approximately 31% of the combined company on a fully-diluted basis. In addition, after completion of the merger, the business conducted by the combined company became the one operated by Old Infinity prior to completion of the merger.

Since former Old Infinity security holders owned, immediately following the merger, approximately 69% of the combined company on a fully-diluted basis and as a result of certain other factors, including that former Old Infinity directors constituted a majority of the combined company's board of directors and all members of the combined company's executive management were from Old Infinity, Old Infinity was deemed to be the acquiring company for accounting purposes and the transaction was accounted for as a reverse acquisition of assets and a recapitalization in accordance with accounting principles generally accepted in the United States. Accordingly, for all purposes, including SEC reporting, our financial statements for periods prior to the merger reflect the historical results of Old Infinity, and not DPI, and our financial statements for all subsequent periods reflect the results of the combined company. In addition, because the business conducted by the combined company became the one operated by Old Infinity prior to the completion of the merger, the discussion below describes the business of Old Infinity prior to completion of the merger and the business of the combined company after the merger.

Unless specifically noted otherwise, as used herein, the terms "Infinity," "we," "us" and "our" refer to the combined company after the merger and the business of Old Infinity prior to the merger, and "DPI" refers to the business of Discovery Partners International, Inc. prior to completion of the merger.

Business Overview

Our mission is to discover, develop, and deliver to patients best-in-class medicines for the treatment of cancer and related conditions. We have built a pipeline of innovative product candidates for multiple cancer indications, all of which represent proprietary applications of our expertise in small molecule drug technologies. In the near term, the key driver of our success will be our ability to successfully commence and complete clinical trials for our product candidates and advance the development of our discovery-stage research programs. In the longer term, the key driver of our success will be our ability to commercialize products based upon our proprietary technologies, either alone or together with our collaboration partners.

Our lead product candidate, IPI-504, is currently being studied in a Phase I clinical trial in patients with Gleevec® refractory gastrointestinal stromal tumors, or GIST, and other soft tissue sarcomas, as well as a Phase I/II clinical trial in patients with advanced non-small cell lung cancer, or NSCLC. We also have completed enrollment in and are analyzing data from our Phase I clinical trial of IPI-504 in patients with refractory multiple myeloma. To date, IPI-504 has been well-tolerated and we have seen promising evidence of biological activity in patients with GIST. We currently expect to initiate additional clinical trials of IPI-504 before the end of 2007, including one or more Phase II clinical trials in indications to be determined based on the preclinical and clinical data we generate and a Phase I clinical trial combining IPI-504 with an existing approved therapy. In addition, we have commenced investigational new drug application, or IND, enabling studies of an oral formulation of IPI-504 as well as a second-generation oral Hsp90 inhibitor, IPI-493. Pending the outcome of these studies, we anticipate filing an IND on one or both of these candidates in late 2007 or early 2008. IPI-504 and IPI-493 are inhibitors of heat shock protein 90, or Hsp90. Hsp90 is a

Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

molecule that maintains the structure and activity of specific proteins, known as client proteins of Hsp90. Many cancers result from specific mutations in these client proteins; Hsp90 enables those cancers to survive by allowing the client proteins to continue functioning.

Table of Contents

Our next most advanced program is directed against the Hedgehog cell signaling pathway, which we refer to as the Hedgehog pathway. Normally, the Hedgehog pathway regulates tissue and organ formation during embryonic development. When abnormally activated during adulthood, however, the Hedgehog pathway is believed to play a central role in allowing the proliferation and survival of certain cancer-causing cells, and is implicated in many of the most deadly cancers. We have selected a lead clinical candidate in our Hedgehog pathway inhibitor program, IPI-926, and have commenced IND-enabling activities for that compound. We intend to commence a Phase I clinical trial of IPI-926 in 2008. Our Hsp90 and Hedgehog pathway inhibitor programs are being pursued in collaboration with MedImmune, Inc., or MedImmune, which now operates as a subsidiary of AstraZeneca PLC. Notwithstanding the acquisition of MedImmune by AstraZeneca PLC in June 2007, our agreement with MedImmune remains in full force and effect on the same terms.

The goal of our third program, which is being undertaken in collaboration with the Novartis Institutes for BioMedical Research, or Novartis, is to identify small molecule compounds that inhibit the Bcl-2 family of proteins. These proteins are key regulators of programmed cell death, or apoptosis. Cancers that have higher than normal levels of Bcl-2 are believed to evade apoptosis and become increasingly resistant to chemotherapy. Using our proprietary small molecule drug discovery technologies, we have identified selective inhibitors of Bcl-2 and its related protein family member, Bcl-xL, and are performing lead optimization activities on these compounds.

We also have other research programs that target cancer and related conditions.

We have incurred net losses since inception as we have devoted substantially all of our resources to research and development, including early-stage clinical trials. We expect to incur substantial and increasing losses for the next several years as we continue to expend substantial resources seeking to successfully research, develop, manufacture, obtain regulatory approval for, market and sell any product candidates. We expect that, in the near term, we will incur substantial losses relating primarily to costs and expenses relating to our efforts to advance the development of IPI-504, IPI-493 and IPI-926.

Collaboration Agreements

We have entered into a product development and commercialization agreement with MedImmune to jointly develop and commercialize novel cancer drugs targeting Hsp90, including IPI-504 and IPI-493, as well as those targeting the Hedgehog pathway, including IPI-926. Under the terms of our agreement with MedImmune, we will share equally with MedImmune all development costs, as well as potential profits and losses, from any future marketed products. MedImmune made a non-refundable, up-front payment totaling \$70 million to us in order to obtain co-exclusive rights to the Hsp90 and Hedgehog pathway development programs. In addition, we could receive up to \$430 million in milestone payments if certain late-stage development and sales objectives are achieved for products resulting from the collaboration, such that total payments to us could equal \$500 million. If any products are successfully developed under the collaboration, we have the right to co-promote these products in the United States, with our promotional costs being included among those that are shared under the collaboration. We may opt-out of a program under the collaboration, in which case we would receive a royalty on sales of products arising from the program, if any, instead of a share of profits and losses.

We have also entered into an alliance with Novartis to discover, develop and commercialize drugs targeting the Bcl-2 family of proteins. Under our agreement with Novartis, Novartis has paid us a \$15 million up-front license fee, an affiliate of Novartis has made a \$5 million equity investment in us, and Novartis has committed to provide us research funding of approximately \$10 million over the initial two-year research term, which expires in February 2008. Novartis has also agreed to make aggregate milestone payments of over \$370 million if certain research, development and commercialization milestones are met for multiple products for multiple indications, such that total payments to us could exceed \$400 million. In addition, we are entitled to receive royalties upon successful commercialization of any products developed under the alliance. The two companies will conduct joint research to identify molecules for clinical development. Once a clinical candidate is identified, we can participate in the clinical development of the candidate under specified conditions. This clinical development will be led and paid for by Novartis. Upon commercialization of any products developed under the collaboration, we have an option to co-detail Bcl-2 family inhibitors in the United States, with our detailing costs to be reimbursed by Novartis.

We have also entered into three technology access alliances relating to our diversity oriented synthesis technologies that have provided us with over \$65 million in up-front license fees, equity payments and other near-term committed revenues and, with respect to one such alliance, potential milestone and royalty payments upon successful commercial development of select products resulting from the alliance partner's use of the compounds to develop drug candidates. Pursuant to these alliances, Novartis International Pharmaceutical Ltd., or Novartis International, Amgen Inc., or Amgen, and Johnson & Johnson Pharmaceutical Research & Development, a division of Janssen Pharmaceutica N.V., or J&J, have each been granted non-exclusive rights to use subsets of our collection of diversity oriented synthesis compounds for use in their respective internal drug discovery programs.

Table of Contents

Financial Overview

Revenue

All of our revenue to date has been derived from license fees, the reimbursement of research and development costs, and contract service revenue received from our collaboration partners. Where the agreement with a collaboration partner, such as our agreement with Novartis, provides that the partner will 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 quarter to quarter as a result of the timing and amount of license fees, research and development reimbursement, milestone and other payments received under our collaborative or strategic relationships, and the amount and timing of payments that we receive 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 & Development Expense

Since inception, we have focused on drug discovery and development programs, with particular emphasis on cancer drugs. We currently have three lead programs in research and development:

a program developing a series of compounds targeting Hsp90, including IPI-504, which is currently being studied in Phase I clinical trials for the treatment of refractory GIST and other soft tissue sarcomas, and advanced NSCLC, an oral formulation of IPI-504 that is currently in IND-enabling studies, and IPI-493, an oral Hsp90 inhibitor for which we have commenced IND-enabling studies;

a program seeking to develop candidate compounds directed against the Hedgehog pathway, including IPI-926, for which we have commenced IND-enabling activities; and

a program seeking to identify small molecule inhibitors of the Bcl-2 family of proteins, which is in the lead optimization stage. The Hsp90 and Hedgehog pathway inhibitor programs are being conducted in collaboration with MedImmune and the Bcl-2 program is being conducted in collaboration with Novartis.

Research and development expense primarily consists of the following:

compensation of personnel associated with research activities, including consultants and 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.

We expense research and development costs as they are incurred.

Under our collaboration with MedImmune, we share research and development expenses for our Hsp90 and Hedgehog pathway inhibitor programs equally with MedImmune. Because this is a cost-sharing arrangement, we will record payments we receive from MedImmune for its share of the development effort as a reduction of research and development expense.

Table of Contents

General & Administrative Expense

General and administrative expense consists primarily of salaries and other related costs for personnel in executive, finance, accounting, legal, business development, information technology infrastructure, corporate communications and human resources functions. Other costs include facilities costs not otherwise included in research and development expense and professional fees for legal and accounting services. General and administrative expense also consists of the costs of maintaining and overseeing our intellectual property portfolio, which include the salaries of in-house patent counsel, the cost of external counsel and the associated filing and maintenance fees.

Other Income & Expense

Interest expense and other interest and investment income consist primarily of interest earned on cash, cash equivalents and available-for-sale securities, net of interest expense, and amortization of warrants.

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 United States generally accepted accounting principles. The preparation of these financial statements requires us to make 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 drug development costs and assumptions in the valuation of stock-based compensation. 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. Interim results are not necessarily indicative of results for a full year or for any subsequent interim period.

We believe that the following accounting policies and estimates are most critical to aid you in understanding and evaluating our reported financial results.

Revenue Recognition

To date, our revenues have been generated under research collaboration agreements and, accordingly, we recognize revenue in accordance with the SEC's Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*, as amended by SAB No. 104, *Revenue Recognition*, and Emerging Issues Task Force No. 00-21, *Revenue Arrangements With Multiple Deliverables*.

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 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 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 revenues 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. To date, we have not made any such changes.

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 and (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone. 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 of licensed products in licensed territories as provided by the licensee, and in the period the sales occur. We have not recognized any royalty revenues 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

Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

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.

Table of Contents**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 will 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 is a cost-sharing arrangement; our collaboration with Novartis provides for the reimbursement of our research and development expenses.

Accrued Drug Development Costs

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 the production of clinical drug supplies and to contract research organizations in connection with preclinical studies and clinical trials. 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. To date, we have been able to reasonably estimate these costs, but our estimates of expenses in future periods may be over- or under-accrued.

Stock-Based Compensation

We adopted Financial Accounting Standards Board Statement No. 123(R), *Share-Based Payment* (SFAS No. 123(R)), as of January 1, 2006 using a modified prospective application, which provides for certain changes in the method for valuing stock-based compensation. SFAS No. 123(R) requires companies to expense the fair value of employee stock options and other equity compensation. We use our judgment in determining the fair value of our common stock, including in selecting the inputs we use in 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 or sold and the associated compensation charge, if any, we record in our financial statements.

Results of Operations

The following tables summarize our results of operations for each of the three and six month periods ended June 30, 2007 and 2006, in thousands, together with the change in these items in dollars and as a percentage:

	For the Three Months Ended June 30,			
	2007	2006	\$ Change	% Change
Revenue	\$ 5,654	\$ 2,819	\$ 2,835	101%
Research and development expense	(8,187)	(8,825)	638	(7)%
General and administrative expense	(3,237)	(1,386)	(1,851)	134%
Interest expense	(29)	(212)	183	(86)%
Interest and investment income	1,640	208	1,432	688%

	For the Six Months Ended June 30,			
	2007	2006	\$ Change	% Change
Revenue	\$ 11,770	\$ 3,537	\$ 8,233	233%
Research and development expense	(15,663)	(18,503)	2,840	(15)%

Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

General and administrative expense	(6,530)	(3,358)	(3,172)	94%
Interest expense	(132)	(354)	222	(63)%
Interest and investment income	3,506	403	3,103	770%

Table of Contents

Revenue

Our revenue during the three-month period ended June 30, 2007 consisted of approximately:

\$2.5 million associated with the amortization of the up-front license fee we received from MedImmune upon entry into our strategic alliance in August 2006;

\$0.9 million related to the amortization of the non-refundable license fee, and \$1.2 million in revenue related to the reimbursable research and development services we performed, under our Bcl-2 collaboration entered into with Novartis in February 2006; and

\$1.0 million related to the delivery of compounds to Novartis International under our technology access agreement.

Our revenue during the three-month period ended June 30, 2006 consisted of approximately:

\$0.9 million related to the amortization of the non-refundable license fee, and \$1.2 million in revenue related to the reimbursable research and development services we performed, under our Bcl-2 collaboration with Novartis; and

\$0.7 million related to the delivery of compounds to Novartis International under our technology access agreement.

Our revenue during the six-month period ended June 30, 2007 consisted of approximately:

\$5.0 million associated with the amortization of the up-front license fee we received from MedImmune;

\$1.9 million related to the amortization of the non-refundable license fee, and \$2.4 million in revenue related to the reimbursable research and development services we performed, under our Bcl-2 collaboration with Novartis; and

\$2.5 million related to the delivery of compounds to Novartis International under our technology access agreement.

Our revenue during the six-month period ended June 30, 2006 consisted of approximately:

\$1.2 million related to the amortization of the non-refundable license fee, and \$1.6 million in revenue related to the reimbursable research and development services we performed, under our Bcl-2 collaboration with Novartis; and

\$0.7 million related to the delivery of compounds to Novartis International under our technology access agreement.

Research and Development Expense

Research and development expense represented approximately 72% and 86% of our total operating expenses for the three months ended June 30, 2007 and 2006, respectively, and approximately 71% and 85% of our total operating expenses for the six months ended June 30, 2007 and 2006, respectively.

Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

The decrease in research and development expense in the three-month period ended June 30, 2007 as compared to the same period in 2006 is primarily attributable to \$3.4 million in reimbursable amounts from MedImmune under the cost-sharing provisions of our collaboration agreement, which is recorded as a credit to research and development expense, partially offset by:

an increase of \$1.2 million in salaries and benefits, including SFAS No. 123(R) stock-based compensation expenses, for our research and development personnel, which was driven by the hiring of new research and development personnel, annual base salary increases, larger annual stock option grants, and the implementation in the fourth quarter of 2006 of a contingent cash compensation program; and

an increase of \$1.2 million in external preclinical expenses for our Hsp90 program.

The decrease in research and development expense in the six-month period ended June 30, 2007 as compared to the same period in 2006 is primarily attributable to \$6.7 million in reimbursable amounts from MedImmune under the cost-sharing provisions of our collaboration agreement which is recorded as a credit to research and development expense, partially offset by:

an increase of \$2.1 million in salaries and benefits, including SFAS No. 123(R) stock-based compensation expenses, for our research and development personnel, which was driven by the hiring of new research and development personnel, annual base salary increases, larger annual stock option grants, and the implementation in the fourth quarter of 2006 of a contingent cash compensation program; and

Table of Contents

an increase of \$1.5 million in development costs for our Hsp90 and Hedgehog programs.

During the three and six month periods ended June 30, 2007 and 2006, 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 and Hedgehog pathway inhibitor programs, these expenses for the three and six months ended June 30, 2007 include a credit of approximately \$3.4 million and \$6.7 million, respectively, attributable to amounts reimbursable by MedImmune following entry into our collaboration agreement in August 2006.

Program	Three Months Ended June 30, 2007	Three Months Ended June 30, 2006
Hsp90 Inhibitors	\$ 3.0 million	\$ 1.8 million
Hedgehog Pathway Inhibitors	1.3 million	2.1 million
Bcl-2	1.3 million	1.0 million

Program	Six Months Ended June 30, 2007	Six Months Ended June 30, 2006
Hsp90 Inhibitors	\$ 5.3 million	\$ 3.2 million
Hedgehog Pathway Inhibitors	2.5 million	5.3 million
Bcl-2	2.6 million	2.1 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. For example, while we expect our research and development expenses to increase as our programs progress through preclinical and clinical development, those expenses attributable to the Hsp90 and Hedgehog pathway inhibitor programs will be shared equally with MedImmune in future periods. Further, there is significant uncertainty regarding our ability to successfully develop any drug candidates. These risks include the uncertainty of:

the scope, rate of progress and cost of our clinical trials of IPI-504, planned clinical trials of product candidates in the Hsp90 and Hedgehog pathway inhibitor programs, and any other clinical trials we may commence in the future;

the scope, rate and progress of our preclinical studies and other research and development activities;

clinical trial results;

the cost of filing, prosecuting, defending and enforcing any patents and other intellectual property rights relating to our research and development programs;

the cost and timing of regulatory approvals;

the cost of establishing clinical supplies of any product candidates; and

the effect of competing technological and market developments.

A further discussion of some of the risks and uncertainties associated with completing our drug development programs on schedule, or at all, and the potential consequences of failing to do so, are set forth in Part II of this report under the section entitled "Risk Factors."

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

the nature, timing or estimated costs of the efforts necessary to complete the development of our programs;

the anticipated completion dates of these programs; or

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

Any failure by us or our strategic alliance partners to complete any stage of the development of any potential products in a timely manner could have a material adverse effect on our results of operations and financial position.

Table of Contents

General and Administrative Expense

The increase in general and administrative expense for the three months ended June 30, 2007 as compared to the same period in 2006 is primarily attributable to:

an increase of \$1.1 million in salaries and benefits, including SFAS No. 123(R) stock-based compensation expense for general and administrative employees, which was driven by the hiring of new general and administrative personnel, annual base salary increases, larger annual stock option grants and the implementation in the fourth quarter of 2006 of a contingent cash compensation program; and

an increase of \$0.4 million in patent, miscellaneous tax expenses, including state franchise taxes, and tax service expense.

The increase in general and administrative expense for the six months ended June 30, 2007 as compared to the same period in 2006 is primarily attributable to:

an increase of \$1.9 million in salaries and benefits, including SFAS No. 123(R) stock-based compensation expense for general and administrative employees, which was driven by the hiring of new general and administrative personnel, annual base salary increases, larger annual stock option grants and the implementation in the fourth quarter of 2006 of a contingent cash compensation program; and

an increase of \$0.8 million in patent, miscellaneous tax expenses, including state franchise taxes, and tax service expense.

Interest Expense

Interest expense decreased in the three and six month periods ended June 30, 2007 as compared to the same periods in 2006 primarily as a result of borrowings outstanding in 2006 under our debt facilities with Oxford Finance Corporation, or Oxford. We repaid in full all of our outstanding debt to Oxford in December 2006.

Interest and Investment Income

Interest and investment income increased in the three and six month periods ended June 30, 2007 as compared to the same periods in 2006 primarily as a result of our higher balance of cash and cash equivalents and available-for-sale securities. The increase in cash and available-for-sale securities balance is primarily attributable to amounts we received upon completion of the DPI merger, and the up-front license fee received from MedImmune in connection with our collaboration.

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, contract service payments and debt to fund our operations. Because our product candidates are at an early stage 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 cash, cash equivalents, available-for-sale securities and working capital are as follows:

	June 30, 2007	December 31, 2006
Cash, cash equivalents and available-for-sale securities	\$ 122,339,876	\$ 101,696,784
Working capital	108,893,125	121,264,233

Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

	Six Months Ended June 30,	
	2007	2006
Cash provided by (used in):		
Operating activities	\$ 21,452,749	\$ (5,584,188)
Investing activities	(78,254,598)	(667,936)
Financing activities	(591,246)	17,856,943
Capital expenditures (included in investing activities above)	(2,009,932)	(470,648)

Cash Flows

The principal use of cash in operating activities in all of the periods presented was the funding of our net loss. 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. In January 2007, we received \$35.0 million from MedImmune, representing the second half of the up-front license payment related to our collaboration agreement.

Table of Contents

Cash flow from operations for the six months ended June 30, 2007 includes a decrease in accrued expenses and other liabilities, which include \$1.7 million in payments under our contingent cash compensation program during 2007 for amounts earned in 2006, \$1.1 million in federal income taxes and \$1.0 million paid to J&J to refund a portion of the upfront license fee paid in connection with our technology access agreement. Cash flow from operations for the six months ended June 30, 2006 includes an increase of \$13.8 million in deferred revenue due to the collaboration agreement with Novartis entered in February 2006, which included a \$15.0 million up-front license fee.

Net cash used in investing activities for the six months ended June 30, 2007 includes the purchase of \$121.8 million of short term corporate obligations. Capital expenditures in the six months ended June 30, 2007 primarily consisted of laboratory equipment and leasehold improvements for a new process scale-up laboratory.

We believe that our existing cash and cash equivalents, will be sufficient to support our current operating plan, including planned increases in research and development and general and administrative expenses, through at least December 31, 2009. Our currently-planned operating and capital requirements primarily include the need for working capital to, among other things:

continue clinical development of an intravenous formulation of IPI-504;

perform preclinical work on, and commence clinical development of, one or more oral Hsp90 inhibitors;

perform preclinical work on, and commence clinical development of, IPI-926; and

advance our additional discovery programs.

Our future operating plan may change, however, as a result of many factors, including those specified in Part II of this report under the section entitled Risk Factors.

We will require substantial additional cash to fund expenses that we expect to incur in the long term in connection with planned preclinical and clinical testing, regulatory review, manufacturing and sales and marketing efforts. We may seek additional capital through a combination of private and public equity offerings, debt financings and strategic alliance and licensing arrangements. Such additional financing may not be available when we need it or may not be available on terms that are favorable to us. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests will be diluted, and the terms may include liquidation or other preferences that adversely affect their rights as stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through strategic alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or drug candidates, or grant licenses on terms that are not favorable to us. If we are unable to obtain adequate financing on a timely basis, we could be required to:

curtail significant discovery-stage drug discovery programs that are designed to identify new drug candidates; and/or

relinquish rights to product candidates or development programs that we may otherwise seek to develop or commercialize ourselves or jointly with our collaborative partners.

Contractual Obligations and Off-Balance Sheet Arrangements

There have been no material changes in our contractual obligations from those disclosed in our annual report on Form 10-K filed on March 14, 2007.

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

Table of Contents

A hypothetical 100 basis point increase in interest rates would result in an approximate \$250,359 decrease in the fair value of our investments as of June 30, 2007. We have the ability to hold our fixed income investments until maturity and, therefore, we do not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments.

Item 4. Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer and treasurer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2007. 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, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2007, our chief executive officer and chief financial officer and treasurer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

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 three months ended June 30, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

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 Business and Our Stage of Development as a Company

Our limited operating history may make it difficult for you to evaluate our business and assess our future viability effectively.

Our operations to date have been limited to organizing and staffing the company, developing, and securing our technology and undertaking preclinical studies and initial clinical trials of our drug candidates. We have not yet demonstrated our ability to obtain regulatory approval for, or to formulate and manufacture at commercial-scale, any of our drug candidates, nor do we have the sales and marketing infrastructure necessary to successfully commercialize any products that may ultimately be approved for sale, if any. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

We have a history of net losses and may never become profitable.

We have incurred significant losses since inception. At June 30, 2007, our accumulated deficit was approximately \$162.7 million. Our net losses for the six months ended June 30, 2007 and the fiscal years ending December 31, 2006, 2005 and 2004 were \$7.0 million, \$28.4 million, \$36.4 million and \$34.1 million, respectively. We have not generated any revenues from the sale of drugs to date and we do not expect to generate revenues from the sale of drugs, or achieve profitability, for several years, if ever. We expect that our annual operating losses will increase substantially over the next several years as we seek to:

complete Phase I clinical trials for IPI-504 and, if supported by the Phase I clinical trial results, initiate larger scale Phase II clinical trials, as well as additional clinical trials, for IPI-504;

perform preclinical work on, and commence clinical development of, one or more of our oral Hsp90 inhibitors;

advance our Hedgehog pathway inhibitor program into preclinical development and clinical trials, if supported by positive data;

discover and develop additional drug candidates, including Bcl-2 inhibitor compounds;

obtain regulatory approval for any drug candidates we successfully develop;

commercialize any drug candidates for which the necessary regulatory approvals are obtained;

prosecute and maintain our intellectual property rights relating to our drug candidates and future products, if any;

hire additional clinical, scientific and management personnel and upgrade our operational, financial and management information systems and facilities; and

identify and acquire rights from third parties to additional compounds, drug candidates or drugs.

To become profitable, we must successfully develop and obtain regulatory approval for our drug candidates and effectively manufacture, market and sell those drug candidates. Consequently, we may never generate significant revenues and, even if we do, we may never achieve profitability.

We will need substantial additional capital to fund our operations, and our business may be threatened if that capital is not available on acceptable terms.

We anticipate that our current cash, cash equivalents and available-for-sale securities will be sufficient to support our current operating plan through at least December 31, 2009. Our currently-planned operating and capital requirements primarily include the need for working capital to, among other things:

continue clinical development of an intravenous formulation of IPI-504;

perform preclinical work on, and commence clinical development of, one or more of our oral Hsp90 inhibitors;

perform preclinical work on, and commence clinical development of, IPI-926; and

Table of Contents

advance our additional discovery programs.

Our future operating plan may change, however, as a result of many factors, including:

the progress and results of clinical trials of IPI-504 and preclinical studies of our oral Hsp90 inhibitors, and our decision to initiate clinical trials of either or both of our oral Hsp90 inhibitors if supported by preclinical results;

the progress and results of preclinical studies of IPI-926, and our decision to initiate clinical trials if supported by preclinical results;

the results of discovery-stage research for Bcl-2 inhibitor compounds and other programs;

our ability to maintain our strategic alliances with MedImmune and Novartis and decisions that may be made by the governing committees under those alliances;

potential business development activities, such as the acquisition or in-licensing of new product candidates;

our ability to meet our compound delivery obligations to Novartis International;

the timing of, and the costs involved in, obtaining regulatory approvals for our drug candidates;

the cost of acquiring raw materials for, and of manufacturing, our drug candidates;

the costs involved in preparing, filing, prosecuting, maintaining and enforcing patents, and other patent-related costs, including litigation costs;

the costs of increasing our clinical research, medical and regulatory affairs functions;

the costs of establishing sales and marketing functions and of establishing commercial manufacturing arrangements if any of our drug candidates are approved;

our needs for office and laboratory facilities and our ability to continue subleasing excess space;

the costs required to satisfy our obligations under our alliance with MedImmune;

the timing and receipt of milestone payments under our collaboration agreements; and

Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

the timing, receipt and amount of sales, profits or royalties on future products, if any.

We will require substantial additional cash to fund expenses that we expect to incur in the long term in connection with planned preclinical and clinical testing, regulatory review, manufacturing and sales and marketing efforts. We may seek additional capital through a combination of private and public equity offerings, debt financings and strategic alliance and licensing arrangements. Such additional financing may not be available when we need it or may not be available on terms that are favorable to us. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests will be diluted, and the terms may include liquidation or other preferences that adversely affect their rights as stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through strategic alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or drug candidates, or grant licenses on terms that are not favorable to us. If we are unable to obtain adequate financing on a timely basis, we could be required to:

curtail significant discovery-stage drug discovery programs that are designed to identify new drug candidates; and/or

relinquish rights to drug candidates or development programs that we may otherwise seek to develop or commercialize ourselves or jointly with our collaborative partners.

Our alliances with MedImmune and Novartis are important to our business. If these alliances are unsuccessful or if conflicts result with our alliance partners, our research and development efforts could be delayed, curtailed or terminated, our revenues could significantly decrease, and our operations may be adversely affected.

We have entered into an alliance with MedImmune to jointly develop and commercialize novel drugs targeting Hsp90 and the Hedgehog pathway. We have also entered into an alliance with Novartis for the development and commercialization of Bcl-2 protein family members in the field of cancer. In these alliances, our collaborators have committed to provide substantial funding, as well as significant capabilities in clinical development, regulatory affairs, marketing and sales.

Table of Contents

In June 2007, AstraZeneca PLC completed its acquisition of MedImmune, resulting in MedImmune operating as a subsidiary of AstraZeneca. In accordance with our agreement with MedImmune, our collaboration continues in effect after a change of control of MedImmune on the same terms. Nevertheless, the merger and attendant integration of operations may have an impact on MedImmune's ability to retain and motivate key personnel, or may divert management attention and resources. These events may result in delays in our development programs and have an adverse effect on our results of operations.

If, for any reason, MedImmune or Novartis does not devote sufficient time and resources to the applicable alliance arrangement, we may not realize the potential commercial benefits of the arrangement, and our results of operations may be adversely affected. In addition, if MedImmune or Novartis were to breach or terminate its arrangement with us, the development and commercialization of the affected drug candidate could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue development and commercialization of the drug candidate on our own.

Under our agreement with MedImmune, MedImmune may opt out of a project by giving us six months' prior written notice, and has the right to terminate the agreement under other circumstances, including if it believes there are safety concerns with respect to a drug being developed under the collaboration. Under our alliance agreement with Novartis, Novartis may terminate the alliance at any time upon 60 days' notice to us. If either MedImmune or Novartis were to exercise its right to opt out of a program or to terminate the applicable alliance, the development and commercialization of products from our Hsp90, Hedgehog pathway inhibitor or Bcl-2 programs could be adversely affected, our potential for generating revenue from these programs may be adversely affected and attracting new alliance partners would be made more difficult.

Much of the potential revenue from our existing and future alliances will consist of contingent payments, such as payments for achieving development and commercialization milestones, royalties payable on sales of any successfully developed drugs, and profit-sharing arrangements. The milestone, royalty and other revenue that we may receive under these alliances 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, accordingly, will depend entirely on our alliance partners. Our alliance partners may fail to develop or effectively commercialize products using our products or technologies because they:

decide 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;

do not have sufficient resources necessary to carry the drug candidate through clinical development, regulatory approval and commercialization; or

cannot obtain the necessary regulatory approvals.

Further, while our agreement with MedImmune precludes MedImmune or its affiliates from developing a competitive Hsp90 or Hedgehog pathway inhibitor outside of our collaboration without our consent, Novartis may decide to pursue a drug candidate targeting the Bcl-2 family of proteins that is developed outside of our collaboration.

If our alliance partners fail to develop or effectively commercialize our drug candidates, we may not be able to develop and commercialize that drug independently, or replace the alliance partner with another suitable partner in a reasonable period of time and on commercially reasonable terms, if at all.

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, Julian Adams, Adelene Perkins and the other members of our executive leadership team. All of these individuals are employees-at-will, which means that neither Infinity nor such 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. Although we do not have any reason to believe that we may lose the services of any of these persons in the foreseeable future, the loss of the services of any of these persons might impede the achievement of our research, development and commercialization objectives. We do not maintain key person insurance on any of our employees.

Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

Recruiting and retaining qualified scientific and business personnel will also be 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. We also experience competition for the hiring of scientific personnel from universities and research

Table of Contents

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.

Risks Related to the Development and Planned Commercialization of Our Drug Candidates

All of our drug candidates are still in the early stages of development and 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 Phase I clinical trials and is the subject of a broad product development and commercialization agreement with MedImmune. Our other drug candidates are 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 our strategic alliance partners, will obtain marketing approval. In connection with the clinical trials of IPI-504 and any other drug candidate we may seek to develop in the future, we face risks that:

the drug candidate may not prove to be safe and/or effective;

the results of later trials may not confirm the positive results from earlier preclinical studies or clinical trials; and

the results may not meet the level of statistical significance required by the FDA or other regulatory agencies.

We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA and/or 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 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 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.

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.

We are also subject to numerous foreign regulatory requirements governing the conduct of clinical trials, manufacturing and marketing authorization, pricing and third party reimbursement. The foreign regulatory approval process includes all of the risks associated with FDA approval described above, as well as risks attributable to the satisfaction of foreign regulations. Approval by the FDA does not ensure approval by regulatory authorities outside the United States, and vice versa. Foreign jurisdictions may have different approval procedures than those required by the FDA and may impose additional testing requirements for our drug candidates.

If clinical trials of our drug candidates are prolonged, delayed or suspended, it may take significantly longer and cost substantially more to obtain marketing approval for our drug candidates and achieve profitability, if at all.

Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

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

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

Table of Contents

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 clinical 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 clinical trials, which could impair the validity or statistical significance of the clinical trials. 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; adverse side effects experienced, 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.

We cannot predict whether any of our drug candidates will encounter problems during clinical trials that will cause us or regulatory authorities to delay or suspend these trials or delay the analysis of data from these trials. In addition, it is impossible to predict whether legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. If we experience any such problems, we may not have the financial resources to continue development of the drug candidate that is affected or the development of any of our other drug candidates.

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 medical institutions and external investigators to enroll qualified patients, conduct our clinical trials and provide services in connection with such clinical trials. We intend to rely on these institutions and investigators, as well as contract research organizations 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. Although we believe there are a number of third party contractors we could engage to continue these activities, replacing a third party contractor may result in a delay of the affected trial. If this were to occur, our efforts to obtain regulatory approvals for and 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 protocols 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

Table of Contents

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 approvals for and commercialize our drug candidates may be delayed.

Even if any of our drug candidates receives regulatory approval, we may still face significant development and regulatory difficulties.

Even if we receive regulatory approval of any drug candidates we are developing or may develop, we will be subject to continuing regulatory review. We may be required, or we may elect, to conduct additional clinical trials of our drug candidates after they have become commercially available approved drugs. As greater numbers of patients use a drug following its approval, side effects and other problems may be observed after approval that were not seen or anticipated during pre-approval clinical trials. Supplemental trials could also produce findings that are inconsistent with the trial results we previously submitted to the FDA, which could result in marketing restrictions or force us to stop marketing previously approved drugs. In addition, the manufacturer and the manufacturing facilities we use to make any approved drugs will be subject to periodic review and inspection by the FDA. The subsequent discovery of previously unknown problems with the drug, manufacturer or facility may result in restrictions on the drug, manufacturer or facility, up to and including withdrawal of the drug from the market. If we fail to comply with applicable continuing regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approval, product recalls and seizures, operating restrictions and criminal prosecutions.

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 may, at any time, audit or inspect a manufacturing facility to ensure compliance with cGMPs. Any failure by our contract manufacturers to achieve and maintain high manufacturing and quality control standards could result in 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 some 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 in quantities for preclinical testing and clinical trials primarily by third party manufacturers. If the FDA or other regulatory agencies approve any of our 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 and/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.

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

Even if our current drug candidates, or drug candidates we may develop or acquire in the future, obtain regulatory approval, they may not gain market acceptance among physicians, patients and the medical community for a variety of reasons including:

timing of market introduction of competitive drugs;

Table of Contents

lower demonstrated clinical safety and efficacy compared to other drugs;

lack of cost-effectiveness;

lack of availability of reimbursement from managed care plans and other third party payors;

inconvenient and/or difficult administration;

prevalence and severity of adverse 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 these therapies; and

ineffective sales, marketing and distribution support.

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

Any drugs we successfully develop may become subject to unfavorable pricing regulations, third party reimbursement practices or healthcare reform initiatives that could harm our business.

Our revenues and profits will depend significantly upon the availability of adequate reimbursement from governmental and other third party payors, both in the United States and in foreign markets, of any of our approved drug candidates. Reimbursement by a third party may depend upon a number of factors, including the third party payor's determination that use of a product is:

a covered benefit under its health plan;

safe, effective and medically necessary;

appropriate for the specific patient;

cost effective; and

neither experimental nor investigational.

Obtaining reimbursement approval for a product from each third party and government payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of any approved drugs to each payor. We may not be

able to provide data sufficient to gain acceptance with respect to reimbursement. There also exists substantial uncertainty concerning third party reimbursement for the use of any drug candidate incorporating new technology, and even if determined eligible, 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 allows us to make a profit or even cover our costs. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower-cost products that are already reimbursed and/or whether the drug is on a state's Medicaid preferred drug list, may be incorporated into existing payments for other products or services and may reflect budgetary constraints and/or imperfections in Medicare or Medicaid data used to calculate these rates. Net prices for products may be reduced by mandatory discounts or rebates required by government health care programs or by any future relaxation of laws that restrict imports of certain medical products from countries where they may be sold at lower prices than in the United States.

There have been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for medical products and services, which may affect payments for any of our approved products. The Centers for Medicare and Medicaid Services frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates and may have sufficient market power to demand significant price reductions. As a result of actions by these third party payors, the health care industry is experiencing a trend toward containing or reducing costs through various means, including lowering reimbursement rates, limiting therapeutic class coverage and negotiating reduced payment schedules with service providers for drug products.

Our inability to promptly obtain coverage and profitable reimbursement rates from government-funded and private payors for any approved products could have a material adverse effect on our operating results and our overall financial condition.

Table of Contents

Risks Related to Our Field

The market for cancer therapeutics is intensely competitive. If we are unable to compete effectively, our drug candidates and any drugs that we may in the future develop may be rendered noncompetitive or obsolete.

We are engaged in seeking to develop drugs in the cancer therapeutic segment of the pharmaceutical industry, which 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., Novartis Pharma AG and Genentech, 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 that there are a number of companies that are currently 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 programs seeking to develop compounds that target Hsp90, which is the target of IPI-504 and IPI-493. These companies include, without limitation, Kosan Biosciences, Biogen Idec Inc. and Serenex, Inc. In addition, Curis, Inc. and Genentech have an early-stage clinical development collaboration seeking to develop drugs that target the Hedgehog signaling pathway, which is also being targeted by IPI-926. Abbott Laboratories (in collaboration with Genentech), Gemin-X Biosciences and Ascenta Therapeutics are believed to be in early-stage development of compounds to target the Bcl-2 family of proteins, which is the target of one of our discovery programs.

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;

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

collaborative arrangements with leading companies and research institutions in our fields of interest.

Competitive products and/or new treatment methods for the diseases we are targeting may render our products, if any, obsolete, noncompetitive or uneconomical before we can recover the expenses of developing and commercializing them. If we successfully develop and obtain approval for our drug candidates, we will face competition based on the safety and effectiveness of our drug candidates, the timing of their entry into the market in relation to competitive products in development, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent position and other factors. If we successfully develop drug candidates but those drug candidates do not achieve and maintain market acceptance, our business will not be successful.

Our business has a substantial risk of product liability claims. The defense of any product liability claim brought against us will divert management time and require significant expense.

We are exposed to significant potential product liability risks that are inherent in the development, manufacture, sales 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 sales and marketing 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 to protect against losses that could have a material adverse effect on us. If a claim is brought against us, we might be required to pay legal and other expenses to defend the claim, as well as uncovered damage awards resulting from a claim brought successfully against us. Furthermore, whether or not we are ultimately successful in defending any such claims, we might be required to redirect significant financial and managerial resources to such defense, and adverse publicity is likely

to result.

We work with hazardous materials. Any claims relating to the improper handling, storage or disposal of these materials could be time consuming, costly, and affect how we conduct our business.

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

Table of Contents

to certain federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials.

In the event of an accident, state or federal 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 and may seriously harm our business. While we believe that the amount of insurance we carry is sufficient for typical risks regarding the handling of these materials, it may not be sufficient to cover pollution conditions or other extraordinary or unanticipated events. Additionally, an accident could damage, or force us to shut down, our operations. In addition, if we were to manufacture our products or drug candidates ourselves, we may incur substantial costs to comply with environmental regulations and would be subject to the risk of accidental contamination or injury from the use of hazardous materials in our manufacturing processes.

Risks Related to Intellectual Property

Our inability to protect our proprietary technologies could significantly harm our business and ability to commercialize our drug candidates successfully.

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 in part 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 their methods of use. Our ability to protect our drug candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents.

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, maintain and enforce patents that may issue from any pending or future patent application 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 ultimately subject to change. To date, no consistent policy has emerged regarding the breadth of claims allowed in biotechnology and 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 or will provide us with any significant protection against competitive products or otherwise be commercially valuable. Accordingly, rights under any issued patents may not provide us with sufficient protection to afford us a commercial advantage against competitive products or processes.

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. 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 employees, consultants, scientific advisors and other collaborators to grant us ownership of new intellectual property that is developed. 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 use as anti-cancer drugs or for other indications. 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 our lead candidate, IPI-504. These third parties have pending applications related to these analogs, but we have the first published application covering IPI-504. 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. 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.

Table of Contents

Claims by third parties of intellectual property infringement would require us to spend time and money and could deprive us of valuable rights needed 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 or processes. Furthermore, 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 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. Although we are not currently aware of any litigation or third party claims of intellectual property infringement related to our drug candidates, the pharmaceutical 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 use of our technologies infringes upon 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 biotechnology related 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, commercializing and selling 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, 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 or successfully avoid them through design innovation. 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 not valid. 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. Furthermore, it is unclear how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court or in other proceedings. Although third parties may challenge our rights to, or the scope or validity of, our patent rights, we have not received any communications from third parties challenging our patent applications covering our drug candidates.

We may be subject to claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers, which could result in substantial costs to defend such claims and may divert management's attention from the operation of our business.

As is commonplace in our industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that we or these employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Confidentiality agreements with employees and others may not adequately prevent unauthorized disclosure of trade secrets and other proprietary information and may not adequately protect our intellectual property.

In order to protect our proprietary technology and processes, we rely in part on confidentiality agreements with our corporate partners, employees, consultants, outside scientific collaborators and other advisors. We require each

Table of Contents

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 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 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 the owners of intellectual property we have licensed do not properly maintain or enforce the licensed intellectual property, our competitive position and business prospects may be harmed.

We have entered into license agreements that give us rights to third party intellectual property, and we may enter into similar agreements in the future. Our success will depend in part on the ability of any key licensors to obtain, maintain and enforce patent protection for their intellectual property, in particular those patents to which we have secured exclusive rights. Our licensors may not successfully prosecute the patent applications to which we are licensed. Even if patents issue in respect of these patent applications, our licensors may fail to maintain these patents, may decide not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects.

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 in-license 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.

Risks Associated with Our Common Stock

Our stock price is likely to be volatile, and the market price of our common stock may decline in value in the future.

The market price of our common stock could be subject to significant fluctuations. Market prices for securities of early-stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. 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 and our other drug candidates;

the results of preclinical studies and planned clinical trials of our discovery-stage and preclinical programs;

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;

Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

the initiation of, material developments in, or conclusion of litigation to enforce or defend any of our intellectual property rights;

failure of any of our drug candidates, if approved, to achieve commercial success;

general and industry-specific economic conditions that may affect our research and development expenditures;

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;

the introduction of technological innovations or new commercial products by our competitors;

Table of Contents

changes in estimates or recommendations by securities analysts, if any, who cover our common stock;

future sales of, and the trading volume in, our common stock;

future financings through the issuance of equity or debt securities;

changes in the structure of health care payment systems; and

period-to-period fluctuations in our financial results.

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, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our financial position and reputation.

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

We anticipate retaining our earnings, if any, for future growth. 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.

Anti-takeover provisions in our stockholder rights plan and in our charter and bylaws may prevent or frustrate attempts by stockholders to change the board of directors or current management and could make a third party 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. The stockholder rights plan and our certificate of incorporation and bylaws contain provisions that may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could limit the price that investors might be willing to pay in the future for shares of our common stock.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

(b) The registration statement (File No. 333-36638) for DPI's initial public offering was declared effective by the SEC on July 27, 2000. DPI received net proceeds from the offering of approximately \$94.7 million. From that date through the completion of the merger on September 12, 2006, DPI used approximately \$18.5 million of the net proceeds for acquisitions of companies, \$6.0 million for prepaid μ ARCS royalties, \$16.8 million for capital expenditures and \$4.3 million for costs associated with restructuring. Following the completion of the merger through June 30, 2007, we used approximately \$13.3 million on our Hsp90 and Hedgehog pathway inhibitor programs and for general corporate purposes.

Item 4. Submission of Matters to a Vote of Security Holders

At our Annual Meeting of Stockholders held on May 30, 2007, our stockholders voted on four matters, each of which was adopted, as follows:

1. A proposal to elect the following four Class I directors to serve for a three-year term expiring at the 2010 annual meeting of stockholders; provided, that if the amendment and restatement of our certificate of incorporation and the amendment of our by-laws described below are approved, their term will expire at the 2008 annual meeting of stockholders:

Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-Q

	Votes For	Votes Against	Votes Abstaining
Eric S. Lander, Ph.D.	15,408,729	16,255	5,248
Franklin H. Moss, Ph.D.	15,391,745	33,242	5,424
Herm Rosenman	15,145,271	193,759	91,382
James B. Tananbaum, M.D., M.B.A.	15,406,871	18,116	5,424

Table of Contents

2. A proposal to approve the amendment and restatement of our certificate of incorporation that would declassify our board of directors, providing for the annual election of each director beginning with the 2008 annual meeting of stockholders, and that would allow for the removal of directors without cause and certain other changes.

Votes For	Votes Against	Votes Abstaining
13,747,434	14,641	1,450

3. A proposal to approve an amendment to Article III, Sections 1 and 13 and Article X, Section 1(b) and (c) of our by-laws that would declassify our board of directors, providing for the annual election of each director beginning with the 2008 annual meeting of stockholders, and that would allow for the removal of directors without cause and certain other changes.

Votes For	Votes Against	Votes Abstaining
13,746,251	15,949	1,325

4. A proposal to ratify the selection of Ernst & Young LLP as our independent registered public accounting firm for the current fiscal year.

Votes For	Votes Against	Votes Abstaining
15,408,325	15,096	6,990

Item 6. Exhibits

(a) Exhibits

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

Table of Contents

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.

Dated: August 9, 2007

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

Table of Contents

EXHIBIT INDEX

Exhibit No.	Description
3.1	Restated Certificate of Incorporation of the Registrant. Filed herewith.
3.2	Bylaws of the Registrant. Previously filed as Exhibit 3.4 to the Registrant's Registration Statement on Form S-1 filed on June 23, 2000 (File No. 333-36638) and incorporated herein by reference.
3.3	Amendment to the Registrant's Amended and Restated Bylaws. Previously filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
3.4	Second Amendment to the Registrant's Amended and Restated Bylaws. Filed herewith.
10.1	Amendment No. 4 to the Registrant's 2000 Stock Incentive Plan. Filed herewith.
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.