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ANNUAL REPORT 2009

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NASDAQ: INFI

# INNOVATION.

Innovation is – and always will be – a defining characteristic of Infinity. It is central to our mission as it is the source of our ability to tackle and solve tough problems and make a meaningful difference in patients' lives.

# EVOLUTION.

Developing drugs and building a company that delivers results is our goal. With many opportunities before us, data will continue to guide our decisions. The data enable us to evolve thoughtfully, prioritizing our efforts on the products and indications most likely to succeed.

# IMPACT.

Since Infinity's inception we have been working to develop a portfolio of products that will make a difference for patients. 2010 is the year for yielding results. We are pursuing several product opportunities in parallel, and we will be guided by data to deliver those products that will have the greatest impact.

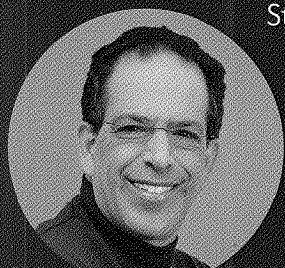
# SHAREHOLDER LETTER

Dear Stakeholders,

2009 was an evolutionary year for Infinity and led us to our position of strength today. 2010 is about results. We are set to demonstrate the impact that our innovative products can have for patients and, thereby, for shareholders.

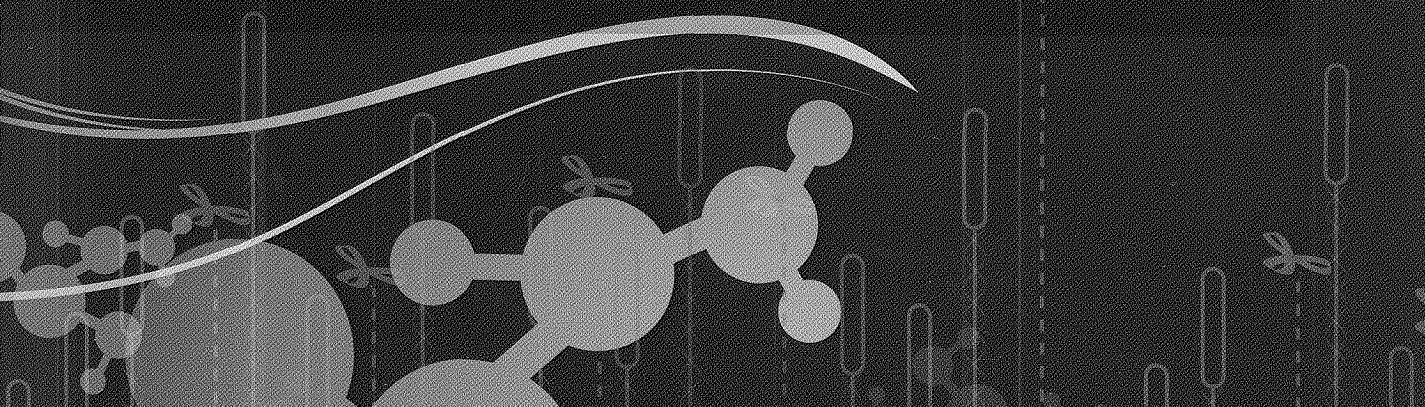
Thanks to the extraordinary efforts of Infinity's Citizen-Owners, we made important progress in evolving our product pipeline and building our company in 2009. We advanced our pipeline of broadly applicable targeted therapies, and filed an Investigational New Drug application for our fourth internally discovered drug candidate – this one in the substantial pain market, a new therapeutic area to Infinity. We built organizational capabilities that have enabled us to better understand the patient populations who will benefit most from our drug candidates and to integrate commercial insights into our development decisions. We made important, and sometimes challenging, decisions throughout the year, and entered 2010 with a strong profile that positions us well for future success, including:

- Four distinct product candidates in the clinic
- A diverse pipeline of preclinical and emerging discovery-stage programs
- \$330 million in cash, available capital, and committed research funding, giving us cash runway into 2013 even while aggressively advancing our pipeline
- Full ownership of our oncology products in the United States
- A thriving strategic partnership with Purdue Pharma and Mundipharma to ensure successful commercialization of our partnered oncology products outside the United States and our pain products worldwide, with attractive royalties on all product sales



Steve Holtzman, Executive Chair

At Infinity, we fully believe that a shared mission, clearly articulated and well-understood corporate goals and, perhaps most importantly, a unique corporate culture of Citizen-Ownership designed to unleash the creative potential and passion of all members of the company, are the empowering forces that enable us to meet our challenges head on and succeed. These elements are intrinsically intertwined and essential to Infinity's ability to realize our collective mission: discovering, developing, and delivering to patients important, new treatments that will make a meaningful difference in their lives.



Looking ahead, 2010 will be a year of continued INNOVATION and EVOLUTION for Infinity and, importantly, a year in which we will demonstrate the IMPACT of our drugs for patients. Already this year we initiated clinical development of IPI-940, a novel inhibitor of fatty acid amide hydrolase that has broad potential to treat neuropathic and inflammatory pain. We are aggressively advancing IPI-926, our novel Hedgehog pathway inhibitor, and rigorously developing two distinct product candidates in our Hsp90 chaperone inhibitor program, IPI-504, our i.v. agent, and IPI-493, our oral agent. Behind these clinical-stage programs, we are driving forward a number of discovery programs in areas including cancer metabolism, apoptosis, and protein homeostasis that we believe will further evolve our clinical pipeline in the years to come.

Infinity has important 2010 development milestones for each of our four clinical candidates:

- IPI-940: Complete Phase 1 development
- IPI-926: Complete and report data from our Phase 1 study and initiate disease-focused Phase 2 development
- IPI-504: Report data from Phase 2 studies in non-small cell lung and breast cancers
- IPI-493: Initiate a Phase 1 study in hematological malignancies and report data from both this and our Phase 1 study in solid tumors

Infinity's position today also enables us to draw upon our operational capabilities and leverage our financial strength by evaluating external programs with distinctive product profiles that could enhance our pipeline.

Finally, our commitment to the discovery and development of important, new medicines is matched by our ongoing commitment to accessing non-dilutive sources of capital and creating shareholder value.

In summary, Infinity has high expectations for 2010. We are well positioned to generate the clinical data necessary to continue moving our most promising drug candidates forward on the path to registration. 2010 is poised to be a year of INNOVATION, EVOLUTION, and IMPACT.

We thank you for your support and look forward to updating you on our progress throughout the year.

*Adelene Q. Perkins*

**Adelene Q. Perkins**  
*President & Chief Executive Officer*



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

2010 is positioned to be an important year for Infinity's clinical and discovery programs. Our expert development teams are advancing our four clinical-stage drug candidates, and we expect to initiate new studies, report data, and complete trials across all of our programs. Meanwhile, our seasoned discovery team continues to fuel our scientific growth with an active and diverse preclinical pipeline. This is an exciting time to be in drug development, and Infinity is remarkably well positioned from both a scientific and business perspective to make this a year of impact.





FOLLOWING IS THE COMPANY'S ANNUAL REPORT ON FORM 10-K  
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2009.

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

SEC Mail Processing  
Section

APR 09 2010

Washington, DC  
110

(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, 2009

Or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission file number: 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 whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark 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, 2009 was \$91,629,062 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, 2010: 26,263,305

Documents incorporated by reference:

Portions of our definitive proxy statement to be filed with the Securities and Exchange Commission no later than April 30, 2010 in connection with our 2010 annual meeting of stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

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## TABLE OF CONTENTS

	<u>Page No.</u>
Part I	
Item 1: Business .....	1
Item 1A: Risk Factors .....	18
Item 1B: Unresolved Staff Comments .....	36
Item 2: Properties .....	36
Item 3: Legal Proceedings .....	37
Item 4: [Reserved] .....	37
Part II	
Item 5: Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities .....	38
Item 6: Selected Financial Data .....	40
Item 7: Management’s Discussion and Analysis of Financial Condition and Results of Operations .....	41
Item 7A: Quantitative and Qualitative Disclosures about Market Risk .....	55
Item 8: Financial Statements and Supplementary Data .....	56
Item 9: Changes in and Disagreements with Accountants on Accounting and Financial Disclosure .....	86
Item 9A: Controls and Procedures .....	86
Item 9B: Other Information .....	88
Part III	
Item 10: Directors, Executive Officers and Corporate Governance .....	88
Item 11: Executive Compensation .....	88
Item 12: Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters .....	88
Item 13: Certain Relationships and Related Transactions and Director Independence .....	88
Item 14: Principal Accountant Fees and Services .....	88
Part IV	
Item 15: Exhibits and Financial Statement Schedules .....	89
Signatures .....	90

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## **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 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 activities, 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 intellectual property rights for our drug candidates, our dependence on our alliance 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**

We are a drug discovery and development company that is utilizing our strength in small molecule drug technologies to discover and develop medicines for the treatment of cancer and related conditions. Our discovery program has generated four clinical stage drug candidates spanning programs in the inhibition of heat shock protein 90, or Hsp90, chaperone system, the Hedgehog signaling pathway and fatty acid amide hydrolase, or FAAH.

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

We are evaluating IPI-504 in multiple clinical trials, including an international Phase 2 clinical trial of IPI-504 in combination with Herceptin® (trastuzumab) in patients with HER2-positive metastatic breast cancer, a Phase 2 clinical trial of IPI-504 in patients with advanced non-small cell lung cancer, or NSCLC, and a Phase 1 clinical trial of IPI-504 in combination with Taxotere® (docetaxel) in patients with advanced solid tumors. The clinical trials of IPI-504 in combination with Herceptin and Taxotere are both actively enrolling patients, and we anticipate reporting preliminary data from the Herceptin combination study in 2010. In May 2009, we presented preliminary data from the NSCLC and advanced solid tumor trials at the 2009 American Society for Clinical Oncology, or ASCO, Annual Meeting demonstrating a generally well-tolerated safety profile in both trials and, in the NSCLC trial, anti-tumor activity evidenced by a 14% overall response rate. We expect to report final data from the NSCLC trial in 2010. We are currently researching genetic biomarkers that could be related to response to IPI-504 in patients with NSCLC. Based on the results of this research, we are evaluating options for the further clinical investigation of IPI-504 in patients with NSCLC whose tumors express a particular biomarker.

We are also enrolling patients in a Phase 1 clinical trial of IPI-493, an orally-delivered inhibitor of Hsp90, in patients with advanced solid tumors. This trial is designed to assess the safety and tolerability of IPI-493 and to

identify a dose and schedule for subsequent studies. We plan to initiate and report data from a Phase 1 clinical trial of IPI-493 in patients with advanced hematological, or blood, cancers in 2010.

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

We have worldwide development and commercialization rights for our Hsp90 chaperone inhibitor program, which includes IPI-504 and IPI-493, subject to the payment to our former partner, MedImmune, Inc., an affiliate of AstraZeneca plc, of a single-digit royalty on net sales of 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 normally active during embryonic development and regulates tissue and organ formation. Malignant activation of the Hedgehog pathway is believed to play a central role in allowing the proliferation and survival of cancer cells, including in pancreatic, prostate, small cell lung, breast, and blood cancers, as well as certain skin and brain cancers. The lead candidate in our Hedgehog pathway program, IPI-926, is a novel, orally-available inhibitor of the Hedgehog pathway that has demonstrated anti-tumor activity in numerous preclinical models. In October 2008, we commenced a Phase 1 clinical trial evaluating IPI-926 in patients with advanced and/or metastatic solid tumors. The primary objectives of this study are to evaluate the safety and tolerability of IPI-926 and to identify a dose and schedule for subsequent studies. We expect to initiate Phase 2 development of IPI-926 in 2010. We are pursuing our Hedgehog pathway program in collaboration with Mundipharma International Corporation Limited, or Mundipharma.

We also have a program directed to FAAH, an emerging target for neuropathic pain. The enzyme FAAH degrades anandamide, which is a neurotransmitter that produces a pain relieving effect in response to pain and nerve injury. FAAH inhibition is believed to increase the duration of anandamide's effect, prolonging pain relief at the site of release. We recently initiated a Phase 1 clinical trial of IPI-940, our novel, orally-available inhibitor of FAAH, and anticipate completing this trial in 2010. The objectives of this clinical trial are to evaluate the safety, tolerability, and pharmacokinetic and pharmacodynamic properties of IPI-940. We are pursuing our FAAH program in collaboration with Mundipharma and an independent associated company, Purdue Pharmaceutical Products L.P., or Purdue.

### **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 IDI, 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."

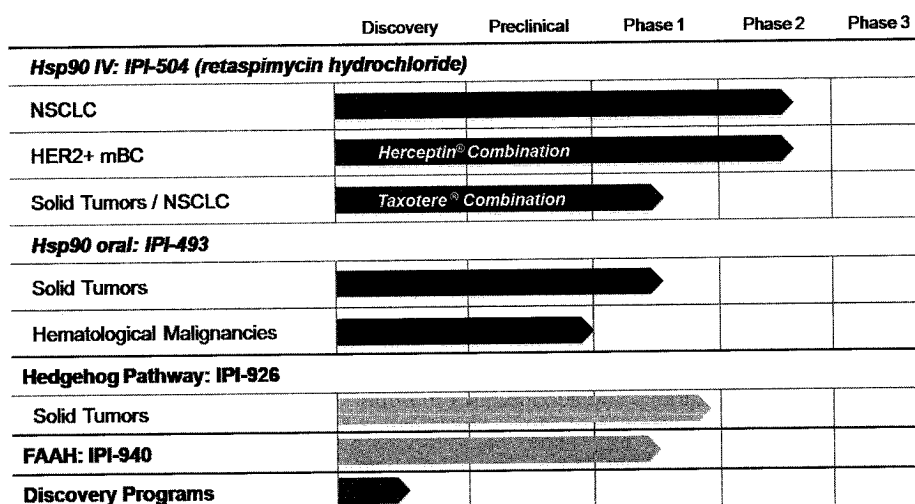
Our principal executive offices are located at 780 Memorial Drive, Cambridge, Massachusetts 02139 and our telephone number at that address is (617) 453-1000.

The Infinity logo and all other Infinity product names are trademarks of Infinity or its subsidiary in the United States and in other select countries. We indicate U.S. trademark registrations and U.S. trademarks with the symbols "®" and "™", respectively. Other third-party logos and product/trade names are registered trademarks or trade names of their respective owners.

## Product Development Pipeline

Our product development programs arise from our innovative approach to drug discovery and our integration of a broad range of research and development capabilities – including strengths in cancer biology, medicinal chemistry, clinical and translational medicine, and drug product process development and formulation. Our strategy is to focus on the discovery and development of drugs directed against specific molecular targets important in the initiation and progression of cancer. These drugs, frequently referred to as targeted therapies, hold the promise of being more selective than traditional chemotherapeutic products, thus harming fewer normal cells, reducing side effects, and improving the quality of life for patients.

In selecting drug targets, we focus on those that serve important unmet medical needs, are supported by strong science, take advantage of our small molecule discovery and development capabilities, and have clearly defined clinical development paths. We also select drug targets that, despite their high level of scientific validation, have not been adequately served by existing chemistries and generally do not have marketed drugs or late-stage clinical product candidates directed against them. We believe this gives us the opportunity to develop potential best-in-class medicines. Our product development programs as of February 28, 2010 are illustrated in the following chart:



During 2010, we expect to advance our product development pipeline by:

- reporting results from our Phase 2 clinical study of IPI-504 in patients with NSCLC;
- reporting preliminary data from our Phase 2 clinical study of IPI-504 in combination with Herceptin® (trastuzumab) in patients with HER2-positive metastatic breast cancer;
- initiating a Phase 2 clinical study of IPI-504 in patients with advanced dedifferentiated liposarcoma if and when we are able to establish a therapeutic window for IPI-504;
- reporting preliminary data from our Phase 1 clinical study of IPI-493 in patients with advanced solid tumors;
- initiating and reporting preliminary data from a Phase 1 clinical study of IPI-493 in patients with advanced hematological cancers;
- reporting Phase 1 data from a clinical study of IPI-926 in patients with advanced solid tumors and initiating Phase 2 development; and
- completing a Phase 1 clinical study of IPI-940.

### ***Hsp90 Chaperone Inhibitor 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, epidermal growth factor receptor, or EGFR, in NSCLC and Human Epidermal Growth Factor Receptor 2, or HER2, in breast cancer. Hsp90 enables those cancers’ survival by maintaining the function of its oncogenic client proteins.

In preclinical studies, inhibition of the Hsp90 chaperone 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 chaperone inhibition. As a result, inhibition of the Hsp90 chaperone has broad therapeutic potential for the treatment of patients with solid tumors and hematological cancers, including cancers that are resistant to other drugs.

We are conducting multiple studies of our Hsp90 chaperone inhibitors, IPI-504 and IPI-493. These studies are focused on establishing a dose and schedule of administration that optimizes safety and efficacy of these candidates, and identifying patient populations most likely to benefit from Hsp90 chaperone inhibition. If we are unable to establish an optimal dose and schedule for either IPI-504 or IPI-493 during 2010, we may elect to discontinue further development of the applicable drug candidate.

**IPI-504.** Our lead Hsp90 inhibitor, IPI-504 (retaspimycin hydrochloride), is a novel, small molecule, semi-synthetic analog of the natural product geldanamycin that is delivered as a water-based, intravenous infusion. 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:

- *Breast Cancer.* The American Cancer Society, or ACS, reports that breast cancer is the most common cancer among women in the United States, other than skin cancer, estimating about 192,000 new cases in women in the United States in 2009. 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 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 are actively enrolling patients in an international Phase 2 clinical trial of IPI-504 in combination with Herceptin® (trastuzumab) in patients with HER2-positive metastatic breast cancer. IPI-504 is being administered intravenously at 300 mg/m<sup>2</sup> on a three-week cycle, consisting of twice-weekly treatment for two weeks

followed by one week off treatment. Herceptin will be administered intravenously once every three weeks. Evidence of anti-tumor activity will be evaluated using Response Evaluation Criteria in Solid Tumors, or RECIST. We expect to report preliminary data from this trial in 2010.

- *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 219,000 new cases of lung cancer in the United States in 2009. According to the ACS, NSCLC is the most common form of lung cancer, accounting for about 85% of all lung cancers. 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 currently available targeted therapies.

We have completed enrollment in 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. The study was designed to evaluate the safety, tolerability, and biologic activity of IPI-504 in two patient populations: one with known EGFR mutations and one with wild-type EGFR expression. In this study, IPI-504 was administered at 400mg/m<sup>2</sup> on a three-week cycle of twice weekly dose administration for two weeks, followed by one week off. We reported preliminary data from this trial at the 2009 ASCO Annual Meeting, which showed that, at the time the data were reported, patients with wild-type EGFR expression NSCLC (n=28), all of whom were heavily pretreated, experienced a 14.2 percent overall response rate (ORR); all four responses were partial responses. Estimated progression free survival for these patients was 3.9 months which, along with the ORR, compares favorably to other treatments frequently used to treat patients with refractory NSCLC. There are no responses to date in patients with mutant EGFR expression (n=19) or in patients whose EGFR status is unknown (n=10). IPI-504 was generally well tolerated in this study, with the most common adverse events being nausea and fatigue. We expect to report final data from this study in 2010. We are currently researching genetic biomarkers that could be related to response to IPI-504 in patients with NSCLC. Based on the results of this research, we are evaluating options for the further clinical investigation of IPI-504 in patients with NSCLC whose tumors express a particular biomarker.

We are also conducting a Phase 1b dose-escalation study of IPI-504 in combination with Taxotere in patients with advanced solid tumors. The study initially enrolled patients with advanced solid tumors, and expanded in late 2009 to focus on patients with advanced NSCLC. Preliminary data from the study presented during the 2009 ASCO Annual Meeting show that, to date, the combination regimen has been generally well tolerated in patients (n=22) with a variety of solid tumor malignancies. Pharmacokinetic data showed no effect of IPI-504 on the clearance of Taxotere from the body. A maximum tolerated dose of 450mg/m<sup>2</sup> was reached when administered every three weeks, and we will continue evaluating IPI-504 in the ongoing study at a dose of 300mg/m<sup>2</sup> in combination with Taxotere. Data reported also show evidence of anti-tumor activity, with one partial response in a patient with metastatic pancreatic cancer refractory to gemcitabine, and six additional patients who experienced stable disease for at least three months. We plan to evaluate additional schedules of administration in this trial.

- *Soft Tissue Sarcomas.* A soft tissue sarcoma is a type of cancer that develops from tissues such as fat, muscle, nerves, fibrous tissues, blood vessels, or deep skin tissues. The ACS estimates approximately 10,600 new cases of soft tissue sarcoma in the United States in 2009. While surgery is the most common form of treatment for soft tissue sarcomas, it remains unavailable for patients with more advanced disease, thus representing an unmet clinical need.

In April 2009, we elected to close our international Phase 3 registration trial of IPI-504 in patients with refractory GIST, a form of soft tissue sarcoma, following the recommendation of the study's IDMC. The IDMC's recommendation to close this study followed an early review of safety data that showed a higher than anticipated mortality rate among patients enrolled in the treatment arm.

If and when we are able to establish a therapeutic window for IPI-504, we plan to initiate a Phase 2 clinical study of IPI-504 in patients with advanced dedifferentiated liposarcoma, a type of sarcoma arising from fatty tissue.

**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 designed to assess 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. Preclinical data 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 2010. We also anticipate initiating a Phase 1 clinical study of IPI-493 in patients with advanced hematological malignancies in early 2010 and reporting preliminary data from the study later in the year.

### ***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 a broad range of cancers. The Hedgehog pathway is normally active during embryonic development and regulates tissue and organ formation. Malignant activation of the Hedgehog pathway is believed to play a central role in allowing the proliferation and survival of cancer cells. In certain cancers, the Hedgehog ligand derived from the tumor either signals to the surrounding stroma, such as in pancreatic, colon, breast and ovarian cancer, or to a subpopulation of Hedgehog-dependent, chemotherapy-resistant, tumor progenitor cells, as may be found in small-cell lung cancer, or SCLC, chronic myelogenous leukemia, and multiple myeloma. These cancers, therefore, may be classified as Hedgehog ligand-dependent. In certain other cancers, there is a genetic mutation resulting in activation of the Hedgehog pathway. These cancers thereby function independently of the Hedgehog ligand and include medulloblastoma and basal cell carcinoma.

We have developed a novel, orally-available Hedgehog pathway inhibitor, IPI-926. IPI-926 is a proprietary, semi-synthetic derivative of the natural product cyclopamine that inhibits the Hedgehog pathway by binding to the Smoothed receptor, a protein that plays a critical role in the malignant activation of the Hedgehog pathway. When systemically administered in multiple preclinical animal models representing both ligand-dependent and ligand-independent cancers, IPI-926 has shown potent and selective inhibition of the Hedgehog pathway, anti-tumor activity, attractive pharmacologic properties including oral bioavailability, long plasma half-life and duration of action, and dose-dependent inhibition of tumor growth.

Additional preclinical data demonstrate 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 down-regulates Hedgehog signaling in tumor stroma, thereby disrupting the communication process between tumor and stroma, ultimately leading to tumor growth inhibition. Preclinical data also show that IPI-926 inhibits the self-renewing capacity of SCLC tumor cells *in vitro*, supporting the evaluation of IPI-926 to prolong relapse-free survival following chemotherapy in SCLC. IPI-926 has also demonstrated anti-tumor activity in a preclinical model of medulloblastoma for which there is a genetic mutation resulting in activation of the Hedgehog pathway.



In October 2008, we commenced a Phase 1 clinical trial evaluating orally-administered 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 anticipate reporting data from this trial and initiating Phase 2 development of IPI-926 in 2010.

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

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

Fatty acid amide hydrolase, or FAAH, is an enzyme that is an emerging target for the treatment of neuropathic, or nerve, and inflammatory pain. Experts believe that nerve pain typically occurs when a nerve is injured, which causes normal sensations of touch, temperature and pain to produce exaggerated painful sensations. Neuropathic pain can also include the lack of sensation or numbness. Although it can be short term, nerve pain is often a chronic problem. Because FAAH is also involved in the normal function of the immune system, the inhibition of FAAH may also be relevant to the treatment of pain caused or exaggerated by inflammation, such as arthritic pain.

FAAH degrades anandamide, which is a neurotransmitter that produces an analgesic effect in response to nerve injury and pain. FAAH inhibition is believed to increase the magnitude and duration of anandamide's effect, producing pain relief at the site of release. We recently initiated a Phase 1 clinical trial of IPI-940, our novel, orally-available inhibitor of FAAH and anticipate completing this trial in 2010. The Phase 1 program includes single- and multiple-ascending dose studies conducted in healthy, adult volunteers. The objectives of the Phase 1 development program are to evaluate the safety, tolerability, and pharmacokinetic and pharmacodynamic properties of IPI-940.

We are pursuing our FAAH program in collaboration with Mundipharma outside of the United States and Purdue in the United States. After Phase 1 investigation, Mundipharma and Purdue will have the right to assume development and commercialization activities under our FAAH program.

### ***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. 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.

### **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. Our strategy in developing alliances has been to enable us to drive forward our proprietary programs while retaining significant value in their downstream potential. Our alliances have brought in substantial 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, and all of our revenue during 2009 was derived from our alliance with Purdue and Mundipharma.

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

Under the strategic alliance agreements, we have responsibility and decision-making authority for the performance of early discovery projects and the development of all product candidates on a worldwide basis. There are no joint steering or similar committees for the alliance. Mundipharma is obligated to pay 100% of our contractually budgeted amounts for research and development expenses incurred by us for early discovery projects and product candidates included in the alliance until the later of December 31, 2013 and the commencement of the first Phase 3 clinical study of such product candidate, which we refer to as the transition date. The contractually budgeted amount for the years ended December 31, 2010 and 2011 is \$65 million and \$85 million, respectively. After the transition date for each product candidate other than those arising out of the FAAH project, we will share with Mundipharma all research and development costs for such product candidate equally. Upon completion of the first Phase 1 clinical study of IPI-940, Purdue and Mundipharma may elect to assume responsibility, at their own expense, for the future development of products arising out of the FAAH project and their sale in and outside of the United States, respectively. We are recording revenue for reimbursed research and development services we perform for Mundipharma and Purdue. We recorded \$46.5 million in such revenue in the year ended December 31, 2009.

Mundipharma has the right to opt out of any early discovery project or any preclinical or clinical development program on an annual basis in November of each year. In the event of an opt-out decision, Mundipharma, together with Purdue with respect to the FAAH project, will continue to provide funding for, in the aggregate, 100% of our contractually budgeted research and development expenses for the applicable project or program for one year after the date of such opt out. Purdue has a comparable opt out right with respect to the FAAH project. In addition to the annual opt-out right, Mundipharma and Purdue will each have the right to opt out of participation in the FAAH project following completion of the first Phase 1 clinical trial of IPI-940. If Mundipharma and Purdue were to exercise this right, there is no residual funding obligation for the FAAH project, but we may redeploy contractually-budgeted amounts that had been allocated to the FAAH project to any other project that is the subject of the alliance. In addition, we and Mundipharma each have the right to opt out of continued development of a product candidate after it has reached the transition date, with a one year tail funding obligation for its 50% of post-transition date research and development expenses. If a party exercises its right to opt out of the development of a product or product candidate after the transition date, the other party may elect to continue the development and assume responsibility for the worldwide commercialization of such product or product candidate, subject to the payment of a royalty.

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

If we in-license any product or product candidate during the funded discovery period for which commercialization rights outside of the United States are available for grant by us to Mundipharma,

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

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

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 a first equity closing in November 2008 an aggregate of four million shares of our common stock at a purchase price of \$11.25 per share, for an aggregate purchase price of \$45 million. Of such shares, two million shares of our common stock were purchased by each purchaser. In January 2009, we conducted a second equity closing where we issued and sold an aggregate of two million shares of our common stock, and warrants to purchase up to an aggregate of six million shares of our common stock, for an aggregate purchase price of \$30 million. Of the second closing securities, an equal number were purchased by each purchaser.

The line of credit agreement provides for the borrowing by us of one or more unsecured loans up to an aggregate maximum principal amount of \$50 million. The loans may be drawn by us through March 31, 2012. The loans, which may be used by us for any proper corporate purpose, mature on April 1, 2019, which we refer to as the maturity date, and will be subordinate to any senior indebtedness that we may incur. Borrowings made under the line of credit agreement will bear interest, payable on the maturity date, at a fluctuating rate set at the

prime rate on the business day prior to the funding of each loan and will be reset on the last business day of each month ending thereafter. Interest will be compounded on each successive three-month anniversary of the funding of each loan. Outstanding loans may be prepaid without penalty or premium prior to the maturity date. Amounts borrowed under the credit agreement, once borrowed, may not be borrowed again. We have certain rights to repay outstanding amounts under the line of credit agreement in shares of our common stock.

The extension of the line of credit at an interest rate below our incremental borrowing rate represents the transfer of additional value to us in the arrangement. As such, we recorded the fair value of the line of credit of \$17.3 million as a loan commitment asset on our balance sheet in 2008. We are amortizing this asset to interest expense over the life of the loan arrangement, or 10 years commencing on April 1, 2009. Because Purdue and its associated companies became significant related parties as a result of the equity issuances, we recorded the offset to this asset as additional paid-in capital in 2008. As of December 31, 2009, no amounts have been borrowed under this line of credit.

In addition to our alliance with Purdue and Mundipharma, we have retained product rights under historic alliance agreements where no active collaboration is currently taking place.

**MedImmune/AZ.** In August 2006, we entered into a product development and commercialization agreement with MedImmune/AZ to jointly develop and commercialize cancer drugs targeting Hsp90 and the Hedgehog pathway. Under the terms of this agreement, we shared equally with MedImmune/AZ all development costs, as well as potential profits and losses, from any future marketed products. In November 2007, we 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. 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. 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. 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.

## **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, 7,375,217, 7,566,706, 7,579,337 and 7,608,613, 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 Nos. 7,230,004 and 7,407,967, each of which is expected to expire no earlier than October 2025. In addition, as of February 28, 2010 we had several hundred 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 2030.

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 Phase 2 clinical trials of BIIB-021 and a Phase 1 clinical trial of BIIB-028;
- Synta Pharmaceuticals Corp., which we believe is conducting Phase 2 clinical trials of STA-9090;
- Vernalis plc, which we believe is conducting Phase 1 clinical trials of AUY-922 in collaboration with Novartis;
- Pfizer, Inc., which we believe is conducting Phase 1 clinical trials of SNX-5422;
- Astex Therapeutics Limited, which we believe is conducting a Phase 1 clinical trial of AT-13387;
- Exelixis, Inc., which we believe is conducting a Phase 1 clinical trial of XL888;
- Myriad Pharmaceuticals, Inc., which we believe is conducting a Phase 1 clinical trial of MPC 3100;

- Kyowa Hakko Kirin Co. Ltd., which we believe is conducting a Phase 1 clinical trial of KW-2478; and
- Abraxis Bioscience, Inc., which we believe is conducting a Phase 1 clinical trial of ABI-010.

In addition, we believe that the following companies, among others, are seeking to develop compounds targeting the Hedgehog pathway:

- Genentech, Inc. through its collaboration with Curis, Inc., which we believe is conducting several Phase 2 clinical trials of GDC-0449, including a pivotal Phase 2 clinical trial in patients with basal cell carcinoma;
- Bristol Myers Squibb Company, through its collaboration with Exelixis, Inc., which we believe is conducting multiple Phase 1 clinical trials of BMS-833923;
- Novartis AG, which we believe is conducting multiple Phase 1 clinical trials of LDE 225; and
- Pfizer, Inc. which we believe will be conducting a Phase 1 clinical trial of PF-04449913.

Finally, we believe that Pfizer, Inc. is conducting a Phase 2 clinical trial and Ironwood Pharmaceuticals, Inc. and sanofi aventis llc are each 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, 2010, our research and development group consisted of 138 individuals, of whom over 36 percent hold Ph.D. or M.D. degrees and over an additional 20 percent hold other 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, 2009, 2008 and 2007 was approximately \$77.9 million, \$47.5 million and \$33.8 million, respectively. Our strategic collaborator-sponsored research and development expenses totaled approximately \$46.5 million, \$20.1 million and \$18.5 million, for the years ended December 31, 2009, 2008 and 2007, 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 limited marketing, and no commercial sales or distribution, capabilities. We do, however, currently have commercialization rights in the United States for products arising out of 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 commercialize any of these drugs if and when they are approved for sale in the United States, we will need to, and we intend to, develop the necessary marketing, sales and distribution capabilities. We intend to partner our Hsp90 program outside the United States and, therefore, do not plan 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, storage, recordkeeping, approval, promotion, labeling, advertising, distribution, marketing, post-approval monitoring and reporting, sampling, 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;
- development of manufacturing processes which conform to FDA-mandated current Good Manufacturing Practices, or cGMPs;
- submission and acceptance of an investigational new drug application, or IND, 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; and
- the submission to and review and approval by the FDA 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 conduct of the pre-clinical tests must comply with federal regulations and requirements including good laboratory practices. We must submit the results of the preclinical tests, together with manufacturing information, analytical data and a proposed clinical trial protocol 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.

With respect to post-market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals, which include, among others, standards for direct-to-consumer advertising, promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Failure to comply with FDA requirements can have negative consequences, including adverse publicity, enforcement letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses.

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 intend to seek Orphan Drug status for our 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. 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, 2010, we had 179 full-time citizen-owners, 138 of whom were engaged in research and development and 41 of whom were engaged in management, administration and finance. Over 53 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, 2010:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Adelene Q. Perkins . . . . .	50	President and Chief Executive Officer
Steven H. Holtzman . . . . .	56	Executive Chair of the Board of Directors
Julian Adams, Ph.D. . . . .	55	President of Research & Development and Chief Scientific Officer
Gerald E. Quirk, Esq . . . . .	42	Vice President, Corporate Affairs and General Counsel
Jeffrey K Tong, Ph.D . . . . .	34	Vice President, Corporate and Product Development

*Adelene Q. Perkins* has served as our President and Chief Executive Officer since January 2010, President and Chief Business Officer from October 2008 through December 2009 and as our Executive Vice President and Chief Business Officer between September 2006 and October 2008. Ms. Perkins served as Executive Vice President of IPI from February 2006 until the merger with DPI in September 2006 and Chief Business Officer of IPI from June 2002 until the DPI merger. Prior to joining IPI, 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® 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.

*Steven H. Holtzman* has served as Chair of our board of directors since September 2006, as Chief Executive Officer between September 2006 and December 2009, and as President between October 2007 and October 2008. Mr. Holtzman was a co-founder of IPI 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 IPI 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.

*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 IPI from February 2006 until the DPI merger and as Chief Scientific Officer of IPI from October 2003 until the DPI merger. Prior to joining IPI, 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.

*Gerald E. Quirk, Esq.*, has served as our Vice President, Corporate Affairs and General Counsel since September 2009 and as Vice President and General Counsel from September 2006 until September 2009. Prior to joining Infinity, Mr. Quirk served in a number of progressively responsible legal and business development positions at Genzyme Corporation, a publicly traded biopharmaceutical company, from 1998 to 2006. From 1994 to 1998 Mr. Quirk served as an associate at Palmer & Dodge LLP, a Boston law firm. Mr. Quirk earned his J.D. from Northeastern University School of Law, an Ed.M. in Educational Administration from Harvard University and a B.A. in Political Science from Swarthmore College.

*Jeffrey K. Tong, Ph.D.*, has served as our Vice President, Corporate and Product Development since September 2006. He also served as Vice President, Corporate and Product Development of IPI from 2005 until the DPI merger in September 2006 and in progressively responsible corporate and product development positions with IPI between 2001 and 2005. Prior to joining Infinity, Dr. Tong was with the Palo Alto office of McKinsey & Company, a management consulting firm, from 2000 to 2001. Prior to McKinsey, Dr. Tong was a founding researcher of the Harvard Center for Genomics Research. Dr. Tong received his educational training at the interface of molecular biology, synthetic chemistry and medicine. Dr. Tong holds A.B. and M.M.S. degrees from Harvard College and Harvard Medical School, respectively, as well as A.M. and Ph.D. degrees from Harvard University.

#### **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. For example, there

can be no guarantee that our strategic alliance with Mundipharma and Purdue will continue for its expected term or that they will fund our programs as agreed, or that any product candidate we are developing will successfully complete necessary preclinical and clinical development phases. Further, there can be no guarantee that any positive developments in our product development pipeline will result in stock price appreciation. 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.

### **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 from sales. We have primarily incurred operating losses. As of December 31, 2009, we had an accumulated deficit of \$181.4 million. We have spent, and expect to continue to spend, significant resources to fund the research and development of IPI-504, IPI-493, IPI-926, IPI-940 and our other drug candidates. While we may have net income in future periods as the result of non-recurring collaboration income, as we did in the year ended December 31, 2008, we expect to incur substantial and increasing operating losses over the next several years as our clinical trial and drug manufacturing activities increase. As a result, we expect that our accumulated deficit will also increase significantly.

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

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

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

- our drug candidates require more extensive clinical or preclinical testing than we currently expect;
- we advance more of our drug candidates than expected into costly later stage clinical trials;
- we advance more preclinical drug candidates than expected into early stage clinical trials;
- the cost of acquiring raw materials for, and of manufacturing, our drug candidates is higher than anticipated;
- we are required, or consider it advisable, to acquire or license intellectual property rights from one or more third parties;
- Mundipharma or Purdue elects to discontinue its participation in a partnered program; or
- we experience a loss in our investments due to general market conditions or other reasons.

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

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

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

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

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

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

Under our agreements with Mundipharma and Purdue, each agreement may be terminated on 60 days' prior written notice if we were to materially breach such agreement and fail to cure such breach within the 60-day notice period. In addition, each of these strategic alliance agreements may be terminated in the event we

experience a change in control or in the event that, during the funded research period, either Julian Adams is no longer a full-time executive of Infinity or both Steven Holtzman and Adelene Perkins are no longer full-time executives of Infinity. In addition:

- Mundipharma has the right to opt out of participation in the Hedgehog pathway and early discovery programs in November of each calendar year, subject to 12 months of continued funding; and
- Purdue and Mundipharma have the right to opt out of participation in the FAAH program immediately following completion of the first Phase 1 clinical trial of IPI-940 and with no further program funding obligation.

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

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

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

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

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

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

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

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.

***Our investments are subject to risks that may cause losses and affect the liquidity of these investments.***

As of December 31, 2009, we had approximately \$131 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 mortgage-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. We may realize losses in the fair value of these investments or a complete loss of these investments. In addition, should our investments cease paying or reduce the amount of interest paid to us, our interest income would suffer. These market risks associated with our investment portfolio may have a material adverse effect on our financial condition and results of operations.

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

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses. Such estimates and judgments include the accrual of research and development expenses and revenue recognition. We base our estimates and judgments on historical experience, facts and circumstances known to us and on various assumptions that we believe to be reasonable under the circumstances. These estimates and judgments, or the assumptions underlying them, may change over time or prove inaccurate.

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

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



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

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

To date, we have not obtained approval from the U.S. Food and Drug Administration, or FDA, or any foreign regulatory authority to market or sell any of our drug candidates. Our success depends primarily upon our, and our strategic alliance partners', ability to develop and commercialize our drug candidates successfully. Our most advanced drug candidate is IPI-504, which is currently in several early-to-mid-stage clinical trials, and our next most advanced drug candidate is IPI-493, for which we commenced our first clinical trial in July 2008. We also commenced our first clinical trial of IPI-926 in October 2008 and IPI-940 in February 2010, and we have other drug candidates in various stages of preclinical development and discovery research.

Our drug candidates are subject to extensive governmental regulations relating to development, clinical trials, manufacturing and commercialization. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process are required in the United States and in many foreign jurisdictions prior to the commercial sale of medicinal products like our drug candidates. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that none of the drug candidates we are developing, or may in the future develop, either alone or in collaboration with strategic alliance partners, will obtain marketing approval. In connection with the clinical trials of IPI-504, IPI-493, IPI-926, IPI-940 and any other drug candidate we may seek to develop in the future, we face, among other risks, risks that:

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

In addition, if we are unable to establish an optimal dose and schedule for either IPI-504 or IPI-493 during 2010, we may elect to discontinue further development of the applicable drug candidate.

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

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

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

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

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

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

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

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

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

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

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

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

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

***We rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily.***

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

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

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

Our drug candidates require precise, high quality manufacturing. The third party manufacturers on which we rely may not be able to comply with the FDA's current good manufacturing practices, or cGMPs, and other applicable government regulations and corresponding foreign standards. These regulations govern manufacturing processes and procedures and the implementation and operation of systems to control and assure the quality of products. The FDA and foreign regulatory authorities may, at any time, audit or inspect a manufacturing facility to ensure compliance with cGMPs and other quality standards. Any failure by our contract manufacturers to

achieve and maintain high manufacturing and quality control standards could result in the inability of our drug candidates to be released for use in one or more countries. In addition, such a failure could result in, among other things, patient injury or death, product liability claims, penalties or other monetary sanctions, the failure of regulatory authorities to grant marketing approval of our drug candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of drug candidates or products, operating restrictions and/or criminal prosecution, any of which could significantly and adversely affect supply of our drug candidates and seriously hurt our business.

Contract manufacturers may also encounter difficulties involving production yields or delays in performing their services. We do not have control over third party manufacturers' performance and compliance with these applicable regulations and standards. If, for any reason, our manufacturers cannot perform as agreed, we may be unable to replace such third party manufacturers in a timely manner and the production of our drug candidates would be interrupted, resulting in delays in clinical trials and additional costs. Switching manufacturers may be difficult because the number of potential manufacturers is limited and, depending on the type of material manufactured at the contract facility, the change in contract manufacturer must be submitted to and/or approved by the FDA and comparable regulatory authorities outside of the United States. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our drug candidates after receipt of regulatory approval. It may be difficult or impossible for us to find a replacement manufacturer on acceptable terms quickly, or at all.

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

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

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

We currently have commercialization rights in the United States for products arising out of our all of our programs, except the FAAH program, and worldwide commercialization rights for our Hsp90 chaperone inhibitor program, including IPI-504 and IPI-493. Additionally, we have the right to co-detail in the United States any products arising from our Bcl-2 collaboration with Novartis. In order to successfully commercialize our drug candidates, we will need to establish adequate marketing and sales capabilities. We may not successfully establish these capabilities or have sufficient resources to do so. If we do not establish adequate marketing and sales capabilities, our ability to successfully commercialize any drug candidates that we

successfully develop will be adversely affected, as will our financial condition and results of operations. Even if we do develop such capabilities, we will compete with other companies that have experienced and well-funded marketing and sales operations, and we will incur additional expenses.

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

Even if any of our drug candidates obtains regulatory approval, that product may not gain market acceptance among physicians, patients and the medical community for a variety of reasons including:

- timing of our receipt of any marketing approvals, the terms of any such approvals and the countries in which any such approvals are obtained;
- timing of market introduction of competitive drugs;
- lower demonstrated clinical safety and efficacy compared to other drugs;
- lack of cost-effectiveness;
- lack of reimbursement from managed care plans and other third-party payors;
- inconvenient or difficult administration;
- prevalence and severity of side effects;
- potential advantages of alternative treatment methods;
- safety concerns with similar drugs marketed by others;
- the reluctance of the target population to try new therapies and of physicians to prescribe those therapies;
- the success of our physician education programs; and
- ineffective sales, marketing and distribution support.

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

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

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

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

Even if we receive regulatory approval for any of our drug candidates, we will have tested them in only a small number of patients during our clinical trials. If our applications for marketing are approved and more patients begin to use our products, new risks and side effects associated with our products may be discovered. In

addition, supplemental clinical trials that may be conducted on a drug following its initial approval may produce findings that are inconsistent with the trial results previously submitted to regulatory authorities. As a result, regulatory authorities may revoke their approvals, or we may be required to conduct additional clinical trials, make changes in labeling of our product, reformulate our product or make changes and obtain new approvals for our and our suppliers' manufacturing facilities. We also might have to withdraw or recall our products from the marketplace. Any safety concerns with respect to a product may also result in a significant drop in the potential sales of that product, damage to our reputation in the marketplace, or result in us becoming subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales of our approved product or substantially increase the costs and expenses of commercializing and marketing our product.

***We are subject to uncertainty relating to reimbursement policies which could hinder or prevent the commercial success of our drug candidates.***

Our ability to commercialize our product candidates successfully will depend in part on the coverage and reimbursement levels set by governmental authorities, private health insurers and other third-party payors. As a threshold for coverage and reimbursement, third-party payors generally require that drug products have been approved for marketing by the FDA. Third-party payors also are increasingly challenging the effectiveness of and prices charged for medical products and services. We may not obtain adequate third-party coverage or reimbursement for our drug candidates or we may be required to sell our drug candidates at prices that are below our expectations.

We expect that private insurers will consider the efficacy, cost effectiveness and safety of our drug candidates in determining whether to approve reimbursement for our drug candidates and at what level. Obtaining these approvals can be a time consuming and expensive process. Our business would be materially adversely affected if we do not receive approval for reimbursement of our drug candidates from private insurers on a timely or satisfactory basis. Our business could also be adversely affected if private insurers, including managed care organizations, the Medicare program or other reimbursing bodies or payors limit the indications for which our drug candidates will be reimbursed to a smaller set than we believe it is effective in treating.

In some foreign countries, particularly Canada and the countries of Europe, the pricing of prescription pharmaceuticals is subject to strict governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory approval and product launch. To obtain favorable reimbursement for the indications sought or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our drug candidates to other available therapies. If reimbursement for our products is unavailable in any country in which reimbursement is sought, limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

We expect to experience pricing pressures in connection with the sale of our drug candidates and our future products due to the potential healthcare reforms discussed below, as well as the trend toward programs aimed at reducing health care costs, the increasing influence of health maintenance organizations and additional legislative proposals.

***Healthcare reform measures could hinder or prevent our product candidates' commercial success.***

The U.S. government and other governments have shown significant interest in pursuing healthcare reform. Any government-adopted reform measures could adversely impact the pricing of healthcare products and services in the U.S. or internationally and the amount of reimbursement available from governmental agencies or other third party payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce health care costs may adversely affect our ability to set prices for our products which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to healthcare availability, methods of delivery or payment for products and services, or sales, marketing or pricing, may limit our potential revenue, and we may need to revise our research and development programs. The pricing and reimbursement environment may change in the future and become more challenging due to several reasons, including policies advanced by the current executive administration in the U.S., new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. In the U.S., changes in federal health care policy are being considered by Congress this year. Some of these proposed reforms could result in reduced reimbursement rates for our potential products, which would adversely affect our business strategy, operations and financial results.

In addition, the Medicare Prescription Drug Improvement and Modernization Act of 2003 reforms the way Medicare will cover and reimburse for pharmaceutical products. This legislation could decrease the coverage and price that we may receive for our products. Other third-party payors are increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for us to go through the process of seeking reimbursement from Medicare and private payors. Our products may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a profitable basis. Further federal and state proposals and health care reforms are likely which could limit the prices that can be charged for the product candidates that we develop and may further limit our commercial opportunity. Our results of operations could be materially adversely affected by the proposed healthcare reforms, by the Medicare prescription drug coverage legislation, by the possible effect of such current or future legislation on amounts that private insurers will pay and by other health care reforms that may be enacted or adopted in the future.

***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” and patient privacy laws and regulations by both the federal government and the states in which we conduct our business. These laws and regulations include:

- the federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers;
- the federal Health Insurance Portability and Accountability Act of 1996, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- the Federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. We are developing and implementing a corporate compliance program designed to ensure that we will market and sell any drug candidates that we successfully develop in compliance with all applicable U.S. laws and regulations, but we cannot guarantee that this program will protect us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

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

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

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

Many of our competitors have:

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

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



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

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

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

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

***Security breaches may disrupt our operations and harm our operating results.***

Our network security and data recovery measures may not be adequate to protect against computer viruses, break-ins, and similar disruptions from unauthorized tampering with our computer systems. The misappropriation, theft, sabotage or any other type of security breach with respect to any of our proprietary and confidential information that is electronically stored, including research or clinical data, could have a material adverse impact on our business, operating results and financial condition. Additionally, any break-in or trespass of our facilities that results in the misappropriation, theft, sabotage or any other type of security breach with respect to our proprietary and confidential information, including research or clinical data, or that results in damage to our research and development equipment and assets could have a material adverse impact on our business, operating results and financial condition.

**Risks Related to Intellectual Property**

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

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

Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the claim scope of these patents, our ability to obtain and enforce patents that may issue from any pending or future patent applications is uncertain and involves complex legal, scientific and factual questions. The standards that the United States Patent and Trademark Office, or PTO, and its foreign counterparts use to grant patents are not always applied predictably or uniformly and are subject to change. To date, no consistent policy has emerged regarding the breadth of claims allowed in pharmaceutical patents. Thus, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us. Even if patents do issue, we cannot guarantee that the claims of these patents will be held valid or enforceable by a court of law, will provide us with any significant protection against competitive products, or will afford us a commercial advantage over competitive products. In addition, the U.S. Congress has considered, and may consider in the future, legislation that could change United States law regarding, among other things, post-grant review of issued patents and the calculation of damages once patent infringement has been determined by a court of law. If enacted into law, these provisions could severely weaken patent protection in the United States.

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

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

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

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

Patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the PTO for the entire time prior to issuance as a U.S. patent. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Consequently, we cannot be certain that we were the first to invent, or the first to file patent applications on, our drug candidates or their therapeutic use. In the event that a third party has also filed a U.S. patent application relating to our drug candidates or a similar invention, we may have to participate in interference

proceedings declared by the PTO or the third party to determine priority of invention in the United States. For example, we are aware of third parties who are actively researching ansamycin analogs that are similar to IPI-504. These third parties have pending applications related to these analogs, but we have the first published application covering IPI-504. Notwithstanding the fact that we filed the first patent application related to these analogs, it is possible that an interference proceeding could be declared between our application covering IPI-504 and one or more of these third party applications, even the one of those applications for which we have secured a license. An adverse decision in an interference proceeding may result in the loss of rights under a patent or patent application. In addition, the cost of interference proceedings could be substantial.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

The PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

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

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

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

- pay substantial damages;
- stop developing, manufacturing and/or commercializing the infringing drug candidates or approved products;

- develop non-infringing products, technologies and methods; and
- obtain one or more licenses from other parties, which could result in our paying substantial royalties or the granting of cross-licenses to our technologies.

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

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

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

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

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

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

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

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

## **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, IPI-926, IPI-940 and our other drug candidates;
- the results of preclinical studies and planned clinical trials of our other discovery-stage programs;
- product portfolio decisions resulting in the delay or termination of our product development programs;
- future sales of, and the trading volume in, our common stock;
- our entry into key agreements, including those related to the acquisition or in-licensing of new programs, or the termination of key agreements, including our strategic alliance agreements with Purdue and Mundipharma;
- the results and timing of regulatory reviews relating to the approval of our drug candidates;
- the initiation of, material developments in, or conclusion of litigation to enforce or defend any of our intellectual property rights;
- the initiation of, material developments in, or conclusion of litigation to defend product liability claims;
- the failure of any of our drug candidates, if approved, to achieve commercial success;
- the results of clinical trials conducted by others on drugs that would compete with our drug candidates;
- issues in manufacturing our drug candidates or any approved products;
- the loss of key employees;
- changes in estimates or recommendations by securities analysts who cover our common stock;
- future financings through the issuance of equity or debt securities or otherwise;
- changes in the structure of health care payment systems;
- our cash position and period-to-period fluctuations in our financial results; and
- general and industry-specific economic conditions.

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

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

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

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

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

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

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

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

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

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

Our executive officers, directors, certain affiliates and other major shareholders control approximately 40% of our outstanding common stock and have the ability to influence the company through this ownership position. For example, as a result of this concentration of ownership, these stockholders, if acting together, may have the ability to determine the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger or similar transaction. This concentration of ownership may, therefore, harm the market price of our common stock by:

- delaying, deferring or preventing a change in control of Infinity;
- impeding a merger, consolidation, takeover or other business combination involving Infinity; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of Infinity.

**Item 1B. Unresolved Staff Comments**

There were no unresolved comments from the Staff of the U.S. Securities and Exchange Commission at December 31, 2009.

**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 13,000 square feet of this space under

a sublease agreement that expires in November 2010 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. [Reserved]**

## 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.

	2009		2008	
	High	Low	High	Low
First quarter .....	\$8.87	\$7.08	\$9.67	\$5.00
Second quarter .....	8.75	4.77	9.62	5.71
Third quarter .....	8.99	5.40	8.11	6.30
Fourth quarter .....	6.60	5.34	8.05	3.74

#### Holdings

As of February 28, 2010, there were 156 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.

#### Comparative Stock Performance Graph

The information included under the heading "Comparative Stock Performance Graph" included in this Item 5 of Part II 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.

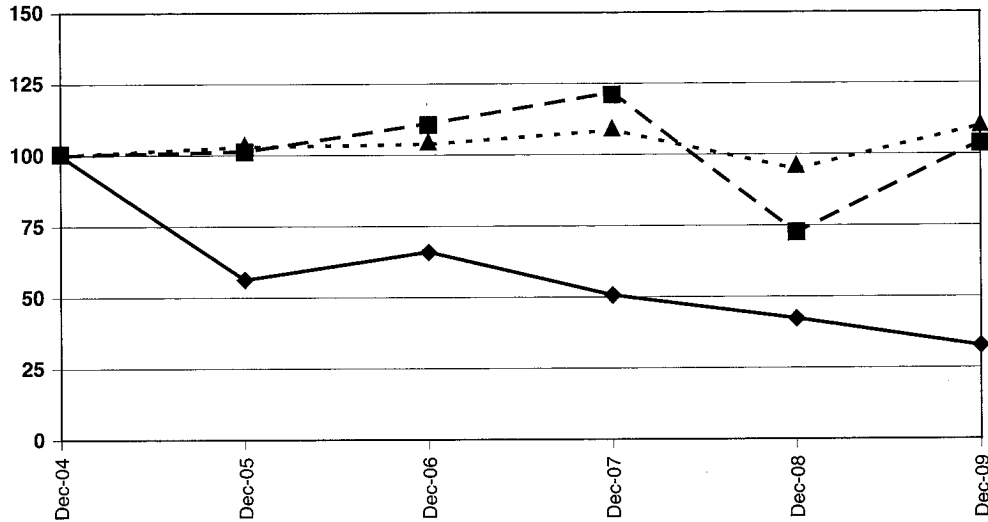
The graph below shows a comparison of cumulative total stockholder returns from December 31, 2004 through December 31, 2009 for our common stock, the NASDAQ Stock Market (U.S.) Index and the NASDAQ Biotechnology Index. The graph assumes that \$100 was invested in our common stock and in each index on December 31, 2004, and that all dividends were reinvested. No cash dividends have been declared or paid on our common stock.

As a result of the merger of Discovery Partners International, Inc. with IPI on September 12, 2006, we changed our corporate name from Discovery Partners International, Inc. to Infinity Pharmaceuticals, Inc. Stock performance shown in the graph below prior to September 12, 2006 reflects results of Discovery Partners International, Inc. prior to the merger.

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-04	31-Dec-05	31-Dec-06	31-Dec-07	31-Dec-08	31-Dec-09
◆ Infinity Pharmaceuticals, Inc.	100.0	56.3	65.9	50.7	42.4	32.8
■ NASDAQ Stock Market (U.S.) Index	100.0	101.4	111.0	121.9	72.5	104.3
▲ NASDAQ Biotechnology Index	100.0	102.8	103.9	108.6	94.9	109.8

## 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. Our financial statements prior to September 12, 2006 reflect results of IPI prior to its merger with Discovery Partners International, Inc. Amounts below are in thousands, except for shares and per share amounts.

	Year Ended December 31,				
	2009	2008	2007	2006	2005
<b>Statement of Operations Data:</b>					
Revenue(1) .....	\$ 49,539	\$ 83,441	\$ 24,536	\$ 18,494	\$ 522
Operating expenses:					
Research and development .....	77,857	47,466	33,793	35,792	31,460
General and administrative .....	19,456	16,837	14,034	9,464	5,530
Total costs and expenses .....	97,313	64,303	47,827	45,256	36,990
Income (loss) from operations .....	(47,774)	19,138	(23,291)	(26,762)	(36,468)
Interest income (expense), net .....	744	3,321	6,393	953	99
Income from NIH reimbursement .....	1,745	—	—	—	—
Income from residual funding after reacquisition of Hsp90 program .....	12,450	1,195	—	—	—
Debt extinguishment charge .....	—	—	—	(1,551)	—
Income (loss) before income taxes .....	(32,835)	23,654	(16,898)	(27,360)	(36,369)
Income tax benefit (expense) .....	330	—	—	(1,088)	—
Net income (loss) .....	\$ (32,505)	\$ 23,654	\$ (16,898)	\$ (28,448)	\$ (36,369)
Earnings (loss) per common share:(2)					
Basic .....	\$ (1.25)	\$ 1.17	\$ (0.87)	\$ (3.81)	\$ (17.01)
Diluted .....	\$ (1.25)	\$ 1.14	\$ (0.87)	\$ (3.81)	\$ (17.01)
Weighted average number of common shares outstanding:(2)					
Basic .....	26,096,515	20,236,743	19,511,485	7,463,426	2,138,331
Diluted .....	26,096,515	20,765,536	19,511,485	7,463,426	2,138,331

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

	As of December 31,				
	2009	2008	2007	2006	2005
<b>Selected Balance Sheet Data:</b>					
Cash, cash equivalents and available-for-sale securities including long-term .....	\$ 130,737	\$ 126,772	\$ 114,189	\$ 101,697	\$ 10,946
Working capital .....	120,635	120,587	97,097	121,264	2,468
Total assets .....	157,318	160,618	129,725	154,648	24,451
Long-term debt and capital leases .....	5	12	20	374	2,041
Accumulated deficit .....	(181,397)	(148,892)	(172,546)	(155,305)	(126,857)
Total stockholders' equity .....	106,260	120,295	51,143	62,425	10,174

## **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 – Item 1A of this report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

### **Business Overview**

We are a drug discovery and development company that is utilizing our strength in small molecule drug technologies to discover and develop medicines for the treatment of cancer and related conditions. Our discovery program has generated four clinical stage drug candidates spanning programs in the inhibition of heat shock protein 90, or Hsp90, chaperone system, the Hedgehog signaling pathway and fatty acid amide hydrolase, or FAAH.

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

We are evaluating IPI-504 in multiple clinical trials, including an international Phase 2 clinical trial of IPI-504 in combination with Herceptin® (trastuzumab) in patients with HER2-positive metastatic breast cancer, a Phase 2 clinical trial of IPI-504 in patients with advanced non-small cell lung cancer, or NSCLC, and a Phase 1 clinical trial of IPI-504 in combination with Taxotere® (docetaxel) in patients with advanced solid tumors. The clinical trials of IPI-504 in combination with Herceptin and Taxotere are both actively enrolling patients, and we anticipate reporting preliminary data from the Herceptin combination study in 2010. In May 2009, we presented preliminary data from the NSCLC and Taxotere combination trials at the 2009 American Society for Clinical Oncology, or ASCO, Annual Meeting demonstrating a generally well-tolerated safety profile in both trials and, in the NSCLC trial, anti-tumor activity evidenced by a 14% overall response rate. We expect to report final data from the NSCLC trial in 2010. We are currently researching genetic biomarkers that could be related to response to IPI-504 in patients with NSCLC. Based on the results of this research, we are evaluating options for the further clinical investigation of IPI-504 in patients with NSCLC whose tumors express a particular biomarker.

We are also enrolling patients in a Phase 1 clinical trial of IPI-493, an orally-delivered inhibitor of Hsp90, in patients with advanced solid tumors. This trial is designed to assess the safety and tolerability of IPI-493 and to identify a dose and schedule for subsequent studies. We plan to initiate and report data from a Phase 1 clinical trial of IPI-493 in patients with advanced hematological, or blood, cancers in 2010.

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

We have worldwide development and commercialization rights for our Hsp90 chaperone inhibitor program, which includes IPI-504 and IPI-493, subject to the payment to our former partner, MedImmune, Inc., an affiliate of AstraZeneca plc, of a single-digit royalty on net sales of 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 normally active during embryonic development and regulates tissue and organ formation. Malignant activation of the Hedgehog pathway is believed to play a central role in allowing the proliferation and survival of cancer cells, including in pancreatic, prostate, small cell lung, breast, blood cancers, as well as certain skin and brain cancers. The lead candidate in our Hedgehog pathway program, IPI-926, is a novel, orally-available inhibitor of the Hedgehog pathway that has demonstrated anti-tumor activity in numerous 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 trial are to evaluate the safety and tolerability of IPI-926 and to identify a dose and schedule for subsequent studies. We expect to initiate Phase 2 development of IPI-926 in 2010. We are pursuing our Hedgehog pathway program in collaboration with Mundipharma International Corporation Limited, or Mundipharma.

We also have a program directed to FAAH, an emerging target for neuropathic pain. The enzyme FAAH degrades anandamide, which is a neurotransmitter that produces a pain relieving effect in response to pain and nerve injury. FAAH inhibition is believed to increase the duration of anandamide's effect, prolonging pain relief at the site of release. We recently initiated a Phase 1 clinical trial of IPI-940, our novel, orally available inhibitor of FAAH, and anticipate completing this trial in 2010. The objectives of this trial are to evaluate the safety, tolerability, and pharmacokinetic and pharmacodynamic properties of IPI-940. 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.

### **Collaboration Agreements**

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

Under the strategic alliance agreements, we have responsibility and decision-making authority for the performance of early discovery projects and the development of all product candidates on a worldwide basis. There are no joint steering or similar committees for the alliance. Mundipharma is obligated to pay 100% of our contractually budgeted amounts for research and development expenses incurred by us for early discovery projects and product candidates included in the alliance until the later of December 31, 2013 and the commencement of the first Phase 3 clinical trial of such product candidate, which we refer to as the transition date. The contractually budgeted amount for the period between November 19, 2008 and December 31, 2009 was \$50 million and the contractually budgeted amount for the years ended December 31, 2010 and 2011 is \$65 million and \$85 million, respectively. After the transition date for each product candidate other than those arising out of the FAAH project, we will share with Mundipharma all research and development costs for such product candidate equally. Upon completion of the first Phase 1 clinical trial of IPI-940, Purdue and Mundipharma may elect to assume responsibility, at their own expense, for the future development of products arising out of the

FAAH project and their sale in and outside of the United States, respectively. We are recording revenue for reimbursed research and development services we perform for Mundipharma and Purdue. We recorded \$46.5 million in such revenue in the year ended December 31, 2009.

Mundipharma has the right to opt out of any early discovery project or any preclinical or clinical development program on an annual basis in November of each year. In the event of an opt-out decision, Mundipharma, together with Purdue with respect to the FAAH project, will continue to provide funding for, in the aggregate, 100% of our contractually budgeted research and development expenses for the applicable project or program for one year after the date of such opt out. Purdue has a comparable opt out right with respect to the FAAH project. In addition to the annual opt-out right, Mundipharma and Purdue will each have the right to opt out of participation in the FAAH project following completion of the first Phase 1 clinical trial of IPI-940. If Mundipharma and Purdue were to exercise this right, there is no residual funding obligation for the FAAH project, but we may redeploy contractually-budgeted amounts that had been allocated to the FAAH project to any other project that is the subject of the alliance. In addition, we and Mundipharma each have the right to opt out of continued development of a product candidate after it has reached the transition date, with a one year tail funding obligation for its 50% of post-transition date research and development expenses. If a party exercises its right to opt out of the development of a product or product candidate after the transition date, the other party may elect to continue the development and assume responsibility for the worldwide commercialization of such product or product candidate, subject to the payment of a royalty.

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

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

Except with respect to products that have been in-licensed by us, for which no royalties will be payable between the parties, we are obligated to pay Mundipharma a 5% royalty on net sales of the commercialized products until such time as Mundipharma has recovered all research and development expenses paid to us under the research program prior to the applicable transition date. After such cost recovery, we are obligated to pay a tiered, 1% to 3% royalty on U.S. net sales of those products. For products in which Mundipharma has opted-out of development prior to the transition date, we are obligated to pay royalties of 1% to 5% of worldwide net sales as a function of the stage of development of the applicable product candidate at the time of opt-out. For products in which either party has opted-out of development following the transition date, the commercializing party is obligated to pay the other party a 5% royalty on net sales. Mundipharma is obligated to pay us a tiered, 10% to 20% royalty on annual net sales outside of the United States of each product arising out of the alliance, and Purdue is obligated to pay us a tiered, 10% to 20% royalty on annual net sales of FAAH products in the United States. Royalties are payable until the later to occur of the last-to-expire of specified patent rights and the expiration of non-patent regulatory exclusivities in a country, provided that if royalties are payable solely on the

basis of non-patent regulatory exclusivity, each of the rates above is reduced by one-half. In addition, all royalties payable under the strategic alliance agreements, whether by us, Purdue or Mundipharma, are subject to reduction on account of third party royalty payments or patent litigation damages or settlements, with any such reductions capped at 50% of the amounts otherwise payable during the applicable royalty payment period.

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 a first equity closing in November 2008 an aggregate of four million shares of our common stock at a purchase price of \$11.25 per share, for an aggregate purchase price of \$45 million. Of such shares, two million shares of our common stock were purchased by each purchaser. In January 2009, we conducted a second equity closing where we issued and sold an aggregate of two million shares of our common stock, and warrants to purchase up to an aggregate of six million shares of our common stock, for an aggregate purchase price of \$30 million. Of the second closing securities, an equal number were purchased by each purchaser.

In 2008, we recorded \$23.8 million as deferred revenue associated with the grant of licenses to Mundipharma and Purdue. This amount represented the excess of the amount paid by Purdue and PPLP for our common stock (\$11.25 per share) over the closing market price on the day before the first equity closing (\$5.29 per share). In 2008, we considered our obligation, absent material adverse changes, to issue Purdue and PPLP the second closing securities to be a forward contract with immaterial intrinsic value, which was recorded in stockholders' equity. This forward contract closed in January 2009 upon the issuance of the second closing securities. In January 2009, we recorded \$18.2 million as deferred revenue associated with the grant of licenses to Mundipharma and Purdue, representing the excess of the \$30 million paid by Purdue and PPLP for the second closing securities over the fair market value of these securities (\$5.29 per share for the common stock and approximately \$1.3 million for the warrants) as of the day before the first equity closing. All deferred revenue related to the strategic alliance with Mundipharma and Purdue will be recognized as revenue ratably over 14 years, which is our estimated period of performance under the arrangement. We will periodically review this estimate and make adjustments as facts and circumstances dictate. We recognized \$3.0 million in such revenue in the year ended December 31, 2009.

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.

The extension of the line of credit at an interest rate below our incremental borrowing rate represents the transfer of additional value to us in the arrangement. As such, we recorded the fair value of the line of credit of \$17.3 million as a loan commitment asset on our balance sheet in 2008. We began amortizing this asset to interest expense over the life of the loan arrangement, or 10 years, on April 1, 2009. Because Purdue and its associated companies became significant related parties as a result of the equity issuances, we recorded the offset to this asset as additional paid-in capital in 2008. As of December 31, 2009, no amounts have been borrowed under this line of credit.

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

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

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

**Novartis.** In February 2006, we entered into a collaboration agreement with Novartis Institute for BioMedical Research, Inc., or Novartis, to discover, develop and commercialize drugs targeting Bcl protein family members for the treatment of a broad range of cancers. Under the terms of this agreement, we granted to Novartis an exclusive, worldwide license to research, develop and commercialize pharmaceutical products that are based upon our proprietary Bcl inhibitors. Novartis paid us a \$15 million up-front license fee, which we originally recognized over an estimated period of performance of four years, an affiliate of Novartis made a \$5 million equity investment in us, and Novartis committed to provide us research funding of approximately \$10 million over the initial two-year research term, which expired in February 2008. Novartis had the right to extend the research term for up to two additional one-year terms, under which Novartis could have obligated us to provide up to five full-time equivalents, at Novartis' expense, to enable the full transition of the Bcl inhibitor program to Novartis. Novartis chose not to exercise its right for the one-year extensions; thus, the research term ended in February 2008. Because we have no further performance obligations to Novartis, we recognized the remaining balance of deferred revenue of \$8.1 million of the up-front license fee as revenue in the three months ended March 31, 2008. We may request to participate in clinical development of any products arising from this collaboration and, if such request is agreed upon by Novartis, Novartis will fund agreed-upon development costs that are incurred by us. We also have a non-exclusive right to detail Bcl-2 family inhibitor products in the United States, with our detailing costs to be reimbursed by Novartis. Novartis has agreed to make milestone payments

totaling over \$370 million if certain specified research, development and commercialization milestones are achieved for multiple products for multiple indications, such that total payments to us could exceed \$400 million. Novartis has also agreed to pay us royalties upon successful commercialization of any products developed under the alliance.

## **Financial Overview**

### ***Revenue***

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

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

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

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

Under our collaboration with MedImmune/AZ, we shared research and development expenses equally with MedImmune/AZ. In December 2008, we reacquired from MedImmune/AZ worldwide development and commercialization rights to our Hsp90 chaperone inhibitor program. Amounts reimbursed by MedImmune/AZ under the cost-sharing provisions of the parties' collaboration agreement incurred prior to our reacquisition of the Hsp90 chaperone inhibitor program were recorded as a reduction of research and development expense in our statements of operations. Amounts reimbursed by MedImmune/AZ incurred following the reacquisition of the Hsp90 chaperone inhibitor program were recorded as income from residual funding after reacquisition of Hsp90 program in our statements of operations. This cost-sharing arrangement also applied to our Hedgehog pathway inhibitor program through May 31, 2008.



### ***General and Administrative Expense***

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

### ***Other Income and Expense***

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

### **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, all of our revenue has been generated under research collaboration agreements. The terms of these research collaboration agreements may include payment to us of non-refundable, up-front license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved, and/or royalties on product sales. We divide agreements containing multiple elements into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the collaborative partner and whether there is objective and reliable evidence of fair value of the undelivered obligation(s). For these agreements, we allocate the consideration that we receive among the separate units based on their respective fair values or, in some cases, 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 as related research costs are incurred. 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 on a prospective basis 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 remaining estimated period of performance under the contract as we complete our performance obligations.

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

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

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

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

### ***Accrued Expenses***

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

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

We expense the fair value of employee stock options and other equity compensation. We use our judgment in determining the fair value of our equity instruments, including in selecting the inputs we use for the Black-Scholes valuation model. Equity instrument valuation models are by their nature highly subjective. Any

significant changes in any of our judgments, including those used to select the inputs for the Black-Scholes valuation model, could have a significant impact on the fair value of the equity instruments granted and the associated compensation charge we record in our financial statements.

### ***Income Taxes***

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

We use our judgment for the recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. We will recognize any material interest and penalties related to unrecognized tax benefits in income tax expense.

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

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

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

In January 2010, the Financial Accounting Standards Board (“FASB”) issued Accounting Standard Update No. 2010-06, *Improving Disclosures about Fair Value Measurements* (“ASU No. 2010-06”), which amends the existing fair value measurements and disclosures guidance currently included in Accounting Standards Codification No. 820 to require additional disclosures regarding fair value measurements. Specifically, ASU No. 2010-06 requires entities to disclose the amounts of significant transfers between Level 1 and Level 2 of the fair value hierarchy and the reasons for these transfers, the reasons for any transfer in or out of Level 3, and information in the reconciliation of recurring Level 3 measurements about purchases, sales, issuance and settlements on a gross basis. In addition, ASU No. 2010-06 also clarifies the requirement for entities to disclose information about both the valuation techniques and inputs used in estimating Level 2 and Level 3 fair value measurements. ASU No. 2010-06 is effective for interim and annual reporting periods beginning after December 15, 2009, except for additional disclosures related to Level 3 fair value measurements, which are effective for fiscal years beginning after December 15, 2010. We do not expect ASU No. 2010-06 to have a material impact on our financial statements or results of operations.

In October 2009, the FASB issued Accounting Standard Update No. 2009-13, *Multiple-Element Revenue Arrangements* (“ASU No. 2009-13”), which updates the existing multiple-element revenue arrangements guidance currently included in Accounting Standards Codification No. 605-25 in two ways. The first change relates to the determination of when the individual deliverables included in a multiple-element arrangement may be treated as separate units of accounting. This is significant as it will likely result in the requirement to separate more deliverables within an arrangement, ultimately leading to less revenue deferral. The second change modifies the manner in which the transaction consideration is allocated across the separately identified deliverables. ASU No. 2009-13 also significantly expands the disclosures required for multiple-element revenue arrangements. ASU No. 2009-13 will be effective for the first annual reporting period beginning on or after June 15, 2010, and may be applied retrospectively for all periods presented or prospectively to arrangements entered into or materially modified after the adoption date. We are currently evaluating the effect of ASU No. 2009-13 and are unable to quantify the impact on our consolidated financial statements or determine the timing and method of its adoption.

## Results of Operations

The following table summarizes our results of operations for the years ended December 31, 2009, 2008 and 2007, in thousands, together with the change in each item as a percentage.

	<u>2009</u>	<u>% Change</u>	<u>2008</u>	<u>% Change</u>	<u>2007</u>
Revenue . . . . .	\$ 49,539	(41)%	\$ 83,441	240%	\$ 24,536
Research and development expense . . . . .	(77,857)	64%	(47,466)	40%	(33,793)
General and administrative expense . . . . .	(19,456)	16%	(16,837)	20%	(14,034)
Interest expense . . . . .	(1,300)	6,090%	(21)	(89)%	(188)
Interest and investment income . . . . .	2,044	(39)%	3,342	(49)%	6,581
Income from settlement with NIH . . . . .	1,745	—	—	—	—
Income from residual funding of Hsp90 program . . . . .	12,450	942%	1,195	—	—
Income tax benefit . . . . .	330	—	—	—	—

### Revenue

Our revenue during the year ended December 31, 2009 consisted of approximately:

- \$46.5 million related to reimbursed research and development services we performed under our strategic alliance entered into with Mundipharma and Purdue in November 2008; and
- \$3.0 million related to the amortization of the deferred revenue associated with the grant of licenses under our strategic alliance with Mundipharma and Purdue.

Our revenue during the year ended December 31, 2008 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;
- \$15.0 million related to a milestone payment from MedImmune/AZ upon initiation of our Phase 3 trial of IPI-504 in patients with GIST;
- \$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 with Novartis; and
- \$2.7 million related to reimbursed 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 in August 2006;
- \$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 in February 2006; and
- \$6.0 million related to the acceptance of compounds by Novartis International Pharmaceutical Ltd. under our technology access agreement.

We currently expect that all of our revenue in 2010 will be derived from reimbursed research and development services and amortization of deferred revenue under our alliance with Purdue and Mundipharma.

### Research and Development Expense

Research and development expenses represented approximately 80% of our total operating expenses for the year ended December 31, 2009, 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 for the year ended December 31, 2009 compared to the year ended December 31, 2008 is primarily attributable to:

- a decrease of \$16.7 million in amounts reimbursed by MedImmune/AZ under the cost-sharing provisions of our collaboration agreement;
- an increase of \$5.5 million in pharmaceutical development expenses as our Hsp90 and Hedgehog programs have advanced;
- an increase of \$3.2 million in compensation and benefits, including stock-based compensation, for our research and development personnel, which was primarily driven by the hiring of new research and development personnel and annual base salary increases, and partially offset by a decrease in accrued amounts under our contingent cash compensation program;
- an increase of \$1.6 million in consulting expenses primarily related to the clinical development of IPI-504; and
- an increase of \$1.5 million in preclinical expenses as our FAAH program has advanced.

The increase in research and development expense for the year ended December 31, 2008 compared to the year ended December 31, 2007 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 advanced; and
- an increase of \$3.7 million in compensation and benefits, including 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 reimbursed 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 three years. These expenses primarily relate to payroll and related expenses for personnel working on the programs, process development and manufacturing, preclinical toxicology studies, clinical trial costs and allocated costs of facilities. Our Hsp90 program and Hedgehog pathway inhibitor 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 chaperone inhibitor 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.

<u>Program</u>	<u>Year Ended December 31, 2009</u>	<u>Year Ended December 31, 2008</u>	<u>Year Ended December 31, 2007</u>
Hsp90 Chaperone Inhibitors .....	\$32.7 million	\$20.4 million	\$12.9 million
Hedgehog Pathway Inhibitors .....	22.8 million	10.8 million	5.3 million
FAAH Inhibitors .....	9.4 million	—	—
Bcl-2 .....	—	0.6 million	4.7 million

We do not believe that the historical costs associated with our lead drug development programs are indicative of the future costs associated with these programs or represent what any other future drug development

program we initiate may cost. Due to the variability in the length of time and scope of activities necessary to develop a drug candidate, uncertainties related to cost estimates and our ability to obtain marketing approval for our drug candidates, accurate and meaningful estimates of the total costs required to bring our product candidates to market are not available.

We are conducting multiple studies of our Hsp90 chaperone inhibitors, IPI-504 and IPI-493. These studies are focused on establishing a dose and schedule of administration that optimizes safety and efficacy of these candidates, and identifying patient populations most likely to benefit from Hsp90 inhibition. If we are unable to establish the optimal dose and schedule for either IPI-504 or IPI-493 during 2010, we may elect to discontinue further development of the applicable drug candidate.

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

#### *General and Administrative Expense*

The increase in general and administrative expense for the year ended December 31, 2009 as compared to the year ended December 31, 2008 is primarily attributable to:

- an increase of \$1.0 million in compensation and benefits, including stock-based compensation expense for general and administrative employees, which was primarily driven by the hiring of new general and administrative personnel, and annual base salary increases, and partially offset by a decrease in accrued amounts under our contingent cash compensation program; and
- an increase of \$0.5 million in consulting expenses, principally related to early commercial development and public relations services.

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 stock-based compensation expense for general and administrative employees, which was primarily driven by the hiring of new general and administrative personnel, accrued amounts under our 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 2010 in support of our research and development initiatives and as we begin to establish commercial capabilities.

#### *Interest Expense*

Interest expense increased for the year ended December 31, 2009 compared to the years ended December 31, 2008 and 2007 as a result of amortizing the loan commitment asset from Purdue.

#### *Interest and Investment Income*

Interest and investment income decreased in the year ended December 31, 2009 as compared to the year ended December 31, 2008 primarily as a result of the lower yields on our cash equivalents and available-for-sale securities. We expect interest and investment income to continue to be lower in 2010 as compared to 2009 due to lower expected yields and lower average balances.

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.

*Income from NIH Reimbursement*

During the year ended December 31, 2009, we received \$1.7 million from the National Institutes of Health related to contract work performed by Discovery Partners International, Inc. from August 2004 through June 2006. We do not expect any such income in future periods.

*Income from Residual Funding 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 the Hsp90 program costs for the ensuing six-month period. Reimbursable amounts from the date of reacquisition (December 11, 2008) to December 31, 2008 were 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 we also recorded as income from residual funding after reacquisition of Hsp90 program in the year ended December 31, 2009.

*Income Tax Benefit*

We realized an income tax benefit of approximately \$0.3 million for the year ended December 31, 2009 primarily due to the Worker, Homeownership, and Business Assistance Act of 2009. This law contains a provision that permits companies to carry back certain 2008 or 2009 net operating losses for a period of up to five years and receive a benefit for prior tax expense.

**Liquidity and Capital Resources**

We have not generated any revenue from the sale of drugs to date, and we do not expect to generate any such revenue for the next several years, if at all. We have instead relied on the proceeds from sales of equity securities, interest on investments, license fees, expense reimbursement under our collaborations, milestone payments, contract service payments and debt to fund our operations. Our available-for-sale debt securities primarily trade in liquid markets, and the average days to maturity of our portfolio as of December 31, 2009 is less than six months. Because our product candidates are in various stages of clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability.

Other significant capital resources are as follows:

	<u>December 31, 2009</u>	<u>December 31, 2008</u>	
Cash, cash equivalents and available-for-sale securities including long term .....	\$130,736,513	\$126,771,687	
Working capital .....	120,634,909	120,587,124	
	<u>Years ended December 31,</u>		
	<u>2009</u>	<u>2008</u>	<u>2007</u>
Cash (used in) provided by:			
Operating activities .....	\$(4,756,922)	\$(10,422,417)	\$ 12,082,295
Investing activities .....	(7,496,170)	(18,183,839)	(62,004,999)
Capital expenditures (included in investing activities above) .....	(2,527,627)	(1,392,377)	(2,405,677)
Financing activities .....	11,965,772	22,016,084	(1,060,054)

## *Cash Flows*

The principal use of cash in operating activities in all of the periods presented was the funding of our research and development expenses, which increase as our drug development programs advance. Cash flows from operations can vary significantly due to various factors, including changes in accounts receivable and unbilled accounts receivable, as well as changes in accounts payable, accrued expenses and deferred revenue.

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. During January 2009, we issued to Mundipharma and Purdue an aggregate of two million shares of our common stock and warrants to purchase up to six million shares of our common stock for cash proceeds of \$30.0 million. These securities were recorded at their fair value of \$11.8 million and reflected as cash flows from financing activities. The balance of \$18.2 million was accounted for as an up-front license fee in deferred revenue and recorded in our cash flows from operating activities. During the year ended December 31, 2009, we collected all of our unbilled receivables from Purdue, Mundipharma and MedImmune/AZ.

Net cash used in investing activities for the year ended December 31, 2009 included \$166.6 million in purchases of available-for-sale securities, proceeds of \$125.4 million from maturities of available-for-sale securities and proceeds of \$36.1 million from sales of available-for-sale securities. Capital expenditures in the year ended December 31, 2009 of \$2.5 million primarily consisted of laboratory equipment, software and computer equipment.

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, resulting in an \$8.1 million decrease in deferred revenue.

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.

We will need substantial additional funds to support our planned operations. In the absence of additional funding or business development activities and based on our current operating plans, we expect that our current cash and investments, together with research and development funding from Purdue and Mundipharma and the \$50.0 million line of credit that has been made available to us by PPLP, are sufficient to fund our planned operations into 2013. We may, however, need to raise additional funds before that date if our research and development expenses exceed our current expectations, if we do not receive the payments we expect to receive from Mundipharma and Purdue, if we acquire a third party or if we acquire or license rights to additional drug candidates or new technologies from one or more third parties. We may need to raise additional funds for other reasons, including:

- our drug candidates require more extensive clinical or preclinical testing than we currently expect;
- we advance more of our drug candidates than expected into costly later stage clinical trials;
- we advance more preclinical drug candidates than expected into early stage clinical trials;
- the cost of acquiring raw materials for, and of manufacturing, our drug candidates is higher than anticipated;
- we are required, or consider it advisable, to acquire or license intellectual property rights from one or more third parties;



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

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

### **Contractual Obligations**

As of December 31, 2009, we had the following contractual obligations:

<u>Contractual Obligations</u>	<u>Payments Due by Period (in thousands)</u>						
	<u>Total</u>	<u>2010</u>	<u>2011</u>	<u>2012</u>	<u>2013</u>	<u>2014</u>	<u>2015 and beyond</u>
Capital lease, including interest . . . . .	\$ 13	\$ 7	\$ 6	\$ —	\$—	\$—	\$—
Software contract obligation . . . . .	230	115	115	—	—	—	—
Operating lease obligations . . . . .	14,757	4,921	5,059	4,777	—	—	—
Total contractual cash obligations . . . . .	<u>\$15,000</u>	<u>\$5,043</u>	<u>\$5,180</u>	<u>\$4,777</u>	<u>\$—</u>	<u>\$—</u>	<u>\$—</u>

In addition to the contractual obligations in the table above, long-term liabilities for unrecognized tax benefits and related accrued interest totaling approximately \$0.7 million at December 31, 2009 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 \$446,000 decrease in the fair value of our investments as of December 31, 2009, as compared to an approximate \$418,000 decrease 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, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2009. 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, 2009 and 2008, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2009, 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, 2009, 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, 2010 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Boston, Massachusetts  
March 11, 2010

**INFINITY PHARMACEUTICALS, INC.**

**Consolidated Balance Sheets**

	December 31,	
	2009	2008
<b>Assets</b>		
Current assets:		
Cash and cash equivalents .....	\$ 16,287,229	\$ 16,574,549
Available-for-sale securities .....	113,758,778	110,197,138
Unbilled accounts receivable .....	—	7,414,570
Notes receivable from employees .....	55,059	42,198
Prepaid expenses and other current assets .....	3,511,968	2,389,411
Total current assets .....	133,613,034	136,617,866
Property and equipment, net .....	5,694,150	5,320,439
Loan commitment asset from Purdue .....	16,020,075	17,319,000
Long-term available-for-sale securities .....	690,506	—
Notes receivable from employees .....	38,036	28,780
Restricted cash .....	1,146,788	1,138,161
Other assets .....	115,244	193,262
Total assets .....	\$ 157,317,833	\$ 160,617,508
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable .....	\$ 1,441,231	\$ 2,759,288
Accrued expenses .....	8,542,923	11,562,641
Deferred revenue from Purdue entities .....	2,987,512	1,702,860
Current portion of capital leases .....	6,459	5,953
Total current liabilities .....	12,978,125	16,030,742
Deferred revenue from Purdue entities, less current portion .....	35,855,463	21,939,251
Other liabilities .....	2,219,224	2,340,099
Capital leases, less current portion .....	5,489	11,949
Total liabilities .....	51,058,301	40,322,041
Commitments and contingencies (note 11) .....	—	—
<b>Stockholders' equity:</b>		
Preferred Stock, \$.001 par value; 1,000,000 shares authorized, no shares issued and outstanding at December 31, 2009 and 2008 .....	—	—
Common Stock, \$.001 par value; 100,000,000 shares authorized, and 26,238,954 and 24,064,857 shares issued and outstanding, at December 31, 2009 and December 31, 2008, respectively .....	26,239	24,065
Additional paid-in capital .....	287,593,176	268,447,955
Accumulated deficit .....	(181,397,174)	(148,891,909)
Accumulated other comprehensive income .....	37,291	715,356
Total stockholders' equity .....	106,259,532	120,295,467
Total liabilities and stockholders' equity .....	\$ 157,317,833	\$ 160,617,508

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

**INFINITY PHARMACEUTICALS, INC.**

**Consolidated Statements of Operations**

	Years Ended December 31,		
	2009	2008	2007
Collaborative research and development revenue:			
From Purdue entities .....	\$ 49,538,714	\$ 2,882,541	\$ —
Other .....	—	80,558,125	24,536,350
Total Revenue .....	49,538,714	83,440,666	24,536,350
Operating expenses:			
Research and development .....	77,856,836	47,466,410	33,793,307
General and administrative .....	19,456,341	16,836,541	14,033,559
Total operating expenses .....	97,313,177	64,302,951	47,826,866
Income (loss) from operations .....	(47,774,463)	19,137,715	(23,290,516)
Other income (expense):			
Interest expense .....	(1,300,184)	(21,368)	(188,035)
Income from NIH reimbursement .....	1,745,386	—	—
Income from residual funding after reacquisition of Hsp90 program .....	12,450,000	1,195,586	—
Interest and investment income .....	2,044,430	3,342,424	6,580,664
Total other income .....	14,939,632	4,516,642	6,392,629
Income (loss) before income taxes .....	(32,834,831)	23,654,357	(16,897,887)
Income tax benefit .....	329,566	—	—
Net income (loss) .....	<u>\$(32,505,265)</u>	<u>\$23,654,357</u>	<u>\$(16,897,887)</u>
Earnings (loss) per common share:			
Basic .....	<u>\$ (1.25)</u>	<u>\$ 1.17</u>	<u>\$ (0.87)</u>
Diluted .....	<u>\$ (1.25)</u>	<u>\$ 1.14</u>	<u>\$ (0.87)</u>
Weighted average number of common shares outstanding:			
Basic .....	<u>26,096,515</u>	<u>20,236,743</u>	<u>19,511,485</u>
Diluted .....	<u>26,096,515</u>	<u>20,765,536</u>	<u>19,511,485</u>

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

**INFINITY PHARMACEUTICALS, INC.**

**Consolidated Statements of Cash Flows**

	Years Ended December 31,		
	2009	2008	2007
<b>Operating activities</b>			
Net income (loss) .....	\$ (32,505,265)	\$ 23,654,357	\$ (16,897,887)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities			
Depreciation .....	2,153,916	1,971,937	2,753,560
Stock-based compensation including 401(k) match .....	7,037,253	5,840,065	5,223,224
(Gain) loss on sale and disposals of property and equipment .....	(79,256)	(56,620)	25,446
Gain on sale of available-for-sale securities .....	(28,051)	(107,313)	—
Net (accretion) amortization of available-for-sale securities .....	129,973	(1,753,531)	(3,597,182)
Impairment of available-for-sale securities .....	15,666	49,428	15,577
Impairment of property and equipment .....	—	84,219	195,690
Amortization of loan commitment asset from Purdue .....	1,298,925	—	—
Other, net .....	60,196	55,114	60,671
Changes in operating assets and liabilities:			
Accounts receivable and unbilled accounts receivable .....	7,414,570	(2,314,334)	37,034,574
Prepaid expenses and other assets .....	(1,075,479)	74,063	(212,856)
Accounts payable, accrued expenses and other liabilities .....	(4,380,234)	3,229,754	1,231,478
Deferred revenue .....	15,200,864	(41,149,556)	(13,750,000)
Net cash provided by (used in) operating activities .....	(4,756,922)	(10,422,417)	12,082,295
<b>Investing activities</b>			
Purchases of property and equipment .....	(2,527,627)	(1,392,377)	(2,405,677)
Proceeds from sale of property and equipment .....	79,256	57,113	15,000
Purchases of available-for-sale securities .....	(166,565,338)	(172,033,407)	(208,173,692)
Proceeds from maturities of available-for-sale securities .....	125,375,803	137,134,757	148,559,370
Proceeds from sales of available-for-sale securities .....	36,141,736	18,050,075	—
Net cash used in investing activities .....	(7,496,170)	(18,183,839)	(62,004,999)

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

	Years Ended December 31,		
	2009	2008	2007
<b>Financing activities</b>			
Proceeds from issuance of common stock to Purdue entities . . . . .	11,830,000	21,160,000	—
Proceeds from issuances of common stock related to stock incentive plans . . . . .	201,726	713,115	342,151
Repurchase of common stock . . . . .	—	(8,115)	(10,640)
Release of restricted cash . . . . .	—	564,986	—
Payments on equipment loan and other debt . . . . .	—	(373,403)	(1,351,049)
Capital lease payments . . . . .	(5,954)	(10,499)	(41,746)
Repayment of employee loans . . . . .	—	—	11,230
New employee loans . . . . .	(60,000)	(30,000)	(10,000)
Net cash provided by (used in) financing activities . . . . .	<u>11,965,772</u>	<u>22,016,084</u>	<u>(1,060,054)</u>
Net decrease in cash and cash equivalents . . . . .	(287,320)	(6,590,172)	(50,982,758)
Cash and cash equivalents at beginning of period . . . . .	16,574,549	23,164,721	74,147,479
Cash and cash equivalents at end of period . . . . .	<u>\$16,287,229</u>	<u>\$16,574,549</u>	<u>\$ 23,164,721</u>
<b>Supplemental cash flow disclosure</b>			
Interest paid . . . . .	<u>\$ 1,247</u>	<u>\$ 14,351</u>	<u>\$ 161,789</u>
Income taxes paid . . . . .	<u>\$ 75,000</u>	<u>\$ 92,000</u>	<u>\$ 1,100,000</u>
<b>Supplemental disclosure of noncash investing and financing activities</b>			
Equipment acquired under capital leases . . . . .	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 28,800</u>
Loan commitment asset from Purdue . . . . .	<u>\$ —</u>	<u>\$17,319,000</u>	<u>\$ —</u>

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

**INFINITY PHARMACEUTICALS, INC.**

**Consolidated Statements of Stockholders' Equity**

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Balance at December 31, 2006	19,523,243	\$19,523	\$219,110,907	\$(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	341,968				342,151
Restricted stock issued in prior years that vested in the year			124,880				124,880
Repurchase of treasury stock				(10,640)			(10,640)
Retirement of common stock	(22,060)	(22)	(1,334,450)	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						279,515	(16,618,372)
Balance at December 31, 2007	19,710,773	\$19,711	\$223,466,502	\$ —	\$(172,546,266)	\$202,956	\$ 51,142,903
Exercise of stock options	306,744	307	712,808				713,115
Issuance of common stock to Purdue	4,000,000	4,000	21,156,000				21,160,000
Restricted stock issued that vested in the year			75,621				75,621
Early exercise of options into restricted stock			(121,989)				(121,989)
Repurchase and retirement of common stock	(4,531)	(5)	5,435,829				(5)
Stock-based compensation expense							5,435,829
401(k) plan match and other issued in common stock							
Loan commitment asset from Purdue	51,871	52	404,184				404,236
Comprehensive income:			17,319,000				17,319,000
Unrealized gain on marketable securities						512,400	512,400
Net income					23,654,357		23,654,357
Comprehensive income							24,166,757
Balance at December 31, 2008	24,064,857	\$24,065	\$268,447,955	\$ —	\$(148,891,909)	\$715,356	\$120,295,467

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

**INFINITY PHARMACEUTICALS, INC.**

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

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Balance at December 31, 2008 .....	24,064,857	\$24,065	\$268,447,955	\$—	\$(148,891,909)	\$ 715,356	\$120,295,467
Exercise of stock options .....	101,384	101	201,625				201,726
Issuance of common stock to Purdue .....	2,000,000	2,000	10,578,000				10,580,000
Restricted stock issued that vested in the year .....			78,416				78,416
Stock-based compensation expense .....			6,506,680				6,506,680
401(k) plan match issued in common stock .....	72,713	73	530,500				530,573
Issuance of warrants to Purdue .....			1,250,000				1,250,000
Comprehensive income:							
Unrealized loss on marketable securities .....						(678,065)	(678,065)
Net loss .....					(32,505,265)		(32,505,265)
Comprehensive loss .....							(33,183,330)
Balance at December 31, 2009 .....	26,238,954	\$26,239	\$287,593,176	\$—	\$(181,397,174)	\$ 37,291	\$106,259,532



**INFINITY PHARMACEUTICALS, INC.**  
**Notes to Consolidated Financial Statements**

**1. Organization**

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

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

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

The 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 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.

**Reclassifications**

Certain amounts in the prior years’ financial statements have been reclassified to conform with the current-year presentation. These reclassifications have no impact on previously reported net income, net loss or cash flows.

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

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

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

We adjust the cost of available-for-sale debt securities for amortization of premiums and accretion of discounts to maturity. We include such amortization and accretion in interest and investment income. The cost of securities sold is based on the specific identification method. Realized gains on our available-for-sale securities were \$28,051 and \$107,313 for the years ended December 31, 2009 and 2008, respectively. Realized gains or losses from the sales of securities for the year ended December 31, 2007 were immaterial. We include interest and dividends on securities classified as available-for-sale in interest and investment income.

## INFINITY PHARMACEUTICALS, INC.

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

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

#### Concentration of Risk

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 of U.S. government-sponsored enterprise obligations, investment grade corporate obligations, U.S. Treasury obligations and mortgage-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

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, 2009, all of our revenues are associated with our strategic alliance with Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products L.P., or Purdue.

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, and Novartis International Pharmaceutical Ltd., or Novartis International, accounted for approximately 11% of our revenue; and
- Revenues associated with our strategic alliances with Mundipharma and 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 accounted for approximately 59% of our revenue; and

## INFINITY PHARMACEUTICALS, INC.

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

- Revenues associated with the up-front license fee we received from MedImmune/AZ accounted for approximately 41% of our revenue.

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.

#### 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. Application development costs incurred for computer software developed or obtained for internal use are capitalized. 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 to 5 years
Leasehold improvements . . . . .	Shorter of life of lease or useful life of asset
Furniture and fixtures . . . . .	7 years

#### Impairment of Long-Lived Assets

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, 2009, 2008 and 2007.

#### Fair Value

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

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

#### Revenue Recognition

To date, all of our revenue has been generated under research collaboration agreements. The terms of these research collaboration agreements may include payment to us of non-refundable, up-front license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved,

## INFINITY PHARMACEUTICALS, INC.

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

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 as related research costs are incurred. 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 on a prospective basis 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 remaining estimated period of performance under the contract as we complete our performance obligations.

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

#### **Income Taxes**

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

We use our judgment for the recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. We recognize any material interest and penalties related to unrecognized tax benefits in income tax expense.

#### **Basic and Diluted Net Income (Loss) per Common Share**

Basic net income or loss per share is based upon the weighted average number of common shares outstanding during the period, excluding restricted stock that has been issued but is not yet vested. Diluted net income or loss per share is based upon the weighted average number of common shares outstanding during the period, plus the effect of additional weighted average common equivalent shares outstanding during the period when the effect of adding such shares is dilutive. Common equivalent shares result from the assumed exercise of outstanding stock options and warrants (the proceeds of which are then assumed to have been used to repurchase outstanding stock using the treasury stock method) and the vesting of restricted shares of common stock. In addition, the assumed proceeds under the treasury stock method include the average unrecognized compensation

**INFINITY PHARMACEUTICALS, INC.**

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

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, 2009 and 2007 because the effect of including them would have been anti-dilutive. Total potential gross common equivalent shares consisted of the following:

	At December 31,		
	2009	2008	2007
Stock options . . . . .	4,954,708	4,762,819	3,876,004
Warrants . . . . .	6,246,629	246,629	246,629
Unvested restricted shares . . . . .	16,396	47,558	54,954

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

	Year Ended December 31,		
	2009	2008	2007
<b>Basic</b>			
Net income (loss) . . . . .	\$(32,505,265)	\$23,654,357	\$(16,897,887)
Weighted average common shares outstanding . . . . .	26,096,515	20,236,743	19,511,485
Basic earnings (loss) per share . . . . .	\$ (1.25)	\$ 1.17	\$ (0.87)
<b>Diluted</b>			
Net income (loss) . . . . .	\$(32,505,265)	\$23,654,357	\$(16,897,887)
Weighted average common shares outstanding . . . . .	26,096,515	20,236,743	19,511,485
Effect of dilutive options . . . . .	—	528,793	—
Weighted average common shares outstanding assuming dilution . . . . .	26,096,515	20,765,536	19,511,485
Diluted earnings (loss) per share . . . . .	\$ (1.25)	\$ 1.14	\$ (0.87)

**Comprehensive Income (Loss)**

Comprehensive income is comprised of net income (loss) and other comprehensive income. Other comprehensive income includes unrealized holding gains and losses on available-for-sale securities that are not other-than-temporarily impaired.

**Stock-Based Compensation Expense**

We measure share-based compensation cost at the grant date based on the estimated fair value of the award, and recognize it as expense over the employee’s requisite service period on a straight-line basis. We have no awards with market or performance conditions. We use the Black-Scholes valuation model in determining the fair value of equity awards.

**Research and Development Expense**

Research and development expense consists of expenses incurred in performing research and development activities, including salaries and benefits, facilities expenses, overhead expenses, materials and supplies, preclinical expenses, clinical trial and related clinical manufacturing expenses, stock-based compensation expense, contract services, and other outside expenses. We expense research and development costs as they are incurred. We have entered into certain collaboration agreements in which expenses are shared with the

## INFINITY PHARMACEUTICALS, INC.

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

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

#### **New Accounting Pronouncement**

In January 2010, the Financial Accounting Standards Board (“FASB”) issued Accounting Standard Update No. 2010-06, *Improving Disclosures about Fair Value Measurements* (“ASU No. 2010-06”), which amends the existing fair value measurements and disclosures guidance currently included in Accounting Standards Codification No. 820 to require additional disclosures regarding fair value measurements. Specifically, ASU No. 2010-06 requires entities to disclose the amounts of significant transfers between Level 1 and Level 2 of the fair value hierarchy and the reasons for these transfers, the reasons for any transfer in or out of Level 3, and information in the reconciliation of recurring Level 3 measurements about purchases, sales, issuance and settlements on a gross basis. In addition, ASU No. 2010-06 also clarifies the requirement for entities to disclose information about both the valuation techniques and inputs used in estimating Level 2 and Level 3 fair value measurements. ASU No. 2010-06 is effective for interim and annual reporting periods beginning after December 15, 2009, except for additional disclosures related to Level 3 fair value measurements, which are effective for fiscal years beginning after December 15, 2010. We do not expect ASU No. 2010-06 to have a material impact on our financial statements or results of operations.

In October 2009, the FASB issued Accounting Standard Update No. 2009-13, *Multiple-Element Revenue Arrangements* (“ASU No. 2009-13”), which updates the existing multiple-element revenue arrangements guidance currently included in Accounting Standards Codification No. 605-25, in two ways. The first change relates to the determination of when the individual deliverables included in a multiple-element arrangement may be treated as separate units of accounting. This is significant as it will likely result in the requirement to separate more deliverables within an arrangement, ultimately leading to less revenue deferral. The second change modifies the manner in which the transaction consideration is allocated across the separately identified deliverables. ASU No. 2009-13 also significantly expands the disclosures required for multiple-element revenue arrangements. ASU No. 2009-13 will be effective for the first annual reporting period beginning on or after June 15, 2010, and may be applied retrospectively for all periods presented or prospectively to arrangements entered into or materially modified after the adoption date. We are currently evaluating the effect of ASU No. 2009-13 and are unable to quantify the impact on our consolidated financial statements or determine the timing and method of its adoption.

### **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, 2009, an aggregate of 6,713,403 shares of our common stock are reserved for issuance under the 2000 Plan, of which 692,079 shares of common stock remain available for future grant. The number of shares of our common stock available for issuance under the 2000 Plan automatically increases on the first

## INFINITY PHARMACEUTICALS, INC.

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

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 provide for monthly vesting over four years.

#### 2001 Stock Incentive Plan

In connection with the merger between Discovery Partners International, Inc. and Infinity Pharmaceuticals, Inc. (“IPI”) in 2006 (the “DPI merger”), we assumed awards that were granted under the Infinity Pharmaceuticals, Inc. Pre-Merger Stock Incentive Plan (the “2001 Plan”), which provided for the grant of incentive stock options and non-statutory stock options and restricted stock awards. Under the 2001 Plan, stock awards were granted to IPI’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 IPI 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, 2009, an aggregate of 650,474 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 DPI merger; therefore, no further grants may be made under the 2001 Plan.

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.

#### Compensation Expense

Total stock-based compensation expense, related to all equity awards, for the years ended December 31, 2009, 2008 and 2007, comprised the following:

	<u>Year Ended December 31, 2009</u>	<u>Year Ended December 31, 2008</u>	<u>Year Ended December 31, 2007</u>
Research and development . . . . .	\$3,501,126	\$2,781,662	\$2,558,655
General and administrative . . . . .	3,536,127	3,058,403	2,664,569

As of December 31, 2009, there was \$8.2 million of total unrecognized compensation cost, net of estimated forfeitures, related to unvested options which is expected to be recognized over a weighted-average period of 2.1 years.

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

**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, 2009</u>	<u>Year Ended December 31, 2008</u>	<u>Year Ended December 31, 2007</u>
Risk-free interest rate . . . . .	2.24%	2.00%	4.35%
Expected annual dividend yield . . . . .	—	—	—
Expected stock price volatility . . . . .	56.73%	56.93%	60.99%
Expected term of options . . . . .	5.4 years	5.2 years	5.1 years

The valuation assumptions were determined as follows:

- *Risk-free interest rate:* The yield on zero-coupon U.S. Treasury securities for a period that is commensurate with the expected term of the awards.
- *Expected annual dividend yield:* The estimate for annual dividends is zero, because we have not historically paid a dividend and do not intend to do so in the foreseeable future.
- *Expected stock price volatility:* We determine the expected volatility by using 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.

We stratify employees into two groups to evaluate exercise and post-vest termination behavior. 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, 2009, 2008 and 2007, the weighted-average forfeiture rate was estimated to be 8%, 7% and 4%, respectively.

All options granted to employees during the years ended December 31, 2009, 2008 and 2007 were granted with exercise prices equal to the fair market value of our common stock on the date of grant. We consider the price of our common stock to be the fair market value.

A summary of our stock option activity for the year ended December 31, 2009 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, 2009 . . . . .	4,762,819	\$ 9.83		
Granted . . . . .	554,635	7.10		
Exercised . . . . .	(101,384)	1.99		
Forfeited . . . . .	(261,362)	13.59		
Outstanding at December 31, 2009 . . . . .	<u>4,954,708</u>	\$ 9.48	7.67	\$2.0
Vested or expected to vest at December 31, 2009 . . . . .	<u>4,803,668</u>	\$ 9.51	7.64	\$2.0
Exercisable at December 31, 2009(1) . . . . .	<u>2,944,842</u>	\$10.03	7.14	\$2.0



**INFINITY PHARMACEUTICALS, INC.**

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

(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, 2009, 2008 and 2007 were \$3.70, \$3.66, and \$6.82, respectively.

The aggregate intrinsic value of options outstanding at December 31, 2009 was calculated based on the positive difference between the closing fair market value of our common stock on December 31, 2009 and the exercise price of the underlying options. The aggregate intrinsic value of options exercised during the years ended December 31, 2009, 2008 and 2007 was \$550,292, \$723,552, and \$1,651,508, respectively. The total cash received from employees and non-employees as a result of stock option exercises during the year ended December 31, 2009 was \$201,726.

A summary of the status of unvested restricted stock as of December 31, 2009, 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, 2009 .....	47,558	\$2.54
Granted .....	—	—
Vested .....	(31,162)	2.74
Repurchased .....	—	—
Unvested at December 31, 2009 .....	<u>16,396</u>	<u>\$2.15</u>

The total fair value of the shares vested during the years ended December 31, 2009, 2008 and 2007 (measured on the date of vesting) was \$213,008, \$318,497 and \$1,451,346, respectively.

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

No related income tax benefits were recorded during the years ended December 31, 2009, 2008 or 2007.

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

During the year ended December 31, 2009, one member of our board of directors retired, but was granted the right to exercise his vested stock options for an additional three-year period. In connection with this extension, we recognized an additional \$42,213 in stock-based compensation expense during the year ended December 31, 2009 with respect to the modification of this award.

During the year ended December 31, 2008, one member of our board of directors retired, 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 continued to vest over the term of the consulting

**INFINITY PHARMACEUTICALS, INC.**

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

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 retired, 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.

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

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

	<b>December 31, 2009</b>			
	<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 . . . . .	\$ 16,287,229	\$ —	\$ —	\$ 16,287,229
Available-for-sale securities				
Corporate obligations due in one year or less . . . . .	31,505,149	13,461	(205)	31,518,405
U.S. Treasury securities due in one year or less . . .	2,268,546	3,684	—	2,272,230
Mortgage-backed securities due after ten years . . . .	699,376	—	(8,870)	690,506
U.S. government-sponsored enterprise obligations due in one year or less . . . . .	64,841,354	71,583	(494)	64,912,443
U.S. government-sponsored enterprise obligations due in one to five years . . . . .	15,097,568	—	(41,868)	15,055,700
Total available-for-sale securities . . . . .	<u>114,411,993</u>	<u>88,728</u>	<u>(51,437)</u>	<u>114,449,284</u>
Total cash, cash equivalents and available-for-sale securities . . . . .	<u>\$130,699,222</u>	<u>\$88,728</u>	<u>\$(51,437)</u>	<u>\$130,736,513</u>
	<b>December 31, 2008</b>			
	<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
Mortgage-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>

There were eight debt securities that had been in an unrealized loss position for less than 12 months at December 31, 2009. The aggregate unrealized loss on these securities was \$51,437 and the fair value was \$22,794,431. To determine whether an other-than-temporary impairment exists, we consider whether we have the ability and intent to hold these investments until a market price recovery, and considered whether evidence indicating the recoverability of the cost of the investments outweighed evidence to the contrary. Since the decline

**INFINITY PHARMACEUTICALS, INC.**

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

in market value was primarily attributable to current economic conditions and we have the ability to hold these investments until a recovery of fair value, we do not consider these investments to be other-than-temporarily impaired at December 31, 2009.

During the year ended December 31, 2009, we determined that one debt security was other-than-temporarily impaired and accordingly recorded a realized loss of \$15,666. 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. We did not recognize any cumulative effect as an adjustment to the opening balance of accumulated deficit with a corresponding adjustment to accumulated other comprehensive income.

**5. Fair Value**

We use a valuation hierarchy for disclosure of the inputs used to measure fair value. This hierarchy prioritizes the inputs into three broad levels. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value. The classification of a financial asset or liability within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement. For our fixed income securities, we reference pricing data supplied by our custodial agent and nationally known pricing vendors, using a variety of daily data sources, largely readily-available market data and broker quotes.

The following table provides the assets carried at fair value measured on a recurring basis as of December 31, 2009:

	<u>Level 1</u>	<u>Level 2</u>
Cash and cash equivalents .....	\$16,287,229	\$ —
Corporate obligations (including commercial paper) .....	—	31,518,405
Mortgage-backed securities .....	—	690,506
U.S. Treasury securities .....	—	2,272,230
U.S. government-sponsored enterprise obligations .....	—	79,968,143
Total .....	<u>\$16,287,229</u>	<u>\$114,449,284</u>

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

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

**INFINITY PHARMACEUTICALS, INC.**

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

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

There have been no changes to the valuation methods during the year ended December 31, 2009.

**6. Property and Equipment**

Property and equipment consist of the following:

	December 31,	
	2009	2008
Laboratory equipment . . . . .	\$ 14,216,196	\$ 13,896,580
Computer hardware and software . . . . .	5,437,027	4,739,045
Office equipment and furniture and fixtures . . . . .	722,683	693,260
Leasehold improvements . . . . .	4,253,799	4,248,274
	24,629,705	23,577,159
Less accumulated depreciation . . . . .	(18,935,555)	(18,256,720)
	\$ 5,694,150	\$ 5,320,439

During the year ended December 31, 2009, we capitalized costs associated with internally developed software in the amount of \$524,496 and recorded depreciation expense associated with this software in the amount of \$101,985.

We did not impair any fixed assets during the year ended December 31, 2009. During the years ended December 31, 2008 and 2007, we impaired laboratory equipment totaling \$84,219 and \$195,690, 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, 2009 was \$16,200. 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, 2009, we disposed of certain fully depreciated laboratory and computer equipment, which had an original cost of \$1,475,082 resulting in a gain of \$79,256.

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.

**7. Loan Commitment Asset**

In November 2008, we entered into strategic alliance agreements with each of Purdue and Mundipharma to develop and commercialize pharmaceutical products. In connection with these agreements, we also entered into a line of credit agreement with Purdue and its independent associated company, Purdue Pharma L.P. (“PPLP”). See Note 12 for discussion on the strategic alliance agreements and the line of credit agreement.

**INFINITY PHARMACEUTICALS, INC.**

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

The extension of the line of credit at an interest rate below our incremental borrowing rate represents the transfer of additional value to us in the arrangement. As such, we recorded this additional value as a loan commitment asset at its fair value of \$17.3 million on our balance sheet in 2008. The fair value of the loan commitment asset was determined using a discounted cash flow model of the differential between the terms and rates of the line of credit and market rates. The loan commitment asset is measured at fair value on a nonrecurring basis and will only be re-measured at fair value for nonrecurring events such as an impairment loss. 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.

We are amortizing this asset to interest expense over the life of the loan arrangement, or 10 years commencing on April 1, 2009, the date we could begin drawing on the line. We recorded approximately \$1.3 million of related amortization expense in the year ended December 31, 2009. As of December 31, 2009, no amounts have been borrowed under this line of credit.

**8. Restricted Cash**

We held \$1,146,788 in restricted cash as of December 31, 2009 and \$1,138,161 in restricted cash as of December 31, 2008. The balances are held on deposit with a bank to collateralize a standby letter of credit in the 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.

**9. Accrued Expenses**

Accrued expenses consisted of the following:

	December 31,	
	2009	2008
Accrued drug manufacturing costs . . . . .	\$2,212,156	\$ 2,768,588
Accrued toxicology studies . . . . .	691,197	261,636
Accrued compensation and benefits . . . . .	2,576,970	5,037,924
Accrued clinical studies . . . . .	920,429	1,284,858
Other . . . . .	2,142,171	2,209,635
Total accrued expenses . . . . .	\$8,542,923	\$11,562,641

**10. Other Long-Term Liabilities**

Other long-term liabilities consisted of the following:

	December 31,	
	2009	2008
Deferred rent . . . . .	\$1,125,369	\$1,505,811
Accrued tax liability . . . . .	684,322	646,338
Other . . . . .	409,533	187,950
Total other long-term liabilities . . . . .	\$2,219,224	\$2,340,099

**INFINITY PHARMACEUTICALS, INC.**

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

**11. Commitments and Contingencies**

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 lease, are approximately as follows:

	<b>Facility Lease</b>
Years Ending December 31:	
2010 .....	\$ 4,915,381
2011 .....	5,056,907
2012 .....	4,776,917
2013 .....	—
2014 .....	—
Total minimum lease payments .....	\$14,749,205

Rent expense of \$4,526,260, \$4,455,781 and \$4,334,575, before considering sublease income, was incurred during the years ended December 31, 2009, 2008 and 2007, respectively. During the years ended December 31, 2009, 2008 and 2007, we subleased a portion of our facility space for total sublease income of \$512,510, \$565,845 and \$551,025, respectively. We record sublease payments as an offset to rental expense in our statement of operations. Future minimum sublease income under noncancelable leases is expected to be \$607,343 for the year ended December 31, 2010.

**12. Collaborations**

**Purdue and Mundipharma**

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

Under the strategic alliance agreements, we have responsibility and decision-making authority for the performance of early discovery projects and the development of all product candidates on a worldwide basis. There are no joint steering or similar committees for the alliance. Mundipharma is obligated to pay 100% of our contractually budgeted amounts for research and development expenses incurred by us for early discovery projects and product candidates included in the alliance until the later of December 31, 2013 and the commencement of the first Phase 3 clinical trial of such product candidate, which we refer to as the transition date. The contractually budgeted amount for the period between November 19, 2008 and December 31, 2009 was \$50 million and the contractually budgeted amount for the years ended December 31, 2010 and 2011 is

## INFINITY PHARMACEUTICALS, INC.

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

\$65 million and \$85 million, respectively. After the transition date for each product candidate other than those arising out of the FAAH project, we will share with Mundipharma all research and development costs for such product candidate equally. Upon completion of the first Phase 1 clinical trial of the first product developed under the research program that inhibits or targets FAAH during 2010, Purdue and Mundipharma may elect to assume responsibility, at their own expense, for the future development of FAAH products and their sale in and outside of the United States, respectively. In addition to the annual opt-out right, Mundipharma and Purdue will each have the right to opt out of participation in the FAAH project following completion of the first Phase 1 clinical trial of IPI-940. If Mundipharma and Purdue were to exercise this right, there is no residual funding obligation for the FAAH project, but we may redeploy contractually-budgeted amounts that had been allocated to the FAAH project to any other project that is the subject of the alliance. We are recording revenue for reimbursed research and development services we perform for Mundipharma and Purdue. We recorded \$46.5 million and \$2.7 million in such revenue in the years ended December 31, 2009 and 2008, respectively. In the first month of each quarter, Purdue and Mundipharma each prepay a quarterly research and development service amount, which we record as deferred revenue and recognize as revenue as expenses are incurred over the period of effort.

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

In connection with the entry into the strategic alliance agreements in November 2008, we also entered into a securities purchase agreement and line of credit agreement (see note 7) with Purdue and its independent associated company, Purdue Pharma L.P. (“PPLP”). In March 2009, Purdue assigned its interest under the line of credit agreement to PPLP. Under the securities purchase agreement we issued and sold in a first equity closing in November 2008 an aggregate of four million shares of our common stock at a purchase price of \$11.25 per share, for an aggregate purchase price of \$45 million. Of such shares, two million shares of our common stock were purchased by each purchaser. In January 2009, we conducted a second equity closing where we issued and sold an aggregate of two million shares of our common stock and warrants to purchase up to an aggregate of six million shares of our common stock, for an aggregate purchase price of \$30 million. An equal number of shares and warrants were purchased by each purchaser.

In November 2008 for financial statement purposes, we recorded \$23.8 million as deferred revenue associated with the grant of licenses to Mundipharma and Purdue. This amount represented the excess of the amount paid by Purdue and PPLP for the four million shares of our common stock (\$11.25 per share) over the closing market price on the day before the first equity closing (\$5.29 per share). In 2008, we considered our obligation, absent material adverse changes, to issue Purdue and PPLP the second closing securities as a forward

## INFINITY PHARMACEUTICALS, INC.

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

contract with immaterial intrinsic value, which was recorded in stockholders' equity. This forward contract closed in January 2009 upon the issuance of the second closing securities. In January 2009, for financial statement purposes, we recorded \$18.2 million as deferred revenue associated with the grant of licenses to Mundipharma and Purdue representing the excess of the \$30 million paid by Purdue and PPLP for the second closing securities over the fair market value of these securities (\$5.29 per share for the common stock and approximately \$1.3 million for the warrants) as of the day before the first equity closing.

All deferred revenue related to this strategic alliance is currently recognized as revenue ratably over 14 years, which is our estimated period of performance under the alliance agreements. We periodically review this estimate and make adjustments as facts and circumstances dictate. We recognized \$3.0 million and \$0.2 million in such revenue in the years ended December 31, 2009 and 2008, respectively.

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

#### **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 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. In December 2008, we regained from MedImmune/AZ worldwide development and commercialization rights under our Hsp90 chaperone inhibitor program. Following the reacquisition of the Hsp90 chaperone inhibitor program in December 2008, we had no substantial performance obligations to MedImmune/AZ and as such, we recognized the remaining portion of the up-front license fee of \$56.7 million as revenue during the year ended December 31, 2008. The change in accounting estimate for the research term 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 also recorded reimbursable amounts from MedImmune/AZ through December 31, 2008 as income from residual funding, a component of other income in our statement of operations. MedImmune/AZ's funding obligation under the Hsp90 chaperone inhibitor program was to continue until June 2009. In January 2009, we reached an agreement with MedImmune/AZ to settle the residual funding obligation remaining for 2009 through lump-sum payments totaling \$12.5 million, which were recorded as income from residual funding after reacquisition of Hsp90 program (a component of other income) in the year ended December 31, 2009. We received \$12.5 million in cash from MedImmune/AZ in the year ended December 31, 2009.



## INFINITY PHARMACEUTICALS, INC.

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

Since the MedImmune/AZ collaboration was a cost-sharing arrangement, we recorded reimbursable amounts for MedImmune/AZ's share of the development effort up through the date of our reacquisition of the Hsp90 chaperone inhibitor program on December 10, 2008 as a reduction of research and development expense. 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 recorded as income from residual funding. During the year ended December 31, 2007, we offset against research and development expense approximately \$13.7 million that was reimbursable from MedImmune/AZ for sharing of costs that we incurred for research and development under the collaboration. We will not recognize any revenue from the up-front license fee nor record any reduction of research and development expense or any income from residual funding after reacquisition of the Hsp90 program related to the MedImmune/AZ collaboration in future periods.

#### 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 resulted in a positive net income impact of \$4.4 million and \$0.22 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. 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 and 2007, we recognized \$8.1 million and \$3.8 million, respectively, in revenue related to the amortization of the non-refundable license fee, and \$0.8 million and \$4.8 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 year ended December 31, 2007, we recognized \$6.0 million 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 years ended December 31, 2009 or 2008.

**INFINITY PHARMACEUTICALS, INC.**

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

**13. Income Taxes**

Our income tax benefit of \$329,566 for the year ended December 31, 2009 primarily consisted of U.S. federal taxes.

Our income tax benefit or expense for the years ended December 31, 2009, 2008 and 2007 differed from the expected U.S. federal statutory income tax expense as set forth below:

	<u>2009</u>	<u>2008</u>	<u>2007</u>
Expected federal tax expense (benefit) . . . . .	\$(11,141,951)	\$ 8,021,401	\$(5,745,282)
Permanent differences . . . . .	1,522,097	1,393,377	698,537
State taxes, net of deferral benefit . . . . .	(1,782,351)	1,479,241	(1,059,498)
Tax credits and related adjustments . . . . .	(2,928,454)	(3,533,790)	559,720
Alternative minimum tax . . . . .	(282,191)	—	—
Effect of change in state tax rate on deferred tax assets and deferred tax liabilities . . . . .	(4,892)	780,028	—
Expired state net operating loss . . . . .	1,085,004	1,794,332	191,611
Limitation on federal net operating loss . . . . .	—	—	2,837,291
Adjustments to deferred tax assets and deferred tax liabilities . . . . .	(47,347)	7,052,325	(74,667)
Change in valuation allowance . . . . .	13,156,402	(16,986,914)	2,592,288
Other . . . . .	94,117	—	—
Income tax benefit . . . . .	<u>\$ (329,566)</u>	<u>\$ —</u>	<u>\$ —</u>

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

	<u>Year Ended December 31,</u>	
	<u>2009</u>	<u>2008</u>
Deferred tax assets:		
Net operating loss carryforwards . . . . .	\$ 39,560,917	\$ 46,250,820
Tax credits . . . . .	14,274,743	11,404,967
Deferred revenue . . . . .	8,659,514	—
Accrued expenses . . . . .	309,667	548,970
Amortization . . . . .	690,840	692,829
Stock-based compensation . . . . .	5,456,411	3,834,023
Other . . . . .	177,856	114,660
Valuation allowance . . . . .	<u>(69,129,948)</u>	<u>(55,916,563)</u>
Total deferred tax assets . . . . .	—	6,929,706
Deferred tax liabilities:		
Loan commitment . . . . .	—	(6,819,703)
Depreciation . . . . .	—	(110,003)
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, 2009, 2008 and 2007 because management believes that it is more likely than not that these assets will not be realized. The valuation allowance increased by approximately \$13,213,000 during the year ended December 31, 2009 primarily as a result of increases in unbenefited deferred tax assets such as deferred revenue and tax credits and decreases in deferred tax liabilities offset by the utilization of previously unbenefited net

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

operating losses. The valuation allowance decreased by approximately \$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. The valuation allowance increased by approximately \$3,600,000 during the year ended December 31, 2007 primarily as a result of unbenefited losses.

Subject to the limitations described below, at December 31, 2009, we had cumulative net operating loss carryforwards of approximately \$107,774,000 and \$63,329,000 available to reduce federal and state taxable income, which expire through 2028 and 2013, respectively. In addition, we have cumulative federal and state tax credit carryforwards of \$10,755,000 and \$5,333,000, respectively, available to reduce federal and state income taxes which expire through 2029 and 2024, respectively. The net operating loss carryforwards include approximately \$1,561,000 of deductions related to the exercise of stock options. This amount represents an excess tax benefit and has not been included in the gross deferred tax asset reflected for net operating losses. 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 increase 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 excluded from the amounts disclosed above.

During the twelve-month period ended December 31, 2009, there were no increases or decreases to our liability for unrecognized tax benefits; however, we recorded an additional interest expense of approximately \$30,000 in connection with uncertain tax positions taken in prior periods. We have approximately \$90,000 of interest and penalties accrued as of December 31, 2009. If the tax benefits are ultimately recognized, the effective tax rates in any future periods would be favorably affected by approximately \$684,000. In addition, it is reasonably possible that during the next twelve month period, our liability for unrecognized tax benefits could decrease anywhere between \$0 and approximately \$684,000 as the result of the expiration of a statute of limitations.

A reconciliation of the allowance for uncertain tax positions for the years ended December 31, 2009 and 2008 is as follows:

	<u>2009</u>	<u>2008</u>
Balance at January 1 .....	\$594,000	\$ 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 .....	—	—
Decrease relating to settlements .....	—	—
Decrease resulting from the expiration of the statute of limitations .....	—	—
Balance at December 31 .....	<u>\$594,000</u>	<u>\$ 594,000</u>

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.

**14. Stockholders' Equity**

**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

## INFINITY PHARMACEUTICALS, INC.

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

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.

#### Treasury Stock Retirements

We retire treasury stock periodically with the approval of our board of directors. Amounts retired have been immaterial for the years ended December 31, 2009, 2008 and 2007. 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, we issued warrants to purchase shares of convertible preferred stock, which subsequently became warrants to purchase common stock. 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 shares of 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, 2009, 2008 and 2007. 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.

## INFINITY PHARMACEUTICALS, INC.

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

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 was recorded as additional paid-in capital in the year ended December 31, 2009.

#### **15. Income from NIH Reimbursement**

During the year ended December 31, 2009, we received \$1.7 million from the National Institutes of Health relating to contract work performed by Discovery Partners International, Inc. from August 2004 through June 2006. As the amount received is not related to our ordinary course of operations, we have recorded the amount as other income.

#### **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, 2009, 2008 and 2007, we matched 50% of the first six percent of participant contributions with shares of our common stock. The cost of our matching contributions during the years ended December 31, 2009, 2008 and 2007 was \$530,573, \$404,236 and \$370,698, respectively.

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

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 was recorded to accumulated deficit and accrued expenses as of January 1, 2007. We recorded additional compensation expense of \$114,199, \$116,761 and \$96,075 during the years ended December 31, 2009, 2008 and 2007, respectively.

**INFINITY PHARMACEUTICALS, INC.**

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

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

	<u>Quarter Ended</u> <u>March 31, 2009</u>	<u>Quarter Ended</u> <u>June 30, 2009</u>	<u>Quarter Ended</u> <u>September 30, 2009</u>	<u>Quarter Ended</u> <u>December 31, 2009</u>
	(In Thousands, Except Shares and Per Share Amounts)			
Collaborative research and development				
revenue from Purdue entities .....	\$ 9,429	\$ 13,165	\$ 13,776	\$ 13,169
Operating expenses:				
Research and development .....	21,242	20,713	18,499	17,404
General and administrative .....	5,330	5,681	4,571	3,874
Total operating expenses .....	<u>26,572</u>	<u>26,394</u>	<u>23,070</u>	<u>21,278</u>
Loss from operations .....	(17,143)	(13,229)	(9,294)	(8,109)
Other (expense) income:				
Interest expense .....	—	(433)	(433)	(433)
Income from residual funding after				
reacquisition of Hsp90 program .....	12,450	—	—	—
Income from NIH reimbursement .....	—	1,745	—	—
Interest and investment income .....	743	592	401	308
Total other income (loss) .....	<u>13,193</u>	<u>1,904</u>	<u>(32)</u>	<u>(125)</u>
Net loss before income taxes .....	(3,950)	(11,325)	(9,326)	(8,234)
Income tax benefit .....	—	—	—	330
Net loss .....	<u>\$ (3,950)</u>	<u>\$ (11,325)</u>	<u>\$ (9,326)</u>	<u>\$ (7,904)</u>
Basic and diluted net loss per common share ..	<u>\$ (0.15)</u>	<u>\$ (0.43)</u>	<u>\$ (0.36)</u>	<u>\$ (0.30)</u>
Basic and diluted weighted average number of				
common shares outstanding .....	<u>25,910,687</u>	<u>26,118,758</u>	<u>26,154,557</u>	<u>26,198,415</u>

**INFINITY PHARMACEUTICALS, INC.**

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

	<b>Quarter Ended March 31, 2008</b>	<b>Quarter Ended June 30, 2008</b>	<b>Quarter Ended September 30, 2008</b>	<b>Quarter Ended December 31, 2008</b>
(In Thousands, Except Shares and Per Share Amounts)				
Collaborative research and development revenue				
From Purdue entities	\$ —	\$ —	\$ —	\$ 2,883
Other	11,391	2,500	2,500	64,167
Total 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	12,293	14,457	15,513	22,040
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	1,324	809	621	1,762
Net income (loss)	\$ 422	\$ (11,148)	\$ (12,392)	\$ 46,772
Earnings (loss) per common share:				
Basic	\$ 0.02	\$ (0.57)	\$ (0.63)	\$ 2.15
Diluted	\$ 0.02	\$ (0.57)	\$ (0.63)	\$ 2.11
Weighted average number of common shares outstanding:				
Basic	19,677,541	19,729,094	19,759,766	21,766,857
Diluted	20,235,482	19,729,094	19,759,766	22,183,541

## **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, 2009. 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 principal executive officer and principal financial officer concluded that as of December 31, 2009, our disclosure controls and procedures were (1) designed to ensure that material information relating to us is made known to our management including our principal executive officer and principal 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.

Management's report on the Company's internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) appears below.

No change in the Company's internal control over financial reporting occurred during the fiscal quarter ended December 31, 2009 that has materially affected, or is reasonably likely to material affect, the Company's internal control over financial reporting.

#### **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, 2009. 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, 2009, our internal control over financial reporting is effective based on those criteria.

Our independent registered public accounting firm has issued an attestation 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, 2009, 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, 2009, 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, 2009 and 2008, and the related consolidated

statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2009 of Infinity Pharmaceuticals, Inc. and our report dated March xx, 2010 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Boston, Massachusetts  
March 11, 2010

***(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, 2009 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 and Committee Meetings," "Section 16(a) Beneficial Ownership Reporting Compliance" and "Corporate Governance Guidelines; 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 May 25, 2010 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 "Executive Officer Compensation" appearing in the definitive proxy statement we will file in connection with our Annual Meeting of Stockholders to be held on May 25, 2010 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 May 25, 2010 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 "Determination of Independence" appearing in the definitive proxy statement we will file in connection with our Annual Meeting of Stockholders to be held on May 25, 2010 are incorporated herein by reference.

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

The section titled "Audit Fees" appearing in the definitive proxy statement we will file in connection with our Annual Meeting of the Stockholders to be held on May 25, 2010 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, 2009 and 2008 . . . . .	58
Consolidated Statements of Operations for the years ended December 31, 2009, 2008, and 2007 . . .	59
Consolidated Statements of Cash Flows for the years ended December 31, 2009, 2008, and 2007 . .	60
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2009, 2008 and 2007 . . . . .	61
Notes to Consolidated Financial Statements . . . . .	63

**(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.



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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. These statements involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. For example, there can be no guarantee that our strategic alliance with Mundipharma and Purdue will continue for its expected term or that they will fund our programs as agreed, or that any product candidate we are developing will successfully complete necessary preclinical and clinical development phases. There can be also no guarantee that any positive developments in our product portfolio will result in stock price appreciation. Our expectations could also be affected by risks and uncertainties inherent in pharmaceutical research and development such as adverse results of clinical trials and preclinical studies; the content and timing of decisions made by the U.S. Food and Drug Administration and other regulatory authorities, investigational review boards at clinical trial sites, and publication review bodies; our ability to enroll patients in our clinical trials; unplanned cash requirements and expenditures, including in connection with business development activities; our dependence on our alliance partners; and our ability to obtain, maintain and enforce patent and other intellectual property protection for any product candidates we are developing. These and other risks that may impact management’s expectations are described in greater detail under the caption “Risk Factors” in the accompanying Annual Report on Form 10-K. Unless required by law, we do not undertake any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.



## HEADQUARTERS

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

## EXECUTIVE LEADERSHIP

### **Adelene Q. Perkins**

President and Chief Executive Officer

### **Steven H. Holtzman**

Executive Chair

### **Julian Adams, Ph.D.**

President of Research & Development and  
Chief Scientific Officer

### **Michael S. Curtis, Ph.D.**

Vice President, Pharmaceutical  
Development

### **David S. Grayzel, M.D.**

Vice President, Clinical Development and  
Medical Affairs

### **John J. Keilty**

Vice President, Information Technology  
and Informatics

### **Jeanette W. Kohlbrenner**

Vice President, Human Resources

### **Christopher M. Lindblom**

Senior Director, Finance; Controller

### **Vito J. Palombella, Ph.D.**

Vice President, Drug Discovery

### **Gerald E. Quirk, Esq.**

Vice President, Corporate Affairs and  
General Counsel

### **Jeffrey K. Tong, Ph.D.**

Vice President, Corporate and Product  
Development

### **Tamyra A. Toole, Esq.**

Vice President, Regulatory Affairs and  
Quality Assurance

## BOARD OF DIRECTORS

### **Steven H. Holtzman**

Executive Chair

### **Adelene Q. Perkins**

President and Chief Executive Officer

### **Martin Babler**

Chief Executive Officer  
Talima Therapeutics, Inc.

### **Anthony B. Evnin, Ph.D.**

Managing General Partner  
Venrock

### **Harry F. Hixson, Jr., Ph.D.**

Chair and Interim Chief Executive Officer  
Sequenom, 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

### **Thomas J. Lynch, Jr., M.D.**

Professor of Medicine  
Yale School of Medicine  
Director, Yale Cancer Center

### **Franklin H. Moss, Ph.D.**

President  
Strategic Software Ventures  
Director and Professor of  
The Media Lab,  
Massachusetts Institute of Technology

### **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.**

President and Chief Scientific Officer  
iPierian, 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  
May 25, 2010 at the  
Doubletree Guest Suites Hotel  
400 Soldiers Field Road  
Boston, MA 02134

## 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, or sending a  
written request to:

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





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