

INFINITY PHARMACEUTICALS, INC.

Form 10-Q

May 09, 2008

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended March 31, 2008

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)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)  
**33-0655706**  
(I.R.S. Employer  
Identification No.)  
**780 Memorial Drive, Cambridge, Massachusetts 02139**  
(Address of principal executive offices) (zip code)  
**(617) 453-1000**  
(Registrant's telephone number, including area code)

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

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

Large accelerated filer ☐  
Non-accelerated filer ☐

Accelerated filer ☒  
Smaller reporting company ☐

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

Number of shares of the registrant's Common Stock, \$0.001 par value, outstanding on March 31, 2008: 19,746,652

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**INFINITY PHARMACEUTICALS, INC.**

**FORM 10-Q**

**FOR THE QUARTER ENDED MARCH 31, 2008**

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**INFINITY PHARMACEUTICALS, INC.****Condensed Consolidated Balance Sheets**

|                                                                                                                                                                                                                      | <b>March 31, 2008</b><br><i>(unaudited)</i> | <b>December 31, 2007</b> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------------------|
| <b>Assets</b>                                                                                                                                                                                                        |                                             |                          |
| Current assets:                                                                                                                                                                                                      |                                             |                          |
| Cash and cash equivalents                                                                                                                                                                                            | \$ 26,206,593                               | \$ 23,164,721            |
| Available-for-sale securities                                                                                                                                                                                        | 78,833,619                                  | 91,024,747               |
| Accounts receivable                                                                                                                                                                                                  | 360,208                                     | 812,500                  |
| Unbilled accounts receivable                                                                                                                                                                                         | 4,611,173                                   | 4,287,736                |
| Notes receivable from employees                                                                                                                                                                                      | 46,839                                      | 53,414                   |
| Prepaid expenses and other current assets                                                                                                                                                                            | 2,056,062                                   | 2,496,814                |
| <b>Total current assets</b>                                                                                                                                                                                          | <b>112,114,494</b>                          | <b>121,839,932</b>       |
| Property and equipment, net                                                                                                                                                                                          | 5,513,872                                   | 5,984,711                |
| Notes receivable from employees                                                                                                                                                                                      | 34,404                                      | 47,928                   |
| Restricted cash                                                                                                                                                                                                      | 1,114,619                                   | 1,661,171                |
| Other assets                                                                                                                                                                                                         | 170,977                                     | 190,862                  |
| <b>Total assets</b>                                                                                                                                                                                                  | <b>\$ 118,948,366</b>                       | <b>\$ 129,724,604</b>    |
| <b>Liabilities and stockholders' equity</b>                                                                                                                                                                          |                                             |                          |
| Current liabilities:                                                                                                                                                                                                 |                                             |                          |
| Accounts payable                                                                                                                                                                                                     | \$ 1,883,640                                | \$ 2,097,190             |
| Accrued expenses                                                                                                                                                                                                     | 6,889,829                                   | 8,519,754                |
| Deferred revenue                                                                                                                                                                                                     | 10,000,000                                  | 13,750,000               |
| Current portion of long-term debt and capital leases                                                                                                                                                                 | 197,158                                     | 375,618                  |
| <b>Total current liabilities</b>                                                                                                                                                                                     | <b>18,970,627</b>                           | <b>24,742,562</b>        |
| Deferred revenue, less current portion                                                                                                                                                                               | 44,166,667                                  | 51,041,667               |
| Other liabilities                                                                                                                                                                                                    | 2,621,442                                   | 2,777,072                |
| Long-term debt and capital leases, less current portion                                                                                                                                                              | 16,458                                      | 20,400                   |
| <b>Total liabilities</b>                                                                                                                                                                                             | <b>65,775,194</b>                           | <b>78,581,701</b>        |
| Stockholders' equity:                                                                                                                                                                                                |                                             |                          |
| Preferred Stock, \$.001 par value; 1,000,000 shares authorized, no shares issued and outstanding at March 31, 2008 and December 31, 2007                                                                             |                                             |                          |
| Common Stock, \$.001 par value; 100,000,000 shares authorized at March 31, 2008 and December 31, 2007; 19,746,652 and 19,710,773 shares issued and outstanding at March 31, 2008 and December 31, 2007, respectively | 19,747                                      | 19,711                   |
| Additional paid-in capital                                                                                                                                                                                           | 224,851,395                                 | 223,466,502              |
| Accumulated deficit                                                                                                                                                                                                  | (172,123,776)                               | (172,546,266)            |
| Accumulated other comprehensive income                                                                                                                                                                               | 425,806                                     | 202,956                  |

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|                                            |                |                |
|--------------------------------------------|----------------|----------------|
| Total stockholders' equity                 | 53,173,172     | 51,142,903     |
| Total liabilities and stockholders' equity | \$ 118,948,366 | \$ 129,724,604 |

*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)*

|                                                       | <b>Three Months Ended<br/>March 31,</b> |                |
|-------------------------------------------------------|-----------------------------------------|----------------|
|                                                       | <b>2008</b>                             | <b>2007</b>    |
| Collaborative research and development revenue        | \$ 11,391,458                           | \$ 6,115,750   |
| Operating expenses:                                   |                                         |                |
| Research and development                              | 8,521,713                               | 7,476,403      |
| General and administrative                            | 3,771,249                               | 3,293,031      |
| Total operating expenses                              | 12,292,962                              | 10,769,434     |
| Loss from operations                                  | (901,504)                               | (4,653,684)    |
| Other (expense)/income:                               |                                         |                |
| Interest expense                                      | (11,630)                                | (102,466)      |
| Interest and investment income                        | 1,335,624                               | 1,866,442      |
| Net other income                                      | 1,323,994                               | 1,763,976      |
| Net income (loss)                                     | \$ 422,490                              | \$ (2,889,708) |
| Earnings (loss) per common share:                     |                                         |                |
| Basic                                                 | \$ 0.02                                 | \$ (0.15)      |
| Diluted                                               | \$ 0.02                                 | \$ (0.15)      |
| Weighted average number of common shares outstanding: |                                         |                |
| Basic                                                 | 19,677,541                              | 19,388,131     |
| Diluted                                               | 20,235,482                              | 19,388,131     |

*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)*

|                                                                                          | Three Months Ended<br>March 31, 2008 | Three Months Ended<br>March 31, 2007 |
|------------------------------------------------------------------------------------------|--------------------------------------|--------------------------------------|
| <b>Operating activities</b>                                                              |                                      |                                      |
| Net income (loss)                                                                        | \$ 422,490                           | \$ (2,889,708)                       |
| Adjustments to reconcile net income (loss) to net cash provided by operating activities: |                                      |                                      |
| Depreciation                                                                             | 529,866                              | 690,620                              |
| Stock-based compensation                                                                 | 1,312,444                            | 1,135,208                            |
| Loan forgiveness                                                                         | 20,549                               | 24,728                               |
| Gain on sale of property and equipment                                                   | (20,000)                             | (7,500)                              |
| Gain on sale of available-for-sale securities                                            | (94,383)                             |                                      |
| Net accretion of available-for-sale securities                                           | (543,285)                            | (461,273)                            |
| Amortization of warrants                                                                 | 10,808                               | 17,808                               |
| Interest income on restricted cash                                                       | (18,434)                             | (20,575)                             |
| Interest income on employee loans                                                        | (450)                                | (1,092)                              |
| Changes in operating assets and liabilities:                                             |                                      |                                      |
| Accounts receivable and unbilled accounts receivable                                     | 128,855                              | 35,696,506                           |
| Prepaid expenses and other assets                                                        | 452,902                              | 331,329                              |
| Accounts payable, accrued expenses and other liabilities                                 | (1,984,009)                          | (4,463,957)                          |
| Deferred revenue                                                                         | (10,625,000)                         | (3,437,500)                          |
| Net cash provided by (used in) operating activities                                      | (10,407,647)                         | 26,614,594                           |
| <b>Investing activities</b>                                                              |                                      |                                      |
| Purchases of property and equipment                                                      | (59,027)                             | (838,781)                            |
| Proceeds from sale of property and equipment                                             | 20,000                               | 7,500                                |
| Purchases of available-for-sale securities                                               | (37,368,111)                         | (78,640,084)                         |
| Sales and maturities of available-for-sale securities                                    | 50,419,757                           | 5,341,091                            |
| Net cash provided by (used in) investing activities                                      | 13,012,619                           | (74,130,274)                         |
| <b>Financing activities</b>                                                              |                                      |                                      |
| Proceeds from issuances of common stock                                                  | 57,389                               | 179,502                              |
| Release of restricted cash                                                               | 564,986                              |                                      |
| Payments on equipment loan and other debt                                                | (179,932)                            | (473,083)                            |
| Capital lease payments                                                                   | (5,543)                              | (26,688)                             |
| Repayment of employee loans                                                              |                                      | 8,347                                |
| New employee loans                                                                       |                                      | (10,000)                             |
| Net cash provided by (used in) financing activities                                      | 436,900                              | (321,922)                            |
| Net increase (decrease) in cash and cash equivalents                                     | 3,041,872                            | (47,837,602)                         |
| Cash and cash equivalents at beginning of period                                         | 23,164,721                           | 74,147,479                           |
| Cash and cash equivalents at end of period                                               | \$ 26,206,593                        | \$ 26,309,877                        |
| <b>Supplemental cash flow disclosure</b>                                                 |                                      |                                      |
| Interest paid                                                                            | \$ 8,228                             | \$ 92,393                            |

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|                   |    |        |    |           |
|-------------------|----|--------|----|-----------|
| Income taxes paid | \$ | 92,000 | \$ | 1,100,000 |
|-------------------|----|--------|----|-----------|

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

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**Infinity Pharmaceuticals, Inc.**

**Notes to Condensed Consolidated Financial Statements**

**(Unaudited)**

**1. Organization**

Infinity Pharmaceuticals, Inc. is a drug discovery and development company that is utilizing its strength in small molecule drug technologies to discover and develop medicines for the treatment of cancer and related conditions. As used throughout these unaudited, condensed consolidated financial statements, the terms Infinity, we, us, and our refer to the business of Infinity Pharmaceuticals, Inc. and its subsidiaries.

**2. Basis of Presentation**

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

The accompanying condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring accruals and revisions of estimates, considered necessary for a fair presentation of the accompanying condensed consolidated financial statements have been included. Interim results for the three months ended March 31, 2008 are not necessarily indicative of the results that may be expected for the year ending December 31, 2008. 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, 2007, which was filed with the U.S. Securities and Exchange Commission ( SEC ) on March 14, 2008.

The information presented in the condensed consolidated financial statements and related footnotes at March 31, 2008, and for the three months ended March 31, 2008 and 2007, is unaudited and the condensed consolidated balance sheet amounts and related footnotes at December 31, 2007 have been derived from our audited financial statements.

**3. Significant Accounting Policies**

***Cash Equivalents and Available-For-Sale Securities***

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

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 March 31, 2008 and December 31, 2007 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.

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. Realized gains for the period ended March 31, 2008 were \$94,383. There were no realized gains for the period ended March 31, 2007.

***Segment Information***

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Financial Accounting Standards Board Statement ( SFAS ) No. 131, *Disclosures About Segments of an Enterprise and Related Information* ( SFAS No. 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.

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All of our revenues to date have been generated under research collaboration agreements. Revenues associated with the up-front license fee and reimbursable research and development services we received from the Novartis Institutes for BioMedical Research, Inc. ( Novartis ) accounted for approximately 78% of our revenue for the three months ended March 31, 2008, and revenues associated with the up-front license fee we received from MedImmune, Inc., a division of AstraZeneca plc ( MedImmune/AZ ), accounted for the remaining 22%. Revenues associated with our collaboration with Novartis, together with those from compound acceptance fees from Novartis International Pharmaceutical Ltd., accounted for approximately 59% of our revenue for the three months ended March 31, 2007, with the remaining 41% of revenue being attributable to the up-front license fee we received from MedImmune/AZ.

Further, payments due from Novartis represented our entire accounts receivable balance as of March 31, 2008 and December 31, 2007. Payments from MedImmune/AZ represented our entire unbilled accounts receivable balance as of March 31, 2008 and 90% of our unbilled accounts receivable balance as of December 31, 2007.

### Basic and Diluted Earnings/Loss per Common Share

Basic net earnings or 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 income or loss per share is based upon the weighted average number of common shares outstanding during the period, plus the effect of additional weighted average common equivalent shares outstanding during the period when the effect of adding such shares is dilutive. Common equivalent shares result from the assumed exercise of outstanding stock options (the proceeds of which are then assumed to have been used to repurchase outstanding stock using the treasury stock method), the exercise of outstanding warrants and the vesting of unvested restricted shares of common stock. In addition, under SFAS No. 123(R),

*Share-Based Payment* ( SFAS No. 123(R) ), the assumed proceeds under the treasury stock method include the average unrecognized compensation expense of stock options that are in-the-money. This results in the assumed buyback of additional shares, thereby reducing the dilutive impact of stock options. Common equivalent shares have not been included in the net loss per share calculations for the three months ended March 31, 2007 because the effect of including them would have been anti-dilutive. Total potential gross common equivalent shares consisted of the following:

|                            | At March 31, |           |
|----------------------------|--------------|-----------|
|                            | 2008         | 2007      |
| Stock options              | 3,774,632    | 2,950,055 |
| Warrants                   | 246,629      | 246,629   |
| Unvested restricted shares | 40,725       | 149,828   |

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

|                                                              | Three Months<br>Ended March 31, |                |
|--------------------------------------------------------------|---------------------------------|----------------|
|                                                              | 2008                            | 2007           |
| <b>Basic</b>                                                 |                                 |                |
| Net income (loss)                                            | \$ 422,490                      | \$ (2,889,708) |
| Weighted average common shares outstanding                   | 19,677,541                      | 19,388,131     |
| Basic earnings (loss) per share                              | \$ 0.02                         | \$ (0.15)      |
| <b>Diluted</b>                                               |                                 |                |
| Net income (loss)                                            | \$ 422,490                      | \$ (2,889,708) |
| Weighted average common shares outstanding                   | 19,677,541                      | 19,388,131     |
| Effect of dilutive options                                   | 557,941                         |                |
| Weighted average common shares outstanding assuming dilution | 20,235,482                      | 19,388,131     |

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|                                   |    |      |    |        |
|-----------------------------------|----|------|----|--------|
| Diluted earnings (loss) per share | \$ | 0.02 | \$ | (0.15) |
|-----------------------------------|----|------|----|--------|

### ***Stock-Based Compensation Expense***

We account for stock-based compensation under SFAS No. 123(R). 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 for the Black-Scholes valuation model. Equity instrument valuation models are by their nature highly subjective. Any significant changes in any of our judgments, including those used to select the inputs for the Black-Scholes valuation model, could have a significant impact on the fair value of the equity instruments granted or sold and the associated compensation charge, if any, we record in our financial statements.

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### ***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 Emerging Issues Task Force (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, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone and (4) the milestone is at risk for both parties. If any of these conditions is not met, we defer the milestone payment and recognize it as revenue over the estimated period of performance under the contract as we complete our performance obligations.

We will recognize royalty revenue, if any, based upon actual and estimated net sales 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, pre-clinical expenses, clinical trial and related clinical manufacturing expenses, stock-based compensation expense, contract services, and other outside expenses. We expense research and development costs as they are incurred. We have entered into certain collaboration agreements in which expenses are shared with the collaborator, and others in which we are reimbursed for work performed on behalf of the collaborator. We record all of our expenses 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/AZ is a cost-sharing arrangement; our collaboration with Novartis provided for the reimbursement of our research and development expenses.

### ***Income Taxes***

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

We account for income taxes under FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - An Interpretation of FASB Statement No. 109*. We use our judgment for the recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return.

Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, we have recorded a full valuation allowance against our otherwise recognizable net deferred tax assets as of March 31, 2008 and December 31, 2007. During the three month period ended March 31, 2008, we recorded a decrease to our liability for unrecognized tax benefits of approximately \$3,262,500, which relates

to positions taken during the current period. This decrease has no impact to our effective tax rate as a result of our full valuation allowance.

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### ***Fair Value Measurements***

We adopted SFAS No. 157, *Fair Value Measurements* ( SFAS No. 157 ), on January 1, 2008. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS No. 157 codifies the definition of fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, clarifies the principle that fair value should be based on the assumptions market participants would use when pricing the asset or liability, and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. In February 2008, the FASB issued Staff Position 157-2, which deferred the effective date of SFAS No. 157 for one year for nonfinancial assets and liabilities recorded at fair value on a non-recurring basis.

### ***New Accounting Pronouncements***

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations* ( SFAS No. 141(R) ). SFAS No. 141(R) is intended to improve the relevance, representational faithfulness, and comparability of the information that a reporting entity provides in its financial reports about a business combination and its effects. SFAS No. 141(R) establishes principles and requirements for how the acquirer:

recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquired company;

recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase; and

determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination.

SFAS No. 141(R) is effective for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. We do not believe that SFAS No. 141(R) will have a material impact on our financial position or results of operations.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements* ( SFAS No. 160 ). SFAS No. 160 is intended to improve the relevance, comparability, and transparency of the financial information that a reporting entity provides in its consolidated financial statements by establishing accounting and reporting standards for noncontrolling interests. SFAS No. 160 is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. We do not believe that SFAS No. 160 will have a material impact on our financial position or results of operations.

In December 2007, the FASB ratified the consensus reached by the EITF on EITF Issue 07-1, *Accounting for Collaborative Arrangements* ( EITF 07-1 ). EITF 07-1 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from, or made to, other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, EITF 07-1 clarified that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to EITF 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)*. EITF 07-1 will be effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. We do not believe that EITF 07-1 will have a material impact on our financial position or results of operations.

### **4. Stock-Based Compensation**

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 use the Black-Scholes valuation model in determining the fair value of equity awards. Total stock-based compensation expense, related to all equity awards, recognized under SFAS No. 123(R) for the three months ended March 31, 2008 and 2007 comprised the following:

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|                                                                              | Three Months Ended<br>March 31, 2008 | Three Months Ended<br>March 31, 2007 |
|------------------------------------------------------------------------------|--------------------------------------|--------------------------------------|
| <i>Effect of stock-based compensation on net income (loss) by line item:</i> |                                      |                                      |
| Research and development                                                     | \$ 575,380                           | \$ 548,817                           |
| General and administrative                                                   | 737,064                              | 586,391                              |

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As of March 31, 2008, there was approximately \$14.0 million of total unrecognized compensation cost, net of estimated forfeitures, related to unvested options and restricted stock granted. Total cost for all unrecognized compensation is expected to be recognized over a weighted-average period of 2.9 years.

During the three months ended March 31, 2008, we granted 54,535 options at a weighted average fair value of \$3.83. During the three months ended March 31, 2007, we granted 1,190,403 options at a weighted average fair value of \$7.72. The weighted average fair values were estimated using the Black-Scholes valuation model using the following assumptions:

|                                 | For the Three Months Ended<br>March 31, 2008 | For the Three Months Ended<br>March 31, 2007 |
|---------------------------------|----------------------------------------------|----------------------------------------------|
| Risk-free interest rate         | 2.65%                                        | 4.81%                                        |
| Expected annual dividend yield  |                                              |                                              |
| Expected stock price volatility | 61.67%                                       | 61.40%                                       |
| Expected term of options        | 4.94 years                                   | 5.05 years                                   |

## 5. Comprehensive Income (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 income (loss) include our net income (loss) and the change in unrealized gains and losses on our available-for-sale securities. For the three months ended March 31, 2008 and 2007, comprehensive income (loss) was as follows:

|                                                                   | Three Months Ended March 31, |                |
|-------------------------------------------------------------------|------------------------------|----------------|
|                                                                   | 2008                         | 2007           |
| Net income (loss)                                                 | \$ 422,490                   | \$ (2,889,708) |
| Net unrealized holding gains on available-for-sale securities (1) | 222,850                      | 52,065         |
| Total comprehensive income (loss)                                 | \$ 645,340                   | \$ (2,837,643) |

- (1) For the three months ended March 31, 2008, the reclassification adjustment for gains included in net income totaled \$94,383. There was no reclassification adjustment needed for the three months ended March 31, 2007.

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

## 6. Fair Value

SFAS No. 157 establishes a valuation hierarchy for disclosure of the inputs to valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value. A financial asset or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

The following table provides the assets carried at fair value measured on a recurring basis as of March 31, 2008:

|                                                                |            |
|----------------------------------------------------------------|------------|
| Quoted prices in active markets for identical assets (Level 1) | \$         |
| Significant other observable inputs (Level 2)                  | 78,833,619 |

Significant other unobservable inputs (Level 3)

|                                     |               |
|-------------------------------------|---------------|
| Total available-for-sale securities | \$ 78,833,619 |
|-------------------------------------|---------------|

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### **7. Collaborations**

#### **Novartis**

In February 2006, we entered into a collaboration agreement with Novartis to discover, develop and commercialize drugs targeting Bcl protein family members for the treatment of a broad range of cancers. Under the terms of this agreement, we granted to Novartis an exclusive, worldwide license to research, develop and commercialize pharmaceutical products that are based upon our proprietary Bcl inhibitors. Novartis paid us a \$15.0 million up-front license fee, which we recognized on a straight-line basis over the potential four year research term, and Novartis committed to provide us research funding of approximately \$10.0 million during the initial two-year research term, which expired in February 2008. Novartis had the right to extend the research term for up to two additional one-year terms, under which Novartis could have obligated us to provide up to five full-time equivalents, at Novartis' expense, to enable the full transition of the Bcl inhibitor program to Novartis. Novartis chose not to exercise its right for the one-year extensions; thus, the research term ended in February 2008 and we have no further performance obligations to Novartis. As a result, we recognized \$8.1 million of the up-front license fee as revenue in the period ended March 31, 2008.

The change in accounting estimate for the research term in accordance with SFAS No. 154, *Accounting Changes and Error Corrections - A Replacement of APB No. 20 and FASB Statement No. 3*, resulted in a positive net income impact of \$7.2 million and \$0.36 in diluted earnings per share for the three months ended March 31, 2008. We will not recognize any revenue from the up-front license fee or for reimbursable research and development services in future periods.

#### **MedImmune/AZ**

In August 2006, we entered into a product development and commercialization agreement with MedImmune/AZ to jointly develop and commercialize cancer drugs targeting Hsp90 and the Hedgehog pathway. Under the terms of this agreement, we share equally with MedImmune/AZ all development costs, as well as potential profits and losses, from any future marketed products. In November 2007, we regained from MedImmune/AZ all development and worldwide commercialization rights under our Hedgehog pathway program on a royalty-free basis, and MedImmune/AZ's funding obligations under this program will end in May 2008. Since the MedImmune/AZ collaboration is a cost-sharing arrangement, we record reimbursable amounts for MedImmune/AZ's share of the development effort as a reduction of research and development expense. We reduced research and development expense for MedImmune/AZ reimbursable amounts by \$4.4 million and \$3.3 million for the three months ended March 31, 2008 and 2007, respectively. The entirety of our deferred revenue at March 31, 2008 is attributable to the up-front license fee we received from MedImmune/AZ upon entry into this collaboration.

### **8. Restricted Cash**

Our restricted cash is held on deposit with a bank to collateralize a standby letter of credit in the name of our facility landlord in accordance with our facility lease agreement. In February 2008, we amended the amount of the standby letter of credit with the permission of our facility landlord, and we accordingly reduced our restricted cash.

### **9. Commitments**

In March 2008, we subleased additional office space under a non-cancelable facility sublease agreement that expires in December 2012. Future minimum payments, excluding operating costs and taxes, under this sublease are \$197,847 per year.

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### **Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations** **Forward-Looking Information**

The following discussion of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and related notes included elsewhere in this report. Some of the information contained in this discussion and analysis and set forth elsewhere in this report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the section titled "Risk Factors" in Part II of this report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

#### **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.

Our lead product candidate, retaspimycin hydrochloride for injection (also known as IPI-504), or retaspimycin, is an intravenously administered small molecule inhibitor of heat shock protein 90, or Hsp90. Hsp90 is a molecule that maintains the structure and activity of specific proteins, known as "client proteins" of Hsp90. Specific mutations in, or the aberrant expression of, these client proteins result in many types of cancer. Hsp90 enables the survival of the cancer cell by allowing the client protein to continue functioning. Retaspimycin is currently being evaluated as a single agent in three disease-focused clinical trials, including a Phase 1 trial in patients with metastatic and/or unresectable gastrointestinal stromal tumors (GIST) and other soft tissue sarcomas, the Phase 2 portion of a Phase 1/2 trial in patients with advanced non-small cell lung cancer, and a Phase 2 trial in patients with hormone-resistant prostate cancer. We are also conducting a Phase 1b clinical trial of retaspimycin in combination with Taxotere® (docetaxel) in patients with advanced solid tumors. We currently expect to initiate additional clinical trials of retaspimycin during 2008, including a Phase 3 clinical trial in patients with GIST in the third quarter of 2008 pending ongoing consultation with advisors and regulatory authorities and analysis of data from the ongoing Phase 1 trial, and one or more Phase 2 clinical trials in additional solid tumor indications. We also intend to begin a Phase 1 clinical trial of IPI-493, an orally available inhibitor of Hsp90, in the second quarter of 2008. We are pursuing our Hsp90 program in collaboration with MedImmune, Inc., a division of AstraZeneca plc. We use the term MedImmune/AZ to identify our Hsp90 collaborator.

Our next most advanced program is directed against the Hedgehog signaling pathway, or 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. The lead candidate in our Hedgehog pathway program, IPI-926, has shown potent and selective inhibition of the Hedgehog pathway as well as anti-tumor activity in preclinical models. We intend to file an investigational new drug, or IND, application for IPI-926 in the third quarter of 2008 and to commence a Phase 1 clinical trial shortly thereafter.

We have historically incurred net losses as we have devoted substantially all of our resources to research and development. 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 our drug candidates. We expect that, in the near term, we will incur substantial losses relating primarily to our efforts to advance the development of retaspimycin, IPI-493 and IPI-926.

#### **Collaboration Agreements**

In August 2006, we entered into a product development and commercialization agreement with MedImmune/AZ to jointly develop and commercialize cancer drugs targeting Hsp90 and the Hedgehog pathway. Under the terms of this agreement, we share equally with MedImmune/AZ all development costs, as well as potential profits and losses, from any future marketed products. MedImmune/AZ made non-refundable, up-front payments totaling \$70 million to us in order to obtain co-exclusive rights to the Hsp90 and Hedgehog pathway development programs. In November 2007, we regained from MedImmune/AZ all development and worldwide commercialization rights under our Hedgehog pathway program on a royalty-free basis, and MedImmune/AZ's funding obligations under this program will end in May 2008. We continue to collaborate with MedImmune/AZ on our Hsp90 program, and could receive up to \$215 million in milestone payments if certain late-stage development and sales objectives are achieved for products arising from this program. 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 the Hsp90 program, in which case we would receive a royalty on sales of any products arising from the program instead of profits and losses.



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In February 2006, we entered into a collaboration agreement with Novartis to discover, develop and commercialize drugs targeting Bcl protein family members for the treatment of a broad range of cancers. Novartis paid us a \$15 million up-front license fee, an affiliate of Novartis made a \$5 million equity investment in us, and Novartis committed to provide us research funding of approximately \$10 million over the initial two-year research term, which expired in February 2008. Novartis had the right to extend the research term for up to two additional one-year terms, under which Novartis could have obligated us to provide up to five full-time equivalents, at Novartis' expense, to enable the full transition of the Bcl inhibitor program to Novartis. Novartis chose not to exercise its right for these one-year extensions; thus, the research term ended in February 2008 and we have no further performance obligations to Novartis. As a result, we recognized \$8.1 million of the up-front license fee as revenue in the period ended March 31, 2008. The change in accounting estimate resulted in a positive net income impact of \$7.2 million for the three months ended March 31, 2008. We will not recognize any revenue from the up-front license fee or for reimbursable research and development services in future periods.

We also entered into technology access alliances with Amgen Inc., Novartis International Pharmaceutical Ltd., or Novartis International, and Johnson & Johnson Pharmaceutical Research & Development, a division of Janssen Pharmaceutical N.V., or J&J, relating to our diversity oriented synthesis technology. As of December 31, 2007, we successfully completed all of our obligations to our partners under these agreements. We do, however, have the right to receive milestone payments under two of these agreements if our alliance partner develops and successfully commercializes products based upon certain compounds licensed to them under the applicable agreement.

## **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. Our primary research and development programs include:

retaspimycin, an Hsp90 inhibitor that is currently in clinical development as a single agent in patients with metastatic and/or unresectable GIST, advanced non-small cell lung cancer and hormone-resistant prostate cancer, as well as in combination with Taxotere® (docetaxel);

IPI-493, a second-generation oral Hsp90 inhibitor for which we have concluded investigational new drug, or IND, enabling studies; and

IPI-926, the lead candidate in our Hedgehog pathway inhibitor program, for which we are conducting IND-enabling studies. Our 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.

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Our Hsp90 program is being conducted in collaboration with MedImmune/AZ. Under our collaboration with MedImmune/AZ, we share research and development expenses equally with MedImmune/AZ. This cost-sharing arrangement also applies to our Hedgehog pathway inhibitor program through May 2008, which is six months from when MedImmune/AZ opted out of that program. Because this is a cost-sharing arrangement, we record amounts that are reimbursable from MedImmune/AZ for its share of the development effort as a reduction of research and development expense.

### ***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 patent 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, assumptions in the valuation of stock-based compensation, income taxes and the measurement of fair value of assets. 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 (SAB) No. 101, *Revenue Recognition in Financial Statements*, as amended by SAB No. 104, *Revenue Recognition*, and Emerging Issues Task Force (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 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.

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



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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 circumstances differ from our initial judgments, our revenue recognition with respect to such transactions would change accordingly and any such change could affect our reported operating results.

### ***Research and Development Expense***

Research and development expense consists of expenses incurred in performing research and development activities. We expense research and development costs as they are incurred. We have entered into certain collaboration agreements in which expenses are shared with the collaborator, and others in which we are reimbursed for work performed on behalf of the collaborator. We record all of these expenses as research and development expense. If the arrangement is a cost-sharing arrangement and there is a period during which we receive payments from the collaborator, we record payments from the collaborator for its share of the development effort as a reduction of research and development expense. If the arrangement is a cost-sharing arrangement and there is a period during which we make payments to the collaborator, we 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/AZ is a cost-sharing arrangement; our collaboration with Novartis provided 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 account for stock-based compensation under Financial Accounting Standards Board Statement No. 123(R), *Share-Based Payment* (SFAS No. 123(R)). 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 for the Black-Scholes valuation model. Equity instrument valuation models are by their nature highly subjective. Any significant changes in any of our judgments, including those used to select the inputs for the Black-Scholes valuation model, could have a significant impact on the fair value of the equity instruments granted or sold and the associated compensation charge, if any, we record in our financial statements.

### ***Income Taxes***

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

We account for income taxes under FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes – An Interpretation of FASB Statement No. 109*. We use our judgment for the recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return.



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### ***Fair Value Measurements***

We adopted FASB issued SFAS No. 157, *Fair Value Measurements* ( SFAS No. 157 ), on January 1, 2008. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS No. 157 codifies the definition of fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, clarifies the principle that fair value should be based on the assumptions market participants would use when pricing the asset or liability, and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. In February 2008, the FASB issued Staff Position 157-2, which deferred the effective date of FAS 157 for one year for nonfinancial assets and liabilities recorded at fair value on a non-recurring basis.

### ***New Accounting Pronouncements***

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations* ( SFAS No. 141(R) ). SFAS No. 141(R) is intended to improve the relevance, representational faithfulness, and comparability of the information that a reporting entity provides in its financial reports about a business combination and its effects. SFAS No. 141(R) establishes principles and requirements for how the acquirer:

recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquired company;

recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase; and

determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination.

SFAS No. 141(R) is effective for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. We do not believe that SFAS No. 141(R) will have a material impact on our financial position or results of operations.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements* ( SFAS No. 160 ). SFAS No. 160 is intended to improve the relevance, comparability, and transparency of the financial information that a reporting entity provides in its consolidated financial statements by establishing accounting and reporting standards for noncontrolling interests. SFAS No. 160 is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. We do not believe that SFAS No. 160 will have a material impact on our financial position or results of operations.

In December 2007, the FASB ratified the consensus reached by the EITF on EITF Issue 07-1, *Accounting for Collaborative Arrangements* ( EITF 07-1 ). EITF 07-1 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from, or made to, other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, EITF 07-1 clarified that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to EITF 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)*. EITF 07-1 will be effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. We do not believe that EITF 07-1 will have a material impact on our financial position or results of operations.

### **Results of Operations**

The following tables summarize our results of operations for each of the three-month periods ended March 31, 2008 and 2007, in thousands, together with the change in these items in dollars and as a percentage:

**For the Three Months  
Ended March 31,**

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|                                    | 2008      | 2007     | \$ Change | % Change |
|------------------------------------|-----------|----------|-----------|----------|
| Revenue                            | \$ 11,391 | \$ 6,116 | \$ 5,275  | 86%      |
| Research and development expense   | (8,522)   | (7,476)  | (1,046)   | 14%      |
| General and administrative expense | (3,771)   | (3,293)  | (478)     | 15%      |
| Interest expense                   | (12)      | (102)    | 90        | (88)%    |
| Interest and investment income     | 1,336     | 1,866    | (530)     | (28)%    |

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### ***Revenue***

Our revenue during the three-month period ended March 31, 2008 consisted of approximately:

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

\$8.1 million related to the amortization of the non-refundable license fee, and \$0.8 million in revenue related to the reimbursable research and development services we performed, under the Bcl-2 collaboration we entered with Novartis in February 2006. The research term of this collaboration ended in February 2008 and we have no further performance obligations to Novartis. As a result, we recognized \$8.1 million of the up-front license fee as revenue in the period ended March 31, 2008. The change in accounting estimate for the research term resulted in a positive net income impact of \$7.2 million for the three months ended March 31, 2008. We will not recognize any revenue from the up-front license fee or for reimbursable research and development services in future periods.

Our revenue during the three-month period ended March 31, 2007 consisted of approximately:

\$2.5 million associated with the amortization of the up-front license fee we received from MedImmune/AZ;

\$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

\$1.5 million related to the acceptance of compounds by Novartis International under our technology access agreement.

### ***Research and Development Expense***

Research and development expense represented approximately 69% of our total operating expenses for the three months ended March 31, 2008 and 2007.

The increase in research and development expense in the three-month period ended March 31, 2008 as compared to the same period in 2007 is primarily attributable to:

an increase of \$1.3 million for pre-clinical costs and an increase of \$0.6 million for drug development costs as we advance our pipeline of drug candidates; and

an increase of \$0.2 million for clinical trials of retaspimycin.

This \$2.1 million increase in research and development expenditures was partially offset by an increase of \$1.1 million in amounts reimbursable by MedImmune/AZ under the cost-sharing provisions of our collaboration agreement.

During the three-month periods ended March 31, 2008 and 2007, 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 months ended March 31, 2008 include a credit of approximately \$4.4 million, and for the three months ended March 31, 2007 include a credit of approximately \$3.3 million, attributable to amounts reimbursable by MedImmune/AZ under the cost-sharing provisions of our collaboration agreement.

| <b>Program</b>              | <b>Three Months Ended<br/>March 31, 2008</b> | <b>Three Months Ended<br/>March 31, 2007</b> |
|-----------------------------|----------------------------------------------|----------------------------------------------|
| Hsp90 Inhibitors            | \$ 3.6 million                               | \$ 2.3 million                               |
| Hedgehog Pathway Inhibitors | 1.2 million                                  | 1.2 million                                  |
| Bcl-2                       | 0.6 million                                  | 1.3 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. We expect our Hsp90 program expenses to increase as we advance retaspimycin into additional and later stage clinical trials and as IPI-493 enters clinical development. In addition, we expect expenses for our Hedgehog pathway inhibitor program to increase as IPI-926 enters clinical development, and as a result of MedImmune/AZ not funding half of the expenses of this program after May 2008. We do not expect to incur any future research and development expenses for the Bcl-2 program because our research obligations under our collaboration with Novartis ended in February 2008.

**Table of Contents****General and Administrative Expense**

The increase in general and administrative expense for the three months ended March 31, 2008 as compared to the three months ended March 31, 2007 is primarily attributable to an increase of \$0.2 million in consulting expenses, principally related to early commercial development, and an increase of \$0.2 million in stock-based compensation expense.

**Interest and Investment Income**

Interest and investment income decreased in the three months ended March 31, 2008 as compared to the three months ended March 31, 2007 primarily as a result of the lower balance of cash, cash equivalents and available-for-sale securities due to our cash burn and lower yields on our cash equivalents and available-for-sale securities.

**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 significant capital resources are as follows:

|                                                               | March 31,<br>2008                            | December 31, 2007 |
|---------------------------------------------------------------|----------------------------------------------|-------------------|
| Cash, cash equivalents and available-for-sale securities      | \$ 105,040,212                               | \$ 114,189,468    |
| Working capital                                               | 93,143,867                                   | 97,097,370        |
|                                                               | <b>Three Months Ended March 31,<br/>2008</b> | <b>2007</b>       |
| Cash (used in) provided by:                                   |                                              |                   |
| Operating activities                                          | \$ (10,407,647)                              | \$ 26,614,594     |
| Investing activities                                          | 13,012,619                                   | (74,130,274)      |
| Capital expenditures (included in investing activities above) | (59,027)                                     | (838,781)         |
| Financing activities                                          | 436,900                                      | (321,922)         |

**Cash Flows**

The principal use of cash in operating activities in all of the periods presented was the funding of our daily operations, principally research and development. 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/AZ, representing the second half of the up-front license payment related to our collaboration agreement. During the three months ended March 31, 2008, we recognized the remaining portion of our deferred revenue or \$8.1 million related to the up-front license fee from Novartis upon conclusion of the research term of our Bcl-2 collaboration.

Cash flow from operations included a decrease in accounts payable, accrued expenses and other liabilities resulting primarily from payments of \$1.9 million in connection with our contingent cash compensation program, representing payments made during the three months ended March 31, 2008 for amounts earned in 2007. Cash flow from operations included a decrease in the accounts payable, accrued expenses and other liabilities resulting primarily from payments of \$1.7 million in connection with our contingent cash compensation program, representing payments made during the three months ended March 31, 2007 for amounts earned in 2006, as well as \$1.1 million for federal income taxes and \$1.0 million to J&J to refund a portion of the upfront license fee paid in connection with our technology access agreement.

We believe that our cash, cash equivalents and available-for-sale securities at March 31, 2008 will be sufficient to support our current operating plan into 2010. Our currently-planned operating and capital requirements primarily include the need for working capital to, among other things:

continue clinical development of retaspimycin;

commence clinical development of, IPI-493;

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

advance our additional discovery programs.

We may, however, need to raise additional funds before that date if our research and development expenses exceed our current expectations or if we do not receive the milestone or other payments we expect to receive from third parties. This could occur for many reasons, including:

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

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

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

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

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

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

we acquire or license rights to additional drug candidates or new technologies from one or more third parties.

While we expect to seek additional funding through public or private financings of equity or debt securities, we may not be able to obtain financing on acceptable terms, or at all. In addition, the terms of our financings may be dilutive to, or otherwise adversely affect, holders of our common stock, or they may impact our ability to make capital expenditures or incur additional debt. We may also seek additional funds through arrangements with collaborators or other third parties, or through project financing. These arrangements would generally require us to relinquish or encumber rights to some of our technologies or drug candidates, and we may not be able to enter into such agreements on acceptable terms, if at all. If we are unable to obtain additional funding on a timely basis, we may be required to curtail or terminate some or all of our development programs, including some or all of our drug candidates.

## **Contractual Obligations and Off-Balance Sheet Arrangements**

In March 2008, we subleased additional office space under a non-cancelable facility sublease agreement that expires in December 2012. Future minimum payments, excluding operating costs and taxes, under this sublease are \$197,847 per year.

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-sponsored enterprise 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.

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A hypothetical 100 basis point increase in interest rates would result in an approximate \$250,550 decrease in the fair value of our investments as of March 31, 2008, as compared to \$322,742 as of December 31, 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.

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**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 March 31, 2008. 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 March 31, 2008, 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 fiscal quarter ended March 31, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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**PART II. OTHER INFORMATION**

**Item 1A. Risk Factors**

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

**Risks Related to Our Stage of Development as a Company**

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

We have a limited operating history for you to evaluate our business. We have no approved products and have generated no product revenue. We have historically incurred operating losses. As of March 31, 2008, we had an accumulated deficit of \$172.1 million, and our net losses for the years ended December 31, 2007, 2006 and 2005 were \$16.9 million, \$28.4 million and \$36.4 million, respectively. We have spent, and expect to continue to spend, significant resources to fund the research and development of retaspimycin and our other drug candidates. We expect to incur substantial and increasing operating losses over the next several years as our research, development, preclinical testing, clinical trial and drug manufacturing activities increase. As a result, our accumulated deficit will also increase significantly.

Our drug candidates are in the early stages of development and may never result in any revenue. We will not be able to generate product revenue unless and until one of our drug candidates successfully completes clinical trials and receives regulatory approval. Since retaspimycin, our most advanced drug candidate, is still in early clinical development, we do not expect to receive revenue from our drug candidates for several years, if at all. We may seek to obtain funding from collaboration or licensing agreements with third parties.

Even if we eventually generate revenues, we may never be profitable, and if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

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

We will need substantial additional funds to support our planned operations. Based on our current operating plans, we expect that our current cash, cash equivalents and available-for-sale securities are sufficient to fund our planned operations into 2010. We may, however, need to raise additional funds before that date if our research and development expenses exceed our current expectations or if we do not receive the milestone or other payments we expect to receive from third parties. This could occur for many reasons, including:

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

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

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

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

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

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

we acquire or license rights to additional drug candidates or new technologies from one or more third parties.

While we expect to seek additional funding through public or private financings of equity or debt securities, we may not be able to obtain financing on acceptable terms, or at all. In addition, the terms of our financings may be dilutive to, or otherwise adversely affect, holders of our common stock, or they may impact our ability to make capital expenditures or incur additional debt. We may also seek additional funds through arrangements with collaborators or other third parties, or through project financing. These arrangements would generally require us to relinquish or encumber rights to some of our technologies or drug candidates, and we may not be able to enter into such agreements on acceptable terms, if at all. If we are unable to obtain additional funding on a timely basis, we may be required to curtail or terminate some or all of our development programs, including some or all of our drug candidates.

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

Our only current clinical candidate, retaspimycin, is at an early stage of development and its risk of failure is high. To date, the data supporting our clinical development strategy for retaspimycin is derived solely from laboratory and preclinical studies and limited early-stage clinical trials. Later clinical trials, including the Phase 3 clinical trial of retaspimycin in GIST that we intend to commence later this year, may not show that retaspimycin is safe and effective in patients with refractory GIST, in which case we would need to change our development strategy or abandon development of that drug candidate, either of which would result in delays and additional costs. It is impossible to predict when or if retaspimycin or any of our other drug candidates will prove safe or effective in humans or receive regulatory approval. These drug candidates may not demonstrate in patients the chemical and pharmacological properties ascribed to them in laboratory studies or early-stage clinical trials, and they may interact with human biological systems or other drugs in unforeseen, ineffective or harmful ways. If we are unable to discover or successfully develop drugs that are safe and effective in humans, we will not have a viable business.

***If our strategic alliance with MedImmune/AZ, or any future alliance we may enter, is unsuccessful, our operations may be negatively impacted.***

We have entered into an alliance with MedImmune/AZ to jointly develop and commercialize novel drugs targeting Hsp90. Under our collaboration agreement, MedImmune/AZ has committed to provide substantial funding, as well as significant capabilities in clinical development, regulatory affairs, marketing and sales. The success of this alliance is largely dependent on the resources, efforts, technology and skills brought to it by MedImmune/AZ. Disputes and difficulties in these types of relationships are common, often due to conflicting priorities or conflicts of interest. Merger and acquisition activity may exacerbate these conflicts. The benefits of this alliance will be reduced or eliminated if MedImmune/AZ:

terminates the agreement;

fails to devote financial or other resources to the alliance, thereby hindering or delaying development, manufacturing or commercialization activities;

fails to successfully develop, manufacture or commercialize any drug candidate under the alliance; or

fails to maintain the financial resources necessary to continue financing its portion of development, manufacturing, and commercialization costs or its own operations.

In June 2007, AstraZeneca plc completed its acquisition of MedImmune, resulting in MedImmune operating as a subsidiary of AstraZeneca. This integration of MedImmune and AstraZeneca's operations is ongoing, and integration activities may have an impact on the combined company's ability to retain and motivate key personnel, divert management attention and resources, or result in portfolio reprioritizations. These events may result in delays in our development programs and have an adverse effect on our financial condition or operations.

Under our agreement with MedImmune/AZ, MedImmune/AZ may opt out of the Hsp90 project, as it did with the Hedgehog pathway project in November 2007, at any time 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. If MedImmune/AZ were to exercise its right to opt out of a program or to terminate the agreement, we may not have sufficient financial resources or capabilities to continue development and commercialization of products from our Hsp90 program, and our ability to attract a new alliance partner would be made more difficult.

Much of the potential revenue from our existing and future alliances, if any, 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 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.

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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, and our financial condition and operations would be negatively impacted.

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

We are highly dependent on our management team, particularly Steve 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 the employee is obligated to a fixed term of service and that the employment relationship may be terminated by either Infinity or the employee at any time, without notice, and whether or not cause or good reason exists for such termination. The loss of the services of any of these individuals might impede the achievement of our research, development and commercialization objectives. We do not maintain key person insurance on any of our employees.

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

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

We are experiencing a period of growth that is placing a strain on our operational infrastructure. We expect this strain to continue as we continue our evolution as a company and seek to obtain and manage relationships with third parties. Our ability to manage our operations and growth effectively depends upon the continual improvement of our processes and procedures, and the preservation of our corporate culture. We may not be able to implement improvements in an efficient or timely manner, or maintain our corporate culture through organizational change. If we do not meet these challenges, we may be unable to take advantage of market opportunities, execute our business strategies or respond to competitive pressures, which in turn may slow our growth or give rise to inefficiencies that would increase our losses or delay our programs.

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

*Our inability to maintain effective internal controls under Section 404 of the Sarbanes-Oxley Act could adversely affect our business and stock price.*

Section 404 of the Sarbanes-Oxley Act of 2002 requires us, on an annual basis, to review and evaluate our internal controls, and requires our independent auditors to attest to the effectiveness of our internal controls. Our failure to maintain the effectiveness of our internal controls in accordance with the requirements of Section 404 of the Sarbanes-Oxley Act, as they exist today or may be modified, supplemented or amended in the future, could have a material adverse effect on our business, operating results and stock price.

## **Risks Related to the Development and Commercialization of Our Drug Candidates**

*All of our drug candidates 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 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 retaspimycin, which is currently in early clinical trials and is the subject of a broad product development and commercialization agreement with MedImmune/AZ. 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

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approval. In connection with the clinical trials of retaspimycin and any other drug candidate we may seek to develop in the future, we face, among other risks, risks that:

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

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the results of later trials may not confirm 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 authorities.

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 changes in government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review.

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.

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

We cannot predict whether we will encounter problems with any of our ongoing or planned clinical trials that will cause us, 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:

unexpected or unfavorable results of discussions with the FDA or comparable foreign authorities regarding the scope or design of our clinical trials, including discussions regarding the special protocol assessment we submitted in anticipation of a potential Phase 3 clinical trial of retaspimycin in GIST;

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

delays in enrolling patients into clinical trials;

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

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

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

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

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

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

the placement by the FDA of a clinical hold on a trial; or

any restrictions on, or post-approval commitments with regard to, any regulatory approval we ultimately obtain that render the drug candidate not commercially viable.

Clinical trials require sufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the trial protocol, the number of clinical trial sites and the proximity of patients to those sites, the availability of effective treatments for the relevant disease, the eligibility criteria for the trial, the commitment of clinical investigators to identify eligible patients, and competing studies or trials. Delays in patient enrollment can result in increased costs and longer development times. Our failure to enroll patients in our clinical trials could delay the completion of the clinical trial beyond current expectations. In

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

### ***Recently enacted legislation may make it more difficult and costly for us to obtain regulatory approval of our product candidates and to produce, market and distribute products after approval.***

In September 2007, the Food and Drug Administration Amendments Act of 2007, or FDAAA, was enacted. The FDAAA grants a variety of new powers to the FDA, many of which are aimed at improving the safety of drug products before and after approval. Under the FDAAA, companies that violate the new law are subject to substantial civil monetary penalties. While we expect the FDAAA to have a substantial effect on the pharmaceutical industry, the extent of that effect is not yet known. As the FDA issues regulations, guidance and interpretations relating to the new legislation, the impact on the industry, as well as our business, will become clearer. The new requirements and other changes that the FDAAA imposes may make it more difficult, and likely more costly, to obtain approval of new pharmaceutical products and to produce, market and distribute products after approval.

### ***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, among other things, patient injury or death, product liability claims, penalties or other



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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 retaspimycin or any of our other drug candidates for commercial sale, we expect that we would continue to rely, at least initially, on third party manufacturers to produce commercial quantities of our approved drug candidates. These manufacturers may not be able to successfully increase the manufacturing capacity for any approved drug candidates in a timely or economical manner, or at all. Significant scale-up of manufacturing might entail changes in the manufacturing process that have to be submitted to 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 retaspimycin or any of our other drug candidates obtains regulatory approval, that product may not gain market acceptance among physicians, patients and the medical community for a variety of reasons including:

timing of market introduction of competitive drugs;

lower demonstrated clinical safety and efficacy compared to other drugs;

lack of cost-effectiveness;

lack of reimbursement from managed care plans and other third-party payers;

inconvenient or difficult administration;

prevalence and severity of side effects;

potential advantages of alternative treatment methods;

safety concerns with similar drugs marketed by others;

the reluctance of the target population to try new therapies and of physicians to prescribe those therapies; and

ineffective sales, marketing and distribution support.

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

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

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

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***Even if we receive regulatory approvals for marketing our drug candidates, if they exhibit harmful side effects after approval, our regulatory approvals could be revoked or otherwise negatively impacted, and we could be subject to costly and damaging product liability claims.***

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

***Healthcare reform measures could adversely affect our business.***

The efforts of governmental and third-party payers to contain or reduce the costs of healthcare may adversely affect the business and financial condition of pharmaceutical companies. In the United States and in foreign jurisdictions there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the healthcare system. For example, in some countries other than the United States, pricing of prescription drugs is subject to government control, and we expect proposals to implement similar controls in the United States to continue. The pendency or approval of such proposals could result in a decrease in our stock price or limit our ability to raise capital or to enter into collaborations or license rights to our drug candidates.

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

The Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA, expanded Medicare coverage for drug purchases by the elderly and disabled beginning in 2006. The new legislation uses formularies, preferred drug lists and similar mechanisms that may limit the number of drugs that will be covered in any therapeutic class or reduce the reimbursement for some of the drugs in a class.

As a result of the expansion of legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. Indeed, legislation that would permit the federal government to negotiate drug prices directly with manufacturers under the Medicare prescription drug programs is a major policy priority for many members of Congress and may be passed in the future. These cost reduction initiatives could decrease the coverage and price that we receive for our products in the future and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own reimbursement systems, and any limits on or reductions in reimbursement that occur in the Medicare program may result in similar limits on or reductions in payments from private payers.

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

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

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

In order for us or our alliance partners to market our drug candidates outside of the United States, separate regulatory approvals must be obtained and we or our alliance partners will need to comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval abroad may differ from and be longer than that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval and additional risks associated with requirements particular to those foreign jurisdictions where we will seek regulatory approval of our products. We may not obtain foreign regulatory approvals on a timely basis, if at all.

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Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We and our alliance partners may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market outside the United States. The failure to obtain these approvals could materially adversely affect our business, financial condition and results of operations.

### **Risks Related to Our Field**

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

We seek to develop new drugs for cancer and related conditions. The cancer therapeutic segment of the pharmaceutical industry is highly competitive and rapidly changing. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations are pursuing the development of novel drugs that target various forms of cancer. We currently face, and expect to continue to face, intense and increasing competition as new products enter the market and advanced technologies become available. Moreover, there are a number of large pharmaceutical companies currently marketing and selling products to treat cancer, including Bristol-Myers Squibb Company, F. Hoffmann-La Roche Ltd., Novartis Pharma AG, Pfizer Inc. 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 of a number of companies seeking to develop drug candidates directed to the same biological targets that our own drug candidates are designed to inhibit. Specifically, we are aware of numerous companies that have clinical development programs for compounds targeting Hsp90, which is the target of retaspimycin and IPI-493. These companies include, without limitation, Kosan Biosciences Incorporated, Biogen Idec Inc., Pfizer (through its acquisition of Serenex, Inc.), Vernalis plc (in collaboration with Novartis), Synta Pharmaceuticals Corp. and Astex Therapeutics Limited (in collaboration with Novartis). In addition, Curis, Inc. (in collaboration with Genentech) and Exelixis, Inc. (in collaboration with Bristol-Myers Squibb) have collaborations under which drugs targeting the Hedgehog signaling pathway, which is also being targeted by IPI-926, are being developed.

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.

Our competitors may commence and complete clinical testing of their product candidates, obtain regulatory approvals, and begin commercialization of their products sooner than we and/or our collaborative partners may for our own drug candidates. These competitive products may have superior safety or efficacy, or may be manufactured less expensively, than our drug candidates. If we are unable to compete effectively against these companies on the basis of safety, efficacy or cost, then we may not be able to commercialize our drug candidates or achieve a competitive position in the market. This would adversely affect our ability to generate revenues.

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

We face exposure to significant product liability or other claims if our drug candidates, products or processes are alleged to have caused harm. These risks are inherent in the testing, manufacturing and marketing of human medicinal products. Although we do not currently commercialize any products, claims could be made against us based on the use of our drug candidates in clinical trials. We currently have clinical trial insurance and will seek to obtain product liability insurance prior to the 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. If we are sued for any injury caused by our products or product candidates, our liability could exceed our

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insurance coverage and our total assets, and we would need to divert management attention to our defense. Claims against us, regardless of their merit or potential outcome, may also generate negative publicity or hurt our ability to recruit investigators and patients to our clinical trials, obtain physician acceptance of our products, or expand our business.

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

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

### **Risks Related to Intellectual Property**

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

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

Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the claim scope of these patents, our ability to obtain and enforce patents that may issue from any pending or future patent applications is uncertain and involves complex legal, scientific and factual questions. The standards which the United States Patent and Trademark Office, or PTO, and its foreign counterparts use to grant patents are not always applied predictably or uniformly and are 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, will provide us with any significant protection against competitive products, or will afford us a commercial advantage over competitive products. In addition, the U.S. Senate is currently considering a bill that could change United States law regarding, among other things, post-grant review of issued patents and the calculation of damages once patent infringement has been determined by a court of law. If enacted into law, these provisions could severely weaken patent protection in the United States.

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

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

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In addition, we rely on intellectual property assignment agreements with our corporate partners, 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 therapeutic use. In the event that a third party has also filed a U.S. patent application relating to our drug candidates or a similar invention, we may have to participate in interference proceedings declared by the PTO or the third party to determine priority of invention in the United States.

For example, we are aware of third parties who are actively researching ansamycin analogs that are similar to our lead candidate, retaspimycin. These third parties have pending applications related to these analogs, but we have the first published application covering retaspimycin. It is possible that an interference proceeding could be declared between our application covering retaspimycin 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.

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

Our commercial success will depend on whether there are third party patents or other intellectual property relevant to our potential products that may block or hinder our ability to develop and commercialize our drug candidates. We may not have identified all U.S. and foreign patents or published applications that may affect our business either by blocking our ability to commercialize our drugs or by covering similar technologies that affect the applicable market. In addition, we may undertake research and development with respect to potential products, even when we are aware of third party patents that may be relevant to such potential products, on the basis that we may challenge or license such patents. For example, in our Hsp90 program, we have initiated a clinical trial evaluating the administration of retaspimycin in combination with Taxotere® (docetaxel), and we may conduct additional trials with retaspimycin in combination with other therapeutic agents. We are aware of issued patents and published applications directed to combinations of Hsp90 inhibitors with a variety of other chemotherapeutic agents. We are also aware of patents and patent applications directed to methods of treating various disorders using a variety of Hsp90 inhibitors. We are in the process of evaluating the scope and validity of these patents and applications to determine whether we need to obtain one or more licenses. While 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 manufacture and sale of our potential products or use of our technologies infringes any patents, or defending against any claim that we are employing any proprietary technology without authorization. The outcome of patent litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of the adverse party, especially in 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

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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.

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

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

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

In addition, we 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 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 common stock may have a volatile trading price and low trading volume.***

The market price of our common stock could be subject to significant fluctuations. Some of the factors that may cause the market price of our common stock to fluctuate include:

the results of our current and any future clinical trials of retaspimycin and our other drug candidates;

the results of preclinical studies and planned clinical trials of IPI-493, IPI-926 and our other discovery-stage programs;

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

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the entry into key agreements, including those related to the acquisition or in-licensing of new programs, or the termination of key agreements;

the results and timing of regulatory reviews relating to the approval of our drug candidates;

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

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;

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

future financings through the issuance of equity or debt securities or otherwise;

changes in the structure of health care payment systems; and

our cash position 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, when the market price of a stock has been volatile, as our stock price may be, holders of that stock have occasionally brought securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit is without merit, we could incur substantial costs defending the lawsuit. A stockholder lawsuit could also divert the time and attention of our management.

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

We anticipate retaining any future earnings for reinvestment in our research and development programs. Therefore, we do not anticipate paying cash dividends in the future. As a result, only appreciation of the price of our common stock will provide a return to stockholders. Investors seeking cash dividends should not invest in our common stock.

***Our stockholder rights plan, anti-takeover provisions in our organizational documents, and Delaware law may make an acquisition of us difficult.***

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

In addition, we are incorporated in Delaware. Anti-takeover provisions of Delaware law and our organizational documents may make a change in control more difficult. Also, under Delaware law, our board of directors may adopt additional anti-takeover measures. For example, our charter authorizes our board of directors to issue up to 901,000 shares of currently undesignated preferred stock and to determine the terms of those shares of stock without any further action by our stockholders. If the board of directors exercises this power, it could be more difficult for a third party to acquire a majority of our outstanding voting stock. Our charter and by-laws also contain provisions limiting the ability of stockholders to call special meetings of stockholders.

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

Under Section 203 of the Delaware General Corporation Law, a corporation may not engage in a business combination with any holder of 15% or more of its capital stock until the holder has held the stock for three years unless, among other possibilities, the board of directors approves the transaction. Our board of directors could use this provision to vote against any such transaction. The existence of the foregoing provisions could limit the price that investors might be willing to pay in the future for shares of our common stock.

*Our officers and directors and other affiliates may be able to exert significant control over the company, which may make an acquisition of us difficult .*

Our executive officers, directors, and other affiliates control approximately 26% of our outstanding common stock and have the ability to influence the company through this ownership position. For example, as a result of this concentration of ownership, these

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stockholders, if acting together, may have the ability to determine the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger or similar transaction. This concentration of ownership may, therefore, harm the market price of our common stock by:

delaying, deferring or preventing a change in control of our company;

impeding a merger, consolidation, takeover or other business combination involving our company; or

discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company.

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

(b) The registration statement (File No. 333-36638) for the initial public offering of Discovery Partners International, Inc. ( DPI ) 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 reverse merger between DPI and Infinity Pharmaceuticals, Inc. (now known as Infinity Discovery, Inc.) on September 12, 2006, DPI used approximately \$18.5 million of the net proceeds for acquisitions of companies, \$6.0 million for prepaid  $\mu$ ARCS royalties, \$16.8 million for capital expenditures and \$4.3 million for costs associated with restructuring. From the completion of the reverse merger through March 31, 2008, we used approximately \$22.8 million on our Hsp90 and Hedgehog pathway inhibitor programs and for general corporate purposes.

### **Item 6. Exhibits**

(a) Exhibits.

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

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**SIGNATURES**

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

**INFINITY PHARMACEUTICALS, INC.**

Date: May 8, 2008

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

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**EXHIBIT INDEX**

| <b>Exhibit</b> | <b>Description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3.1            | Restated Certificate of Incorporation of the Registrant. Previously filed as Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (File No. 000-31141) and incorporated herein by reference.                                                                                                                                                                                                                                                                                                                 |
| 3.2            | 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 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 Bylaws. Previously filed as Exhibit 3.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (File No. 000-31141) and incorporated herein by reference.                                                                                                                                                                                                                                                                                                                             |
| 4.1            | Form of Common Stock Certificate. Previously filed as Exhibit 4.1 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2007 (File No. 000-31141) and incorporated herein by reference.                                                                                                                                                                                                                                                                                                                                          |
| 4.2            | Rights Agreement between the Registrant and American Stock Transfer & Trust Company dated February 13, 2003, which includes the form of Certificate of Designation for the Series A junior participating preferred stock as Exhibit A, the form of Rights Certificate as Exhibit B and the Summary of Rights to Purchase Series A junior participating preferred stock as Exhibit C. Previously filed as Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed on February 24, 2003 (File No. 000-31141) and incorporated herein by reference. |
| 4.3            | First Amendment to the Rights Agreement between the Registrant and American Stock Transfer & Trust Company dated April 11, 2006. Previously filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on April 12, 2006 (File No. 000-31141) and incorporated herein by reference.                                                                                                                                                                                                                                                        |
| 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.                                                                                                                                                                                                                                                                                                                                                                                           |