



09011191

ANNUAL REPORT 2008 ■



INNOVATIVE. INDEPENDENT. INSPIRED.

NASDAQ: INFI

Received SEC  
MAY 01 2009  
Washington, DC 20549

## INNOVATIVE.

Infinity is advancing the clinical development of its novel targeted agents for the treatment of a broad range of cancers and other indications. We're expanding and accelerating our growing pipeline of targeted agents to hone in on the body's pathways that regulate and control cancer cell survival, proliferation, and recurrence. Our innovative thinking is not limited to our exceptional science — we also apply it to our business and financing efforts, enabling us to build and support pioneering programs that have the potential to change patients' lives.

## INDEPENDENT.

The strategic alliances forged by Infinity have positioned us to financially support all of our programs and activities through at least 2012 — and to generate new, value-creating opportunities in the future.

This financial autonomy supports our independent spirit and enables us to advance our clinical programs, drive the U.S. commercialization of our entire oncology portfolio, and aggressively pursue our mission to bring important new medicines to patients.

## INSPIRED.

Every Citizen-Owner at Infinity shares a passion for bringing better cancer therapeutics to patients in need of new, effective treatments. Our intense focus on this ultimate goal — making a meaningful difference in patients' lives — is what inspires our Citizen-Owners and what drives the integration and collaboration between our R&D and business teams. As a community, we at Infinity believe we can help transform cancer from a life-threatening diagnosis to a chronic, treatable condition.





**Geoff Sylvester, Associate Director, Quality Assurance**

*The key to our Citizen-Owner culture, and to our success as a group, is that not any one person shapes our values — each of us is responsible for our values and living them every day.*

**Nafeeza Hafeez, Scientist, Cancer Biology**

*Working as a team, we each have an opportunity to play a role in the development of potentially life-changing medicines. From biology, to information technology, to clinical — we all work together toward the ultimate goal of bringing our drug candidates to market. Our teamwork has the ability to directly impact a patient's life.*

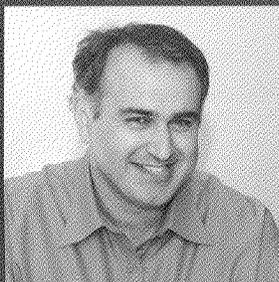


**Laverne Auguste, Senior Paralegal/Contracts Specialist**

*At Infinity, we're not employees; we're Citizen-Owners. From your very first day with Infinity, if you have an idea and present it to the team, you can see it embraced and see it through from start to finish. I think Infinity is going to make a difference and I'm thrilled to be a part of that change.*

**Matthew Campbell, Group Leader, Pharmaceutical Development**

*What we do at Infinity — and how we do it — is important because the end goal is to affect positive change in patients' lives. Ultimately, it's all about helping people and using what we collectively know to make someone's life better.*



**Janid Ali, Director, Biochemistry**

*I love working with people and experts from all different backgrounds and scientific specialties. I am proud of the fact that Infinity pulls from all parts of this spectrum of expertise to work to solve such a challenging problem — how to treat cancer. With this approach, I'm optimistic our team will be able to push forward to make a real difference in people's lives.*

# I4

# shareholder letter

Dear Fellow Infinity Stakeholders:

Infinity embarked on 2008 with a rallying theme of: *Passion and Promise for Patients*. Our *Passion* is for discovering, developing, and delivering to patients novel medicines that will truly make a difference in their lives. The *Promise* we seek to fulfill is the translation of our innovative science into those medicines.

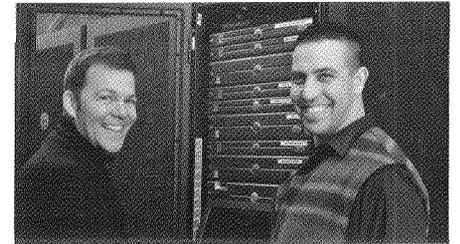
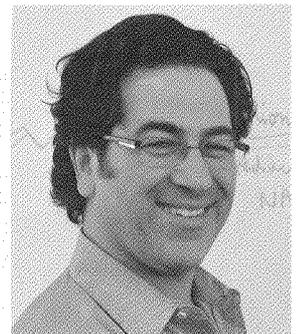
I am proud to report to you that, fueled by that passion, Infinity made significant progress on delivering on that promise. In particular, in 2008, Infinity:

- Progressed clinical trials of IPI-504 (retaspimycin hydrochloride), our lead anti-cancer agent targeting inhibition of heat shock protein 90 (Hsp90), in multiple indications
- Filed two Investigational New Drug (IND) applications and initiated clinical trials with two Infinity-discovered molecules: IPI-493, our oral Hsp90 inhibitor, and IPI-926, our oral Hedgehog pathway inhibitor
- Nominated IPI-940 as our clinical candidate for neuropathic pain targeting fatty acid amide hydrolase (FAAH)

Julian Adams, Ph.D.

President of Research & Development and Chief Scientific Officer

*At Infinity, we are committed in our pursuit of "fearless chemistry and breakthrough biology" to unlock the potential of promising oncology targets and discover innovative new medicines. Infinity's passion to explore uncharted territory is essential in developing new and better treatments that will make a meaningful difference in the lives of patients, their families, and their caregivers.*





**Adelene Q. Perkins**  
 President and Chief Business Officer

*Infinity is beautifully positioned to realize our mission of discovering, developing, and importantly, delivering new medicines to patients. With the right to commercialize all of our oncology products in the U.S., we are building our commercial organization and expect to bring the same level of innovation to the delivery of our drugs as we have to their discovery and development.*

Against a backdrop of exceptionally challenging market conditions, particularly for early-stage biotechnology companies, Infinity entered into transformative strategic alliances with Purdue Pharmaceuticals and Mundipharma. Today, Infinity has U.S. commercialization rights to our entire portfolio of oncology drug candidates. Additionally, Infinity has sufficient capital to aggressively invest in our clinical and discovery pipeline for four years, through 2012.

These successes set the stage for Infinity's 2009 theme:



INFINITY: INNOVATIVE. INDEPENDENT. INSPIRED.

Our *Innovative* pipeline features our leading Hsp90 chaperone inhibitor program. We are pursuing the clinical development of IPI-504 in multiple indications, including non-small cell lung cancer and HER2-positive breast cancer. Simultaneously, we are seeking to expand the potential of our Hsp90 inhibitor program via the development of our oral candidate, IPI-493, which is in early clinical trials. Our Hedgehog signaling pathway inhibitor, oral IPI-926, is also in the clinic. We continue to add to the scientific validation of the importance of this pathway and anticipate future clinical trials in several major cancers. Additionally, our newest clinical development candidate, oral IPI-940, targeting FAAH for the treatment of neuropathic pain, has entered IND-enabling studies.

Pipeline as of April 30, 2009

	Discovery	Precinical	Phase 1	Phase 2	Phase 3
<b>Hsp90 Franchise</b>					
<i>Hsp90 i.v.: IPI-504 (retaspimycin hydrochloride)</i>					
NSCLC					
HER2+ mBC					
Taxotere® Combo					
Additional Solid Tumor					
<i>Hsp90 oral: IPI-493</i>					
Solid Tumors					
<b>Hedgehog Pathway: IPI-926</b>					
Solid Tumors					
<b>FAAH: IPI-940</b>					
Bcl-2/Bcl-xL*					
Discovery Programs					

\*Transitioned to Novartis

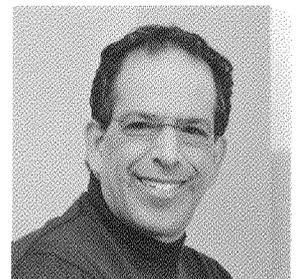


As a result of business transactions accomplished in 2008, Infinity is both *Independent* and financially strong. Our solid financial position, with capital to fund operations through 2012, enables Infinity to aggressively pursue the promise of our pipeline. We have operational independence to lead the worldwide discovery and development of our oncology product candidates. We also have U.S. commercialization rights to our entire oncology portfolio which provides the opportunity to optimize the benefit to patients and to create significant value for our shareholders.

The Citizen-Owners of Infinity remain ever more *Inspired* by our passionate commitment to our mission: to build a community and company capable of sustainably discovering, developing, and delivering to patients innovative, important new medicines that will make a material difference in their health, well-being, and lives. We appreciate your support and participation in our cause.

Rock 'n' Roll.

Steven H. Holtzman  
*Chair and Chief Executive Officer*





FOLLOWING IS THE COMPANY'S ANNUAL REPORT ON FORM 10-K  
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2008.

[THIS PAGE INTENTIONALLY LEFT BLANK]

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 10-K**

SEC  
Mail Processing  
Section  
MAY 07 2009  
Washington, DC

(Mark One)

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

For the fiscal year ended: December 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: 0-31141

**INFINITY PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**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)

**Registrant's telephone number, including area code: (617) 453-1000**

**Securities registered pursuant to Section 12(b) of the Act:**

**Common Stock, \$.001 par value**  
(Title of each class)

**NASDAQ Global Market**  
(Name of each exchange on which listed)

**Securities registered pursuant to Section 12(g) of the Act:**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(Do not check if a 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

The aggregate market value of voting Common Stock held by non-affiliates of the registrant as of June 30, 2008 was \$155,070,033 based on the last reported sale price of the registrant's Common Stock on the NASDAQ Global Market on that date.

Number of shares outstanding of the registrant's Common Stock as of February 28, 2009: 26,133,330

**Documents incorporated by reference:**

Portions of our definitive proxy statement to be filed with the Securities and Exchange Commission no later than April 30, 2009 in connection with our 2009 annual meeting of stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

**[THIS PAGE INTENTIONALLY LEFT BLANK]**

## TABLE OF CONTENTS

	<u>Page No.</u>
Part I	
Item 1: Business .....	1
Item 1A: Risk Factors .....	19
Item 1B: Unresolved Staff Comments .....	36
Item 2: Properties .....	36
Item 3: Legal Proceedings .....	36
Item 4: Submission of Matters to a Vote of Security Holders .....	36
Part II	
Item 5: Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities .....	37
Item 6: Selected Financial Data .....	39
Item 7: Management’s Discussion and Analysis of Financial Condition and Results of Operations .....	40
Item 7A: Quantitative and Qualitative Disclosures about Market Risk .....	56
Item 8: Financial Statements and Supplementary Data .....	57
Item 9: Changes in and Disagreements with Accountants on Accounting and Financial Disclosure .....	92
Item 9A: Controls and Procedures .....	92
Item 9B: Other Information .....	94
Part III	
Item 10: Directors, Executive Officers and Corporate Governance .....	94
Item 11: Executive Compensation .....	94
Item 12: Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters .....	94
Item 13: Certain Relationships and Related Transactions and Director Independence .....	94
Item 14: Principal Accountant Fees and Services .....	94
Part IV	
Item 15: Exhibits and Financial Statement Schedules .....	95
Signatures .....	96

[THIS PAGE INTENTIONALLY LEFT BLANK]

## Forward-Looking Information

*This report contains forward-looking statements regarding our future discovery and development efforts, our collaborations, our future operating results and financial position, our business strategy, and other objectives for future operations. You can identify these forward-looking statements by their use of words such as “anticipate,” “believe,” “estimate,” “expect,” “forecast,” “intend,” “plan,” “project,” “target,” “will” and other words and terms of similar meaning. You also can identify them by the fact that they do not relate strictly to historical or current facts. There are a number of important risks and uncertainties that could cause our actual results to differ materially from those indicated by such forward-looking statements. These risks and uncertainties include those inherent in pharmaceutical research and development, such as adverse results in our drug discovery and clinical development processes, decisions made by the U.S. Food and Drug Administration and other regulatory authorities with respect to the development and commercialization of our drug candidates, our ability to obtain, maintain and enforce proprietary rights for our products, our dependence on collaborative partners, our ability to obtain any necessary financing to conduct our planned activities, and other risk factors. Please refer to the section entitled “Risk Factors” in Part I of this report for a description of these risks and uncertainties. Unless required by law, we do not undertake any obligation to publicly update any forward-looking statements.*

## PART I

### Item 1. Business

#### Overview

Our mission is to build a community and company capable of sustainably discovering, developing and delivering to patients innovative, important new medicines that will make a material difference in their health, well-being and lives.

Our lead product candidate, IPI-504 (retaspimycin hydrochloride) is an intravenously-administered small molecule inhibitor of heat shock protein 90, or Hsp90. Hsp90 is a central component of the cellular chaperone system – a system that supports and stabilizes cancer-causing proteins such as c-Kit, EGFR, and HER2, enabling multiple forms of cancer to thrive. Inhibition of the Hsp90 chaperone knocks out this critical source of support for cancer cells, leading to tumor growth inhibition and cancer cell death. Thus, targeted anti-chaperone therapy via inhibition of Hsp90 may represent a significant yet currently unaddressed strategy for treating patients with cancer. In October 2008, we commenced an international Phase 3 registration study of IPI-504 in patients with refractory gastrointestinal stromal tumors, or GIST, based on the activity and safety data from a Phase 1 trial reported in 2008. This registration study, called the RING (Retaspimycin hydrochloride IN GIST) trial, is being conducted under a Special Protocol Assessment agreement with the U.S. Food and Drug Administration, or FDA, and pursuant to scientific advice from the European Medicines Agency. We estimate that this trial will be completed by the end of 2010 positioning IPI-504 as the potential first-to-market inhibitor of Hsp90. IPI-504 is also being evaluated as a single agent in the expansion phase of the Phase 2 portion of a Phase 1/2 clinical trial in patients with advanced non-small cell lung cancer, or NSCLC, and in a Phase 1b clinical trial in combination with Taxotere® (docetaxel) in patients with advanced solid tumors. Additional clinical trials of IPI-504, including a trial in HER2-positive metastatic breast cancer, are expected to commence in 2009.

In July 2008, we commenced a Phase 1 clinical trial of IPI-493, an orally-delivered inhibitor of Hsp90, in patients with advanced solid tumors. This trial is designed to assess the safety and tolerability of IPI-493 and to identify a dose and schedule for further clinical development. Biological activity of IPI-493 is being measured by computed tomography, or CT, imaging using Response Evaluation Criteria in Solid Tumors, otherwise known as RECIST criteria, as well as disease specific markers.

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

Our next most advanced program is directed against the Hedgehog signaling pathway, or Hedgehog pathway. The Hedgehog pathway is highly active in regulating tissue and organ formation during embryonic development. When abnormally activated, the Hedgehog pathway is believed to play a central role in allowing the proliferation and survival of several types of cancers, including pancreatic, prostate, lung, breast and certain brain cancers. The lead candidate in our Hedgehog pathway program, IPI-926, has shown potent and selective inhibition of the Hedgehog pathway as well as anti-tumor activity in preclinical models. In October 2008, we commenced a Phase 1 clinical trial evaluating IPI-926 in patients with advanced and/or metastatic solid tumors. The primary objectives of this study are to evaluate the safety, tolerability, and pharmacokinetics of IPI-926 and to determine a recommended dose and schedule for subsequent studies. Additionally, we will evaluate potential anti-tumor activity of IPI-926 and examine pharmacodynamic markers of its biological activity. We are pursuing our Hedgehog pathway program in collaboration with Mundipharma International Corporation Limited, or Mundipharma. For a description of this collaboration, see "Strategic Alliances: Purdue and Mundipharma" below.

We also have a discovery program directed to fatty acid amide hydrolase, or FAAH, an emerging target for neuropathic pain. The enzyme FAAH degrades anandamide, which is an endogenous cannabinoid that produces an analgesic effect in response to pain and nerve injury. FAAH inhibition increases the duration of anandamide's analgesic effect, prolonging pain relief at the site of release. In early 2009, we selected IPI-940 as our clinical candidate in this program and are conducting studies directed to the filing of an investigational new drug application, or IND, with the FDA. We are pursuing our FAAH program in collaboration with Mundipharma and an independent associated company, Purdue Pharmaceutical Products L.P., or Purdue. For a description of this collaboration, see "Strategic Alliances: Purdue and Mundipharma" below.

### **Corporate Information**

We were incorporated in California on March 22, 1995 under the name IRORI and, in 1998, we changed our name to Discovery Partners International, Inc., or DPI. In July 2000, we reincorporated in Delaware. On September 12, 2006, DPI completed a merger with Infinity Pharmaceuticals, Inc., or IPI, pursuant to which a wholly-owned subsidiary of DPI merged with and into IPI. IPI was the surviving corporation in the merger, changed its name to Infinity Discovery, Inc., or Old Infinity, and became a wholly owned subsidiary of DPI. In addition, we changed our corporate name from Discovery Partners International, Inc. to Infinity Pharmaceuticals, Inc., and our ticker symbol on the NASDAQ Global Market to "INFI."

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

Since former Old Infinity security holders owned, immediately following the DPI merger, approximately 69% of the combined company on a fully-diluted basis and as a result of certain other factors, including that former Old Infinity directors constituted a majority of the combined company's board of directors and all members of the combined company's executive management were from Old Infinity, Old Infinity was deemed to be the acquiring company for accounting purposes and the transaction was accounted for as a reverse acquisition of assets and a recapitalization in accordance with accounting principles generally accepted in the United States. Accordingly, for all purposes, including financial reporting, our financial statements for periods prior to the merger reflect the historical results of Old Infinity, and not DPI, and our financial statements for all subsequent periods reflect the results of the combined company. In addition, because the business conducted by the combined company became the one operated by Old Infinity prior to the completion of the merger, this annual report on Form 10-K describes the business of Old Infinity immediately prior to the completion of the merger



During 2009, we expect to advance our product development pipeline by:

- continuing enrollment of our Phase 3 clinical trial of IPI-504 in refractory GIST;
- reporting data from our Phase 2 clinical trial of IPI-504 in advanced NSCLC in mid-2009;
- reporting preliminary data from our Phase 1b clinical trial of IPI-504 in combination with Taxotere® in mid-2009;
- initiating additional clinical trials in our Hsp90 program, including a Phase 2 clinical trial of IPI-504 in combination with Herceptin® (trastuzumab) in HER2-positive metastatic breast cancer;
- reporting preliminary data from our Phase 1 clinical trial of IPI-493 in the second half of 2009;
- reporting preclinical data evaluating IPI-926 in multiple tumor models in mid-2009; and
- advancing IPI-940 to IND by the end of 2009.

### ***Hsp90 Program***

Hsp90 is emerging as a major therapeutic target of interest for the treatment of a broad range of cancers. Proteins are the essential building blocks and machines of the human body, and in order for proteins to function properly they must be stable and properly folded. The “chaperone” system of proteins, of which Hsp90 is a member, serves to maintain the structure and activity of specific proteins within the cell. The proteins “chaperoned” by Hsp90 are known as its “client proteins.” Many cancers result from specific mutations in, or aberrant expression of, client proteins of Hsp90. Examples of cancer promoting, or oncogenic, client proteins of Hsp90 include c-Kit in GIST, epidermal growth factor receptor, or EGFR, in NSCLC, and HER2 in breast cancer. Hsp90 enables those cancers’ survival by maintaining the function of its oncogenic client proteins.

In preclinical studies, inhibition of Hsp90 has been shown to lead to the degradation of these client proteins and to cancer cell growth inhibition or cell death. Importantly, cancers featuring oncogenic client proteins that have become resistant to approved targeted therapies have also been shown preclinically to remain sensitive to Hsp90 inhibition. As a result, inhibition of Hsp90 has broad therapeutic potential for the treatment of patients with solid tumors and blood-related cancers, including cancers that are resistant to other drugs.

**IPI-504.** IPI-504 (retaspimycin hydrochloride) is our lead Hsp90 inhibitor. It is a novel, small molecule, semi-synthetic analog of the natural product geldanamycin that is delivered as a water-based, intravenous infusion. To date, IPI-504 has been well-tolerated up to a dose of 400 mg/m<sup>2</sup>, and has shown promising early evidence of biological activity in clinical trials in patients with metastatic and/or unresectable GIST and in patients with advanced NSCLC. IPI-504 has also been shown in preclinical studies to inhibit Hsp90 potently and selectively, thereby inhibiting cancer cell growth. In these preclinical studies, IPI-504 has demonstrated a broad potential to inhibit cancer cell growth as a single agent as well as in combination with existing anti-cancer drugs. In addition, preclinical studies suggest that IPI-504 preferentially targets and accumulates in tumor tissues. For these reasons, we believe that IPI-504 has broad potential for the treatment of patients with a wide variety of solid and hematological tumors, including cancers that are resistant to other drugs.

We have a broad clinical program evaluating IPI-504, alone and in combination with other drugs, in a variety of tumor types. Recent and planned clinical trial activities with IPI-504 are summarized below:

- ***Gastrointestinal Stromal Tumors.*** The American Cancer Society, or ACS, reports that GIST is the most common form of gastrointestinal sarcoma, a life-threatening disease highly resistant to traditional cytotoxic chemotherapy and radiation treatment. According to the ACS, 4,500 – 6,000 people develop GIST annually in the United States. In Europe, 5,000 – 10,000 people develop GIST annually according to a 2005 report in *Cancer* by Nilsson, et. al. The ACS reports that approximately 100,000 individuals are living with the disease. In the majority of GIST cases, specific mutations in cellular signaling enzymes, or kinases, called c-Kit or PDGFRA cause the growth and survival signal of the cell

to become permanently active, leading to cancer. Both c-Kit and PDGFRA are stabilized by Hsp90, suggesting that inhibition of Hsp90 in GIST is an attractive area for clinical study. Both c-Kit and PDGFRA are also client proteins of Hsp90, and in preclinical experiments are degraded in cancer cells upon treatment with IPI-504 leading to cancer cell death. These data suggest that Hsp90 inhibition with IPI-504 is a promising area for clinical investigation. Furthermore, with a complementary, novel mechanism of action, inhibition of Hsp90 has the potential to aid in overcoming resistance to kinase inhibitor therapy.

IPI-504 is being evaluated in the RING trial, an international Phase 3 registration study of IPI-504 in patients with refractory GIST. Initiated in October 2008, the RING trial is a randomized, double-blind, placebo-controlled study evaluating approximately 200 patients with refractory GIST in over 20 countries and 50 sites worldwide. Patients whose tumors have grown despite treatment with at least Gleevec® (imatinib mesylate) and Sutent® (sunitinib malate) are eligible to enroll in the RING trial and there is no limit to the number of prior therapies they may have received. The primary endpoint of the study is progression free survival; secondary endpoints include disease control rate, time to progression, and overall survival. Patients are being randomized 2:1 to IPI-504 or placebo, with a cross-over to treatment with IPI-504 if progression occurs. Response is being evaluated by RECIST and imaging with CT scans is being obtained at early time points to enable close monitoring of tumor activity. IPI-504 is being administered intravenously at 400 mg/m<sup>2</sup> on a three-week cycle, consisting of twice-weekly treatment for two weeks followed by one week off treatment. The RING trial protocol has been granted a Special Protocol Assessment agreement by the FDA, and the European Medicines Agency has provided scientific advice consistent with that of the FDA regarding the trial design. We expect the RING trial to be completed by the end of 2010, thus enabling a targeted market launch of IPI-504 in GIST in 2011 and positioning IPI-504 as the potential first-to-market inhibitor of Hsp90.

Initiation of the RING trial follows promising safety and activity data from our Phase 1 study in patients with refractory GIST and other soft tissue sarcomas reported at the Annual Meeting of the American Society for Clinical Oncology in June 2008. Results from the study showed that patients with GIST (n=36), who were heavily pre-treated, experienced a 70 percent overall disease control rate, with three percent Partial Response and 67 percent Stable Disease at six weeks. Estimated median progression free survival for these patients was 12 weeks.

We have been granted orphan drug designation for IPI-504 for the treatment of GIST by both the FDA's Office of Orphan Products Development and the European Medicines Agency Committee for Orphan Medicinal Products.

- *Non-Small Cell Lung Cancer.* The ACS reports that lung cancer is the leading cause of cancer death for both men and women, estimating approximately 215,000 new cases of lung cancer in the United States in 2008. According to the ACS, NSCLC is the most common form of lung cancer, accounting for about 85% of all lung cancers, or approximately 182,000 new cases in 2008. In some cases of NSCLC, specific mutations have been identified in a cellular signaling enzyme called epidermal growth factor receptor, or EGFR. Patients with NSCLC who have EGFR mutations (estimated to be approximately 15% of NSCLC patients in the United States and up to 30% of NSCLC patients outside of the United States) have been found to benefit from existing therapies that block EGFR signaling, including targeted kinase inhibitors. Unfortunately, additional resistance mutations in EGFR often lead to disease progression, even in patients who initially respond to kinase inhibitor therapy, necessitating the development of new therapeutics with novel mechanisms of action. Multiple cellular proteins or pathways have been linked to the progression and resistance to therapy of NSCLC, including Akt, cMet, and mutated EGFR. These proteins are all client proteins of Hsp90 and in preclinical experiments are degraded in cancer cells upon treatment with IPI-504, leading to cancer cell death. This suggests that Hsp90 inhibition with IPI-504 in NSCLC is a promising area for clinical investigation. Furthermore, with a complementary, novel mechanism of action, inhibition of Hsp90 has the potential to aid in overcoming resistance to kinase inhibitor therapy.

We are currently conducting the Phase 2 portion of our open-label, multi-center Phase 1/2 clinical trial of IPI-504 as a monotherapy in patients with Stage IIIb/IV NSCLC whose tumors have relapsed or

become refractory to prior treatment with a tyrosine kinase inhibitor. Twenty patients were initially enrolled in this portion of the study: 10 with known EGFR mutations and 10 with wild-type EGFR and no evidence of mutation. The study was designed to enroll additional patients in each arm if clinical benefit is observed in that arm, defined as a partial response or as stable disease greater than 12 weeks by RECIST. At least one patient in each arm met the criteria to trigger the expansion phase of the study by achieving extended stable disease during treatment with IPI-504. The study is now expected to enroll an additional 19 patients in each arm, for a total of 58 patients. IPI-504 is being administered intravenously at 400 mg/m<sup>2</sup> on a three-week cycle, consisting of twice-weekly treatment for two weeks followed by one week off treatment. We anticipate publishing data from the full trial at an appropriate medical conference in mid-2009.

- *IPI-504 in combination with Taxotere® (docetaxel).* In preclinical models of prostate cancer and NSCLC, Taxotere® (docetaxel) demonstrates increased anti-tumor activity when administered in combination with IPI-504. In addition, preclinical data suggest that IPI-504 may have anti-cancer properties in prostate, lung and breast cancers—all tumors in which Taxotere has demonstrated clinical efficacy. These data provide a rationale for investigating IPI-504 in combination with Taxotere in multiple tumor types.

We are conducting a Phase 1b clinical trial of IPI-504 in combination with Taxotere in patients with advanced solid tumors. The goal of this open-label, dose-escalation study is to establish the safety, maximum tolerated dose and optimal schedule of administration for IPI-504 in combination with Taxotere. Initially, patients will receive 75 mg/m<sup>2</sup> of Taxotere followed by 300 mg/m<sup>2</sup> of IPI-504 on day one of each 21-day cycle. Once a maximum tolerated dose is reached, the trial will expand to enroll up to 20 additional patients. Additional schedules, including once-weekly dosing of IPI-504 and Taxotere, may also be explored as the trial progresses. We anticipate reporting data on this trial in mid-2009.

- *IPI-504 in Combination with Herceptin® (trastuzumab).* The ACS reports that breast cancer is the most common cancer among women in the United States, other than skin cancer, estimating about 182,000 new cases in women in the United States in 2008. According to the ACS, it is the second leading cause of cancer death in women, after lung cancer. Statistically, one in eight women will be diagnosed with invasive breast cancer. Studies show that approximately 25% of breast cancer patients have an over-expression of a protein called Human Epidermal Growth Factor Receptor 2, or HER2, and this over-expression is referred to as HER2-positive. HER2 is a protein that stimulates cancer cells to divide and protects them from cell death. HER2-positive breast cancer is an aggressive subtype of breast cancer. While current therapies targeting HER2 have demonstrated significant clinical benefit, a substantial number of patients with HER2-positive breast cancer develop recurrent disease, for which novel therapies are needed. HER2 is a client protein of Hsp90, and in preclinical tumor models, administration of IPI-504 stimulates the degradation of HER2, leading to the inhibition of tumor growth. In addition, IPI-504 administration in combination with Herceptin® has shown enhanced activity in preclinical tumor models compared to either agent alone. We plan to initiate in 2009 a Phase 2 clinical trial evaluating IPI-504 in combination with Herceptin in HER2-positive metastatic breast cancer.
- *Hormone Resistant Prostate Cancer.* In July 2008, we discontinued further enrollment in our Phase 2 single agent, signal-finding study of IPI-504 in advanced hormone-refractory prostate cancer, or HRPC. The goal of this open-label, multi-center study was to determine the anti-tumor activity of IPI-504 in patients with HRPC and to correlate prior treatment status with clinical response. We did not observe evidence of biologic activity in the trial, and in this patient population IPI-504 was less well-tolerated compared to all other studies of IPI-504 at this dose and schedule. Therefore, we concluded that the overall risk-benefit ratio did not justify continuing the study as a single agent in this indication.

**IPI-493.** In parallel with the development of IPI-504, we are pursuing development of IPI-493, a proprietary, orally available inhibitor of Hsp90. Like IPI-504, IPI-493 is a semi-synthetic analog of geldanamycin. In preclinical models, IPI-493 has demonstrated high oral bioavailability in animals and selective and potent inhibition of Hsp90. In July 2008, we initiated a Phase 1 clinical trial evaluating IPI-493 in patients

with advanced solid tumors. The study is assessing safety and tolerability of IPI-493, with the objective of identifying a dose and schedule for subsequent studies. Anti-tumor activity will be evaluated by RECIST and disease-specific markers. Additionally, Infinity presented preclinical data demonstrating anti-tumor activity of IPI-493 in multiple xenograft models at the 2008 European Organization for Research and Treatment of Cancer – National Cancer Institute – American Association for Cancer Research Symposium on “Molecular Targets and Cancer Therapeutics” (EORTC). Data presented showed evidence of significant dose-dependent inhibition of tumor growth in a xenograft model of human-derived NSCLC, with tumor regression seen at higher doses. IPI-493 demonstrated strong pharmaceutical properties *in vitro* and *in vivo*, including potent inhibition of Hsp90, selectivity for cancer cells over normal cells, as well as high oral bioavailability. We anticipate reporting preliminary data of this Phase 1 study in the second half of 2009.

### ***Hedgehog Pathway Inhibitor Program***

The Hedgehog pathway is a target of growing interest in the oncology community. It represents a new way of understanding and potentially attacking the progression and reoccurrence of cancer. The Hedgehog pathway is normally active during embryonic development and regulates tissue and organ formation. When abnormally activated in adults, the Hedgehog pathway is believed to play a central role in allowing the proliferation and survival of cancer cells, including pancreatic cancer, prostate cancer, small cell lung cancer, breast cancer, hematologic cancers, skin cancers, and certain brain cancers. In addition, recent evidence points to a potentially important role for the Hedgehog pathway in tumor progenitor cells. Tumor progenitor cells are resistant to standard anti-cancer agents and radiation, and are therefore suspected to be responsible for disease relapse following treatment with conventional therapeutic agents.

We have developed a novel, proprietary Hedgehog pathway inhibitor, IPI-926. IPI-926 is a semi-synthetic derivative of cyclopamine, a natural product that inhibits the Hedgehog pathway by binding to the Smoothed receptor. When systemically administered in multiple preclinical animal models, IPI-926 has shown potent and selective inhibition of the Hedgehog pathway, anti-tumor activity, and attractive pharmacologic properties including oral bioavailability and extended half-life. In October 2008, we commenced a Phase 1 clinical trial evaluating IPI-926 in patients with advanced and/or metastatic solid tumors. The primary objectives of this study are to evaluate the safety, tolerability, and pharmacokinetics of IPI-926 and to determine a recommended dose and schedule for subsequent studies. Additionally, we will evaluate potential anti-tumor activity of IPI-926 and examine pharmacodynamic markers of its biological activity.

At the 2008 Annual Meeting of the American Association for Cancer Research, we reported preclinical data on IPI-926 demonstrating significant anti-tumor activity and excellent pharmaceutical properties, including oral bioavailability, long plasma and tumor half-life, and dose-dependent inhibition of tumor growth, in a number of preclinical models. We presented additional preclinical data at EORTC in 2008 demonstrating rapid and sustained Hedgehog pathway inhibition in stromal cells after a single administration of IPI-926 in a model of human pancreatic cancer. These findings suggest that IPI-926 inhibits tumor growth by down-regulating Hedgehog signaling to tumor associated stroma. The interaction between tumor cells and their supporting stromal cells is believed to be critical for cell growth in several cancers, including pancreatic, colon, breast and ovarian cancer, suggesting broad potential of IPI-926 in several tumor types. In mid-2009, we plan to report additional preclinical data evaluating IPI-926 in multiple tumor models.

We are pursuing our Hedgehog pathway program in collaboration with Mundipharma outside the United States.

### ***Fatty Acid Amide Hydrolase Program***

Fatty acid amide hydrolase, or FAAH, is an emerging target for the treatment of neuropathic pain. The enzyme FAAH degrades anandamide, which is an endogenous cannabinoid that produces an analgesic effect in response to pain and nerve injury. FAAH inhibition increases the duration of anandamide’s analgesic effect,

prolonging pain relief at the site of release. We recently selected IPI-940 as our clinical development candidate. Currently in IND-enabling studies, we anticipate advancing IPI-940 to an IND by the end 2009. We are pursuing our FAAH program in collaboration with Mundipharma outside of the United States and Purdue in the United States.

### ***Bcl-2 Program***

We have developed highly potent compounds that target the Bcl-2 and Bcl-xL anti-apoptotic proteins. These proteins play an important role in resistance to chemotherapy. These compounds either selectively target Bcl-2 or target both Bcl-2 and Bcl-xL. In cells, the compounds disrupt the protein-protein interactions between Bcl-2 and its pro-apoptotic binding partners and selectively induce cell death in cancer cells that depend on Bcl-2 for survival. In preclinical studies in a variety of tumor types, antagonism of Bcl-2 using our compounds also results in synergy with multiple chemotherapeutic agents. In 2006, we entered into a collaboration agreement with Novartis Institute for BioMedical Research, Inc., or Novartis, to discover, develop, and commercialize drugs targeting Bcl protein family members for the treatment of a broad range of cancers and in the first quarter of 2008, we completed the transition of this program to Novartis, which now has responsibility for further pre-clinical, clinical development and commercialization of any products based upon compounds discovered under the joint research program. We may request to participate in clinical development of any such products and, if such request is agreed upon by Novartis, Novartis will fund agreed-upon development costs that are incurred by us.

### **Diversity Oriented Synthesis Technology**

Our diversity oriented synthesis chemistry technology consists of methods to create collections of novel, diverse, natural product-like compounds potentially able to interact with biological targets that have not been accessible to traditional synthetic chemistries. We have produced large libraries of structurally diverse and complex molecules for pharmaceutical screening. We believe these libraries embody all of the advantages of natural products, such as diversity and structural complexity, without the historic difficulties of synthesis and replication. We have entered into technology access alliances with Amgen Inc., Novartis International Pharmaceutical Ltd. and Johnson & Johnson Pharmaceutical Research & Development, a division of Janssen Pharmaceutical N.V., relating to our diversity oriented synthesis technology. We have 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.

### **Strategic Alliances**

Developing alliances has been a key strategic element in our evolution. Our alliances complement our expertise in small molecule drug discovery and development with important scientific, clinical, and business capabilities. We have developed significant alliances with leading pharmaceutical and biotechnology companies that enable us to drive forward our proprietary programs while retaining significant value in their downstream potential. These alliances have brought in over \$200 million in capital, allowing us to continue to advance our pipeline of novel small molecules and pursue potential additional product opportunities. Since our inception, all of our revenue has been derived from our strategic alliances. For the fiscal year ended December 31, 2008, our collaboration with MedImmune/AZ accounted for 86% of our revenue, our Bcl-2 collaboration with Novartis accounted for 11% of our revenue, and our alliances with Purdue and Mundipharma accounted for 3% of our revenue.

***Purdue and Mundipharma.*** In November 2008, we entered into strategic alliance agreements with each of Mundipharma and Purdue to develop and commercialize pharmaceutical products. The alliances include product candidates that inhibit or target the Hedgehog pathway and FAAH, and product candidates arising out of all our discovery projects in all disease fields that achieve development candidate status on or before December 31, 2011 (with Mundipharma having the right, through the exercise of two consecutive one-year options, to extend

such period through December 31, 2013). We refer to such three to five year period as the funded discovery period. Our Hsp90 and Bcl-2 programs are expressly excluded from the alliances. The agreement with Purdue is focused on the development and commercialization of products targeting FAAH for sale in the United States. The agreement with Mundipharma is focused on the development and commercialization of all products and product candidates covered by the alliance, including those targeting FAAH, for sale outside of the United States.

We have responsibility and decision-making authority for the performance of early discovery projects and the development of all product candidates on a worldwide basis. Mundipharma will pay for 100% of all research and development expenses incurred by Infinity for early discovery projects and product candidates included in the alliance until the later of December 31, 2013 or the commencement of the first phase 3 clinical study of such product candidate. We refer to such date as the transition date. After the transition date for each product candidate other than those arising out of the FAAH project, Mundipharma and Infinity will share all research and development costs for such product candidate equally. Upon completion of the first phase 1 clinical study of the first product developed under the research program that inhibits or targets FAAH, Purdue and Mundipharma may elect to assume responsibility, at their own expense, for the future development and commercialization of FAAH products for sale in and outside of the United States, respectively. We are recording revenue for reimbursable research and development services we perform for Mundipharma and Purdue. We recorded \$2.7 million in such revenue in the year ended December 31, 2008.

Mundipharma has the right to opt out of any early discovery project or any preclinical or clinical development program on an annual basis in November of each year. Mundipharma also has a one-time right in mid-2009 to opt out of either or both of the Hedgehog development program or the FAAH project. In the event of an opt-out decision, Mundipharma, together with Purdue with respect to the FAAH program, will continue to provide funding for, in the aggregate, 100% of our budgeted research and development expenses for the applicable project or program for one year after the date of such opt-out. Purdue has a comparable opt out right with respect to the FAAH project. In addition, we and Mundipharma each have the right to opt out of continued development of a product candidate after it has reached the transition date, with a one year tail funding obligation for its 50% of post-transition date research and development expenses. If a party exercises its right to opt-out of the development of a product or product candidate after the transition date, the other party may elect to continue the development and assume responsibility for the worldwide commercialization of such product or product candidate, subject to the payment of a royalty.

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

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

Except with respect to products that have been in-licensed by us, for which no royalties will be payable between the parties, we are obligated to pay Mundipharma a 5% royalty on net sales of the commercialized

products until such time as Mundipharma has recovered all research and development expenses paid to us under the research program prior to the applicable transition date. After such cost recovery, we will owe a tiered, 1% to 3% royalty on U.S. net sales of those products. For products in which Mundipharma has opted-out of development prior to the transition date, we will owe royalties of 1% to 5% of net sales as a function of the stage of development of the applicable product candidate at the time of opt-out. For products in which either party has opted-out of development following the transition date, the commercializing party will pay the other party a 5% royalty on net sales. Mundipharma is obligated to pay us a tiered, 10% to 20% royalty on calendar year net sales outside of the United States of each product arising out of the alliance, and Purdue is obligated to pay us a tiered, 10% to 20% royalty on calendar year net sales of FAAH products in the United States. Royalties are payable until the later to occur of the last-to-expire of specified patent rights and the expiration of non-patent regulatory exclusivities in a country, provided that if royalties are payable solely on the basis of non-patent regulatory exclusivity, each of the rates above are reduced by one-half. In addition, all royalties payable under the strategic alliance agreements, whether by Infinity, Purdue or Mundipharma, are subject to reduction on account of third party royalty payments or patent litigation damages or settlements, with any such reductions capped at 50% of the amounts otherwise payable during the applicable royalty payment period.

Each of the strategic alliance agreements expire when the parties thereto have no further obligations to each other thereunder. Either party may terminate the strategic alliance agreement to which it is a party on 60 days prior written notice if the other party materially breaches the agreement and fails to cure such breach within the 60-day notice period. The agreements may also be terminated by Purdue or Mundipharma in the event of a change in control of Infinity or in the event that, during the funded research period, (i) Julian Adams is no longer a full-time executive of Infinity, or (ii) both Steven H. Holtzman and Adelene Q. Perkins are no longer full-time executives of Infinity. Upon termination of either strategic alliance agreement by us or either Purdue or Mundipharma, either party to the other strategic alliance agreement may terminate that agreement.

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

The line of credit agreement provides for the borrowing by us of one or more unsecured loans up to an aggregate maximum principal amount of \$50 million. The loans may be drawn by us during the three-year period beginning on April 1, 2009. The loans, which may be used by us for any proper corporate purpose, mature on April 1, 2019, which we refer to as the maturity date, and will be subordinate to any senior indebtedness that we may incur. Borrowings made under the line of credit agreement will bear interest, payable on the maturity date, at a fluctuating rate set at the prime rate on the business day prior to the funding of each loan and will be reset on the last business day of each month ending thereafter. Interest will be compounded on each successive three-month anniversary of the funding of each loan. Outstanding loans may be prepaid without penalty or premium prior to the maturity date. Amounts borrowed under the credit agreement, once borrowed, may not be borrowed again. We have certain rights to repay outstanding amounts under the line of credit agreement in shares of our common stock.

In the event that the strategic alliance agreements are terminated, we must provide the lenders with notice of such termination within two business days. Within 45 days of such notice, each of the lenders may accelerate our obligations under the credit agreement to such lender, whereupon the commitments of such lender may be automatically terminated and all of our outstanding obligations to such lender will become due and payable in one year, or, if earlier, the maturity date.

The line of credit agreement provides for certain events of default, including a change in control of Infinity, and other customary events of default. The credit agreement also provides for an event of default if Purdue and Mundipharma exercise their respective rights to terminate the strategic alliance agreements if, during the funded research period, (i) Julian Adams is no longer a full-time executive of Infinity, or (ii) both Steven H. Holtzman and Adelene Q. Perkins are no longer full-time executives of Infinity. In the event of a default by us, the lenders may declare all obligations under the credit agreement immediately due and payable, terminate the lenders' commitments to make loans under the credit agreement, and enforce any and all rights of the lenders under the credit agreement and related documents. For certain events of default related to bankruptcy, the commitments of lenders will be automatically terminated and all of our outstanding obligations will become immediately due and payable.

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

Under the terms of this agreement, we shared equally with MedImmune/AZ all development costs, as well as potential profits and losses, from any future marketed products. MedImmune/AZ made non-refundable, up-front payments totaling \$70 million to us in order to obtain co-exclusive rights to the Hsp90 and Hedgehog pathway development programs, and paid a \$15 million milestone to us in 2008 upon initiation of the RING trial. Upon the reacquisition of rights to the Hsp90 program, we recognized all of the remaining deferred revenue related to the up-front license fee from MedImmune/AZ, as we had no further performance obligations to MedImmune/AZ. During the year ended December 31, 2008, we recognized \$56.7 million in revenue, of which \$49.2 million was recorded in the fourth quarter of 2008, from such fee. Further, because the agreement was a cost-sharing arrangement rather than one in which research and development expenses were reimbursed, we recorded amounts reimbursable by MedImmune/AZ with respect to research and development prior to the date we reacquired the Hsp90 program as a reduction to research and development expense, and not as revenue. For the year ended December 31, 2008, we offset approximately \$16.7 million in amounts reimbursable by MedImmune/AZ against research and development expense. The \$1.2 million in reimbursable amounts incurred between the date on which the Hsp90 program was reacquired and December 31, 2008 is recorded as income from residual funding in our statement of operations.

Following the reacquisition of the Hsp90 program, MedImmune/AZ remained obligated to fund an amount equivalent to its share of Hsp90 program costs for the ensuing six-month period. In January 2009, however, we agreed with MedImmune/AZ to settle these residual funding obligations through lump-sum payments totaling \$12.5 million, which we intend to record as income from residual funding in our statement of operations in the first quarter of 2009.

The profit and cost sharing provisions of our arrangement with MedImmune/AZ are no longer applicable, and we have full control over all future development and commercialization activities under our Hsp90 and Hedgehog pathway programs, subject to the payment of single-digit royalties to MedImmune/AZ on worldwide net sales, if any, of each of IPI-504 and IPI-493. We do not have a royalty obligation to MedImmune/AZ on any future sales of IPI-926. In addition, in connection with the reacquisition of rights to the Hedgehog pathway program and the waiver by us of the non-competition clause applicable to MedImmune/AZ under the collaboration agreement, we obtained the right to opt-in to the development and commercialization of certain Hedgehog pathway programs being developed by MedImmune/AZ.

**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 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. Pursuant to this agreement, we conducted joint research with Novartis to identify molecules for clinical development. For the year ended December 31, 2008, we recognized approximately \$8.1 million in revenue related to the amortization of the up-front license fee and approximately \$0.8 million in revenue related to the reimbursable research and development services we performed for Novartis under the agreement. Novartis now has responsibility for further pre-clinical, clinical development and commercialization of any products based upon compounds discovered under the joint research program. We may request to participate in clinical development of any such products and, if such request is agreed upon by Novartis, Novartis will fund agreed-upon development costs that are incurred by us. We also have a non-exclusive right to detail Bcl-2 family inhibitor products in the United States, with our detailing costs to be reimbursed by Novartis.

Novartis has agreed to make milestone payments totaling over \$370 million if certain specified research, development and commercialization milestones are achieved for multiple products for multiple indications, such that total payments to us could exceed \$400 million. Novartis has also agreed to pay us royalties upon successful commercialization of any products developed under the alliance. Novartis has the right to terminate the agreement at any time upon 60 days prior written notice. In addition, Novartis has the right to terminate the agreement in the event of a material breach by us that remains uncured for a period of 120 days after notice. We can terminate specified programs under this agreement as to breaches by Novartis relating solely to such programs that remain uncured for a period of 120 days after notice or can terminate the agreement in its entirety in the event of a material breach by Novartis that remains uncured for a period of 120 days after notice.

## **Intellectual Property**

Our intellectual property consists of patents, trademarks, trade secrets and know-how. Our ability to compete effectively depends in large part on our ability to obtain patents and trademarks for our technologies and products, maintain trade secrets, operate without infringing the rights of others and prevent others from infringing our proprietary rights. We will be able to protect our technologies from unauthorized use by third parties only to the extent that they are covered by valid and enforceable patents, or are effectively maintained as trade secrets. As a result, patents or other proprietary rights are an essential element of our business.

IPI-504 and related molecules are protected by U.S. Patent Nos. 7,282,493, 7,361,647 and 7,375,217, each of which is expected to expire no earlier than March 2025. These patents include composition of matter, pharmaceutical composition, method of treatment, and synthetic method claims. IPI-926 is protected by U.S. Patent No. 7,230,004, which is expected to expire no earlier than October 2025. In addition, as of February 28, 2009 we had approximately 195 other patents and patent applications worldwide, substantially all of which pertain to our key product development programs. Any patents that may issue from our pending patent applications would expire between 2024 and 2029.

Our practice is to file patent applications to protect technology and compounds that are commercially important to our business, and to do so in countries where we believe it is commercially reasonable and advantageous to do so. We also rely on trade secrets to protect our technology where patent protection is deemed inappropriate or unobtainable. We protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants, collaborators and contractors.

## **Competition**

The pharmaceutical and biotechnology industries are intensely competitive. Many companies, including biotechnology, chemical and pharmaceutical companies, are actively engaged in research and development of drugs for the treatment of the same diseases and conditions as our current and potential future product candidates. Many of these companies have substantially greater financial and other resources, larger research and

development staffs and more extensive marketing and manufacturing organizations than we do. In addition, some of them have considerable experience in preclinical testing, clinical trials and other regulatory approval procedures. There are also academic institutions, governmental agencies and other research organizations that are conducting research in areas in which we are working. They may also market commercial products, either on their own or through collaborative efforts.

We and our alliance partners expect to encounter significant competition for any drugs we develop. Companies that complete clinical trials, obtain required regulatory approvals and commence commercial sales of their products before their competitors may achieve a significant competitive advantage. We are aware that many other companies or institutions are pursuing the development of drugs in the areas in which we are currently seeking to develop our own drug candidates, and there may be other companies working on competitive projects of which we are not aware. For example, we believe that the following companies, among others, are seeking to develop compounds targeting Hsp90:

- Bristol Myers Squibb Company, which we believe is conducting a Phase 3 and multiple Phase 2 clinical trials of tanespimycin and multiple Phase 1 clinical trials of alvespimycin;
- Biogen Idec Inc., which we believe is conducting a Phase 2 clinical trial of BIIB-021;
- Vernalis plc, which we believe is conducting a Phase 1 clinical trial of an Hsp90 inhibitor in collaboration with Novartis;
- Pfizer, Inc., which we believe is conducting two Phase 1 clinical trials of SNX-5422;
- Synta Pharmaceuticals Corp., which we believe is conducting two Phase 1 clinical trials of STA-9090;
- Astex Therapeutics Limited, which we believe is conducting a Phase 1 clinical trial of AT-13387; and
- Exelixis, Inc., which we believe is conducting a Phase 1 clinical trial of XL888.

In addition, we believe that Genentech, Inc. through its collaboration with Curis, Inc., is conducting several Phase 2 clinical trials of GDC-0449, its Hedgehog pathway antagonist, including a pivotal Phase 2 clinical trial initiated in early 2009, and Bristol-Myers Squibb Company, through its collaboration with Exelixis, Inc., is conducting a Phase 1 clinical trial of XL139, a Hedgehog pathway inhibitor.

Finally, we believe that each of Pfizer, Inc. and Sanofi-Aventis are conducting Phase 1 clinical trials of inhibitors of FAAH.

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 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 business.

## **Research and Development**

As of February 28, 2009, our research and development group consisted of 129 individuals, of whom over 33 percent hold Ph.D. or M.D. degrees and over 22 percent hold advanced degrees. Our research and development group is focusing on drug discovery, preclinical research, clinical trials and manufacturing technologies. Our research and development expense for the years ended December 31, 2008, 2007 and 2006 was approximately \$47.5 million, \$33.8 million, and \$35.8 million, respectively. Our strategic collaborator-sponsored research and development expenses totaled approximately \$20.1 million, \$18.5 million, and \$8.1 million for the years ended December 31, 2008, 2007 and 2006, respectively. In calculating strategic collaborator-sponsored

research and development expenses, we have included all reimbursement for our research and development efforts, whether the amounts are included in revenue or as a credit to research and development expense, and excluded license fees. Our remaining research and development expense is company-sponsored.

### **Manufacturing and Supply**

We rely primarily on third parties, and in some instances we rely on only one third party, to manufacture critical raw materials, drug substance and final drug product for our research, preclinical development and clinical trial activities. Commercial quantities of any drugs we seek to develop will have to be manufactured in facilities and by processes that comply with FDA and other regulations, and we plan to rely on third parties to manufacture commercial quantities of any products we successfully develop.

### **Sales and Marketing**

We currently have no marketing, sales or distribution capabilities. We do, however, currently have commercialization rights in the United States for products arising out of our all of our programs, except the FAAH program, and worldwide commercialization rights for our Hsp90 inhibitor program, including IPI-504 and IPI-493. Additionally, we have the right to co-detail in the United States any products arising from our collaboration with Novartis. We are actively developing our United States commercialization capabilities in preparation for a targeted market launch of IPI-504 in GIST in 2011. We believe we will partner our Hsp90 program outside the United States and, therefore, do not intend to develop marketing, sales or distribution capabilities outside the United States for the foreseeable future.

### **Government Regulation**

Government authorities in the United States and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, labeling, promotion, advertising, distribution, marketing, and export and import of pharmaceutical products such as those we are developing. There is no assurance that any of our drug candidates will prove to be safe or effective, will receive regulatory approvals or will be successfully commercialized.

### ***New Drug Approval in the United States***

In the United States, drugs and drug testing are regulated by the FDA and other federal agencies, as well as by state and local government authorities. Before any of our products may be marketed in the United States, we must comply with the Federal Food, Drug and Cosmetic Act, which generally involves the following:

- preclinical laboratory and animal tests performed under the FDA's Good Laboratory Practices regulations;
- submission and acceptance of an IND application, which must become effective before clinical trials may begin in the United States;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug candidate for its intended use;
- development of manufacturing processes which conform to FDA-mandated current Good Manufacturing Practices, or cGMPs; and
- FDA review and approval of a New Drug Application, or NDA, prior to any commercial sale or shipment of a product.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approval will be granted on a timely basis, if at all.

**Preclinical testing.** Preclinical tests include laboratory evaluation of a drug candidate, its chemistry, formulation, safety and stability, as well as animal studies to assess the potential safety and efficacy of the drug candidate. The results of the preclinical tests, together with manufacturing information, analytical data and other available information about the drug candidate, are submitted to the FDA as part of an IND. An IND is a request for FDA authorization to administer an investigational drug to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug that is not the subject of an approved new drug application. Preclinical tests and studies can take several years to complete, and despite completion of those tests and studies, the FDA may not permit clinical testing to begin.

**The IND process.** The FDA requires a 30-day waiting period after the filing of each IND application before clinical trials may begin. This waiting period is designed to allow the FDA to review the IND to determine whether human research subjects will be exposed to unreasonable health risks. At any time during this 30-day period or at any time thereafter, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin or continue. The IND application process may become extremely costly and substantially delay development of our products. Moreover, positive results of preclinical tests will not necessarily indicate positive results in clinical trials.

Prior to initiation of clinical studies, an independent Institutional Review Board, or IRB, at each medical site proposing to conduct the clinical trial must review and approve each study protocol and study subjects must provide informed consent.

**Clinical trials.** Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1: The drug candidate is initially introduced into healthy human subjects or patients and tested for safety, dosage tolerance, bioavailability, absorption, distribution, excretion and metabolism. For cancer drugs such as those we are developing, this phase of study is generally conducted in patients.
- Phase 2: The drug candidate is introduced into a limited patient population to: (1) assess the efficacy of the candidate in specific, targeted indications; (2) assess dosage tolerance and optimal dosage; and (3) identify possible adverse effects and safety risks.
- Phase 3: These are commonly referred to as pivotal studies. If a drug candidate is found to have an acceptable safety profile and to be potentially effective in Phase 1 and 2 trials, Phase 3 clinical trials will be initiated to further demonstrate clinical efficacy, optimal dosage and safety within an expanded and diverse patient population at geographically dispersed clinical study sites.

We cannot be certain that we will successfully complete Phase 1, Phase 2 or Phase 3 testing of our drug candidates within any specific time period, if at all. Clinical testing must meet requirements for IRB oversight, informed consent and good clinical practices. The FDA and the IRB at each institution at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable health risk.

**The NDA process.** If clinical trials are successful, the next step in the drug regulatory approval process is the preparation and submission to the FDA of an NDA. The NDA is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for marketing and sale in the United States. The NDA must contain a description of the manufacturing process and quality control methods, as well as results of preclinical tests, toxicology studies, clinical trials and proposed labeling, among other things. A substantial user fee must also be paid with the NDA, unless an exemption applies. Every new drug must be the subject of an approved NDA before commercialization in the United States.

Upon submission of the NDA, the FDA will make a threshold determination of whether the application is sufficiently complete to permit review, and, if not, will issue a refuse-to-file letter. If the application is accepted

for filing, the FDA will attempt to review and take action on the application in accordance with performance goal commitments the FDA has made in connection with the user fee law. Current timing commitments under the user fee laws vary depending on whether an NDA is for a priority drug or not, and in any event are not a guarantee that an application will be approved or even acted upon by any specific deadline. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved, but the FDA is not bound by the recommendation of an advisory committee. The FDA may deny or delay approval of applications that do not meet applicable regulatory criteria or if the FDA determines that the clinical data do not adequately establish the safety and efficacy of the drug. In addition, the FDA may approve a drug candidate subject to the completion of post-marketing studies, referred to as Phase 4 trials, to monitor the effect of the approved product. The FDA may also grant approval with restrictive product labeling, or may impose other restrictions on marketing or distribution such as the adoption of a special risk management plan. The FDA has broad post-market regulatory and enforcement powers, including the ability to issue warning letters, levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals.

***Manufacturing and post-marketing requirements.*** If approved, a drug may only be marketed in the dosage forms and for the indications approved in the NDA. Special requirements also apply to any drug samples that are distributed in accordance with the Prescription Drug Marketing Act. The manufacturers of approved products and their manufacturing facilities are subject to continual review and periodic inspections by the FDA and other authorities where applicable, and must comply with ongoing requirements, including the FDA's cGMP requirements. Once the FDA approves a product, a manufacturer must provide certain updated safety and efficacy information, submit copies of promotional materials to the FDA, and make certain other required reports. Product and labeling changes, as well as certain changes in a manufacturing process or facility or other post-approval changes, may necessitate additional FDA review and approval. Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, such as untitled letters, warning letters, suspension of manufacturing, seizure of product, voluntary recall of a product, injunctive action or possible criminal or civil penalties. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval. Because we intend to contract with third parties for manufacturing of our products, our ability to control third party compliance with FDA requirements will be limited to contractual remedies and rights of inspection. Failure of third party manufacturers to comply with cGMP or other FDA requirements applicable to our products may result in, among other things, total or partial suspension of production, failure of the government to grant approval for marketing, and withdrawal, suspension, or revocation of marketing approvals.

The FDA's policies may change and additional government regulations may be enacted which could prevent or delay regulatory approval of our potential products. Moreover, increased attention to the containment of health care costs in the United States and in foreign markets could result in new government regulations that could have a material adverse effect on our business. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

#### ***New Drug Approval Outside of the United States***

Approval of a drug in the United States does not guarantee approval in any other country and vice versa. Thus, we will have to complete approval processes that are similar to those in the United States in virtually every foreign market in order to conduct clinical or preclinical research and to commercialize our drug candidates in those countries. The approval procedures and the time required for approvals vary from country to country, may involve additional testing, and may take longer than in the United States. Foreign approvals may not be granted on a timely basis, or at all. In addition, regulatory approval of drug prices is required in most countries other than the United States. We face the risk that the resulting prices would be insufficient to generate an acceptable return to us or our collaborators.

In common with the United States, the various phases of preclinical and clinical research are subject to significant regulatory controls within the European Union. Variations in the national regimes exist. Most jurisdictions, however, require regulatory and institutional review board approval of interventional clinical trials. Most European regulators also require the submission of adverse event reports during a study and a copy of the final study report. Under European Union regulatory systems, products that have an Orphan Drug designation or which target cancer, such as the drug candidates we are currently developing, marketing authorizations must be submitted under a centralized procedure that provides for the grant of a single marketing authorization that is valid for all European Union member states.

### ***Orphan Drug Designation***

Under the Orphan Drug Act and corresponding European Union regulations, the FDA and European Union regulatory authorities may grant Orphan Drug designation to drugs intended to treat a rare disease or condition. In the United States, a rare disease or condition is one that affects fewer than 200,000 individuals, or more than 200,000 individuals but for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States of that drug. In the European Union, a rare disease or condition is one that affects fewer than 5 in 10,000 individuals. In the United States, Orphan Drug designation must be requested before submitting an NDA. After the FDA grants Orphan Drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan Drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, nor does it assure approval.

In the United States, if a product that has Orphan Drug designation receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for seven years. In the European Union, the period of product exclusivity is ten years. Orphan Drug exclusivity, however, also could block the approval of one of our products in the United States for seven years for an Orphan Drug indication if a competitor obtains approval of the same drug, as defined by the FDA, for such Orphan Drug indication or if our product candidate is determined to be contained within the competitor's product for the same indication or disease. We have obtained Orphan Drug designation for IPI-504 for GIST in both the United States and the European Union and intend to seek Orphan Drug status for our other product candidates as appropriate. Orphan Drug designation may not, however, provide us with a material commercial advantage.

### ***Other Regulatory Matters***

In the United States, manufacturing, sales, promotion and other activities following the approval of a new drug are subject to regulation by regulatory authorities in addition to the FDA, including the Federal Trade Commission, the Department of Justice, the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, and state and local governments. Among other laws and requirements, our sales, marketing and scientific/educational programs would need to comply with the anti-kickback provisions of the Social Security Act, the False Claims Act and similar state laws. Our pricing and rebate programs would need to comply with pricing and reimbursement rules, including the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws. Finally, certain jurisdictions have other trade regulations from time to time to which our business is subject such as technology or environmental export controls and political trade embargoes. Depending on the circumstances, failure to meet these applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into supply contracts, including government contracts.

In addition to regulations enforced by the FDA, we also are subject to regulation under the Occupational Safety and Health Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, and other present and potential future foreign, federal, state, and local laws and regulations. Our research and development involves the controlled use of hazardous materials, including corrosive, explosive and flammable chemicals, various radioactive compounds, and compounds known to cause birth defects. Although we believe that our safety procedures for storing, handling, using, and disposing of such materials comply with the standards prescribed by applicable regulations, the risk of contamination or injury from these materials cannot be completely eliminated. In the event of an accident, we could be held liable for any damages that result, and any such liability could materially affect our ongoing business.

## Employees

We refer to our employees as citizen-owners. As of February 28, 2009, we had 161 full-time citizen-owners, 129 of whom were engaged in research and development and 32 of whom were engaged in management, administration and finance. Over 44 percent of our citizen-owners hold advanced degrees. Our success depends, in part, on our ability to recruit and retain talented and trained scientific and business personnel and senior leadership. We believe that we have been successful to date in obtaining and retaining these individuals, but we do not know whether we will be successful doing so in the future. None of our citizen-owners are represented by a labor union or covered by a collective bargaining agreement, nor have we experienced work stoppages. We believe that relations with our citizen-owners are good.

## Executive Officers

The following table lists the positions, names and ages of our executive officers as of February 28, 2009:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Steven H. Holtzman . . . . .	55	Chair and Chief Executive Officer
Adelene Q. Perkins . . . . .	49	President and Chief Business Officer
Julian Adams, Ph.D. . . . .	54	President of Research & Development and Chief Scientific Officer

*Steven H. Holtzman* has served as Chief Executive Officer and as Chair of our board of directors since September 2006, and as our President between October 2007 and October 2008. Mr. Holtzman was a co-founder of Old Infinity and served as its Chief Executive Officer and Chair of its board of directors from 2001 until the DPI merger. Mr. Holtzman also served as President of Old Infinity from July 2001 to February 2006. From 1994 to 2001, Mr. Holtzman served as Chief Business Officer of Millennium Pharmaceuticals, Inc., a publicly traded pharmaceutical company. From 1996 to 2001, Mr. Holtzman served as a presidential appointee to the National Bioethics Advisory Commission, the principal advisory body to the President and Congress on ethical issues in the biomedical and life sciences. Prior to joining Millennium Pharmaceuticals, Inc., from 1986 to 1994, Mr. Holtzman was a founder and Executive Vice President of DNX Corporation, a publicly traded biotechnology company. Mr. Holtzman is a director of Anadys Pharmaceuticals, Inc., a publicly traded biopharmaceutical company, and a trustee of the Berklee College of Music. Mr. Holtzman received a B.A. in Philosophy from Michigan State University and a B.Phil. in Philosophy from Oxford University, which he attended as a Rhodes Scholar.

*Adelene Q. Perkins* has served as our President and Chief Business Officer since October 2008 and as our Executive Vice President and Chief Business Officer between September 2006 and October 2008. Ms. Perkins served as Executive Vice President of Old Infinity from February 2006 until the merger and Chief Business Officer of Old Infinity from June 2002 until the DPI merger. Prior to joining Old Infinity, Ms. Perkins served as Vice President of Business and Corporate Development of TransForm Pharmaceuticals, Inc., a private pharmaceutical company, from 2000 to 2002. From 1992 to 1999, Ms. Perkins held various positions at Genetics Institute, now a business unit of Wyeth Pharmaceuticals, Inc., most recently serving as Vice President of Emerging Business and General Manager of the DiscoverEase<sup>®</sup> business unit. From 1985 to 1992, Ms. Perkins

held a variety of positions at Bain & Company, a strategy consulting firm. Ms. Perkins received a B.S. in Chemical Engineering from Villanova University and an M.B.A. from Harvard Business School.

*Julian Adams, Ph.D.* has served as our President of Research & Development and Chief Scientific Officer since October 2007 and as our President and Chief Scientific Officer from September 2006 until October 2007. Dr. Adams served as President of Old Infinity from February 2006 until the merger and as Chief Scientific Officer of Old Infinity from October 2003 until the DPI merger. Prior to joining Old Infinity, Dr. Adams served as Senior Vice President, Drug Discovery and Development with Millennium Pharmaceuticals, Inc. from 1999 to 2001. Dr. Adams served as Senior Vice President, Research and Development with LeukoSite Inc., a private biopharmaceutical company, from July 1999 until its acquisition by Millennium in December 1999. Dr. Adams served as a director and Executive Vice President of Research and Development with ProScript, Inc., a private biopharmaceutical company, from 1994 until its acquisition by LeukoSite in 1999. Prior to joining ProScript, Dr. Adams held a variety of positions with Boehringer Ingelheim, a private pharmaceutical company, and Merck & Co., Inc., a publicly traded pharmaceutical company. Dr. Adams received a B.S. from McGill University and a Ph.D. from the Massachusetts Institute of Technology in the field of synthetic organic chemistry.

### **Available Information**

Our Internet website is <http://www.infi.com>. We make available free of charge through our website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended. We make these reports available through our website as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to, the U.S. Securities and Exchange Commission. In addition, we regularly use our website to post information regarding our business, product development programs and governance, and we encourage investors to use our website, particularly the information in the section entitled “Investors/Media,” as a source of information about us.

Our Code of Business Conduct and Ethics and the charters of the Audit, Compensation and Nominating & Corporate Governance Committees of our Board of Directors are all available on the corporate governance section of our website at <http://investor.ipi.com>. Stockholders may request a free copy of any of these documents by writing to Investor Relations, Infinity Pharmaceuticals, Inc., 780 Memorial Drive, Cambridge, Massachusetts 02139, U.S.A.

The foregoing references to our website are not intended to, nor shall they be deemed to, incorporate information on our website into this report by reference.

### **Item 1A. Risk Factors**

This Annual Report on Form 10-K and certain other communications made by us contain forward-looking statements, including statements about our growth and future operating results, discovery and development of products, strategic alliances and intellectual property. For this purpose, any statement that is not a statement of historical fact should be considered a forward-looking statement. We often use the words “believe,” “anticipate,” “plan,” “expect,” “intend,” “may,” “will” and similar expressions to help identify forward-looking statements.

We cannot assure you that our assumptions and expectations will prove to have been correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements, including those discussed below. We undertake no intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

In September 2006, we completed our merger with Old Infinity. Upon completion of the merger, the business of the combined company became the one operated by Old Infinity prior to the merger. As a result, the

risk factors set forth below discuss the business of the combined company after the merger, which includes a discussion of the business of Old Infinity prior to the merger. For a further discussion of the merger, please see “Business—Corporate Information” above.

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

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

We have a limited operating history for you to evaluate our business. We have no approved products and have generated no product revenue. We have primarily incurred operating losses. As of December 31, 2008, we had an accumulated deficit of \$148.9 million. We have spent, and expect to continue to spend, significant resources to fund the research and development of IPI-504, IPI-493, IPI-926, IPI-940 and our other drug candidates. While we may have net income in future periods as the result of non-recurring collaboration income, as we did in the year ended December 31, 2008, we expect to incur substantial and increasing operating losses over the next several years as our clinical trial and drug manufacturing activities for our heat shock protein 90, or Hsp90, program increase and as we incur pre-commercialization expenses in anticipation of a potential commercial launch of IPI-504. As a result, our accumulated deficit will also increase significantly.

Our drug candidates are in varying stages of preclinical and clinical development and may never be approved for sale or generate any revenue. We will not be able to generate product revenue unless and until one of our drug candidates successfully completes clinical trials and receives regulatory approval. Since IPI-504, our most advanced drug candidate, is not expected to be commercialized before 2011, if at all, we do not expect to receive revenue from our drug candidates for several years, if at all. Even if we eventually generate revenues, we may never be profitable, and if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. We may seek to obtain funding from collaboration or licensing agreements with third parties.

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

We will need substantial additional funds to support our planned operations. In the absence of additional funding and based on our current operating plans, we expect that our current cash, cash equivalents and available-for-sale securities, together with the \$50 million line of credit that has been made available to us by an entity associated with Purdue Pharmaceutical Products L.P., or Purdue, are sufficient to fund our planned operations through the end of 2012. 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 payments we expect to receive from Mundipharma and Purdue. 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;
- we acquire or license rights to additional drug candidates or new technologies from one or more third parties;

- Mundipharma International Corporation Limited, or Mundipharma, or Purdue elects to discontinue its participation in a partnered program; or
- we experience a loss in our investments due to general market conditions or other reasons.

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

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

At December 31, 2008, we had approximately \$127 million in cash, cash equivalents and available-for-sale securities. We historically have invested these amounts in money market funds, corporate obligations, U.S. government-sponsored enterprise obligations, U.S. Treasury securities and asset-backed securities meeting the criteria of our investment policy, which is focused on the preservation of our capital. These investments are subject to general credit, liquidity, market and interest rate risks, which may be affected by U.S. sub-prime mortgage defaults that have affected various sectors of the financial markets and caused credit and liquidity issues. We may realize losses in the fair value of these investments or a complete loss of these investments, which would have a negative effect on our consolidated financial statements. In addition, should our investments cease paying or reduce the amount of interest paid to us, our interest income would suffer. These market risks associated with our investment portfolio may have a material adverse effect on our financial condition and results of operations.

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

This risk of failure of our current clinical candidates is high. To date, the data supporting our clinical development strategy for IPI-504, IPI-493, and IPI-926 are derived solely from laboratory and preclinical studies and, in the case of IPI-504, limited early-stage clinical trials. Later clinical trials, including our recently-commenced Phase 3 clinical trial of IPI-504 in refractory gastrointestinal stromal tumors, or GIST, may not show that IPI-504 is safe and effective in patients with this disease, 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 IPI-504, IPI-493, IPI-926 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 alliances with Mundipharma and Purdue, or any future alliance we may enter into, are unsuccessful, our operations may be negatively impacted.***

We have strategic alliances with Mundipharma International Corporation Limited, or Mundipharma, to research, develop and jointly commercialize IPI-926 and product candidates arising out of our other discovery programs, and with Purdue to commercialize product candidates arising out of our fatty acid amide hydrolase, or

FAAH, program in the United States. Under these alliance agreements, Mundipharma and Purdue have committed to provide substantial funding, significant capabilities in the field of pain and, in the case of Mundipharma, significant capabilities in marketing and sales outside of the United States. The success of these alliances is largely dependent on the resources, efforts, technology and skills brought to such alliances by Mundipharma and Purdue. Disputes and difficulties in these types of relationships are common, often due to conflicting priorities or conflicts of interest. Merger and acquisition activity may exacerbate these conflicts. The benefits of these alliances will be reduced or eliminated if Mundipharma and/or Purdue:

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

Under our agreements with Mundipharma and Purdue, each agreement may be terminated on 60 days' prior written notice if we were to materially breach such agreement and fail to cure such breach within the 60-day notice period. In addition, each of these strategic alliance agreements may be terminated in the event of a change in control of Infinity or in the event that, during funded research period, either Julian Adams is no longer a full-time executive of Infinity or both Steven Holtzman and Adelene Perkins are no longer full-time executives of Infinity. In addition, Mundipharma has the right to opt out of participation in the Hedgehog pathway and/or FAAH programs in July 2009 or in November of each calendar year beginning in November 2009, in each case subject to 12 months of continued funding, and Purdue has a similar right with respect to the FAAH program. If Mundipharma and/or Purdue were to exercise its right to opt out of a program or to terminate its respective agreement, we may not have sufficient financial resources or capabilities to continue development and commercialization of products from the affected program and our ability to attract a new alliance partner would be made more difficult.

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

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

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

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

We are highly dependent on our management team, particularly Steven Holtzman, Adelene Perkins, Julian Adams and the other members of our executive leadership team. All of these individuals are employees-at-will, which means that neither Infinity nor the employee is obligated to a fixed term of service and that the employment relationship may be terminated by either Infinity or the employee at any time, without notice, and whether or not cause or good reason exists for such termination. The loss of the services of any of these individuals might impede the achievement of our research, development and commercialization objectives. For example, Purdue and Mundipharma each has the right to terminate its strategic alliance with us if, during the funded research period, either Julian Adams is no longer a full-time executive of Infinity or both Steven Holtzman and Adelene Perkins are no longer full-time executives of Infinity. We do not maintain “key person” insurance on any of our employees.

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

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

We are experiencing a period of rapid growth and expect to continue to experience rapid growth throughout 2009. Our ability to manage our growth effectively depends upon the continual improvement of our processes and procedures, and the preservation of our corporate culture. We may not be able to implement improvements in an efficient or timely manner, or maintain our corporate culture through organizational change. If we do not meet these challenges, we may be unable to take advantage of market opportunities, execute our business strategies or respond to competitive pressures, which in turn may slow our growth or give rise to inefficiencies that would increase our losses or delay our programs.

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

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

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

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

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

To date, we have not obtained approval from the U.S. Food and Drug Administration, or FDA, or any foreign regulatory authority to market or sell any of our drug candidates. Our success depends primarily upon

our, and our strategic alliance partners', ability to develop and commercialize our drug candidates successfully. Our most advanced drug candidate is IPI-504, which is currently in early and late-stage clinical trials and our next most advanced drug candidate is IPI-493, for which we commenced our first clinical trial in July 2008. We also commenced our first clinical trial of IPI-926 in October 2008 and have other drug candidates are in various stages of preclinical development and discovery research. IPI-926 and all of our preclinical and discovery research programs are the subject of a strategic alliance agreement with Mundipharma.

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

- the drug candidate may not prove to be safe or effective;
- the results of later trials may not confirm positive results from earlier preclinical studies or clinical trials; and
- the results may not meet the level of statistical significance required by the FDA or other regulatory authorities.

We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA and comparable foreign regulatory agencies. The time required to complete clinical trials and for regulatory review by the FDA and other countries' regulatory agencies is uncertain and typically takes many years. Some of our drug candidates may be eligible for the FDA's programs that are designed to facilitate the development and expedite the review of certain drugs, but we cannot provide any assurance that any of our drug candidates will qualify for one or more of these programs. Even if a drug candidate qualifies for one or more of these programs, the FDA may later decide that the drug 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.

***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;

- delays in receiving, or the inability to obtain, required approvals from institutional review boards or other reviewing entities at clinical sites selected for participation in our clinical trials;
- delays in enrolling patients into clinical trials;
- a lower than anticipated retention rate of patients in clinical trials;
- the need to repeat clinical trials as a result of inconclusive or negative results or unforeseen complications in testing;
- inadequate supply or deficient quality of drug product or other materials necessary to conduct our clinical trials;
- unfavorable FDA inspection and review of a clinical trial site or records of any clinical or preclinical investigation;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials;
- a finding that the trial participants are being exposed to unacceptable health risks;
- the placement by the FDA of a clinical hold on a trial; or
- any restrictions on, or post-approval commitments with regard to, any regulatory approval we ultimately obtain that render the drug candidate not commercially viable.

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

- the size of the patient population;
- the nature of the trial protocol;
- the number of clinical trial sites and the proximity of patients to those sites;
- the availability of effective treatments for the relevant disease;
- the eligibility criteria for the trial;
- the commitment of clinical investigators to identify eligible patients; and
- competing studies or trials.

Delays in patient enrollment can result in increased costs and longer development times. Our failure to enroll patients in our clinical trials could delay the completion of the clinical trial beyond current expectations. In addition, the FDA could require us to conduct clinical trials with a larger number of subjects than has been projected for any of our drug candidates. As a result of these factors, we may not be able to enroll a sufficient number of patients in a timely or cost-effective manner.

Furthermore, enrolled patients may drop out of a clinical trial, which could impair the validity or statistical significance of the clinical trial. A number of factors can influence the patient discontinuation rate, including, but not limited to:

- the inclusion of a placebo arm in a trial;
- possible inactivity or low activity of the drug candidate being tested at one or more of the dose levels being tested;
- the occurrence of adverse side effects, whether or not related to the drug candidate; and
- the availability of numerous alternative treatment options that may induce patients to discontinue their participation in the trial.

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

We cannot predict whether any of our drug candidates will encounter problems during clinical trials that will cause us or regulatory authorities to delay, suspend or discontinue 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 any such changes 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 and unplanned costs. If this were to occur, our efforts to obtain regulatory approval for and to commercialize our drug candidates may be delayed.

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

***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, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. 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 biopharmaceutical 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 medicines and to produce, market and distribute those 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 monetary sanctions, the failure of regulatory authorities to grant marketing approval of our drug candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of drug candidates or products, operating restrictions and/or criminal prosecution, any of which could significantly and adversely affect supply of our drug candidates and seriously hurt our business. Contract manufacturers may also encounter difficulties involving production yields or delays in performing their services. We do not have control over third party manufacturers' performance and compliance with these applicable regulations and standards. If, for any reason, our manufacturers cannot perform as agreed, we may be unable to replace such third party manufacturers in a timely manner and the production of our drug candidates would be interrupted, resulting in delays in clinical trials and additional costs. Switching manufacturers may be difficult because the number of potential manufacturers is limited and, depending on the type of material manufactured at the contract facility, the change in contract manufacturer must be submitted to and/or approved by the FDA and comparable regulatory authorities outside of the United States. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our drug candidates after receipt of regulatory approval. It may be difficult or impossible for us to find a replacement manufacturer on acceptable terms quickly, or at all.

To date, our drug candidates have been manufactured for preclinical testing and clinical trials primarily by third party manufacturers. If the FDA or other regulatory agencies approve IPI-504 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 or approved by the FDA or other regulatory agencies. If contract manufacturers engaged by us are unable to successfully increase the manufacturing capacity for a drug candidate, or we are unable to establish our own manufacturing capabilities, the commercial launch of any approved products may be delayed or there may be a shortage in supply.

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

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

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

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

Even if IPI-504 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, we could lose our regulatory approvals and our business would be adversely affected if we, our collaborators, or our contract manufacturers fail to comply with continuing regulatory requirements.***

The FDA continues to review products even after they receive initial approval. If we receive approval to commercialize IPI-504 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.

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

Even if we receive regulatory approval for IPI-504 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 biopharmaceutical 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 healthcare-related costs. Indeed, legislation that would permit the federal government to negotiate drug prices directly with manufacturers under the Medicare prescription drug programs is a major policy priority for many members of Congress and may be passed in the future. These cost reduction initiatives could decrease the coverage and price that we receive for 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 programs 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 strategic alliance partners to market our drug candidates outside of the United States, separate regulatory approvals must be obtained and we or our alliance partners will need to comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval abroad may differ from and be longer than that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval and additional risks associated with requirements particular to those foreign jurisdictions where we will seek regulatory approval of our products. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory

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

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

As our pipeline of drug candidates matures, we are becoming increasingly subject to extensive and complex laws and regulations, including but not limited to health care “fraud and abuse” laws, such as the federal false claims act, the federal anti-kickback statute, and other state and federal laws and regulations. We are developing and implementing a corporate compliance program designed to ensure that we will market and sell those drug candidates that we successfully develop in compliance with all applicable U.S. laws and regulations, but we cannot guarantee that this program will protect us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

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

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

We seek to develop new drugs for cancer and related conditions. The cancer therapeutic segment of the pharmaceutical industry is highly competitive and rapidly changing. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations are pursuing the development of novel drugs that target various forms of cancer. We currently face, and expect to continue to face, intense and increasing competition as new products enter the market and advanced technologies become available. Moreover, there are a number of large pharmaceutical companies currently marketing and selling products to treat cancer, including Bristol-Myers Squibb Company, F. Hoffmann-La Roche Ltd., 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 IPI-504 and IPI-493. These companies include, without limitation, Bristol-Myers Squibb Company, Biogen Idec Inc., Pfizer, Inc., Vernalis plc (in collaboration with Novartis), Synta Pharmaceuticals Corp., Exelixis, Inc. and Astex Therapeutics Limited. In addition, Genentech (in collaboration with Curis, Inc.) and Bristol-Myers Squibb Company (through its collaboration with Exelixis, Inc.) have collaborations under which drugs targeting the Hedgehog signaling pathway, which is also being targeted by IPI-926, are being developed. Finally, we believe that each of Pfizer, Inc. and Sanofi-Aventis are developing inhibitors of FAAH.

Many of our competitors have:

- significantly greater financial, technical and human resources than us, and may be better equipped to discover, develop, manufacture and commercialize drug candidates;
- more extensive experience in preclinical testing and clinical trials, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products; and/or
- drug candidates that have been approved or are in later-stage clinical development than our own drug candidates.

Our competitors may commence and complete clinical testing of their product candidates, obtain regulatory approvals, and begin commercialization of their products sooner than we and/or our collaborative partners may

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

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

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

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

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

**Risks Related to Intellectual Property**

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

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

Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the claim scope of these patents, our ability to obtain and enforce patents that may issue from any pending or future patent applications is uncertain and involves complex legal, scientific and factual questions. The standards which the United States Patent and Trademark Office, or PTO, and its foreign counterparts use to grant patents are not always applied predictably or uniformly and are subject to change. To

date, no consistent policy has emerged regarding the breadth of claims allowed in pharmaceutical patents. Thus, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us. Even if patents do issue, we cannot guarantee that the claims of these patents will be held valid or enforceable by a court of law, will provide us with any significant protection against competitive products, or will afford us a commercial advantage over competitive products. In addition, the U.S. Senate has considered, and may consider in the future, legislation that could change United States law regarding, among other things, post-grant review of issued patents and the calculation of damages once patent infringement has been determined by a court of law. If enacted into law, these provisions could severely weaken patent protection in the United States.

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

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

In addition, we rely on intellectual property assignment agreements with our corporate partners, employees, consultants, scientific advisors and other collaborators to grant us ownership of new intellectual property that is developed by them. These agreements may not result in the effective assignment to us of that intellectual property. As a result, our ownership of key intellectual property could be compromised.

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

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

declared between our application covering IPI-504 and one or more of these third party applications, even the one of those applications for which we have secured a license. An adverse decision in an interference proceeding may result in the loss of rights under a patent or patent application. In addition, the cost of interference proceedings could be substantial.

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

Our commercial success will depend on whether there are third party patents or other intellectual property relevant to our potential products that may block or hinder our ability to develop and commercialize our drug candidates. We may not have identified all U.S. and foreign patents or published applications that may affect our business either by blocking our ability to 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 IPI-504 in combination with docetaxel, and we may conduct additional trials with IPI-504 in combination with other therapeutic agents. We are aware of issued patents and published applications directed to combinations of Hsp90 inhibitors with a variety of other therapeutic agents. We are also aware of patents and patent applications directed to methods of treating various disorders using a variety of Hsp90 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 biopharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents and claim that the use of our technologies infringes these patents or that we are employing their proprietary technology without authorization. We could incur substantial costs and diversion of management and technical personnel in defending against any claims that the manufacture and sale of our potential products or use of our technologies infringes any patents, or defending against any claim that we are employing any proprietary technology without authorization. The outcome of patent litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of the adverse party, especially in pharmaceutical patent cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. In the event of a successful claim of infringement against us, we may be required to:

- pay substantial damages;
- stop developing, commercializing and selling the infringing drug candidates or approved products;
- develop non-infringing products, technologies and methods; and
- obtain one or more licenses from other parties, which could result in our paying substantial royalties or the granting of cross-licenses to our technologies.

If this were to occur, we may be unable to commercialize the affected products, or we may elect to cease certain of our business operations, either of which could severely harm our business.

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

Competitors may infringe our patents. To prevent infringement or unauthorized use, we may need to file infringement suits, which are expensive and time-consuming. In an infringement proceeding, a court may decide that one or more of our patents is 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.

***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, scientific advisors, clinical investigators and other collaborators. We generally require each of these individuals and entities to execute a confidentiality agreement at the commencement of a relationship with us. These agreements may not effectively prevent disclosure of confidential information, and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information or other breaches of the agreements.

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

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

We may decide to 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 IPI-504, IPI-493 and IPI-926 and our other drug candidates;
- the results of preclinical studies and planned clinical trials of our other discovery-stage programs;
- future sales of, and the trading volume in, our common stock;
- the entry into key agreements, including those related to the acquisition or in-licensing of new programs, or the termination of key agreements;
- the results and timing of regulatory reviews relating to the approval of our drug candidates;
- the initiation of, material developments in, or conclusion of litigation to enforce or defend any of our intellectual property rights;

- the initiation of, material developments in, or conclusion of litigation to defend products liability claims;
- the failure of any of our drug candidates, if approved, to achieve commercial success;
- the results of clinical trials conducted by others on drugs that would compete with our drug candidates;
- issues in manufacturing our drug candidates or any approved products;
- the loss of key employees;
- changes in estimates or recommendations by securities analysts who cover our common stock;
- future financings through the issuance of equity or debt securities or otherwise;
- changes in the structure of health care payment systems;
- our cash position and period-to-period fluctuations in our financial results; and
- general and industry-specific economic conditions.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock.

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

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

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

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

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

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

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

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 44% of our outstanding common stock. Our executive officers, directors and other affiliates have the ability to influence the company through this ownership position. For example, as a result of this concentration of ownership, these stockholders, if acting together, may have the ability to determine the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger or similar transaction. This concentration of ownership may, therefore, harm the market price of our common stock by:

- delaying, deferring or preventing a change in control of 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 1B. Unresolved Staff Comments**

There were no unresolved comments from the Staff of the U.S. Securities and Exchange Commission at December 31, 2008.

**Item 2. Properties**

We currently lease under two lease agreements an aggregate of approximately 73,900 square feet of laboratory and office space among three buildings located at 780, 784, and 790 Memorial Drive in Cambridge, Massachusetts. The first lease covering a total of approximately 67,000 square feet of laboratory and office space has a term ending in December 2012. We currently sublease approximately 16,000 square feet of this space under a sublease agreement that expires in November 2009 and for which the subtenant has extension options through December 2012. The second lease covers approximately 6,900 square feet of office space and has a term ending in December 2012 with an option to extend through October 2014. Should we require additional space, we believe that a suitable facility would be available to accommodate expansion of our operations on commercially reasonable terms.

**Item 3. Legal Proceedings**

We are not a party to any material legal proceedings.

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

At a Special Meeting of Stockholders held on January 7, 2009, our stockholders voted on a proposal to approve the issuance and sale of shares of our common stock and warrants to purchase shares of our common stock to Purdue and Purdue Pharma L.P. pursuant to the Marketplace Rules of the NASDAQ Stock Market. Our stockholders adopted the proposal as follows:

<u>Votes For</u>	<u>Votes Against</u>	<u>Votes Abstaining</u>
15,699,261*	6,853	1,000

\* The 4,000,000 shares of our common stock held by companies associated with Purdue and Purdue Pharma L.P. were not counted as shares voted in favor of this proposal.

## PART II

### Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

#### Market Information

Our common stock is traded on the NASDAQ Global Market under the symbol "INFI." The following table sets forth the range of high and low sales prices on the NASDAQ Global Market of our common stock for the quarterly periods indicated, as reported by NASDAQ. Such quotations represent inter-dealer prices without retail mark up, mark down or commission and may not necessarily represent actual transactions.

	2008		2007	
	High	Low	High	Low
First quarter .....	\$9.67	\$5.00	\$15.00	\$10.66
Second quarter .....	9.62	5.71	12.07	10.37
Third quarter .....	8.11	6.30	11.42	8.48
Fourth quarter .....	8.05	3.74	10.84	8.94

#### Holdings

As of February 28, 2009, there were 119 holders of record of our common stock.

#### Dividends

We have never paid cash dividends on our common stock, and we do not expect to pay any cash dividends in the foreseeable future.

#### Use of Proceeds

The registration statement (File No. 333-36638) for DPI's initial public offering was declared effective by the U.S. Securities and Exchange Commission 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 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 merger through December 31, 2008, we used the remaining amounts on our Hsp90, Hedgehog pathway inhibitor, and other research programs and for general corporate purposes.

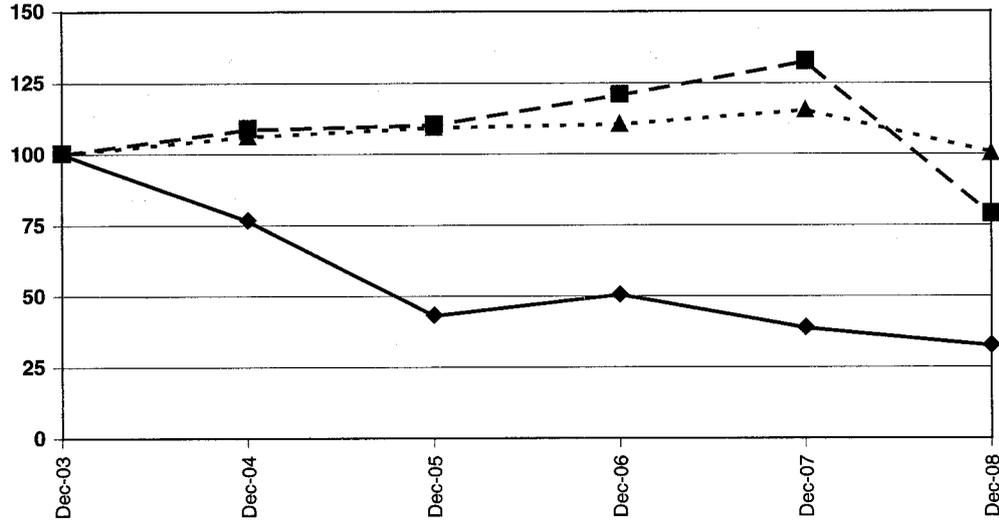
#### Comparative Stock Performance Graph

The information included under the heading "Comparative Stock Performance Graph" included in Item 5 of this Annual Report on Form 10-K shall not be deemed to be "soliciting material" or subject to Regulation 14A or 14C, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act.

The graph below shows a comparison of cumulative total stockholder returns from December 31, 2003 through December 31, 2008 for our common stock, the NASDAQ Stock Market (U.S. Companies) Index and the NASDAQ Biotechnology Index. The graph assumes that \$100 was invested in our common stock and in each index on December 31, 2003, and that all dividends were reinvested. No cash dividends have been declared or paid on our common stock.

The stockholder returns shown on the graph below are not necessarily indicative of future performance, and we will not make or endorse any predictions as to future stockholder returns.

**Comparison of 5-Year Cumulative Total Return  
among Infinity Pharmaceuticals, Inc. (known as Discovery Partners International, Inc. prior to 9/12/06),  
the NASDAQ Stock Market (U.S.) Index,  
and the NASDAQ Biotechnology Index**



	31-Dec-03	31-Dec-04	31-Dec-05	31-Dec-06	31-Dec-07	31-Dec-08
◆ Infinity Pharmaceuticals	100.0	76.6	43.1	50.4	38.8	32.5
■ NASDAQ Stock Market (U.S.) Index	100.0	108.6	110.1	120.6	132.4	78.7
▲ - NASDAQ Biotechnology Index	100.0	106.1	109.1	110.3	115.3	100.7

## Item 6. Selected Financial Data

The following financial data should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this report. As discussed elsewhere in this report, our financial statements for periods prior to the DPI merger reflect the historical results of Old Infinity, and not DPI, and our financial statements subsequent to September 12, 2006 reflect the results of the combined company. Amounts below are in thousands, except for per share amounts.

	Year Ended December 31,				
	2008	2007	2006	2005	2004
<b>Statement of Operations Data:</b>					
Revenue(1) .....	\$ 83,441	\$ 24,536	\$ 18,494	\$ 522	\$ —
Operating expenses:					
Research and development .....	47,466	33,793	35,792	31,460	28,396
General and administrative .....	16,837	14,034	9,464	5,530	5,290
Total costs and expenses .....	64,303	47,827	45,256	36,990	33,686
Income (loss) from operations .....	19,138	(23,291)	(26,762)	(36,468)	(33,686)
Interest income (expense), net .....	3,321	6,393	953	99	(402)
Income from residual funding after reacquisition of Hsp90 program .....	1,195	—	—	—	—
Debt extinguishment charge .....	—	—	(1,551)	—	—
Income (loss) before income taxes .....	23,654	(16,898)	(27,360)	(36,369)	(34,088)
Income taxes .....	—	—	(1,088)	—	—
Net income (loss) .....	\$ 23,654	\$ (16,898)	\$ (28,448)	\$ (36,369)	\$ (34,088)
Earnings (loss) per common share:(2)					
Basic .....	\$ 1.17	\$ (0.87)	\$ (3.81)	\$ (17.01)	\$ (18.72)
Diluted .....	\$ 1.14	\$ (0.87)	\$ (3.81)	\$ (17.01)	\$ (18.72)
Weighted average number of common shares outstanding:(2)					
Basic .....	20,236,743	19,511,485	7,463,426	2,138,331	1,821,285
Diluted .....	20,765,536	19,511,485	7,463,426	2,138,331	1,821,285

- (1) Revenue for the year ended December 31, 2008 is impacted by the acceleration of revenue recognition for the up-front license fees received from Novartis and MedImmune/AZ.
- (2) Basic and diluted net loss per common share and weighted average shares outstanding were impacted by the conversion of preferred stock and issuance of common stock in connection with the DPI merger on September 12, 2006.

	As of December 31,				
	2008	2007	2006	2005	2004
<b>Selected Balance Sheet Data:</b>					
Cash, cash equivalents and available-for-sale securities .....	\$ 126,772	\$ 114,189	\$ 101,697	\$ 10,946	\$ 44,548
Working capital .....	120,587	97,097	121,264	2,468	38,051
Total assets .....	160,618	129,725	154,648	24,451	61,966
Long term capital leases and debt .....	12	20	374	2,041	4,047
Accumulated deficit .....	(148,892)	(172,546)	(155,305)	(126,857)	(90,488)
Total stockholders' equity .....	120,295	51,143	62,425	10,174	45,831

## **Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**

The following discussion of our financial condition and results of operations should be read in conjunction with our 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 I of this report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

### **DPI Merger**

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

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

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

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

### **Business Overview**

Our mission is to build a community and company capable of sustainably discovering, developing and delivering to patients innovative, important new medicines that will make a material difference in their health, well-being and lives.

Our lead product candidate, IPI-504 (retaspimycin hydrochloride) is an intravenously-administered small molecule inhibitor of heat shock protein 90, or Hsp90. Hsp90 is a central component of the cellular chaperone

system—a system that supports and stabilizes cancer-causing proteins such as c-Kit, EGFR, and HER2, enabling multiple forms of cancer to thrive. Inhibition of the Hsp90 chaperone knocks out this critical source of support for cancer cells, leading to tumor growth inhibition and cancer cell death. Thus, targeted anti-chaperone therapy via inhibition of Hsp90 may represent a significant yet currently unaddressed strategy for treating patients with cancer. In October 2008, we commenced an international Phase 3 registration study of IPI-504 in patients with refractory gastrointestinal stromal tumors, or GIST, based on the activity and safety data from a Phase 1 trial reported in 2008. This registration study, called the RING (Retaspimycin hydrochloride IN GIST) trial, is being conducted under a Special Protocol Assessment agreement with the U.S. Food and Drug Administration, or FDA, and pursuant to scientific advice from the European Medicines Agency. We estimate that this trial will be completed by the end of 2010, positioning IPI-504 as the potential first-to-market inhibitor of Hsp90. IPI-504 is also being evaluated as a single agent in the expansion phase of the Phase 2 portion of a Phase 1/2 clinical trial in patients with advanced non-small cell lung cancer, or NSCLC, and in a Phase 1b clinical trial in combination with Taxotere® (docetaxel) in patients with advanced solid tumors. Additional clinical trials of IPI-504, including a trial in HER2-positive metastatic breast cancer, are expected to commence in 2009.

In July 2008, we commenced a Phase 1 clinical trial of IPI-493, an orally-delivered inhibitor of Hsp90, in patients with advanced solid tumors. This trial is designed to assess the safety and tolerability of IPI-493 and to identify a dose and schedule for further clinical development. Biological activity of IPI-493 is being measured by computed tomography, or CT, imaging using Response Evaluation Criteria in Solid Tumors, otherwise known as RECIST, as well as disease specific markers.

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

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

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

We have spent, and expect to continue to spend, significant resources to fund the research and development of IPI-504, IPI-493, IPI-926, IPI-940 and our other drug candidates. While we may have net income in future periods as the result of non-recurring collaboration income, as we did in the year ended December 31, 2008, we expect to incur substantial and increasing operating losses over the next several years as our clinical trial and drug manufacturing activities for our Hsp90 program increase and as we incur pre-commercialization expenses in anticipation of a potential commercial launch of IPI-504.

## Collaboration Agreements

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

We have responsibility and decision-making authority for the performance of early discovery projects and the development of all product candidates on a worldwide basis. Mundipharma will pay for 100% of all research and development expenses incurred by Infinity for early discovery projects and product candidates included in the alliance until the later of December 31, 2013 and the commencement of the first phase 3 clinical study of such product candidate. We refer to such date as the transition date. After the transition date for each product candidate other than those arising out of the FAAH project, Mundipharma and Infinity will share all research and development costs for such product candidate equally. Upon completion of the first phase 1 clinical study of the first product developed under the research program that inhibits or targets FAAH, Purdue and Mundipharma may elect to assume responsibility, at their own expense, for the future development and commercialization of FAAH products for sale in and outside of the United States, respectively. We are recording revenue for reimbursable research and development services we perform for Mundipharma and Purdue. We recorded \$2.7 million in such revenue in the year ended December 31, 2008.

Mundipharma has the right to opt out of any early discovery project or any preclinical or clinical development program on an annual basis in November of each year. Mundipharma also has a one-time right in mid-2009 to opt out of either or both of the Hedgehog development program or the FAAH project. In the event of an opt-out decision, Mundipharma, together with Purdue with respect to the FAAH program, will continue to provide funding for, in the aggregate, 100% of our budgeted research and development expenses for the applicable project or program for one year after the date of such opt-out. Purdue has a comparable opt out right with respect to the FAAH project. In addition, we and Mundipharma each have the right to opt out of continued development of a product candidate after it has reached the transition date, with a one year tail funding obligation for its 50% of post-transition date research and development expenses. If a party exercises its right to opt-out of the development of a product or product candidate after the transition date, the other party may elect to continue the development and assume responsibility for the worldwide commercialization of such product or product candidate, subject to the payment of a royalty.

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

If we in-license any product or product candidate during the funded discovery period for which commercialization rights outside of the United States are available for grant by Infinity to Mundipharma, Mundipharma will have the option to include such in-licensed product or product candidate in the alliance by paying Infinity a prescribed percentage of the up-front license fee or other acquisition cost, which percentage could be up to 60% of such fee or cost, in order for Mundipharma to obtain rights in all countries outside of the

United States, and by funding research and development costs in the same manner as products or product candidates arising out of Infinity's internal discovery programs. The agreement with Mundipharma provides for the agreed-upon research and development budgets to be updated to reflect the inclusion of any in-licensed products or product candidates. There will be no royalties paid between the parties on in-licensed candidates.

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

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

The line of credit agreement provides for the borrowing by us of one or more unsecured loans up to an aggregate maximum principal amount of \$50 million. The loans may be drawn by us during the three-year period beginning on April 1, 2009. The loans, which may be used by us for any proper corporate purpose, mature on April 1, 2019, which we refer to as the maturity date, and will be subordinate to any senior indebtedness that we may incur. Borrowings made under the line of credit agreement will bear interest, payable on the maturity date, at a fluctuating rate set at the prime rate on the business day prior to the funding of each loan and will be reset on the last business day of each month ending thereafter. Interest will be compounded on each successive three-month anniversary of the funding of each loan. Outstanding loans may be prepaid without penalty or premium prior to the maturity date. Amounts borrowed under the credit agreement, once borrowed, may not be borrowed again. We have certain rights to repay outstanding amounts under the line of credit agreement in shares of our common stock.

In 2008, we recorded \$23.8 million as deferred revenue associated with the grant of licenses to Mundipharma and Purdue representing the excess of the amount paid by Purdue and Purdue Pharma, L.P. for our common stock (\$11.25 per share) over the closing market price on the day before the first equity closing (\$5.29 per share). In the year ended December 31, 2008, we recognized \$0.2 million in revenue in connection with the amortization of the deferred revenue. In January 2009, we will record the additional equity and warrants issued to Purdue and Purdue Pharma, L.P. at the second equity closing at their fair value as of the first equity closing, and the excess of the amount paid over fair value as deferred revenue. We considered our obligation, absent material

adverse changes, to issue Purdue and Purdue Pharma, L.P. the second equity closing shares and warrants as a forward contract with immaterial intrinsic value, which was recorded in stockholders' equity. The deferred revenue will be recognized as revenue ratably over our estimated period of performance under the arrangement, which is 14 years. We will periodically review this estimate and make adjustments as facts and circumstances dictate. There are no joint steering committees for the strategic alliances. The extension of the line of credit at an interest rate below our incremental borrowing rate represents the transfer of additional value to us in the arrangement. As such, we have recorded the fair value of the line of credit of \$17.3 million as a loan commitment asset on our balance sheet in 2008, which we will amortize to interest expense over the life of the loan arrangement, or the 10 years commencing on April 1, 2009. Because Purdue and its associated companies became significant related parties as a result of the equity issuances, we recorded the offset to this asset as additional paid in capital in 2008.

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

Under the terms of this agreement, we shared equally with MedImmune/AZ all development costs, as well as potential profits and losses, from any future marketed products. MedImmune/AZ made non-refundable, up-front payments totaling \$70 million to us in order to obtain co-exclusive rights to the Hsp90 and Hedgehog pathway development programs, and paid a \$15 million milestone to us in 2008 upon initiation of the RING trial. Upon the reacquisition of rights to the Hsp90 program, we recognized all of the remaining deferred revenue related to the up-front license fee from MedImmune/AZ, as we had no further performance obligations to MedImmune/AZ. During the year ended December 31, 2008, we recognized \$56.7 million in revenue, of which \$49.2 million was recorded in the fourth quarter of 2008, from such fee. Further, because the agreement was a cost-sharing arrangement rather than one in which research and development expenses were reimbursed, we recorded amounts reimbursable by MedImmune/AZ with respect to research and development prior to the date we reacquired the Hsp90 program as a reduction to research and development expense, and not as revenue. For the year ended December 31, 2008, we offset approximately \$16.7 million in amounts reimbursable by MedImmune/AZ against research and development expense. The \$1.2 million in reimbursable amounts incurred between the date on which the Hsp90 program was reacquired and December 31, 2008 is recorded as income from residual funding in our statement of operations.

Following the reacquisition of the Hsp90 program, MedImmune/AZ remained obligated to fund an amount equivalent to its share of Hsp90 program costs for the ensuing six-month period. In January 2009, however, we agreed with MedImmune/AZ to settle these residual funding obligations through lump-sum payments totaling \$12.5 million, which we intend to record as income from residual funding in our statement of operations in the first quarter of 2009.

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

**Novartis.** In February 2006, we entered into a collaboration agreement with Novartis Institute for BioMedical Research, Inc., or Novartis, to discover, develop and commercialize drugs targeting Bcl protein family members for the treatment of a broad range of cancers. Under the terms of this agreement, we granted to Novartis an exclusive, worldwide license to research, develop and commercialize pharmaceutical products that are based upon our proprietary Bcl inhibitors. Novartis paid us a \$15 million up-front license fee, which we were originally recognizing over an estimated period of performance of four years, an affiliate of Novartis made a \$5 million equity investment in us, and Novartis committed to provide us research funding of approximately \$10 million over the initial two-year research term, which expired in February 2008. Pursuant to this agreement, we

conducted joint research with Novartis to identify molecules for clinical development. Novartis now has responsibility for further pre-clinical, clinical development and commercialization of any products based upon compounds discovered under the joint research program. Because we had no further performance obligations to Novartis, we recognized the remaining balance of deferred revenue in the first quarter of 2008. We may request to participate in clinical development of any such products and, if such request is agreed upon by Novartis, Novartis will fund agreed-upon development costs that are incurred by us. We also have a non-exclusive right to detail Bcl-2 family inhibitor products in the United States, with our detailing costs to be reimbursed by Novartis. Novartis has agreed to make milestone payments totaling over \$370 million if certain specified research, development and commercialization milestones are achieved for multiple products for multiple indications, such that total payments to us could exceed \$400 million. Novartis has also agreed to pay us royalties upon successful commercialization of any products developed under the alliance.

**Technology Access Alliances.** We have also entered into technology access alliances with Amgen Inc., or Amgen, 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 had 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, contract service revenue and milestones payments received from our collaboration partners. Where the agreement with a collaboration partner, such as our agreements with Purdue and Novartis, provide 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 year to year as a result of the timing and amount of license fees, research and development reimbursement, milestone and other payments earned under our collaborative or strategic relationships, and the amount and timing of payments that we earn upon the sale of our products, to the extent any are successfully commercialized. If we fail to complete the development of our drug candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

### ***Research & 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:

- IPI-504, an intravenously-administered Hsp90 inhibitor for which we are conducting a Phase 3 clinical trial in patients with refractory GIST, and which is also being evaluated as a single agent in advanced non-small cell lung cancer and in combination with docetaxel in patients with solid tumors;
- IPI-493, an orally-delivered Hsp90 inhibitor, for which we initiated a Phase 1 clinical trial in July 2008 in patients with advanced solid tumors;
- IPI-926, the orally-delivered lead candidate in our Hedgehog pathway inhibitor program, for which we commenced a Phase 1 clinical trial in patients with advanced and/or metastatic solid tumors in October 2008; and
- IPI-940, the clinical development candidate for neuropathic pain targeting fatty acid amide hydrolase (FAAH).

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.

Under our collaboration with MedImmune/AZ, we shared research and development expenses equally with MedImmune/AZ. In December 2008, we reacquired from MedImmune/AZ worldwide development and commercialization rights to our Hsp90 program. Reimbursable amounts from MedImmune/AZ under the cost-sharing provisions of the parties' collaboration agreement incurred prior to our reacquisition of the Hsp90 program are recorded as a reduction of research and development expense in our statements of operations. Reimbursable amounts from MedImmune/AZ incurred following the reacquisition of the Hsp90 program are recorded as income from residual funding after reacquisition of Hsp90 program on our statements of operations. This cost-sharing arrangement also applied to our Hedgehog pathway inhibitor program through May 31, 2008. Because this was a cost-sharing arrangement, we recorded appropriate reimbursable amounts 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 primarily consists of salaries and other related costs for personnel in executive, finance, accounting, legal, information technology infrastructure, corporate communications and human resources functions. Other costs include facilities costs not otherwise included in research and development expense, professional fees for legal and accounting services and early commercial development costs. General and administrative expense also consists of the costs of maintaining and overseeing our intellectual property portfolio, which include the salaries of in-house patent counsel, the cost of external counsel and the associated filing and maintenance fees.

#### ***Other Income & Expense***

Interest expense and other interest and investment income primarily consist of interest earned on cash, cash equivalents and available-for-sale securities, and interest expense, which includes 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 accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make judgments, estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, accrued expenses, assumptions in the valuation of stock-based compensation and income taxes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ from those estimates. We believe that the following accounting policies and estimates are most critical to aid you in understanding and evaluating our reported financial results.

### ***Revenue Recognition***

To date, 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*, Emerging Issues Task Force (EITF) No. 00-21, *Revenue Arrangements With Multiple Deliverables* and EITF No. 99-19, *Revenue Recognition Gross as a Principal Versus Net as an Agent*.

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

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

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

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

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

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

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

### ***Accrued Expenses***

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves identifying services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date. Examples of services for which we must estimate accrued expenses include contract service fees paid to contract manufacturers in conjunction with pharmaceutical development work and to contract research organizations in connection with clinical trials and preclinical studies. In connection with these service fees, our estimates are most affected by our understanding of the status and timing of services provided. The majority of our service providers invoice us in arrears for services performed. In the event that we do not identify certain costs that have been incurred by our service providers, or if we over- or under-estimate the level of services performed or the costs of such services in any given period, our reported expenses for such period would be too low or too high. We often rely on subjective judgments to determine the date on which certain services commence, the level of services performed on or before a given date, and the cost of such services. We make these judgments based upon the facts and circumstances known to us. 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 (SFAS) 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 the Black-Scholes valuation model in determining the fair value of equity awards. 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 Financial Accounting Standards Board (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.

### ***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 non-financial assets and liabilities recorded at fair value on a non-recurring basis.

We adopted SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities—Including an Amendment of FASB Statement No. 115* (“SFAS No. 159”), on January 1, 2008. SFAS No. 159 permits an entity to choose to measure many financial instruments and certain other items at fair value at specified election dates. Subsequent unrealized gains and losses on items for which the fair value option has been elected will be reported in earnings. We did not elect to measure any additional financial instruments or other items at fair value.

### ***New Accounting Pronouncement***

In December 2007, the FASB ratified the consensus reached by the EITF on 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 Generally Accepted Accounting Principles, or 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**

#### ***Comparison of the Years Ended December 31, 2008 and 2007***

The following table summarizes our results of operations for the years ended December 31, 2008 and 2007, in thousands, together with the change in each item in dollars and as a percentage.

	<b>For the Years Ended December 31,</b>			
	<b>2008</b>	<b>2007</b>	<b>\$ Change</b>	<b>% Change</b>
Revenue .....	\$ 83,441	\$ 24,536	\$ 58,905	240%
Research and development expense .....	(47,466)	(33,793)	(13,673)	40%
General and administrative expense .....	(16,837)	(14,034)	(2,803)	20%
Interest expense .....	(21)	(188)	167	(89)%
Interest and investment income .....	3,342	6,581	(3,239)	(49)%
Income from residual funding of Hsp90 program .....	1,195	—	1,195	—

#### ***Revenue***

Our revenue during the year ended December 31, 2008 primarily consisted of approximately:

- \$56.7 million associated with the amortization and acceleration of the up-front license fee received from MedImmune/AZ upon entry into our strategic alliance in August 2006;
- \$15.0 million related to a milestone payment from MedImmune/AZ upon initiation of the RING trial;
- \$8.1 million related to the amortization and acceleration of the non-refundable license fee, and \$0.8 million related to the reimbursable research and development services we performed, under our Bcl-2 collaboration entered into with Novartis in February 2006; and

- \$2.7 million related to reimbursable research and development services we performed under our strategic alliances entered into with Mundipharma and Purdue in November 2008.

Our revenue during the year ended December 31, 2007 consisted of approximately:

- \$10.0 million associated with the amortization of the up-front license fee received from MedImmune/AZ upon entry into our strategic alliance;
- \$3.75 million related to the amortization of the non-refundable license fee, and \$4.8 million related to the reimbursable research and development services we performed, under our Bcl-2 collaboration entered into with Novartis; and
- \$6.0 million related to the acceptance of compounds by Novartis International under our technology access agreement.

We currently expect that all of our revenue in 2009 will be derived from our alliances with Purdue and Mundipharma.

*Research and Development Expense*

Research and development expenses represented approximately 74% of our total operating expenses for the year ended December 31, 2008 and 71% of our total operating expenses for the year ended December 31, 2007.

The increase in research and development expense is primarily attributable to:

- an increase of \$8.9 million in expenses for clinical trials of IPI-504, IPI-493 and IPI 926;
- an increase of \$4.7 million in pharmaceutical development expenses as our Hsp90 and Hedgehog programs have advanced; and
- an increase of \$3.7 million in compensation and benefits, including SFAS No. 123(R) stock-based compensation, for our research and development personnel, which was primarily driven by the hiring of new research and development personnel, our contingent cash compensation program and annual base salary increases.

This \$17.3 million increase in research and development expenditures was partially offset by an increase of \$3.0 million in amounts reimbursable by MedImmune/AZ under the cost-sharing provisions of our collaboration agreement.

The following table sets forth our estimates of research and development expenses, by program, over the last two years. These expenses primarily relate to payroll and related expenses for personnel working on the programs, drug development and manufacturing, preclinical toxicology studies and clinical trial costs. Our Hsp90 program and Hedgehog pathway inhibitors programs were being conducted in collaboration with MedImmune/AZ. We reacquired all development and worldwide commercialization rights to our Hsp90 program and Hedgehog pathway inhibitor programs in December 2008 and November 2007, respectively. Under this collaboration, we shared research and development expenses equally with MedImmune/AZ. Pursuant to our cost-sharing agreement, reimbursable amounts from MedImmune/AZ were credited to research and development expenses for our Hsp90 program through December 10, 2008 and for our Hedgehog pathway inhibitors program through May 31, 2008. The expenses for the Hsp90 and Hedgehog pathway inhibitor programs include credits of approximately \$16.7 million for the year ended December 31, 2008, and \$13.7 million for the year ended December 31, 2007, attributable to amounts reimbursable by MedImmune/AZ under the cost-sharing provisions of our collaboration agreement.

<u>Program</u>	<u>Year Ended December 31, 2008</u>	<u>Year Ended December 31, 2007</u>
Hsp90 .....	\$20.4 million	\$12.9 million
Hedgehog Pathway Inhibitors .....	10.8 million	5.3 million
Bcl .....	0.6 million	4.7 million

We began to track and accumulate costs by major programs starting on January 1, 2006. Our research and development costs prior to December 31, 2005 were largely related to Hsp90.

We do not believe that the historical costs associated with our lead drug development programs are indicative of the future costs associated with these programs or represent what any other future drug development program we initiate may cost. Due to the variability in the length of time and scope of activities necessary to develop a drug candidate, uncertainties related to cost estimates and our ability to obtain marketing approval for our drug candidates, accurate and meaningful estimates of the total costs required to bring our product candidates to market are not available. We expect our Hsp90 program expenses to increase as we seek to advance IPI-504 into additional and later stage clinical trials and make progress in clinical development of IPI-493. In addition, we expect expenses for our Hedgehog pathway inhibitor program to increase as we make progress in the clinical development of IPI-926. 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. We also expect Hsp90 and Hedgehog pathway inhibitor expenses to increase as a result of MedImmune/AZ no longer funding half of the expenses on these programs.

#### *General and Administrative Expense*

The increase in general and administrative expense for the year ended December 31, 2008 as compared to the year ended December 31, 2007 is primarily attributable to:

- an increase of \$1.6 million in compensation and benefits, including SFAS No. 123(R) stock-based compensation expense for general and administrative employees, which was primarily driven by the hiring of new general and administrative personnel, the contingent cash compensation program and annual base salary increases; and
- an increase of \$1.0 million in consulting expenses, principally related to early commercial development and public relations services.

We expect our general and administrative expense to increase in 2009 in support of our research and development initiatives and as we begin to establish commercial capabilities.

#### *Interest and Investment Income*

Interest and investment income decreased in the year ended December 31, 2008 as compared to the year ended December 31, 2007 primarily as a result of lower yields on our available-for-sale securities and cash equivalents and the lower quarterly average balance of available-for-sale securities and cash equivalents due to our cash burn and the timing of cash receipts during the year. We expect interest and investment income to be lower in 2009 primarily due to lower expected yields, partially offset by higher average balances due to the Purdue transaction.

#### *Interest Expense*

We expect to record interest expense in future years related to the amortization of the loan commitment asset from the Purdue transaction.

#### *Income from Residual Funding After Reacquisition of Hsp90 Program*

Following our reacquisition of the Hsp90 program in December 2008, MedImmune/AZ remained obligated to fund an amount equivalent to its share of Hsp90 program costs for the ensuing six-month period. Reimbursable amounts from the date of reacquisition (December 11, 2008) to December 31, 2008 are recorded as income from residual funding after reacquisition of Hsp90 program. In January 2009, we agreed with MedImmune/AZ to settle the residual funding obligations through lump sum payments totaling \$12.5 million, which will also be recorded as income from residual funding after reacquisition of Hsp90 program in the first quarter of 2009.

### *Comparison of the Years Ended December 31, 2007 and 2006*

The following table summarizes our results of operations for the years ended December 31, 2007 and 2006, in thousands, together with the change in each item in dollars and as a percentage.

	For the Years Ended December 31,			
	2007	2006	\$ Change	% Change
Revenue .....	\$ 24,536	\$ 18,494	\$ 6,042	33%
Research and development expense .....	(33,793)	(35,792)	1,999	(6)%
General and administrative expense .....	(14,034)	(9,464)	(4,570)	48%
Interest expense .....	(188)	(1,507)	1,319	(88)%
Interest and investment income .....	6,581	2,460	4,121	168%
Debt extinguishment charge .....	—	(1,551)	1,551	(100)%
Income taxes .....	—	(1,088)	1,088	(100)%

#### *Revenue*

Our revenue during the year ended December 31, 2007 consisted of approximately:

- \$10.0 million associated with the amortization of the up-front license fee received from MedImmune/AZ upon entry into our strategic alliance;
- \$3.75 million related to the amortization of the non-refundable license fee, and \$4.8 million related to the reimbursable research and development services we performed, under our Bcl-2 collaboration entered into with Novartis; and
- \$6.0 million related to the acceptance of compounds by Novartis International under our technology access agreement.

Our revenue during the year ended December 31, 2006 consisted of approximately:

- \$3.3 million associated with the amortization of the up-front license fee received from MedImmune/AZ upon entry into our strategic alliance;
- \$2.5 million in license fees received upon the amendment of our technology access agreement with Amgen in July 2006;
- \$3.1 million related to the amortization of the non-refundable license fee, and \$4.1 million related to the reimbursable research and development services we performed, under our Bcl-2 collaboration entered into with Novartis;
- \$4.5 million related to the acceptance of compounds by Novartis International under our technology access agreement; and
- \$1.0 million related to the acceptance of compounds by J&J under our technology access agreement.

#### *Research and Development Expense*

Research and development expenses represented approximately 71% of our total operating expenses for the year ended December 31, 2007 and 79% of our total operating expenses for the year ended December 31, 2006.

The decrease in research and development expense is primarily attributable to an increase of \$9.7 million in reimbursable amounts from MedImmune/AZ under the cost-sharing provisions of our collaboration agreement, which are recorded as a credit to research and development expense. This increase in reimbursable amounts was principally the result of costs under the MedImmune/AZ collaboration being shared for only four months of the year ended December 31, 2006. Notwithstanding the amounts reimbursable by MedImmune/AZ, we recorded:

- an increase of \$4.0 million in pharmaceutical development expenses as our Hsp90 and Hedgehog programs have advanced; and

- an increase of \$3.3 million in compensation and benefits, including SFAS No. 123(R) stock-based compensation, for our research and development personnel, which was driven by the hiring of new research and development personnel, annual base salary increases and larger annual stock option grants.

The following table sets forth our estimates of research and development expenses, by program, over the years ending December 31, 2007 and 2006. These expenses primarily relate to payroll and related expenses for personnel working on the programs, drug development and manufacturing, preclinical toxicology studies and clinical trial costs. Under our collaboration with MedImmune/AZ, we shared research and development expenses equally with MedImmune/AZ. The cost-sharing agreement applied to our Hsp90 program and our Hedgehog pathway inhibitors program during the year ended December 31, 2007, and also for the last four months of the year ended December 31, 2006. The expenses for the Hsp90 and Hedgehog pathway inhibitor programs include credits of approximately \$13.7 million for the year ended December 31, 2007, and \$4.0 million for the year ended December 31, 2006, attributable to amounts reimbursable by MedImmune/AZ under the cost-sharing provisions of our collaboration agreement.

<u>Program</u>	<u>Year Ended December 31, 2007</u>	<u>Year Ended December 31, 2006</u>
Hsp90 .....	\$12.9 million	\$7.6 million
Hedgehog Pathway Inhibitors .....	5.3 million	8.0 million
Bcl .....	4.7 million	4.2 million

#### *General and Administrative Expense*

The increase in general and administrative expense for the year ended December 31, 2007 as compared to year ended December 31, 2006 is primarily attributable to:

- an increase of \$2.8 million in compensation and benefits, including SFAS No. 123(R) stock-based compensation expense for general and administrative employees, which was driven by the hiring of new general and administrative personnel, annual base salary increases and larger annual stock option grants; and
- an increase of \$1.3 million in patent costs, tax service expense, and miscellaneous tax expense, including state franchise taxes.

#### *Interest Expense*

Interest expense decreased in the year ended December 31, 2007 as compared to the year ended December 31, 2006 primarily due to the repayment in December 2006 of all of our outstanding debt to Oxford Finance Corporation, or Oxford, and Horizon Technology Funding Company LLC, or Horizon.

#### *Interest and Investment Income*

Interest and investment income increased by \$4.1 million in the year ended December 31, 2007 as compared to the year ended December 31, 2006 primarily as a result of our higher average balance of cash, cash equivalents and available-for-sale securities during 2007, which was, in turn, primarily attributable to amounts received upon completion of the DPI merger and up-front license fees received from MedImmune/AZ and Novartis in connection with our collaborations.

#### *Debt Extinguishment Charge*

In connection with the early retirement of our outstanding indebtedness to Oxford and Horizon in December 2006, we recorded a debt extinguishment charge of approximately \$1.6 million during the year ended December 31, 2006. This debt extinguishment charge represents the write-off of the unamortized portion of the

warrants that we issued to Oxford and Horizon when we originally entered into these debt facilities, as well as a 4% prepayment penalty.

### 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 and investment income on cash, cash equivalents and available-for-sale securities, license fees, expense reimbursement under our collaborations, milestone payments, contract service payments and debt to fund our operations. Because our drug candidates are in varying stages of clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our drug candidates or whether, or when, we may achieve profitability.

Other significant capital resources are as follows:

	<u>December 31, 2008</u>	<u>December 31, 2007</u>
Cash, cash equivalents and available-for-sale securities .....	\$126,771,687	\$114,189,468
Working capital .....	120,587,124	97,097,370

	<u>Years ended December 31,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
Cash (used in) provided by:			
Operating activities .....	\$(10,422,417)	\$ 12,082,295	\$ 9,615,770
Investing activities .....	(18,183,839)	(62,004,999)	13,479,706
Capital expenditures (included in investing activities above) .....	(1,392,377)	(2,405,677)	(946,565)
Financing activities .....	22,016,084	(1,060,054)	41,609,247

### Cash Flows

The principal use of cash in operating activities in all of the periods presented was the funding of our research and development expenses, which increase as the pipeline advances. 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 November 2008, we entered into strategic alliances with Mundipharma and Purdue and issued four million shares of our common stock to Purdue and one of its independent associated companies for cash proceeds of \$45.0 million. Of this amount, these shares were recorded at \$21.2 million, which represents the fair market value of our issued common stock and recorded in our cash flows from financing activities and \$23.8 million was accounted for as an up-front license fee in deferred revenue and recorded in our cash flows from operating activities.

Our reacquisition of the Hsp90 program from MedImmune/AZ in December 2008 resulted in a \$56.7 million decrease in deferred revenue. In February 2008, Novartis chose not to exercise its options for two one-year extensions of the research period under our Bcl collaboration, thus resulting in an \$8.1 million decrease in deferred revenue.

Cash flows from operating activities for the year ended December 31, 2008 included an increase in unbilled accounts receivable primarily due to the strategic alliances with Mundipharma and Purdue and an increase in accounts payable, accrued expenses and other liabilities primarily due to our contingent cash compensation program and higher research and development activities.

Net cash used in investing activities for the year ended December 31, 2008 included \$172.0 million in purchases of available-for-sale securities, proceeds of \$137.1 million from maturities of available-for-sale securities and proceeds of \$18.1 million from sales of available-for-sale securities. Capital expenditures in the year ended December 31, 2008 primarily consisted of laboratory equipment and leasehold improvements for additional office space.

In January 2007, we received \$35.0 million from MedImmune/AZ, representing the second half of the up-front license fee related to our collaboration agreement, which was recorded as an unbilled receivable as of December 31, 2006. Cash flow from operating activities for the year ended December 31, 2007 included higher stock-based compensation as well as increased net accretion on available-for-sale securities, as we invested portions of the MedImmune/AZ and Novartis up-front license fees and the proceeds from the DPI merger into available-for-sale securities. Cash flows from operating activities for the year ended December 31, 2007 also included an increase to accounts payable, accrued expenses and other liabilities primarily due to higher research and development activities.

Net cash used in investing activities for the year ended December 31, 2007 included \$208.2 million in purchases of available-for-sale securities and \$148.6 million in maturities of available-for-sale securities. Capital expenditures in the year ended December 31, 2007 primarily consisted of laboratory equipment and leasehold improvements for a new process scale-up laboratory.

We will need substantial additional funds to support our planned operations. In the absence of additional funding and based on our current operating plans, we expect that our current cash, cash equivalents and available-for-sale securities, together with the \$50 million line of credit that has been made available to us by an entity associated with Purdue, are sufficient to fund our planned operations through the end of 2012. 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 payments we expect to receive from Mundipharma and Purdue. 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;
- we acquire or license rights to additional drug candidates or new technologies from one or more third parties;
- Mundipharma or Purdue elects to discontinue its participation in a partnered program; or
- we experience a loss in our investments due to general market conditions or other reasons.

We may seek additional funding through public or private financings of equity or debt securities, but such financing may not be available on acceptable terms, or at all, particularly in light of current market conditions. In addition, the terms of our financings may be dilutive to, or otherwise adversely affect, holders of our common stock, and such terms may impact our ability to make capital expenditures or incur additional debt. We may also seek additional funds through arrangements with collaborators or other third parties, or through project financing. These arrangements would generally require us to relinquish or encumber rights to some of our technologies or

drug candidates, and we may not be able to enter into such agreements on acceptable terms, if at all. If we are unable to obtain additional funding on a timely basis, we may be required to curtail or terminate some or all of our development programs, including some or all of our drug candidates.

### **Contractual Obligations**

As of December 31, 2008, we had the following contractual obligations:

<b>Contractual Obligations</b>	<b>Payments Due by Period (in thousands)</b>						
	<b>Total</b>	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>2014 and beyond</b>
Capital lease, including interest . . . . .	\$ 20	\$ 7	\$ 7	\$ 6	\$ —	\$—	\$—
Software contract obligation . . . . .	150	150	—	—	—	—	—
Operating lease obligations—other . . . . .	14	6	6	2	—	—	—
Operating lease obligations—facilities . . . . .	19,527	4,778	4,915	5,057	4,777	—	—
<b>Total contractual cash obligations . . . . .</b>	<b>\$19,711</b>	<b>\$4,941</b>	<b>\$4,928</b>	<b>\$5,065</b>	<b>\$4,777</b>	<b>\$—</b>	<b>\$—</b>

In addition to the contractual obligations in the table above, long-term liabilities for unrecognized tax benefits and related accrued interest totaling approximately \$0.6 million at December 31, 2008 are not included in the contractual obligations table because, due to their nature, there is a high degree of uncertainty regarding the timing of future cash outflows and other events that extinguish these liabilities.

### **Off-Balance Sheet Arrangements**

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

### **Inflation**

We do not believe that inflation has had a significant impact on our revenues or results of operations since inception.

### **Item 7A. 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, 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.

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

**Item 8. Financial Statements and Supplementary Data**

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders of  
Infinity Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Infinity Pharmaceuticals, Inc. as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2008. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Infinity Pharmaceuticals, Inc. at December 31, 2008 and 2007, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2008, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Infinity Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2008, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 11, 2009 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Boston, Massachusetts  
March 11, 2009

**INFINITY PHARMACEUTICALS, INC.**

**Consolidated Balance Sheets**

	December 31,	
	2008	2007
<b>Assets</b>		
Current assets:		
Cash and cash equivalents .....	\$ 16,574,549	\$ 23,164,721
Available-for-sale securities .....	110,197,138	91,024,747
Accounts receivable .....	—	812,500
Unbilled accounts receivable .....	7,414,570	4,287,736
Notes receivable from employees .....	42,198	53,414
Prepaid expenses and other current assets .....	2,389,411	2,496,814
Total current assets .....	136,617,866	121,839,932
Property and equipment, net .....	5,320,439	5,984,711
Loan commitment asset from Purdue .....	17,319,000	—
Notes receivable from employees .....	28,780	47,928
Restricted cash .....	1,138,161	1,661,171
Other assets .....	193,262	190,862
Total assets .....	\$ 160,617,508	\$ 129,724,604
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable .....	\$ 2,759,288	\$ 2,097,190
Accrued expenses .....	11,562,641	8,519,754
Deferred revenue .....	1,702,860	13,750,000
Current portion of capital leases and long-term debt .....	5,953	375,618
Total current liabilities .....	16,030,742	24,742,562
Deferred revenue, less current portion .....	21,939,251	51,041,667
Other liabilities .....	2,340,099	2,777,072
Capital leases and long-term debt, less current portion .....	11,949	20,400
Total liabilities .....	40,322,041	78,581,701
Commitments and contingencies (note 10) .....	—	—
<b>Stockholders' equity:</b>		
Preferred Stock, \$.001 par value; 1,000,000 shares authorized, no shares issued and outstanding at December 31, 2008 and 2007 .....	—	—
Common Stock, \$.001 par value; 100,000,000 shares authorized, and 24,064,857 shares issued and outstanding, at December 31, 2008; 100,000,000 shares authorized, and 19,710,773 shares issued and outstanding, at December 31, 2007 .....	24,065	19,711
Additional paid-in capital .....	268,447,955	223,466,502
Accumulated deficit .....	(148,891,909)	(172,546,266)
Accumulated other comprehensive income .....	715,356	202,956
Total stockholders' equity .....	120,295,467	51,142,903
Total liabilities and stockholders' equity .....	\$ 160,617,508	\$ 129,724,604

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

**INFINITY PHARMACEUTICALS, INC.**

**Consolidated Statements of Operations**

	Years Ended December 31,		
	2008	2007	2006
Collaborative research and development revenue .....	\$83,440,666	\$ 24,536,350	\$ 18,494,558
Operating expenses:			
Research and development .....	47,466,410	33,793,307	35,792,278
General and administrative .....	16,836,541	14,033,559	9,464,283
Total operating expenses .....	64,302,951	47,826,866	45,256,561
Income (loss) from operations .....	19,137,715	(23,290,516)	(26,762,003)
Other income (expense):			
Interest expense .....	(21,368)	(188,035)	(1,507,102)
Debt extinguishment charge .....	—	—	(1,550,860)
Income from residual funding after reacquisition of Hsp90 program .....	1,195,586	—	—
Interest and investment income .....	3,342,424	6,580,664	2,459,952
Total other income (expense) .....	4,516,642	6,392,629	(598,010)
Income (loss) before income taxes .....	23,654,357	(16,897,887)	(27,360,013)
Income taxes .....	—	—	(1,087,960)
Net income (loss) .....	\$23,654,357	\$(16,897,887)	\$(28,447,973)
Earnings (loss) per common share:			
Basic .....	\$ 1.17	\$ (0.87)	\$ (3.81)
Diluted .....	\$ 1.14	\$ (0.87)	\$ (3.81)
Weighted average number of common shares outstanding:			
Basic .....	20,236,743	19,511,485	7,463,426
Diluted .....	20,765,536	19,511,485	7,463,426

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

**INFINITY PHARMACEUTICALS, INC.**

**Consolidated Statements of Cash Flows**

	Years Ended December 31,		
	2008	2007	2006
<b>Operating activities</b>			
Net income (loss) .....	\$ 23,654,357	\$ (16,897,887)	\$(28,447,973)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities			
Depreciation .....	1,971,937	2,753,560	3,416,774
Stock-based compensation including 401(k) match .....	5,840,065	5,223,224	1,974,731
Write-off of warrants associated with debt extinguishment .....	—	—	950,860
Loan forgiveness .....	61,972	92,747	114,830
(Gain) loss on sale and disposals of property and equipment .....	(56,620)	25,446	16,518
Gain on sale of available-for-sale securities .....	(107,313)	—	—
Net accretion of available-for-sale securities .....	(1,753,531)	(3,597,182)	(39,937)
Impairment of available-for-sale securities .....	49,428	15,577	—
Impairment of property and equipment .....	84,219	195,690	873,000
Amortization of warrants .....	36,726	53,816	269,937
Interest income on restricted cash .....	(41,976)	(82,472)	(77,123)
Interest income on employee loans .....	(1,608)	(3,420)	(6,492)
Changes in operating assets and liabilities:			
Accounts receivable and unbilled accounts receivable .....	(2,314,334)	37,034,574	(42,134,810)
Prepaid expenses and other assets .....	74,063	(212,856)	(2,349,627)
Accounts payable, accrued expenses and other liabilities .....	3,229,754	1,231,478	(2,458,335)
Deferred revenue .....	(41,149,556)	(13,750,000)	77,513,417
Net cash provided by (used in) operating activities .....	(10,422,417)	12,082,295	9,615,770
<b>Investing activities</b>			
Purchases of property and equipment .....	(1,392,377)	(2,405,677)	(946,565)
Proceeds from sale of property and equipment .....	57,113	15,000	—
Purchases of available-for-sale securities .....	(172,033,407)	(208,173,692)	(1,705,437)
Proceeds from maturities of available-for-sale securities .....	137,134,757	148,559,370	16,131,708
Proceeds from sales of available-for-sale securities .....	18,050,075	—	—
Net cash provided by (used in) investing activities .....	(18,183,839)	(62,004,999)	13,479,706

**INFINITY PHARMACEUTICALS, INC.**  
**Consolidated Statements of Cash Flows—(Continued)**

	Years Ended December 31,		
	2008	2007	2006
<b>Financing activities</b>			
Cash proceeds from reverse acquisition of assets of DPI . . . . .	—	—	40,113,005
Proceeds from issuance of common stock to Purdue entities . . . . .	21,160,000	—	—
Proceeds from sale of Series D Convertible Preferred Stock . . . . .	—	—	5,000,000
Proceeds from issuances of common stock related to stock incentive plans . . . . .	713,115	342,151	864,614
Repurchase of common stock . . . . .	(8,115)	(10,640)	(287,588)
Release of restricted cash . . . . .	564,986	—	—
Proceeds from equipment loan and other debt . . . . .	—	—	15,000,000
Payments on equipment loan and other debt . . . . .	(373,403)	(1,351,049)	(18,849,379)
Capital lease payments . . . . .	(10,499)	(41,746)	(144,196)
Repayment of employee loans . . . . .	—	11,230	7,791
New employee loans . . . . .	(30,000)	(10,000)	(95,000)
Net cash provided by (used in) financing activities . . . . .	<u>22,016,084</u>	<u>(1,060,054)</u>	<u>41,609,247</u>
Net increase (decrease) in cash and cash equivalents . . . . .	(6,590,172)	(50,982,758)	64,704,723
Cash and cash equivalents at beginning of period . . . . .	23,164,721	74,147,479	9,442,756
Cash and cash equivalents at end of period . . . . .	<u>\$16,574,549</u>	<u>\$ 23,164,721</u>	<u>\$ 74,147,479</u>
<b>Supplemental cash flow disclosure</b>			
Interest paid . . . . .	<u>\$ 14,351</u>	<u>\$ 161,789</u>	<u>\$ 1,235,310</u>
Income taxes paid . . . . .	<u>\$ 92,000</u>	<u>\$ 1,100,000</u>	<u>\$ —</u>
<b>Supplemental disclosure of noncash investing and financing activities</b>			
Equipment acquired under capital leases . . . . .	<u>\$ —</u>	<u>\$ 28,800</u>	<u>\$ —</u>
Loan commitment asset from Purdue . . . . .	<u>\$17,319,000</u>	<u>\$ —</u>	<u>\$ —</u>

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

**INFINITY PHARMACEUTICALS, INC.**

**Consolidated Statements of Stockholders' Equity**

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series D Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Deferred Stock Compensation	Accu- mulated Other Compre- hensive Income (Loss)	Total Stock- holders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount						
Balance at December 31, 2005	1,597,510	\$ 1,598	5,279,428	\$ 5,279	2,894,972	\$ 2,895	—	\$ —	2,726,374	\$ 2,726	\$137,066,851	—	\$(126,857,133)	\$(46,197)	\$( 2,041)	\$ 10,173,978
Issuance of Series D Convertible Preferred Stock							266,313	266			4,999,734					5,000,000
Exercise of stock options									133,152	133	864,481					864,614
Restricted stock issued in prior years that vested in the year											127,047					127,047
Repurchase of common stock									(2,771)	(3)	(4,984)	(287,588)				(287,588)
Retirement of common stock																—
Conversion of preferred stock and issuance of common stock for reverse acquisition of assets of DPI	(1,597,510)	(1,598)	(5,279,428)	(5,279)	(2,894,972)	(2,895)	(266,313)	(266)	16,664,940	16,665	73,012,884	(1,041,209)				71,978,302
Stock-based compensation expense											1,974,731					1,974,731
Issuance of Series B warrants in connection with long-term debt																1,116,360
Exercise of warrants									1,548	2						2
Reversal of deferred compensation upon adoption of SFAS 123(R)											(46,197)			46,197		—
Comprehensive loss: Unrealized loss on marketable securities													(28,447,973)		(74,518)	(74,518)
Net loss																(28,447,973)
Comprehensive loss																(28,522,491)
Balance at December 31, 2006	—	\$ —	—	\$ —	—	\$ —	—	\$ —	19,523,243	\$19,523	\$219,110,907	\$(1,323,810)	\$(155,305,106)	—	\$(76,559)	\$ 62,424,955

**INFINITY PHARMACEUTICALS, INC.**

**Consolidated Statements of Stockholders' Equity—(Continued)**

	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2006	19,523,243	\$19,523	\$ (1,323,810)	\$(155,305,106)	\$ (76,559)	\$ 62,424,955
Cumulative effect of accounting change				(343,273)		(343,273)
Exercise of stock options	182,461	183				342,151
Restricted stock issued in prior years that vested in the year						124,880
Repurchase of treasury stock			(10,640)			(10,640)
Retirement of common stock	(22,060)	(22)	1,334,450			(22)
Stock-based compensation expense		4,852,526				4,852,526
401(k) plan match issued in common stock	27,129	27	370,671			370,698
Comprehensive loss:						
Unrealized gain on marketable securities					279,515	279,515
Net loss				(16,897,887)		(16,897,887)
Comprehensive loss				(16,897,887)	279,515	(16,618,372)
Balance at December 31, 2007	19,710,773	\$19,711	\$ —	\$(172,546,266)	\$202,956	\$ 51,142,903
Exercise of stock options	306,744	307				713,115
Issuance of common stock to Purdue	4,000,000	4,000				21,160,000
Restricted stock issued that vested in the year						75,621
Early exercise of options into restricted stock						(121,989)
Repurchase and retirement of common stock	(4,531)	(5)				(5)
Stock-based compensation expense		5,435,829				5,435,829
401(k) plan match and other issued in common stock	51,871	52				404,236
Loan commitment asset from Purdue			17,319,000			17,319,000
Comprehensive income:						
Unrealized gain on marketable securities					512,400	512,400
Net income				23,654,357		23,654,357
Comprehensive income				23,654,357	512,400	24,166,757
Balance at December 31, 2008	24,064,857	\$24,065	\$ —	\$(148,891,909)	\$715,356	\$120,295,467

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

## **INFINITY PHARMACEUTICALS, INC.**

### **Notes to Consolidated Financial Statements**

#### **1. Organization**

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

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

Since former Old Infinity security holders owned, immediately following the DPI merger, approximately 69% of the combined company on a fully-diluted basis and as a result of certain other factors, including that former Old Infinity directors constituted a majority of the combined company's board of directors and all members of the combined company's executive management were from Old Infinity, Old Infinity was deemed to be the acquiring company for accounting purposes and the transaction was accounted for as a reverse acquisition of assets and a recapitalization in accordance with accounting principles generally accepted in the United States. These financial statements reflect the historical results of Old Infinity prior to the merger and that of the combined company following the merger, and do not include the historical financial results of DPI prior to the completion of the merger. Stockholders' equity has been retroactively restated to reflect the number of shares of common stock received by former Old Infinity security holders in the merger, after giving effect to the difference between the par values of the capital stock of Old Infinity and Infinity common stock, with the offset to additional paid-in capital. In addition, the pre-merger financial information has been restated to reflect the 1-for-4 reverse split of DPI common stock that became effective immediately prior to the closing of the merger, the closing of the merger, and the related conversion of all of the capital stock of Old Infinity into Infinity common stock. See Note 13 for a discussion of the conversion of such stock in the merger.

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

#### **2. Summary of Significant Accounting Policies**

##### **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 preparation of consolidated financial statements in accordance with generally accepted accounting principles requires our management to make estimates and judgments that may affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an

## INFINITY PHARMACEUTICALS, INC.

### Notes to Consolidated Financial Statements—(Continued)

ongoing basis, we evaluate our estimates, including those related to revenue recognition. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions.

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

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

We determine the appropriate classification of available-for-sale securities at the time of purchase and reevaluate such designation at each balance sheet date. We have classified all of our marketable securities at December 31, 2008 and 2007 as “available-for-sale.” We carry available-for-sale securities at fair value, with the unrealized gains and losses reported in accumulated other comprehensive income (loss), which is 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. To determine whether an other-than-temporary impairment exists, we consider whether we have the ability and intent to hold the investment until a market price recovery, and consider whether evidence indicating the recoverability of the cost of the investment outweighs evidence to the contrary. During the year ended December 31, 2008, we determined that one debt security was other-than-temporarily impaired and accordingly recorded a realized loss of \$49,428 as an offset to interest and investment income. During the year ended December 31, 2007, we determined that five debt securities were other-than-temporarily impaired and accordingly recorded realized losses totaling \$15,577 as an offset to interest and investment income. There were no other-than-temporary impairments for the year ended December 31, 2006.

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 on our available-for-sale securities were \$107,313 for the year ended December 31, 2008. Realized gains or losses from the sales of securities for the years ended December 31, 2007 and 2006 were immaterial.

#### Concentration of Risk

Statement of Financial Accounting Standard (“SFAS”) No. 105, *Disclosure of Information About Financial Instruments With Off-Balance-Sheet Risk and Financial Instruments With Concentration of Credit Risk*, requires disclosure of any significant off-balance sheet risk or credit risk concentration. We have no significant off-balance sheet risk.

Cash and cash equivalents are primarily maintained with two major financial institutions in the United States. Deposits at banks may exceed the insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal risk. Financial instruments that potentially subject us to concentration of credit risk primarily consist of available-for-sale securities. Available-for-sale securities consist

## INFINITY PHARMACEUTICALS, INC.

### Notes to Consolidated Financial Statements—(Continued)

of U.S. government-sponsored enterprise obligations, investment grade corporate obligations, U.S. Treasury obligations and asset-backed securities. Our investment policy, which has been approved by our Board of Directors, limits the amount that we may invest in one issuer of investments, thereby reducing credit risk concentrations. Accounts receivable include amounts due under strategic alliances for which we do not obtain collateral.

#### Segment Information

SFAS No. 131, *Disclosures About Segments of an Enterprise and Related Information* (“SFAS No. 131”), establishes standards for the manner in which companies report information about operating segments in their financial statements. SFAS No. 131 also establishes standards for related disclosures about products and services. We make operating decisions based upon performance of the enterprise as a whole and utilize our consolidated financial statements for decision making. We operate in one business segment, which focuses on drug discovery and development.

All of our revenues to date have been generated under research collaboration agreements. During the year ended December 31, 2008:

- Revenues associated with the amortization and acceleration of the up-front license fee we received from MedImmune, Inc., a division of AstraZeneca plc, or MedImmune/AZ, and a milestone payment from MedImmune/AZ upon initiation of the first patient in a pivotal trial, accounted for approximately 86% of our revenue;
- Revenues associated with the up-front license fee and reimbursable research and development services we received from Novartis Institutes for BioMedical Research, Inc., or Novartis, accounted for approximately 11% of our revenue; and
- Revenues associated with our strategic alliances with Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products L.P., or Purdue, accounted for approximately 3% of our revenue.

During the year ended December 31, 2007:

- Revenues associated with the up-front license fee, reimbursable research and development services and compound acceptance fees we received from Novartis and Novartis International Pharmaceutical Ltd., or Novartis International, accounted for approximately 59% of our revenue; and
- Revenues associated with the up-front license fee we received from MedImmune/AZ, accounted for approximately 41% of our revenue.

During the year ended December 31, 2006:

- Revenues associated with the up-front license fee, reimbursable research and development services and compound acceptance fees we received from Novartis and Novartis International accounted for approximately 63% of our revenue;
- Revenues associated with the up-front license fee we received from MedImmune/AZ accounted for approximately 18% of our revenue; and
- Revenues associated with the license fee we received from Amgen Inc., or Amgen, accounted for approximately 14% of our revenue.

## INFINITY PHARMACEUTICALS, INC.

### Notes to Consolidated Financial Statements—(Continued)

Payments due from MedImmune/AZ represented 64% of our unbilled accounts receivable balance as of December 31, 2008. Payments due from Mundipharma and Purdue represented the remaining 36% of our unbilled accounts receivable balance at December 31, 2008. Payments due from Novartis represented 100% of our accounts receivable balance as of December 31, 2007. Payments due from MedImmune/AZ and Novartis represented 90% and 10% of our unbilled accounts receivable balance as of December 31, 2007, respectively. We did not have an allowance for doubtful accounts for the years ended December 31, 2008 and 2007.

#### Property and Equipment

Property and equipment are stated at cost. Depreciation is recorded using the straight-line method over the estimated useful lives of the applicable assets. Upon sale or retirement, the cost and related accumulated depreciation are eliminated from the respective account and the resulting gain or loss, if any, is included in current operations. Amortization of leasehold improvements and capital leases are included in depreciation expense. Repairs and maintenance charges that do not increase the useful life of the assets are charged to operations as incurred. Property and equipment are depreciated over the following periods:

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

#### Impairment of Long-Lived Assets

Consistent with SFAS No. 144, *Accounting for the Impairment of Long-Lived Assets and Long-Lived Assets to be Disposed Of*, when impairment indicators exist, we evaluate our long-lived assets for potential impairment. Potential impairment is assessed when there is evidence that events or changes in circumstances have occurred that indicate that the carrying amount of a long-lived asset may not be recovered. Recoverability of these assets is assessed based on undiscounted expected future cash flows from the assets, considering a number of factors, including past operating results, budgets and economic projections, market trends, and product development cycles. An impairment in the carrying value of each asset is assessed when the undiscounted expected future cash flows derived from the asset are less than its carrying value. Impairments, if any, are recognized in earnings. An impairment loss would be recognized in an amount equal to the excess of the carrying amount over the undiscounted expected future cash flows. See Note 6 for discussion on impairment charges recognized during the years ended December 31, 2008, 2007 and 2006.

#### Fair Value

We adopted SFAS No. 157, *Fair Value Measurement* ("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 non-financial assets and liabilities recorded at fair value on a non-recurring basis.

We adopted SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities—Including an Amendment of FASB Statement No. 115* ("SFAS No. 159"), on January 1, 2008. SFAS

## INFINITY PHARMACEUTICALS, INC.

### Notes to Consolidated Financial Statements—(Continued)

No. 159 permits an entity to choose to measure many financial instruments and certain other items at fair value at specified election dates. Subsequent unrealized gains and losses on items for which the fair value option has been elected will be reported in earnings. We did not elect to measure any additional financial instruments or other items at fair value.

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

#### 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*, Emerging Issues Task Force ("EITF") No. 00-21, *Revenue Arrangements With Multiple Deliverables* and EITF No. 99-19, *Revenue Recognition Gross as a Principal Versus Net as an Agent*.

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

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.

#### 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.

**INFINITY PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements—(Continued)**

We adopted Financial Accounting Standards Board (“FASB”) Interpretation No. 48, *Accounting for Uncertainty in Income Taxes—an Interpretation of FASB Statement No. 109* (“FIN 48”), on January 1, 2007. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise’s financial statements in accordance with SFAS No. 109, *Accounting for Income Taxes*. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. In accordance with FIN 48, we will recognize any material interest and penalties related to unrecognized tax benefits in income tax expense.

**Basic and Diluted Earnings (Loss) per Common Share**

Basic 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 earnings 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 assumed conversion of preferred stock, the exercise of outstanding warrants and the vesting of 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 years ended December 31, 2007 and 2006 because the effect of including them would have been anti-dilutive. Total potential gross common equivalent shares consisted of the following:

	At December 31,		
	2008	2007	2006
Stock options .....	4,762,819	3,876,004	1,889,572
Warrants .....	246,629	246,629	246,629
Unvested restricted shares .....	47,558	54,954	190,359

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

	Year Ended December 31,		
	2008	2007	2006
<b>Basic</b>			
Net income (loss) .....	\$23,654,357	\$(16,897,887)	\$(28,447,973)
Weighted average common shares outstanding .....	20,236,743	19,511,485	7,463,426
Basic earnings (loss) per share .....	\$ 1.17	\$ (0.87)	\$ (3.81)
<b>Diluted</b>			
Net income (loss) .....	\$23,654,357	\$(16,897,887)	\$(28,447,973)
Weighted average common shares outstanding .....	20,236,743	19,511,485	7,463,426
Effect of dilutive options .....	528,793	—	—
Weighted average common shares outstanding assuming dilution .....	20,765,536	19,511,485	7,463,426
Diluted earnings (loss) per share .....	\$ 1.14	\$ (0.87)	\$ (3.81)

## INFINITY PHARMACEUTICALS, INC.

### Notes to Consolidated Financial Statements—(Continued)

#### Comprehensive Income (Loss)

SFAS No. 130, *Reporting Comprehensive Income*, requires us to display comprehensive income (loss) and its components as part of our full set of financial statements. Comprehensive income is comprised of net income (loss) and other comprehensive income (loss). Other comprehensive income (loss) includes unrealized holding gains and losses on available-for-sale securities that are not other-than-temporarily impaired.

#### Stock-Based Compensation Expense

We adopted SFAS No. 123(R) as of January 1, 2006. SFAS No. 123(R) revises FAS Statement No. 123, *Accounting for Stock-Based Compensation*, supersedes Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends FAS Statement No. 95, *Statement of Cash Flows*. SFAS No. 123(R) requires companies to expense the fair value of employee stock options and other equity compensation. We apply the recognition provisions of SFAS No. 123(R) and EITF No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring or in Connection with Selling Goods or Services* for all stock option grants to non-employees.

#### 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 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 was a cost-sharing arrangement; our collaborations with Mundipharma, Purdue and Novartis provide for the reimbursement of our research and development expenses.

#### Accounting for Sabbatical Leave

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

## INFINITY PHARMACEUTICALS, INC.

### Notes to Consolidated Financial Statements—(Continued)

#### **New Accounting Pronouncement**

In December 2007, the FASB ratified the consensus reached by the EITF on 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 Generally Accepted Accounting Principles, or 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.

#### **3. Stock-Based Compensation**

##### **2000 Stock Incentive Plan**

Our 2000 Stock Incentive Plan (the “2000 Plan”) provides for the grant of stock options intended to qualify as incentive stock options under the Internal Revenue Code or as nonqualified stock options, as well as restricted stock. As of December 31, 2008, an aggregate of 5,750,809 shares of our common stock are reserved for issuance under the 2000 Plan, of which 27,758 shares of common stock remained available for future grant. The number of shares of our common stock available for issuance under the 2000 Plan automatically increases on the first trading day of each calendar year by an amount equal to 4% of the total number of shares of our common stock that are outstanding on the last trading day of the preceding calendar year, but in no event may this increase exceed 2,000,000 shares. The exercise price of all options granted under the “discretionary option grant program” of the 2000 Plan must equal at least the fair value of our common stock on the date of grant. Outstanding options granted under the 2000 Plan are exercisable as the options vest, which is generally over a four-year period. All options granted under the 2000 Plan expire no later than ten years after the date of grant.

For grants made to new employees upon commencement of employment, awards typically provide for vesting of 25% of shares at the end of the first year of service with the remaining 75% vesting ratably on a monthly basis over the following three-year period. Annual grants to existing employees typically provided for monthly vesting over four years.

##### **2001 Stock Incentive Plan**

In connection with the DPI merger, we assumed awards that were granted by Old Infinity under Old Infinity’s 2001 Stock Incentive Plan (now known as the Infinity Pharmaceuticals, Inc. Pre-Merger Stock Incentive Plan) (the “2001 Plan”), which provided for the grant of incentive and non-statutory options and restricted stock awards. Under the 2001 Plan, stock awards were granted to Old Infinity’s employees, officers, directors and consultants. Incentive stock options were granted at a price not less than fair value of the common stock on the date of grant. The board of directors of Old Infinity determined the vesting of the awards. For grants made to new employees upon commencement of employment, awards typically provided for vesting of 25% of shares at the end of the first year of service with the remaining 75% vesting ratably on a monthly basis over the following three-year period. Annual grants to existing employees typically provided for monthly vesting over four years. The maximum contractual term of stock options granted under the 2001 Plan was ten years. As of December 31, 2008, an aggregate of 804,675 shares of our common stock are reserved for issuance upon the exercise of outstanding assumed awards. The 2001 Plan was not assumed by us following the merger; therefore, no further grants may be made under the 2001 Plan.

**INFINITY PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements—(Continued)**

All stock options granted under the 2001 Plan contained provisions allowing for the early exercise of such options. All shares of common stock issued upon exercise of these options contain certain provisions that allow us to repurchase unvested shares at their original purchase price, such as upon termination of employment. The repurchase provisions for unvested shares issued upon the exercise of options granted as part of an employee's initial employment generally lapse as follows: 25% at the end of the first year of service with the remaining 75% lapsing ratably on a monthly basis over the following three-year period. The repurchase provisions for unvested shares issued upon exercise of options granted as part of annual grants to existing employees generally lapse on a monthly basis over a four-year period.

**SFAS No. 123(R) Compensation Expense**

Under SFAS No. 123(R), stock-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the employee's requisite service period. We have no awards with market or performance conditions. We adopted the provisions of SFAS No. 123(R) on January 1, 2006, using the modified prospective method. Under the modified prospective method, prior periods have not been restated. The provisions of SFAS No. 123(R) apply to new awards, unvested awards that are outstanding on the effective date, and awards subsequently modified or cancelled. Estimated compensation expense for unvested awards outstanding at the date of adoption will be recognized over the remaining service period on a straight-line basis using the compensation cost previously calculated for pro forma disclosure purposes under SFAS No. 123. Upon the adoption of SFAS No. 123(R), we elected to continue to use the Black-Scholes valuation model in determining the fair value of equity awards and to recognize compensation expense for unvested awards on a straight-line basis over the service period.

Total stock-based compensation expense, related to all equity awards, recognized under SFAS No. 123(R) for the years ended December 31, 2008, 2007 and 2006, comprised the following:

	<u>Year Ended December 31, 2008</u>	<u>Year Ended December 31, 2007</u>	<u>Year Ended December 31, 2006</u>
Research and development .....	\$2,781,662	\$2,558,655	\$1,112,602
General and administrative .....	3,058,403	2,664,569	862,129

As of December 31, 2008, there was \$12,445,666 of total unrecognized compensation cost, net of estimated forfeitures, related to unvested options and restricted stock, including \$3,009 of unrecognized compensation expense associated with the forgiveness of the nonrecourse loans. The unrecognized compensation cost is expected to be recognized over a weighted-average period of 3.2 years.

**SFAS No. 123(R) Valuation Assumptions**

We estimate the fair value of stock options at the date of grant using the Black-Scholes valuation model using the following weighted-average assumptions:

	<u>Year Ended December 31, 2008</u>	<u>Year Ended December 31, 2007</u>	<u>Year Ended December 31, 2006</u>
Risk-free interest rate .....	2.00%	4.35%	4.73%
Expected annual dividend yield .....	—	—	—
Expected stock price volatility .....	56.93%	60.99%	63.42%
Expected term of options .....	5.2 years	5.1 years	5.2 years

## INFINITY PHARMACEUTICALS, INC.

### Notes to Consolidated Financial Statements—(Continued)

The valuation assumptions were determined as follows:

- *Risk-free interest rate:* The yield on zero-coupon U.S. Treasury securities for a period that is commensurate with the expected term of the awards.
- *Expected annual dividend yield:* The estimate for annual dividends is zero, because we have not historically paid a dividend and do not intend to do so in the foreseeable future.
- *Expected stock price volatility:* We determine the expected volatility by using a weighted average of selected peer companies as well as our available historical price information.
- *Expected term of options:* The expected term of the awards represents the period of time that the awards are expected to be outstanding. We use historical data and expectations for the future to estimate employee exercise and post-vest termination behavior.

For the year ended December 31, 2006, we believed that all groups of employees exhibited similar exercise and post-vest termination behavior and therefore did not stratify employees into multiple groups. For the years ended December 31, 2007 and 2008, we stratified employees into two groups, which we considered a change in accounting estimate per SFAS No. 154, *Accounting Changes and Error Corrections*. This change in accounting estimate did not have a material effect in the period of change.

SFAS No. 123(R) requires the application of an estimated forfeiture rate to current period expense to recognize compensation expense only for those awards expected to vest. We estimate forfeitures based upon historical data, adjusted for known trends, and will adjust the estimate of forfeitures if actual forfeitures differ or are expected to differ from such estimates. Subsequent changes in estimated forfeitures are recognized through a cumulative adjustment in the period of change and will also impact the amount of stock-based compensation expense in future periods. As of December 31, 2008, 2007 and 2006, the weighted-average forfeiture rate was estimated to be 7%, 4% and 3%, respectively.

All options granted to employees during the years ended December 31, 2008, 2007 and 2006 were granted with exercise prices equal to the fair market value of our common stock on the date of grant.

#### Determination of Fair Value

Prior to the closing of the DPI merger, our common stock had never been publicly traded. From inception through the closing of the merger, the fair value of our common stock for accounting purposes was determined by the board of directors with input from management.

Because we were not profitable and did not have significant revenue, we believed that a key factor in determining changes in the fair value of our common stock was the stage of, and changes in, our clinical pipeline. In the biotechnology and pharmaceutical industries, the progression of a drug candidate from preclinical development into clinical trials and the progression from one phase of clinical trials to the next may increase the enterprise's fair value. In addition to this factor, the board of directors determined the fair market value of our common stock based on other objective and subjective factors, including:

- its knowledge and experience in valuing early-stage life sciences companies;
- comparative values of public companies, discounted for the risk and limited liquidity provided for in the shares subject to the options we had issued;
- pricing of private sales of our preferred stock;

**INFINITY PHARMACEUTICALS, INC.**  
**Notes to Consolidated Financial Statements—(Continued)**

- prior valuations of stock grants;
- the effect of events that had occurred between the times of such determinations; and
- economic trends in the biotechnology and pharmaceutical industries specifically, and general economic trends.

From January 1, 2006 until the closing of the DPI merger, in addition to the foregoing factors, the board of directors considered contemporaneous estimations of the fair value of our common stock using the Probability-Weighted Expected Return method to estimate the increase in our value created by our collaboration with Novartis. These valuation analyses and the resulting estimates of our enterprise value were based on the market valuation method, specifically the guideline company approach. The enterprise value was allocated to the different classes of our equity instruments using the Probability-Weighted Expected Return method.

Upon the announcement of the proposed DPI merger on April 11, 2006, the board of directors began considering the price of DPI's common stock in determining fair market value.

A summary of our stock option activity for the year ended December 31, 2008 is as follows:

	<u>Stock Options</u>	<u>Weighted-Average Exercise Price</u>	<u>Weighted-Average Contractual Life (years)</u>	<u>Aggregate Intrinsic Value (in millions)</u>
Outstanding at January 1, 2008 .....	3,876,004	\$10.24		
Granted .....	1,412,979	7.11		
Exercised .....	(306,744)	2.32		
Forfeited .....	(219,420)	10.13		
Outstanding at December 31, 2008 .....	<u>4,762,819</u>	9.83	8.38	\$4.7
Vested or expected to vest at December 31, 2008 .....	<u>4,567,145</u>	\$ 9.85	8.36	\$4.6
Exercisable at December 31, 2008(1) .....	<u>2,105,723</u>	\$10.21	7.45	\$3.5

(1) All stock options granted under the 2001 Plan contain provisions allowing for the early exercise of such options into restricted stock.

The weighted-average fair values per share of options granted during the years ended December 31, 2008, 2007 and 2006 were \$3.66, \$6.82, and \$6.88, respectively.

The aggregate intrinsic value of options outstanding at December 31, 2008 was calculated based on the positive difference between the closing fair market value of our common stock on December 31, 2008 and the exercise price of the underlying options. The aggregate intrinsic value of options exercised during the years ended December 31, 2008, 2007 and 2006 was \$723,552, \$1,651,508, and \$495,129, respectively. The total cash received from employees and non-employees as a result of stock option exercises during the year ended December 31, 2008 was approximately \$713,115.

**INFINITY PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements—(Continued)**

A summary of the status of unvested restricted stock as of December 31, 2008, and changes during the year then ended, is presented below:

	<u>Restricted Stock</u>	<u>Weighted-Average Grant Date Fair Value</u>
Unvested at January 1, 2008 .....	54,954	\$1.99
Granted (1) .....	46,391	2.63
Vested .....	(49,761)	1.95
Repurchased .....	(4,026)	2.03
Unvested at December 31, 2008 .....	47,558	\$2.54

(1) Early exercised from stock options under the 2001 Plan

During the year ended December 31, 2008, we repurchased an aggregate of 4,026 unvested restricted shares of our common stock from employees who ceased employment with us. These repurchases were made at the original purchase prices, totaling \$8,115. During the year ended December 31, 2007, we repurchased an aggregate of 5,389 unvested restricted shares of our common stock from employees who ceased employment with us. These repurchases were made at the original purchase prices, totaling \$10,893. During the year ended December 31, 2006, we repurchased an aggregate of 2,769 unvested restricted shares of our common stock from employees who ceased employment with us. These repurchases were made at the original purchase prices, totaling \$4,989. The total fair value of the shares vested during the years ended December 31, 2008, 2007, and 2006 (measured on the date of vesting) was \$318,497, \$1,451,346, and \$2,685,758, respectively.

During the year ended December 31, 2008, two of our employees exercised an aggregate of 46,391 stock options under the 2001 Plan that had not yet vested. The stock received for these exercises is restricted and will vest into common stock over the original option vesting schedule.

No related income tax benefits were recorded during the years ended December 31, 2008, 2007 or 2006.

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

During the year ended December 31, 2008, one member of our Board of Directors resigned, but was granted the right to exercise his vested stock options for an additional two-year period. In connection with this extension, we recognized an additional \$21,495 in stock-based compensation expense during the year ended December 31, 2008 with respect to the modification of this award.

During the year ended December 31, 2007, one employee whose employment terminated, but who entered into a consulting agreement with us, retained unvested awards even though he would not provide any continuing substantive service as a non-employee. These awards continue to vest over the term of the consulting agreement. In connection with such termination of employment, we recognized \$108,939 in additional stock-based compensation expense during the year ended December 31, 2007 with respect to the modification of this award. Additionally, during the year ended December 31, 2007, one member of our Board of Directors resigned, but was granted the right to exercise his vested stock options for an additional two-year period. In connection with this extension, we recognized an additional \$79,880 in stock-based compensation expense during the year ended December 31, 2007 with respect to the modification of this award.

During the year ended December 31, 2006, two employees whose employment terminated, but who entered into consulting agreements with us, retained unvested awards even though they would not provide any continuing

**INFINITY PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements—(Continued)**

substantive service as a non-employee. These awards continued to vest over the term of the consulting agreements. In connection with such termination of employment, we recognized \$125,912 in additional stock-based compensation expense during the year ended December 31, 2006.

In March 2006, we forgave certain outstanding nonrecourse loans that were given to certain of our employees in previous years to enable these employees to exercise stock options. This forgiveness constituted a modification of the awards under SFAS No. 123(R), and resulted in compensation expense of \$510,000, of which \$347,000 was recognized immediately since portions of the awards were vested. We recognized \$13,972, \$67,857 and \$425,162 of compensation expense related to the forgiveness of the nonrecourse loans for the years ended December 31, 2008, 2007 and 2006, respectively.

**4. Cash, Cash Equivalents and Available-for-Sale Securities**

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

	<u>December 31, 2008</u>			
	<u>Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</u>
Cash and cash equivalents due in 90 days or less . . . . .	\$ 16,566,285	\$ 8,264	\$ —	\$ 16,574,549
Available-for-sale securities				
Corporate obligations due in one year or less . . . . .	40,888,605	320,025	—	41,208,630
U.S. Treasury securities due in one year or less . . . . .	1,520,153	1,057	—	1,521,210
Asset backed securities due after ten years . . . . .	765,845	345	(16,633)	749,557
U.S. government-sponsored enterprise obligations due in one year or less . . . . .	66,315,443	402,298	—	66,717,741
Total available-for-sale securities . . . . .	<u>109,490,046</u>	<u>723,725</u>	<u>(16,633)</u>	<u>110,197,138</u>
Total cash, cash equivalents and available-for-sale securities . . . . .	<u>\$126,056,331</u>	<u>\$731,989</u>	<u>\$(16,633)</u>	<u>\$126,771,687</u>
	<u>December 31, 2007</u>			
	<u>Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</u>
Cash and cash equivalents due in 90 days or less . . . . .	\$ 23,164,721	\$ —	\$ —	\$ 23,164,721
Available-for-sale securities				
Corporate obligations due in one year or less . . . . .	64,067,447	199,633	(17,551)	64,249,529
Asset backed securities				
Due in one year or less . . . . .	2,477,892	5,158	—	2,483,050
Due in one to five years . . . . .	23,362,884	32,712	—	23,395,596
Due after ten years . . . . .	219,473	—	(16,996)	202,477
U.S. government-sponsored enterprise obligations due after ten years . . . . .	694,095	—	—	694,095
Total available-for-sale securities . . . . .	<u>90,821,791</u>	<u>237,503</u>	<u>(34,547)</u>	<u>91,024,747</u>
Total cash, cash equivalents and available-for-sale securities . . . . .	<u>\$113,986,512</u>	<u>\$237,503</u>	<u>\$(34,547)</u>	<u>\$114,189,468</u>

**INFINITY PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements—(Continued)**

There was one debt security that had been in an unrealized loss position for less than 12 months at December 31, 2008. The unrealized loss on that security was \$16,633 and the fair value was \$118,486. To determine whether an other-than-temporary impairment exists, we considered whether we have the ability and intent to hold the investment until a market price recovery, and considered whether evidence indicating the recoverability of the cost of the investment outweighed evidence to the contrary. Since the decline in market value was primarily attributable to current economic conditions and we have the ability to hold this investment until a recovery of fair value, we do not consider this investment to be other-than-temporarily impaired at December 31, 2008.

During the year ended December 31, 2008, we determined that one debt security was other-than-temporarily impaired and accordingly recorded a realized loss of \$49,428. During the year ended December 31, 2007, we determined that five debt securities were other-than-temporarily impaired and accordingly recorded realized losses totaling \$15,577. All of these securities had been in an unrealized loss position for 12 or more months.

**5. Fair Value**

SFAS No. 157 establishes a valuation hierarchy for disclosure of the inputs used to measure fair value. This hierarchy prioritizes the inputs into three broad levels. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value. A financial asset's or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement. For our fixed income securities, we reference pricing data supplied by our custodial agent and nationally known pricing vendors, using a variety of daily data sources, largely readily-available market data and broker quotes.

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

	<u>Level 1</u>	<u>Level 2</u>
Cash and cash equivalents (including commercial paper) .....	\$11,574,749	\$ 4,999,800
Corporate obligations (including commercial paper) .....	—	41,208,630
Asset-backed securities .....	—	749,557
U.S. Treasury securities .....	—	1,521,210
U.S. government-sponsored enterprise obligations .....	—	66,717,741
Total .....	<u>\$11,574,749</u>	<u>\$115,196,938</u>

The fair value of the available-for-sale securities and cash and cash equivalents (specifically commercial paper) is based on the following inputs:

- *Corporate Obligations* :
  - Commercial Paper: Calculations by custodian based on three month Treasury bill published on last business day of the month.
  - Other: Benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data.

## INFINITY PHARMACEUTICALS, INC.

### Notes to Consolidated Financial Statements—(Continued)

- *Asset-backed securities* : Benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data, new issue data, monthly payment information and collateral performance.
- *U.S. Treasury securities* : Benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data and vendor trading platform data.
- *U.S. government-sponsored enterprise obligations* : Benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data.

We did not change these valuation methods during the year ended December 31, 2008.

#### 6. Property and Equipment

Property and equipment consist of the following:

	December 31,	
	2008	2007
Laboratory equipment . . . . .	\$ 13,896,580	\$ 13,825,219
Computer hardware and purchased software . . . . .	4,739,045	5,011,159
Office equipment and furniture and fixtures . . . . .	693,260	554,698
Leasehold improvements . . . . .	4,248,274	4,118,903
	23,577,159	23,509,979
Less accumulated depreciation . . . . .	(18,256,720)	(17,525,268)
	\$ 5,320,439	\$ 5,984,711

During the years ended December 31, 2008, 2007 and 2006, we impaired laboratory equipment totaling \$84,219, \$195,690 and \$873,000, respectively, as we ceased using the equipment. These impairment charges are included in research and development expense for the years in which they were impaired.

During the year ended December 31, 2007, we leased office equipment under capital lease arrangements, totaling \$28,800; related accumulated amortization at December 31, 2008 was \$9,000. The lease is for 48 months, with an annual interest rate of 8.2%. The leased equipment secures the lease.

During the year ended December 31, 2008, we disposed of certain laboratory equipment, which had a cost of \$1,325,196 and accumulated depreciation of \$1,324,703 for proceeds of \$57,113, resulting in a gain of \$56,620.

During the year ended December 31, 2007, we disposed of certain laboratory equipment, which had a cost of \$502,445 and accumulated depreciation of \$461,999 for proceeds of \$15,000, resulting in a loss of \$25,446.

During the year ended December 31, 2006, we disposed of certain laboratory equipment, which had a cost of \$113,085 and accumulated depreciation of \$96,567 for proceeds of \$0, resulting in a loss of \$16,518.

#### 7. Restricted Cash

We held \$1,138,161 in restricted cash as of December 31, 2008 and \$1,661,171 in restricted cash as of December 31, 2007. The balances are held on deposit with a bank to collateralize a standby letter of credit in the

**INFINITY PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements—(Continued)**

name of our facility lessor in accordance with our facility lease agreement. During the year ended December 31, 2008, we amended the amount of a standby letter of credit with the permission of our facility lessor, and we accordingly reduced our restricted cash by \$564,986.

**8. Accrued Expenses**

Accrued expenses consisted of the following:

	<u>December 31,</u>	
	<u>2008</u>	<u>2007</u>
Accrued drug manufacturing costs .....	2,768,588	2,072,916
Accrued toxicology studies .....	261,636	623,567
Accrued compensation and benefits .....	5,037,924	3,248,123
Accrued clinical studies .....	1,284,858	423,172
Other .....	2,209,635	2,151,976
Total accrued expenses .....	<u>\$11,562,641</u>	<u>\$8,519,754</u>

**9. Other Long-Term Liabilities**

Other long-term liabilities consisted of the following:

	<u>December 31,</u>	
	<u>2008</u>	<u>2007</u>
Deferred rent .....	\$1,505,811	\$1,748,848
Accrued tax liability .....	646,338	636,338
Other .....	187,950	391,886
Total other long-term liabilities .....	<u>\$2,340,099</u>	<u>\$2,777,072</u>

**10. Commitments and Contingencies**

**Facility Leases**

We lease our office and laboratory space under noncancelable facility lease agreements that expire in December 2012. We have the right to extend our primary office and laboratory lease for up to two consecutive five-year terms. We can exercise our right to extend on the same terms and conditions under the original leases by giving the landlord notice before the term of the lease expires.

Future minimum payments, excluding operating costs and taxes, under the facility leases, are approximately as follows:

Years Ending December 31:	<u>Facility Lease</u>
2009 .....	\$ 4,777,977
2010 .....	4,915,381
2011 .....	5,056,907
2012 .....	4,776,917
2013 .....	—
Total minimum lease payments .....	<u>\$19,527,182</u>

**INFINITY PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements—(Continued)**

Rent expense of \$4,455,781, \$4,334,575, and \$4,339,610, before considering sublease income, was incurred during the years ended December 31, 2008, 2007, and 2006, respectively. During the years ended December 31, 2008, 2007 and 2006, we subleased a portion of our facility space for total sublease income of \$565,845, \$551,025, and \$549,678, respectively. We record sublease payments as an offset to rental expense in our statement of operations. Future minimum sublease income under noncancelable leases is \$518,691 for the year ended December 31, 2009.

**Equipment Loans, Capital Leases, and Long-Term Debt**

In December 2002, we secured an equipment financing agreement with a finance company allowing for financings of up to an aggregate of \$6 million to finance the acquisition of certain equipment. Interest was charged between 8% and 10% and fluctuated depending on whether the note is for laboratory or other equipment and when the funds were drawn down by us. Amounts borrowed under this agreement were collateralized by the equipment financed through the respective loans. In March 2004, the equipment line was increased to \$9 million. In January 2005, the equipment line was increased to \$12 million. On August 11, 2004, we executed a master lease agreement with the finance company allowing for leases to be created for equipment financing under the total equipment line of \$12 million. No borrowings remain available to be drawn under the equipment loan and master lease agreement at December 31, 2008. We repaid the remaining amounts due under the equipment loan and master lease agreement during the year ended December 31, 2008. In connection with the entry of this agreement, we issued warrants. See Note 13 for a further discussion of warrants.

In September 2007, we leased office equipment for \$28,800. Interest is charged at approximately 8%. Amounts borrowed under this agreement are collateralized by the equipment financed through the respective loan.

Capital lease obligations are as follows:

Years Ended December 31:		
	2009 .....	\$ 7,200
	2010 .....	7,200
	2011 .....	<u>5,803</u>
Total .....		20,203
Less amount representing interest .....		<u>(2,301)</u>
Amounts excluding interest .....		17,902
Less current portion .....		<u>(5,953)</u>
Capital lease obligations—long term portions .....		<u>\$11,949</u>

We had the following capital lease obligations and equipment loans at December 31, 2008 and 2007:

	<u>2008</u>	<u>2007</u>
Total capital lease obligations and equipment loans .....	\$17,902	\$ 396,018
Less current portion .....	<u>(5,953)</u>	<u>(375,618)</u>
Total long-term capital lease obligations and equipment loans .....	<u>\$11,949</u>	<u>\$ 20,400</u>

On October 16, 2002, we entered into a master loan and security agreement with Oxford Finance Corporation (“Oxford”) providing for a credit facility to finance the purchase of laboratory equipment, computer hardware, office furniture and equipment, computer software, and other equipment and property. We amended

## INFINITY PHARMACEUTICALS, INC.

### Notes to Consolidated Financial Statements—(Continued)

this agreement on March 31, 2006 (as so amended, the “Oxford Agreement”) to allow for us to borrow up to \$7.5 million for use in operations. Under the Oxford Agreement, we had borrowed an aggregate principal amount of \$7.5 million from Oxford pursuant to promissory notes dated as of March 31, 2006 and June 30, 2006 (the “Oxford Notes”). The Oxford Notes bore interest at a rate of 11.26% and 11.75% per annum, respectively, and were payable in 39 consecutive monthly installments, the first nine of which were interest only, beginning in May 2006. The Oxford Notes could be prepaid upon payment of a pre-payment penalty of up to 4% of the outstanding principal balance. Further, in connection with the execution of the March 2006 amendment to the Oxford Agreement, we issued warrants. See Note 13 for a further discussion of warrants.

On June 30, 2006, we entered into a venture loan and security agreement (the “Horizon Agreement”) with Horizon Technology Funding Company LLC (“Horizon”) under which we borrowed an aggregate principal amount of \$7.5 million pursuant to the terms of two promissory notes, each dated as of June 30, 2006 (the “Horizon Notes”). The Horizon Notes bore interest at a rate equal to 11.93% per annum and were payable in 39 consecutive monthly installments, the first nine of which were interest only, beginning in July 2006. The Horizon Notes could be prepaid upon payment of a pre-payment penalty of up to 4% of the outstanding principal balance. Further, in connection with the execution of the Horizon Agreement, we issued warrants. See Note 13 for a further discussion of warrants.

In December 2006, we paid \$15,905,210 to extinguish all of our outstanding indebtedness to Oxford and Horizon. Of this amount, \$15,275,547 represented outstanding principal, and \$29,663 represented outstanding interest. We recorded a debt extinguishment charge of \$1,550,860, which included the non-cash write-off of the unamortized warrants for \$950,860 and the 4% penalties both to Oxford and Horizon totaling \$600,000.

## 11. Collaboration Agreements

### Purdue and Mundipharma

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

We have responsibility and decision-making authority for the performance of early discovery projects and the development of all product candidates on a worldwide basis. Mundipharma will pay for 100% of all research and development expenses incurred by Infinity for early discovery projects and product candidates included in the alliance until the later of December 31, 2013 and the commencement of the first phase 3 clinical study of such product candidate. We refer to such date as the transition date. After the transition date for each product candidate other than those arising out of the FAAH project, Mundipharma and Infinity will share all research and development costs for such product candidate equally. Upon completion of the first phase 1 clinical study of the first product developed under the research program that inhibits or targets FAAH, Purdue and Mundipharma may elect to assume responsibility, at their own expense, for the future development and commercialization of FAAH products for sale in and outside of the United States, respectively. We are recording revenue for reimbursable research and development services we perform for Mundipharma and Purdue. We recorded \$2.7 million in such revenue in the year ended December 31, 2008.

## INFINITY PHARMACEUTICALS, INC.

### Notes to Consolidated Financial Statements—(Continued)

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

In connection with the entry into the strategic alliance agreements, we also entered into a securities purchase agreement and line of credit agreement with Purdue and its independent associated company, Purdue Pharma L.P., or PPLP. In March 2009, Purdue assigned its interest under the line of credit agreement to PPLP. Under the securities purchase agreement we issued and sold in November 2008 an aggregate of four million shares of our common stock at a purchase price of \$11.25 per share for an aggregate purchase price of \$45 million. Of the initial closing shares, two million shares of our common stock were purchased by each purchaser. In January 2009, we conducted a second closing where we issued and sold an aggregate of two million shares of our common stock, and warrants to purchase up to an aggregate of six million shares of our common stock, for an aggregate purchase price of \$30 million. Of the second closing shares and warrants, an equal number were purchased by each purchaser. See Note 13 for a further discussion of warrants.

The line of credit agreement provides for the borrowing by us of one or more unsecured loans up to an aggregate maximum principal amount of \$50 million. The loans may be drawn by us during the three-year period beginning on April 1, 2009. The loans, which may be used by us for any proper corporate purpose, mature on April 1, 2019, which we refer to as the maturity date, and will be subordinate to any senior indebtedness that we may incur. Borrowings made under the line of credit agreement will bear interest, payable on the maturity date, at a fluctuating rate set at the prime rate on the business day prior to the funding of each loan and will be reset on the last business day of each month ending thereafter. Interest will be compounded on each successive three-month anniversary of the funding of each loan. Outstanding loans may be prepaid without penalty or premium prior to the maturity date. Amounts borrowed under the credit agreement, once borrowed, may not be borrowed again. We have certain rights to repay outstanding amounts under the line of credit agreement in shares of our common stock.

In 2008, we recorded \$23.8 million as deferred revenue associated with the grant of licenses to Mundipharma and Purdue representing the excess of the amount paid by Purdue and Purdue Pharma, L.P. for our common stock (\$11.25 per share) over the closing market price on the day before the first equity closing (\$5.29 per share). In the year ended December 31, 2008, we recognized \$0.2 million in revenue in connection with the amortization of the deferred revenue. In January 2009, we will record the additional equity and warrants issued to Purdue and Purdue Pharma, L.P. at the second equity closing at their fair value as of the first equity closing, and the excess of the amount paid over fair value as deferred revenue. We considered our obligation,

## INFINITY PHARMACEUTICALS, INC.

### Notes to Consolidated Financial Statements—(Continued)

absent material adverse changes, to issue Purdue and Purdue Pharma, L.P. the second equity closing shares and warrants as a forward contract with immaterial intrinsic value, which was recorded in stockholders' equity. The deferred revenue will be recognized as revenue ratably over our estimated period of performance under the arrangement, which is 14 years. We will periodically review this estimate and make adjustments as facts and circumstances dictate. There are no joint steering committees for the strategic alliances. The extension of the line of credit at an interest rate below our incremental borrowing rate represents the transfer of additional value to us in the arrangement. As such, we have recorded the fair value of the line of credit of \$17.3 million as a loan commitment asset on our balance sheet in 2008, which we will amortize to interest expense over the life of the loan arrangement, or the 10 years commencing on April 1, 2009. Because Purdue and its associated companies became significant related parties as a result of the equity issuances, we recorded the offset to this asset as additional paid in capital in 2008.

#### MedImmune/AZ

In August 2006, we entered into a product development and commercialization agreement with MedImmune/AZ to jointly develop and commercialize cancer drugs targeting Hsp90 and the Hedgehog pathway. Under the terms of this agreement, we shared equally with MedImmune/AZ all development costs, as well as potential profits and losses, from any future marketed products. MedImmune/AZ made non-refundable, up-front payments totaling \$70.0 million to us in order to obtain co-exclusive rights to the Hsp90 and Hedgehog pathway development programs. These payments were made in two tranches of \$35.0 million each, with the first having been paid in September 2006 and the second having been paid in January 2007. We began recognizing the up-front license fee as revenue on a straight-line basis over seven years, which was based on our estimate of the period under which product candidates would be developed by us under the collaboration. In November 2007, we regained from MedImmune/AZ worldwide development and commercialization rights under our Hedgehog pathway program on a royalty-free basis, and MedImmune/AZ's funding obligation under this program ended in May 2008. In December 2008, we regained from MedImmune/AZ worldwide development and commercialization rights under our Hsp90 program. As we have no more substantial performance obligations to MedImmune/AZ, we recognized the remaining portion of the up-front license fee in the amount of \$56.7 million during the year ended December 31, 2008. The change in accounting estimate for the research term is in accordance with SFAS No. 154, *Accounting Changes and Error Corrections – A Replacement of APB No. 20 and FASB Statement No. 3*, and resulted in a positive net income impact of \$46.7 million and \$2.31 in basic earnings per share for the year ended December 31, 2008. We will not recognize any revenue from the up-front license fee in future periods. During the year ended December 31, 2007, we recognized \$10.0 million in revenue from such fee, and during the year ended December 31, 2006, we recognized \$3.3 million in revenue from such fee.

Because we shared development costs equally, we recorded reimbursable amounts from MedImmune/AZ with respect to research and development costs that we incurred as a reduction to research and development expense, and not as revenue. During the years ended December 31, 2007 and 2006, we offset against research and development expense approximately \$13.7 million and \$4.0 million, respectively, that is reimbursable from MedImmune/AZ for sharing of costs that we incurred for research and development under the collaboration. MedImmune/AZ's funding obligation under this program was to continue until June 2009. Reimbursable amounts from MedImmune/AZ under the cost-sharing provisions of the parties' collaboration agreement incurred prior to our reacquisition of the Hsp90 program on December 10, 2008 are recorded as a credit to research and development expense on our statements of operations. Reimbursable amounts from MedImmune/AZ incurred following the reacquisition of the Hsp90 program are recorded as income from residual funding, a component of other income in our statement of operations. Of the amounts reimbursable by MedImmune/AZ in the year ended December 31, 2008, \$16.7 million was credited against research and development expenses and \$1.2 million was

## INFINITY PHARMACEUTICALS, INC.

### Notes to Consolidated Financial Statements—(Continued)

recorded as income from residual funding. In January 2009, we reached an agreement with MedImmune/AZ to settle the residual funding obligation through lump sum payments totaling \$12.5 million. This \$12.5 million will be recorded as income from residual funding of the Hsp90 program in the first quarter of 2009.

#### Novartis

In February 2006, we entered into a collaboration agreement (the “Novartis Product Development 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 the Novartis Product Development 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 option 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 year ended December 31, 2008. The change in accounting estimate for the research term is in accordance with SFAS No. 154, *Accounting Changes and Error Corrections—A Replacement of APB No. 20 and FASB Statement No. 3*, and resulted in a positive net income impact of \$4.4 million and \$0.22 in basic earnings per share and \$0.21 in diluted earnings per share for the year ended December 31, 2008. We will not recognize any revenue from the up-front license fee in future periods. Novartis has agreed to make milestone payments totaling over \$370 million if certain specified research, development and commercialization milestones are achieved for multiple products for multiple indications, such that total payments to us could exceed \$400 million. Novartis has also agreed to pay us royalties upon successful commercialization of any products developed under the alliance. During the years ended December 31, 2008, 2007 and 2006, we recognized \$8.1 million, \$3.8 million and \$3.1 million, respectively, in revenue related to the amortization of the non-refundable license fee and \$0.8 million, \$4.8 million and \$4.1 million, respectively, in revenue related to the reimbursable research and development services we performed for Novartis under the Novartis Product Development Agreement.

In November 2004, we entered into a collaboration and option agreement (the “Novartis Collaboration Agreement”) with Novartis International. Pursuant to the Novartis Collaboration Agreement, we and Novartis International agreed to jointly design a collection of novel small molecules that would be synthesized by us using our diversity oriented synthesis chemical technology platform. Under the Novartis Collaboration Agreement, Novartis International may use the resulting compound collection in its independent drug discovery efforts. We have certain rights to use the resulting compound collection in our own drug discovery efforts, and Novartis International has the option to license from us on an exclusive worldwide basis specified lead compounds for further development and commercialization. In the event that Novartis International exercises its option to license specified lead compounds, it will pay us milestone payments and royalties on net sales of certain drug products incorporating such compounds. In addition, Novartis International has paid us \$10.5 million for the successful acceptance of compounds. During the years ended December 31, 2007 and 2006, we recognized \$6.0 million and \$4.5 million, respectively, as revenue for acceptance of compounds under the Novartis Collaboration Agreement. We did not recognize any revenue from the successful acceptance of compounds during the year ended December 31, 2008.

**INFINITY PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements—(Continued)**

**Amgen**

In July 2006, we amended our technology access agreement with Amgen by extending the period over which Amgen may screen the compounds that had already been delivered under the original agreement in exchange for a license fee of \$2.5 million, which was paid in July 2006. Under this amendment, we have no future obligations to Amgen; therefore, we recognized the entire license fee as revenue during 2006. Amgen has also agreed to make milestone payments of up to an aggregate of \$31.35 million for each product that Amgen develops based upon a licensed compound, assuming that Amgen achieves specified clinical and regulatory objectives, and to pay royalties on sales of any products Amgen commercializes based upon a licensed compound. Amgen has also agreed to make additional milestone payments of up to an aggregate of \$12.0 million for each product that Amgen develops and successfully commercializes based upon a specified subset of the licensed compounds, assuming that Amgen achieves specified clinical and regulatory objectives for those licensed compounds. Finally, Amgen has agreed to make success payments totaling up to an aggregate of \$6.0 million if Amgen achieves specified research and/or intellectual property milestones.

**J&J**

In December 2004, we entered into a technology access agreement with J&J. Pursuant to this agreement, we granted to J&J a non-exclusive worldwide license to use certain of our small molecules in J&J's drug discovery efforts. Under the terms of the agreement, J&J paid us an up-front license fee of \$2.5 million. On March 2, 2006, we amended the agreement to, among other things, allow for a reduction in the number of compounds to be accepted by J&J under the agreement, which was recorded as a reduction to revenue. In connection with the reduction in compounds, we agreed to refund to J&J a portion of the up-front license fee in proportion to the number of compounds actually accepted. We refunded the up-front license fee of approximately \$1,020,000 during 2007. We recognized approximately \$958,000 in revenue during the year ended December 31, 2006 upon acceptance of the remaining compounds by J&J. There is no deferred revenue as of December 31, 2008 or 2007 related to the J&J agreement.

**12. Income Taxes**

Our income tax expense of \$1,087,960 for the year ended December 31, 2006 consisted of current U.S. federal taxes.

Our effective income tax rate for the years ended December 31, 2008, 2007 and 2006 differed from the expected US federal statutory income tax rate as set forth below:

	<u>2008</u>	<u>2007</u>	<u>2006</u>
Expected federal tax expense (benefit) . . . . .	\$ 8,021,401	\$(5,745,282)	\$ (9,302,405)
Permanent differences . . . . .	1,393,377	698,537	290,788
State taxes, net of deferral benefit . . . . .	1,479,241	(1,059,498)	(1,715,473)
Tax credits and related adjustments . . . . .	(3,533,790)	559,720	(3,457,466)
Alternative minimum tax . . . . .	—	—	1,087,960
Other . . . . .	—	—	(43,724)
Change in valuation allowance . . . . .	<u>(7,360,229)</u>	<u>5,546,523</u>	<u>14,228,280</u>
Income tax provision . . . . .	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,087,960</u>

**INFINITY PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements—(Continued)**

The significant components of our deferred tax assets and liabilities are as follows:

	<u>Year Ended December 31,</u>	
	<u>2008</u>	<u>2007</u>
Deferred tax assets:		
Net operating loss carryforwards .....	\$ 46,250,820	\$ 35,891,924
Tax credits .....	11,404,967	8,465,672
Deferred revenue .....	—	26,091,604
Accrued expenses .....	548,970	462,835
Amortization .....	692,829	678,040
Stock based compensation .....	3,834,023	2,407,232
Other .....	114,660	116,990
Valuation allowance .....	<u>(55,916,563)</u>	<u>(73,931,930)</u>
Total deferred tax assets .....	6,929,706	182,367
Deferred tax liabilities:		
Loan commitment .....	(6,819,703)	—
Depreciation .....	<u>(110,003)</u>	<u>(182,367)</u>
Net deferred tax asset .....	<u>\$ —</u>	<u>\$ —</u>

We have recorded a valuation allowance against our deferred tax assets in each of the years ended December 31, 2008 and 2007 because management believes that it is more likely than not that these assets will not be realized. The valuation allowance decreased by \$18,015,000 during the year ended December 31, 2008 primarily as a result of the utilization of previously unbenefited deferred tax assets and an increase in deferred tax liabilities.

At December 31, 2008, we have federal and state net operating loss carryforwards for income tax purposes of approximately \$120,568,000 and \$98,640,000, respectively, to offset future taxable income. We have an additional \$1,442,000 of federal net operating losses not reflected above, that are attributable to stock option exercises which will be recorded as an increase in additional paid in capital on the balance sheet once they are “realized” in accordance with SFAS No. 123(R). We also have federal and state tax credits to offset future tax liabilities of approximately \$8,344,000 and \$4,637,000, respectively. Our net operating losses and tax credits each begin to expire in 2021 for federal purposes and each began expiring in 2006 for state purposes. These tax attributes will continue to expire through 2028 if not utilized. Additionally, our net operating loss carryforwards and tax credits are limited as a result of certain ownership changes, as defined under Sections 382 and 383 of the Internal Revenue Code. This limits the annual amount of these tax attributes that can be utilized to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on our value immediately prior to an ownership change. Subsequent ownership changes may further affect the limitation in future years. The net operating losses and tax credits that will expire unused in the future as a result of Section 382 and 383 limitations have been eliminated as of December 31, 2008 from the amounts disclosed above.

During the twelve month period ended December 31, 2008, we recorded a decrease to our liability for unrecognized tax benefits of approximately \$13,050,000 as the uncertainty about the timing of such deductibility no longer exists. We have a total of \$50,000 of interest and penalties accrued as of December 31, 2008. If the tax benefits are ultimately recognized, the effective tax rates in any future periods would be favorably affected by approximately \$644,000. In addition it is reasonably possible that during the next 12 month period, our liability for unrecognized tax benefits could decrease anywhere between approximately \$0 and \$644,000 as new facts may arise that could clarify the uncertainty associated with our uncertain tax positions.

**INFINITY PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements—(Continued)**

A reconciliation of the allowance for uncertain tax positions is as follows:

	2008	2007
Balance at January 1	\$ 13,644,000	\$ —
Increase or decrease for tax positions taken during a prior period	(13,050,000)	—
Increase or decrease for tax positions taken during the current period	—	13,644,000
Decrease relating to settlements	—	—
Decrease resulting from the expiration of the statute of limitations	—	—
Balance at December 31	\$ 594,000	\$13,644,000

We file income tax returns in the U.S. federal, Massachusetts, and other state jurisdictions and are generally subject to examinations by those authorities for all tax years from 2001 to the present.

**13. Stockholders' Equity**

During the year ended December 31, 2006, stockholders' equity was retroactively restated to reflect the number of shares of common stock received by former Old Infinity security holders in the DPI merger, after giving effect to the difference between the par values of the capital stock of Old Infinity and Infinity common stock, with the offset to additional paid-in capital. In addition, the pre-merger financial information of Old Infinity has been restated to reflect the 1-for-4 reverse split of DPI common stock that became effective immediately prior to the closing of the merger, the closing of the merger, and the related conversion of all the capital stock of Old Infinity into Infinity common stock at the ratios set forth below:

Conversion Ratio for Class or Series of Old Infinity Stock					
Series A Preferred	Group 1, Series B Preferred	Group 2, Series B Preferred	Series C Preferred	Series D Preferred	Common
0.78550	0.99894	1.12375	1.04219	1.06525	0.88411

**Convertible Preferred Stock**

In February 2006, we issued 266,313 shares of Series D Convertible Preferred Stock, \$.001 par value, to an affiliate of Novartis at a price of \$18.77 per share. Proceeds from this stock issuance were \$5,000,000. All of these shares of preferred stock were converted into common stock in connection with the DPI merger. Immediately prior to the effective time of the merger, DPI completed a 1-for-4 reverse stock split. In addition, all outstanding Series A, Series B, Series C and Series D Convertible Preferred Stock was converted into common stock in the merger. No shares of convertible preferred stock were outstanding at December 31, 2008.

**Stockholder Rights Agreement**

We have a stockholder rights agreement that provides for a dividend distribution of one preferred share purchase right for each outstanding share of our common stock held of record at the close of business on February 24, 2003. The rights are not currently exercisable. Under certain conditions involving an acquisition or proposed acquisition by any person or group holding 15% or more of our outstanding common stock, or in the case of entities associated with Purdue, 33% or more of fully diluted number of shares of common stock outstanding (giving effect to all securities that are then exercisable for, or convertible into, common stock), the rights permit the holders to purchase from us one unit consisting of one-thousandth of a share of our Series A junior participating preferred stock at a price of \$76.00 per unit, subject to adjustment. Under certain conditions, the rights may be redeemed by our Board of Directors in whole, but not in part, at a price of \$0.01 per right.

## INFINITY PHARMACEUTICALS, INC.

### Notes to Consolidated Financial Statements—(Continued)

#### Treasury Stock Retirements

We retire treasury stock periodically with the approval of our Board of Directors. We retired 4,531, 22,060 and 2,771 shares of treasury stock during the years ended December 31, 2008, 2007, and 2006, respectively. These were all non-cash transactions, with the offset to additional paid-in capital.

#### Warrants

In connection with various loan and financing agreements during the period from December 2001 through December 2006, including our agreements with Horizon and Oxford, we issued warrants to purchase shares of convertible preferred stock, which became warrants to purchase common stock as a result of the DPI merger. The fair value of the warrants was estimated using the Black-Scholes valuation model assuming no expected dividends, a volatility ranging from 64% to 95%, a contractual life of ten years, and a risk-free interest rate ranging from 3.1% to 5.5%. The warrants have been recorded as a reduction of the associated debt and were amortized to interest expense over the life of the loans. These warrants are fully amortized.

In July 2002, we issued warrants to purchase shares of convertible preferred stock, which became warrants to purchase common stock as a result of the DPI merger, in conjunction with the entry of our facility lease. The fair value of the warrants was estimated using the Black-Scholes valuation model assuming no expected dividends, a volatility of 75%, an estimated contractual life of ten years, and a risk-free interest rate of 5%. The warrants have been recorded in other non-current assets and are being amortized over the lease period as rent expense.

Warrants described above to purchase 246,629 shares of our common stock were outstanding at December 31, 2008, 2007 and 2006. These warrants are currently exercisable and expire on dates ranging from February 28, 2012 to June 30, 2016 and have exercise prices ranging from \$7.64 to \$13.35 per share.

In connection with the strategic alliance agreements we entered into with Mundipharma and Purdue, in January 2009 we issued warrants to purchase up to an aggregate of six million shares of our common stock. These warrants are exercisable for:

- 1,000,000 shares of our common stock at any time up to July 1, 2010, with an initial exercise price of \$15.00 per share, with such exercise price increasing over time depending on when such warrants are exercised, up to a maximum exercise price of \$20.00 per share,
- 2,000,000 shares of our common stock at any time up to July 1, 2011, with an initial exercise price of \$20.00 per share, with such exercise price increasing over time depending on when such warrants are exercised, up to a maximum exercise price of \$30.00 per share, and
- 3,000,000 shares of our common stock at any time up to July 2, 2012, with an initial exercise price of \$30.00 per share, with such exercise price increasing over time depending on when such warrants are exercised, up to a maximum exercise price of \$40.00 per share.

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

#### Notes Receivable From Stock Purchase Agreements

In 2002, we loaned four employees \$202,500 and one consultant \$45,000 to effect the purchase of shares of our restricted common stock. The loans were considered nonrecourse and nonsubstantive; therefore, we did not record the loans on our balance sheet and consequently continued to account for these awards as stock options for

## INFINITY PHARMACEUTICALS, INC.

### Notes to Consolidated Financial Statements—(Continued)

accounting purposes. The unvested portion of the shares were subject to repurchase by us, at our option, at the original issuance price. The repurchase restriction lapsed as follows: 20% to 25% at the end of the first year of service with the remaining 75% to 80% lapsing ratably on a monthly basis over the following four- to five-year period, as applicable. Interest on the loans accrued at various rates from 4.5% to 5.0%. On certain notes, the principal and accrued interest were forgiven ratably or repaid over approximately 48 months provided that the employees remained employed by us. In the event of termination, the unforgiven principal plus accrued interest was due. Options that were exercised using proceeds from the loans were subject to variable accounting. We recorded \$58,464 of variable stock compensation expense during the year ended December 31, 2006. We did not record any stock compensation expense during the years ended December 31, 2008 and 2007, related to these shares. During 2003, two of the four employees who entered into notes receivable from stock purchase agreements with us ceased to be employed by us. These loans plus accrued interest were repaid by the individuals in accordance with the original terms for all vested shares. These payments were accounted for as stock option exercises.

In 2003, we loaned two employees a total of \$341,985 to effect the purchase of shares of restricted common stock pursuant to the 2001 Plan. The loans were nonrecourse and nonsubstantive; therefore, we did not record the loans on our balance sheet and consequently accounted for these awards as stock options for expense purposes. The unvested portions of the shares were subject to repurchase by us, at our option, at the original issuance price. The repurchase restriction lapsed as follows: 25% at the end of the first year of service with the remaining 75% lapsing ratably on a monthly basis over the following three-year period. Interest on the loans accrued at 3.65%. The principal of the note and accrued interest became due upon an event that resulted in the underlying shares becoming publicly traded or if the person left our employ. In the event of termination, the unforgiven principal plus accrued interest became due. The stock purchases were subject to variable accounting until they vested. We recorded \$1,456, \$38,044 and \$144,583, in variable stock compensation expense during the years ended December 31, 2008, 2007 and 2006, respectively, related to these shares.

In 2004, we loaned one of our executive officers a total of \$341,910 to effect the exercise of stock options pursuant to the 2001 Plan. The loan was nonrecourse and nonsubstantive; therefore, we did not record the loan on our balance sheet and consequently continued to account for those awards as stock options for expense purposes. The unvested shares were subject to repurchase by us, at our option or upon certain events, at the original issuance price. The repurchase restriction lapsed ratably on a monthly basis over a four-year period. Interest on the loan accrued at 3.11%. The principal of the note and accrued interest was repaid or forgiven depending upon certain future events, provided that the employee remained employed by us. In the event of termination, the unforgiven principal plus accrued interest became due. The stock purchases were subject to variable accounting. We recorded \$1,550, \$17,429 and \$198,151, in variable stock compensation expense during the years ended December 31, 2008, 2007 and 2006, respectively, related to these shares. The loan was secured by the common stock purchased.

In 2005, we loaned two employees a total of \$85,378 to effect the exercise of stock options pursuant to the 2001 Plan. The loans were nonrecourse and nonsubstantive; therefore, we did not record the loans on our balance sheet and consequently continued to account for those awards as stock options for expense purposes. These unvested shares were subject to repurchase by us, at our option or upon certain events, at the original issuance price. The repurchase restriction lapsed ratably on a monthly basis over a four-year period. Interest on the loan accrued at 4.20%. The principal on the note and accrued interest were repaid or forgiven depending upon certain future events, provided that the employee remained employed by us. In the event of termination, the unforgiven principal plus accrued interest became due. The stock purchases were subject to variable accounting. We recorded \$10,966, \$12,383 and \$23,964 in variable stock compensation expense during the years ended December 31, 2008, 2007 and 2006, respectively, related to these shares. The loan was secured by the common stock purchased.

## **INFINITY PHARMACEUTICALS, INC.**

### **Notes to Consolidated Financial Statements—(Continued)**

On March 31, 2006, the board of directors forgave the foregoing indebtedness, of which \$845,992 in principal remained outstanding, in exchange for which each employee agreed to subject certain shares of our common stock held by such employee to a right of repurchase in our favor for a period of two years.

#### **14. Notes Receivable from Employees**

During 2002, we established a First Time Homebuyer Assistance Program under which our employees can apply for a forgivable loan for \$10,000 or \$16,000, depending on when they were hired, towards the purchase of their first home. The loans are forgiven over a period of three to four years. In the event of termination, the unforgiven principal of the note, plus interest accrued at a rate of between 2.5% and 4.8% per year, will be due and payable within 30 days. We may also provide loans to new employees to assist with relocation.

#### **15. Other Related-Party Transactions**

We paid consulting fees of approximately \$25,000 to \$75,000 per year per individual to five of our former board members and one of our scientific founders in connection with service on our scientific advisory board. Our scientific advisory board disbanded in December 2006. Total consulting fees paid to these individuals for the year ended December 31, 2006 was approximately \$209,142.

#### **16. Defined Contribution Benefit Plan**

We sponsor a 401(K) retirement plan in which substantially all of our full-time employees are eligible to participate. Participants may contribute a percentage of their annual compensation to this plan, subject to statutory limitations. During the years ended December 31, 2008 and 2007, we matched 50% of the first six percent of participant contributions with our common stock. The cost of our matching contributions during the years ended December 31, 2008 and 2007 was \$404,236 and \$370,698, respectively. We did not contribute to this plan during the year ended December 31, 2006.

#### **17. Accounting for Sabbatical Leave**

On January 1, 2007, we adopted EITF 06-2 to account for sabbatical leaves. All of our full-time employees are eligible to receive four paid weeks of sabbatical leave after five years of continuous employment. The cumulative effect of a change in accounting principle as a result of adoption of EITF 06-2 was \$343,273, which was recorded to accumulated deficit and accrued expenses as of January 1, 2007. We recorded additional compensation expense of \$116,761 and \$96,075 during the years ended December 31, 2008 and 2007, respectively. Prior to the adoption of EITF 06-2, we did not accrue for sabbatical leaves.

**INFINITY PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements—(Continued)**

**18. Quarterly Financial Information (unaudited)**

	<u>Quarter Ended March 31, 2008</u>	<u>Quarter Ended June 30, 2008</u>	<u>Quarter Ended September 30, 2008</u>	<u>Quarter Ended December 31, 2008</u>
	<b>(In Thousands, Except Per Share Amounts)</b>			
Collaborative research and development revenue .....	\$ 11,391	\$ 2,500	\$ 2,500	\$ 67,050
Operating expenses:				
Research and development .....	8,522	10,775	11,732	16,437
General and administrative .....	3,771	3,682	3,781	5,603
Total operating expenses .....	<u>12,293</u>	<u>14,457</u>	<u>15,513</u>	<u>22,040</u>
Income (Loss) from operations .....	(902)	(11,957)	(13,013)	45,010
Other (expense)/income:				
Interest expense .....	(12)	(6)	(3)	(2)
Income from residual funding after reacquisition of Hsp90 program .....	—	—	—	1,195
Interest and investment income .....	1,336	815	624	569
Total other income .....	<u>1,324</u>	<u>809</u>	<u>621</u>	<u>1,762</u>
Net income (loss) .....	<u>\$ 422</u>	<u>\$ (11,148)</u>	<u>\$ (12,392)</u>	<u>\$ 46,772</u>
Earnings (loss) per common share:				
Basic .....	<u>\$ 0.02</u>	<u>\$ (0.57)</u>	<u>\$ (0.63)</u>	<u>\$ 2.15</u>
Diluted .....	<u>\$ 0.02</u>	<u>\$ (0.57)</u>	<u>\$ (0.63)</u>	<u>2.11</u>
Weighted average number of common shares outstanding:				
Basic .....	<u>19,677,541</u>	<u>19,729,094</u>	<u>19,759,766</u>	<u>21,766,857</u>
Diluted .....	<u>20,235,482</u>	<u>19,729,094</u>	<u>19,759,766</u>	<u>22,183,541</u>
	<u>Quarter Ended March 31, 2007</u>	<u>Quarter Ended June 30, 2007</u>	<u>Quarter Ended September 30, 2007</u>	<u>Quarter Ended December 31, 2007</u>
	<b>(In Thousands, Except Per Share Amounts)</b>			
Collaborative research and development revenue .....	\$ 6,116	\$ 5,654	\$ 7,507	\$ 5,259
Operating expenses:				
Research and development .....	7,476	8,187	8,166	9,964
General and administrative .....	3,294	3,237	2,899	4,604
Total operating expenses .....	<u>10,770</u>	<u>11,424</u>	<u>11,065</u>	<u>14,568</u>
Loss from operations .....	(4,654)	(5,770)	(3,558)	(9,309)
Other (expense)/income:				
Interest expense .....	(102)	(30)	(30)	(26)
Interest and investment income .....	1,866	1,640	1,590	1,485
Total other (expense)/income .....	<u>1,764</u>	<u>1,610</u>	<u>1,560</u>	<u>1,459</u>
Net loss .....	<u>\$ (2,890)</u>	<u>\$ (4,160)</u>	<u>\$ (1,998)</u>	<u>\$ (7,850)</u>
Basic and diluted net loss per common share ...	<u>\$ (0.15)</u>	<u>\$ (0.21)</u>	<u>\$ (0.10)</u>	<u>\$ (0.40)</u>
Basic and diluted weighted average number of common shares outstanding .....	<u>19,388,131</u>	<u>19,505,672</u>	<u>19,576,199</u>	<u>19,628,653</u>

## **Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

There have been no disagreements with our independent accountants on accounting and financial disclosure matters.

### **Item 9A. Controls and Procedures**

#### **Disclosure Controls and Procedures**

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of December 31, 2008. In designing and evaluating our disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our chief executive officer and chief financial officer concluded that as of December 31, 2008, our disclosure controls and procedures were (1) designed to ensure that material information relating to us is made known to our chief executive officer and chief financial officer by others, particularly during the period in which this report was prepared and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

#### **Internal Control Over Financial Reporting**

##### ***(a) Management's Report on Internal Control Over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, the company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2008. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control—Integrated Framework*. Based on its assessment, management believes that, as of December 31, 2008, our internal control over financial reporting is effective based on those criteria.

Our independent registered public accounting firm has issued an audit report of our internal control over financial reporting. This report appears below.

***(b) Attestation Report of the Independent Registered Public Accounting Firm on Internal Control over Financial Reporting***

The Board of Directors and Shareholders of  
Infinity Pharmaceuticals, Inc.

We have audited Infinity Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2008, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Infinity Pharmaceuticals, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying management's report on internal control over financial reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Infinity Pharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2008 of Infinity Pharmaceuticals, Inc. and our report dated March 11, 2009 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Boston, Massachusetts  
March 11, 2009

***(c) Changes in Internal Control Over Financial Reporting***

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 December 31, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information**

Not applicable.

**PART III**

**Item 10. Directors, Executive Officers and Corporate Governance**

The sections titled “Proposal 1—Election of Directors,” “Board Meetings and Attendance,” “Board Committees,” “Section 16(a) Beneficial Ownership Reporting Compliance” and “Code of Business Conduct and Ethics” appearing in the definitive proxy statement we will file in connection with our Annual Meeting of Stockholders to be held on June 17, 2009 are incorporated herein by reference. The information required by this item relating to executive officers may be found in Part I, Item 1 of this report under the heading “Business—Executive Officers.”

**Item 11. Executive Compensation**

The section titled “Compensation of Executive Officers and Directors” appearing in the definitive proxy statement we will file in connection with our Annual Meeting of Stockholders to be held on June 17, 2009 is incorporated herein by reference.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

The sections titled “Stock Ownership of Certain Beneficial Owners and Management” and “Securities Authorized for Issuance under Equity Compensation Plans” appearing in the definitive proxy statement we will file in connection with our Annual Meeting of Stockholders to be held on June 17, 2009 are incorporated herein by reference.

**Item 13. Certain Relationships and Related Transactions, and Director Independence**

The sections titled “Transactions with Related Persons,” “Policies and Procedures for Related Persons Transactions,” and “Board Determination of Independence” appearing in the definitive proxy statement we will file in connection with our Annual Meeting of Stockholders to be held on June 17, 2009 are incorporated herein by reference.

**Item 14. Principal Accountant Fees and Services**

The section titled “Auditors’ Fees” appearing in the definitive proxy statement we will file in connection with our Annual Meeting of the Stockholders to be held on June 17, 2009 is incorporated herein by reference.

**PART IV**

**Item 15. Exhibits and Financial Statement Schedules**

**(a)(1) Financial Statements**

The financial statements listed below are filed as a part of this Annual Report on Form 10-K

	<u>Page number</u>
Report of Independent Registered Public Accounting Firm on Financial Statements .....	57
Consolidated Balance Sheets at December 31, 2008 and 2007 .....	58
Consolidated Statements of Operations for the years ended December 31, 2008, 2007, and 2006 ...	59
Consolidated Statements of Cash Flows for the years ended December 31, 2008, 2007, and 2006 ..	60
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2008, 2007 and 2006 .....	62
Notes to Consolidated Financial Statements .....	64

**(a)(2) Financial Statement Schedules**

Financial statement schedules have been omitted because of the absence of conditions under which they are required or because the required information, where material, is shown in the financial statements or notes thereto.

**(a)(3) Exhibits**

The Exhibits listed in the Exhibit Index are filed as a part of this Annual Report on Form 10-K.



[THIS PAGE INTENTIONALLY LEFT BLANK]



This report contains forward-looking statements regarding our future discovery and development efforts, our collaborations, our future operating results and financial position, our business strategy, and other objectives for future operations. You can identify these forward-looking statements by their use of words such as “anticipate,” “believe,” “estimate,” “expect,” “forecast,” “intend,” “plan,” “project,” “target,” “will” and other words and terms of similar meaning. You also can identify them by the fact that they do not relate strictly to historical or current facts. There are a number of important risks and uncertainties that could cause our actual results to differ materially from those indicated by such forward-looking statements. These risks and uncertainties include those inherent in pharmaceutical research and development, such as adverse results in our drug discovery and clinical development processes, decisions made by the U.S. Food and Drug Administration and other regulatory authorities with respect to the development and commercialization of our drug candidates, our ability to obtain, maintain and enforce proprietary rights for our products, our dependence on collaborative partners, our ability to obtain any necessary financing to conduct our planned activities, and other risk factors. Please refer to the section entitled “Risk Factors” in our Annual report on Form 10-K for a description of these risks and uncertainties. Unless required by law, we do not undertake any obligation to publicly update any forward-looking statements.

## HEADQUARTERS

Infinity Pharmaceuticals, Inc.  
780 Memorial Drive  
Cambridge, MA 02139  
Phone: 617-453-1000  
Fax: 617-453-1001  
www.infi.com

## EXECUTIVE LEADERSHIP

Steven H. Holtzman  
*Chair and Chief Executive Officer*

Julian Adams, Ph.D.  
*President of Research & Development and  
Chief Scientific Officer*

Adelene Q. Perkins  
*President and Chief Business Officer*

Michael S. Curtis, Ph.D.  
*Vice President, Pharmaceutical Development*

David S. Grayzel, M.D.  
*Vice President, Clinical Development and  
Medical Affairs*

Steven J. Kafka, Ph.D.  
*Vice President, Finance*

John J. Keilty  
*Vice President, Information Technology  
and Informatics*

Jeanette W. Kohlbrenner  
*Senior Director, Human Resources*

Vito J. Palombella, Ph.D.  
*Vice President, Drug Discovery*

Gerald E. Quirk, Esq.  
*Vice President and General Counsel*

Jeffrey K. Tong, Ph.D.  
*Vice President, Corporate and Product  
Development*

Tamyra A. Toole, Esq.  
*Senior Director, Regulatory Affairs and  
Quality Assurance*

## BOARD OF DIRECTORS

Steven H. Holtzman  
*Chair and Chief Executive Officer*

Martin Babler  
*Chief Executive Officer  
Talima Therapeutics, Inc.*

Anthony B. Evnin, Ph.D.  
*Managing General Partner  
Venrock Associates*

Harry F. Hixson, Jr., Ph.D.  
*Chair  
BrainCells, Inc.*

Eric S. Lander, Ph.D.  
*Professor  
Broad Institute  
Massachusetts Institute of Technology  
Harvard Medical School  
Whitehead Institute*

Patrick P. Lee  
*General Partner  
Ares Life Sciences*

Arnold J. Levine, Ph.D.  
*Professor  
The Cancer Institute of New Jersey,  
Institute for Advanced Study*

Franklin H. Moss, Ph.D.  
*President  
Strategic Software Ventures  
Director and Professor of  
The Media Lab,  
Massachusetts Institute of Technology*

Vicki L. Sato, Ph.D.  
*Professor  
Harvard University*

Ian F. Smith  
*Executive Vice President and  
Chief Financial Officer  
Vertex Pharmaceuticals*

James B. Tananbaum, M.D.,  
*Managing Director  
Prospect Venture Partners*

Michael C. Venuti, Ph.D.  
*Chief Executive Officer  
BioSeek, Inc.*

## INDEPENDENT AUDITORS

Ernst & Young LLP  
Boston, MA

## ANNUAL MEETING

The Annual Meeting of Stockholders will be held at 8:00 a.m. EDT on June 17, 2009 at Stonehenge Inn, 160 Pawtucket Boulevard, Tyngsboro, MA 01879.

## STOCK LISTING

The common stock of the company is traded on the NASDAQ Global Market System under the symbol INFI.

## TRANSFER AGENT

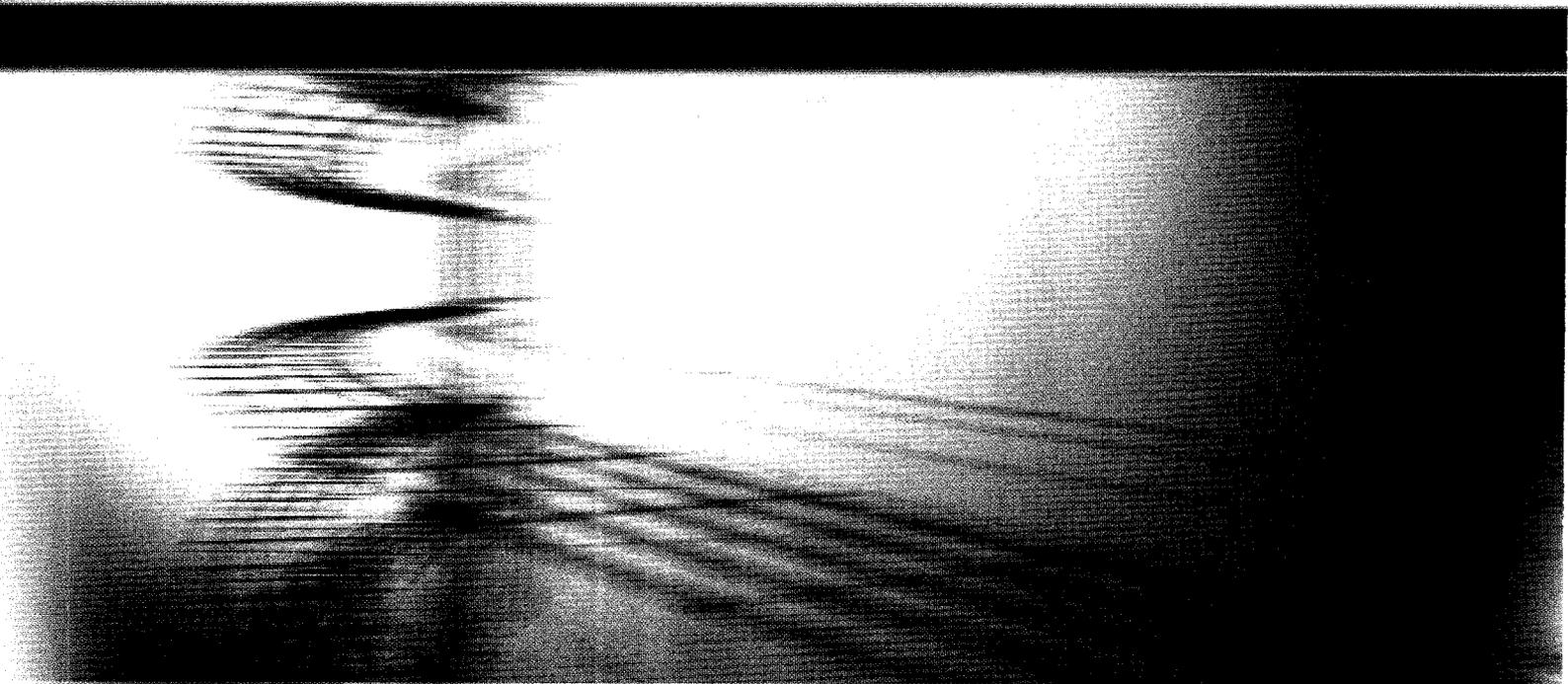
The transfer agent is responsible, among other things, for handling stockholder questions regarding lost stock certificates, address changes, including duplicate mailings, and changes in ownership or name in which shares are held. These requests may be directed to the transfer agent at the following address: American Stock Transfer & Trust Company, LLC  
6201 15th Avenue  
Brooklyn, NY 11219  
www.amstock.com

## SEC FORM 10-K

A copy of Infinity's annual report on Form 10-K filed with the Securities and Exchange Commission is available free of charge from the company's Investor Relations Department by calling 617.453.1015, sending a request by email to [irpr\\_info@infi.com](mailto:irpr_info@infi.com), or sending a written request to:

Investor Relations  
Infinity Pharmaceuticals, Inc.  
780 Memorial Drive  
Cambridge, MA 02139

creating value  
driving our destiny  
transforming medicine



780 Memorial Drive  
Cambridge, MA 02139

Phone: 617-453-1000



[www.infi.com](http://www.infi.com)