

INFINITY PHARMACEUTICALS, INC.

Form 10-K

March 14, 2008

Table of Contents

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

Washington, D.C. 20549

**FORM 10-K**

(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, 2007

Or

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

For the transition period from            to

Commission file number: 0-31141

**INFINITY PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

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

**Delaware** **33-0655706**  
(State or other jurisdiction of **(I.R.S. Employer**  
  
**incorporation or organization)** **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:**

<b>Common Stock, \$.001 par value</b>	<b>NASDAQ Global Market</b>
(Title of each class)	(Name of each exchange on which listed)

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

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

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

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

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

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

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

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

The aggregate market value of voting Common Stock held by non-affiliates of the registrant as of June 29, 2007 was \$155,973,123 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 29, 2008: 19,737,359

**Documents incorporated by reference:**

## Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-K

Portions of our definitive proxy statement to be filed with the Securities and Exchange Commission no later than April 29, 2008 in connection with our 2008 annual meeting of stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

**Table of Contents****TABLE OF CONTENTS**

	<b>Page No.</b>
<b><u>PART I</u></b>	
Item 1: <u>Business</u>	1
Item 1A: <u>Risk Factors</u>	18
Item 1B: <u>Unresolved Staff Comments</u>	33
Item 2: <u>Properties</u>	33
Item 3: <u>Legal Proceedings</u>	33
Item 4: <u>Submission of Matters to a Vote of Security Holders</u>	33
<b><u>PART II</u></b>	
Item 5: <u>Market for Registrant's Common Equity; Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	34
Item 6: <u>Selected Financial Data</u>	36
Item 7: <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	37
Item 7A: <u>Quantitative and Qualitative Disclosures about Market Risk</u>	51
Item 8: <u>Financial Statements and Supplementary Data</u>	52
Item 9: <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	85
Item 9A: <u>Controls and Procedures</u>	85
Item 9B: <u>Other Information</u>	87
<b><u>PART III</u></b>	
Item 10: <u>Directors, Executive Officers and Corporate Governance</u>	87
Item 11: <u>Executive Compensation</u>	87
Item 12: <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	87
Item 13: <u>Certain Relationships and Related Transactions and Director Independence</u>	87
Item 14: <u>Principal Accountant Fees and Services</u>	87
<b><u>PART IV</u></b>	
Item 15: <u>Exhibits and Financial Statement Schedules</u>	88
<u>Signatures</u>	89

---

**Table of Contents**

**Forward-Looking Information**

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

**PART I**

**Item 1. Business Overview**

Our mission is to discover, develop, and deliver to patients best-in-class medicines for the treatment of cancer and related conditions. A best-in-class drug refers to a drug, among all drugs within a class of drugs that operate through a particular target or molecular mechanism in the body to affect a particular disease, that is superior to all of the other drugs in the class by virtue of its superior efficacy, superior safety, ease of administration, or some combination of the foregoing. We have built a pipeline of innovative product candidates for multiple cancer indications, all of which represent proprietary applications of our expertise in small molecule drug technologies. We believe that our small molecule discovery and development capabilities, strategic alliances, team of highly experienced management and scientists, and corporate culture form the basis of our potential long-term competitive advantage in seeking to deliver best-in-class medicines to patients.

Our lead product candidate, retaspimycin hydrochloride for injection (formerly known as IPI-504), or retaspimycin, is an intravenously administered small molecule inhibitor of heat shock protein 90, or Hsp90. Hsp90 is a molecule that maintains the structure and activity of specific proteins, known as client proteins of Hsp90; specific mutations in, or the aberrant expression of, these client proteins result in many types of cancer. Hsp90 enables the survival of the cancer cell by allowing the client protein to continue functioning. We believe that the inhibition of Hsp90 has broad therapeutic potential for patients with solid tumors and blood-related cancers, including those that are resistant to other drugs. As of February 29, 2008, retaspimycin is being evaluated as a single agent in three disease-focused clinical trials, including a Phase 1 trial in patients with metastatic and/or unresectable gastrointestinal stromal tumors (GIST) and other soft tissue sarcomas (STS), the Phase 2 portion of a Phase 1/2 trial in patients with advanced non-small cell lung cancer (NSCLC), and a Phase 2 trial in patients with hormone-resistant prostate cancer (HRPC). We are also conducting a Phase 1b clinical trial of retaspimycin in combination with Taxotere® (docetaxel) in patients with advanced solid tumors. We currently expect to initiate additional clinical trials of retaspimycin during 2008, including a Phase 3 clinical trial in GIST in the third quarter of 2008 pending ongoing consultation with advisors and regulatory authorities and analysis of data from the ongoing Phase 1 trial, and one or more Phase 2 clinical trials in additional solid tumor indications. We also intend to begin a Phase 1 clinical trial of IPI-493, an orally available inhibitor of Hsp90, in the second quarter of 2008. We are pursuing our Hsp90 program in collaboration with MedImmune, Inc., a division of AstraZeneca plc. We use the term MedImmune/AZ to identify our Hsp90 collaborator.

---

## **Table of Contents**

Our next most advanced program is directed against the Hedgehog signaling pathway, or Hedgehog pathway. Normally, the Hedgehog pathway regulates tissue and organ formation during embryonic development. When abnormally activated during adulthood, however, the Hedgehog pathway is believed to play a central role in allowing the proliferation and survival of certain cancer-causing cells, and is implicated in many of the most deadly cancers. The lead candidate in our Hedgehog pathway program, IPI-926, has shown potent and selective inhibition of the Hedgehog pathway as well as anti-tumor activity in preclinical models. We intend to file an investigational new drug, or IND, application for IPI-926 by the third quarter of 2008 and to commence a Phase 1 clinical trial shortly thereafter.

We also have other research programs that target cancer and related conditions, including a program being conducted in collaboration with the Novartis Institutes for BioMedical Research, or Novartis, to identify small molecule compounds that inhibit the Bcl-2 family of proteins.

## **Corporate Information**

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

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

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

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 subsidiaries 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.

## **Table of Contents**

### **Business Strategy**

We intend to accomplish our mission of discovering, developing and delivering to patients best-in-class medicines for the treatment of cancer and related conditions by executing on a strategy to:

***Focus our efforts on cancer and related conditions.*** We have focused the majority of our efforts in the field of cancer, otherwise known as oncology, because we expect this focus will enable us to develop and build expertise and critical mass. Furthermore, we have chosen to focus our efforts strategically in oncology for scientific, clinical/regulatory and commercial reasons.

*Scientific.* In the last decade, advances in the basic molecular understanding of the pathways that drive the development of a cancer cell have grown. Many of the field's most important drug targets have only recently been discovered, and new approaches to drug development continue to evolve. We believe that our proprietary small molecule capabilities and the depth, breadth and experience of our scientific team provide us a competitive advantage in potentially overcoming the hurdles of cancer drug development.

*Clinical/Regulatory.* Because of the life-threatening nature of cancer and the side effects caused by many existing cancer drugs, there are several regulatory programs designed to provide an expedited path for developing and achieving marketing approval for cancer drugs which, if available for our drug candidates, may give us the opportunity to deliver new medicines to patients more rapidly.

*Commercial.* We believe that the large unmet medical need in oncology remains a significant market opportunity. Recently approved oncology drugs have experienced significant sales growth despite addressing relatively small patient populations. The American Cancer Society estimates that there were approximately 1.4 million newly diagnosed cases of cancer in the United States in 2007 and that approximately 560,000 people in the United States died of cancer in 2007.

***Focus on therapies that serve an unmet medical need.*** To date, our strategy has been to focus on the discovery and development of drugs directed against specific molecular targets. These drugs, which are frequently referred to as targeted therapies, hold the promise of being more selective than traditional cytotoxic drugs, thus harming fewer normal cells, reducing side effects and improving the quality of life for patients. In selecting drug targets, we have focused on those that serve important unmet medical needs, are supported by strong science, leverage our small molecule discovery and development capabilities, and have clearly defined clinical development paths. We have also selected 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 a best-in-class medicine.

***Focus our development efforts on rapidly obtaining product approval, while in parallel pursuing the broadest market opportunities.*** Our clinical development strategy is informed by our desire to reach the market with best-in-class drug candidates as rapidly as possible. Our clinical strategy with retaspimycin has been to initiate disease-focused Phase 1 trials, testing the drug candidate as a single agent in refractory settings where we believe there is a strong scientific rationale for the use of an Hsp90 inhibitor in the indication, substantial unmet medical need, and potential for accelerated approval. In addition to choosing targeted disease settings supported by strong science, we have also chosen indications in which we have the potential to observe signals of biological activity using surrogate markers, such as positron emission tomography, or PET, imaging. Combined, these strategies have the potential to markedly accelerate clinical development by producing valuable data on biological activity in a comparatively large sample of patients in the same indication, all in Phase 1. For more advanced stages of clinical development, we are making development decisions based on a rigorous scientific interpretation of clinical data, our growing understanding of the biology of our drug targets, and the interests of patients, all in an effort to expand our drug candidates into additional indications, earlier lines of therapy, and combination studies with other approved agents in order to enhance their market potential. Whenever possible, we will seek to obtain FastTrack designation, accelerated approval and priority review from the U.S. Food and Drug Administration, or FDA, for our drug candidates.

## **Table of Contents**

***Establish strategic alliances to accelerate and maximize the potential of our product portfolio.*** We believe that our long-term value will be driven by the medicines we create. We have adopted an efficient strategy for funding our research activities to provide us with the financial strength to support our scientific innovation. We have established alliances with leading pharmaceutical and biotechnology companies that have been instrumental in providing capital and complementary capabilities to support our internal research. We have product development alliances with MedImmune/AZ relating to our Hsp90 program and with Novartis relating to our Bcl-2 program. In both of these alliances, we have the right to take an active role in product development and to participate significantly in any downstream commercial activities and financial return generated by them. In addition, the cost-sharing provisions of these alliances help us control our cash burn rate, which enables us both to invest heavily in our programs and, potentially, to reach key development milestones before requiring additional financing.

***Attract and develop outstanding scientists, clinicians, and business people.*** We believe that our people and the culture in which they operate are as important to our success as are our technologies, and that living our core values of diversity, citizenship, passionate innovation, transparent communication, mutual respect, social responsibility and integrity provides a key competitive advantage. Embracing a culture of citizen-ownership in which our employees work together as a community with the objective of bringing important new medicines to patients, we aspire to empower each individual to think innovatively and achieve his or her fullest potential. This culture has enabled us to use a relatively small team to perform virtually all of our discovery, development, and formulation sciences work internally, and to integrate our scientific and business teams to create value for shareholders and patients. In addition, our management team has an extensive track record in discovering, developing and commercializing innovative medicines and leading and/or managing successful biotechnology enterprises. This track record has also allowed us to attract and engage industry-leading external advisors and top clinical investigators to assist us in formulating our research and development strategies and conducting our clinical trials.

## **Product Development Pipeline**

We focus our product development efforts on targeted therapies for cancer and related conditions. Our product development programs as of February 29, 2008 are illustrated in the following chart:



## **Table of Contents**

During 2008, we expect to advance our product development pipeline by:

launching a Phase 3 clinical trial of retaspimycin in refractory GIST, pending ongoing consultation with our advisors and regulatory authorities, and analysis of data from our ongoing Phase 1 clinical trial;

initiating one or more Phase 2 clinical trials of retaspimycin in additional solid tumor indications;

commencing a Phase 1 clinical trial of IPI-493;

commencing a Phase 1 clinical trial of IPI-926; and

making progress towards naming clinical candidates in our discovery-stage programs.

### ***Hsp90 Program***

Hsp90 is emerging as a significant 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, these client proteins. Examples of cancer-promoting, or oncogenic, client proteins of Hsp90 include c-Kit in GIST, epidermal growth factor receptor, or EGFR, in NSCLC, and Her-2 in breast cancer. Hsp90 enables those cancers' survival by maintaining the function of oncogenic client proteins.

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

***Retaspimycin hydrochloride for injection.*** Retaspimycin is our lead Hsp90 inhibitor. It is a novel, small molecule, semi-synthetic analog of geldanamycin that is delivered as a water-based, intravenous infusion. To date, retaspimycin has been well-tolerated up to a dose of 400 mg/m<sup>2</sup>, and has shown promising early evidence of biological activity in clinical trials in patients with metastatic and/or unresectable GIST and in patients with advanced NSCLC. Retaspimycin has also been shown in preclinical studies to inhibit Hsp90 potently and selectively, thereby killing cancer cells. In these preclinical studies, retaspimycin has demonstrated a broad potential to kill cancer cells as a single agent as well as in combination with existing anti-cancer drugs. In addition, preclinical studies suggest that retaspimycin preferentially targets and accumulates in tumor tissues. For these reasons, we believe that retaspimycin 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 are conducting multiple clinical trials with retaspimycin:

***Gastrointestinal Stromal Tumors.*** GIST is a life threatening type of sarcoma that is highly resistant to traditional cytotoxic chemotherapy or radiation treatment. The American Cancer Society estimates that between 4,500 and 6,000 Americans develop GIST each year. In the majority of GIST cases, there are specific mutations in cellular signaling enzymes, or kinases, such as c-Kit and platelet-derived growth factor receptor-alpha (PDGFRA), that are responsible for the growth and survival of the tumor. Kinase inhibitor drugs target these enzymes and have dramatically improved disease control and survival for patients with GIST. Resistance to kinase inhibitors is, however, an emerging problem, necessitating the development of new drugs with novel mechanisms of action. Both c-Kit and PDGFRA are also client proteins of Hsp90, and in preclinical experiments are degraded in cancer cells upon treatment with retaspimycin, leading to cancer cell death. These data suggest that Hsp90 inhibition with retaspimycin is a promising area for clinical investigation.



---

**Table of Contents**

We have completed enrollment and are analyzing data from the expansion phase of our open-label, dose-escalation Phase 1 clinical trial of retaspimycin in patients with metastatic and/or unresectable GIST or other soft tissue sarcomas. More than twenty patients with GIST or other soft tissue sarcomas were enrolled in the expansion phase of this trial, with retaspimycin being administered at the maximum tolerated dose of 400 mg/m<sup>2</sup> on a three-week cycle of twice-weekly treatment for two weeks followed by one week off treatment. We anticipate presenting data from the expansion phase of this trial at the American Society of Clinical Oncology's (ASCO) Annual Meeting in June 2008. Preliminary data from the dose-escalation portion of this trial were presented at the ASCO Annual Meeting in June 2007. The data presented showed that 16 of 21 evaluated patients, or 76%, had a best response of stable disease as measured by RECIST (Response Evaluation Criteria in Solid Tumors). In addition, an assessment of PET responses revealed that 15 of 18, or 83%, of evaluable patients achieved a partial response or stable disease using the European Organization for the Research and Treatment of Cancer's (EORTC) PET response criteria, which involves a quantitative measurement of the uptake of 18-fluorodeoxyglucose, an imaging agent.

We believe that stable disease is meaningful in patients with refractory GIST. Published data from a clinical trial of Gleevec® (imatinib) in this patient population reveal that overall survival in patients with stable disease is generally consistent with those having a radiographic response following administration with imatinib. Further, a statistically significant increase in time to disease progression in refractory GIST patients in response to administration with Sutent® (sunitinib) as compared to placebo formed the basis for approval of that drug for use in refractory GIST. On this basis, we are planning to launch a Phase 3 clinical trial of retaspimycin in refractory GIST in the third quarter of 2008, subject to our ongoing consultation with our advisors and regulatory authorities as well as our analysis of data emerging from the expansion phase of our ongoing Phase 1 clinical trial. In this regard, we submitted a special protocol assessment with the FDA in February 2008.

*Non-Small Cell Lung Cancer.* The American Cancer Society reports that lung cancer is the leading cause of cancer death for both men and women, estimating that approximately 215,000 new cases of lung cancer were diagnosed in the United States in 2007. NSCLC is the most common form of lung cancer, accounting for about 85% of all lung cancers, or approximately 170,000 new cases. Patients with NSCLC who have EGFR mutations (estimated to be approximately 15% of NSCLC patients in the United States and up to 30% of NSCLC patients outside of the United States) have been found to benefit from existing therapies that block EGFR signaling, including targeted kinase inhibitors. Unfortunately, additional resistance mutations in EGFR often lead to disease progression, even in patients who initially respond to kinase inhibitor therapy, necessitating the development of new therapeutics with novel mechanisms of action. Multiple cellular proteins or pathways have been linked to the progression and resistance to therapy of NSCLC, including mutated EGFR, Akt, and cMet. These proteins are all client proteins of Hsp90 and in preclinical experiments are degraded in cancer cells upon treatment with retaspimycin, leading to cancer cell death. This suggests that Hsp90 inhibition with retaspimycin in NSCLC is a promising area for clinical investigation. Furthermore, with a complementary, novel mechanism of action, inhibition of Hsp90 has the potential to aid in overcoming resistance to kinase inhibitor therapy.

We are currently conducting the Phase 2 portion of our open-label, multi-center Phase 1/2 clinical trial of retaspimycin in patients with NSCLC. In this portion of the study, a total of 20 patients are being enrolled in two equal groups: one group with known EGFR mutations and one group with unmutated, or wild-type, EGFR. Evidence of anti-tumor activity is being evaluated using RECIST criteria. If sufficient evidence of clinical benefit is observed in either cohort, 19 additional patients will be enrolled in that cohort. Retaspimycin is being administered intravenously at 400 mg/m<sup>2</sup> on a three-week cycle, consisting of twice-weekly treatment for two weeks followed by one week off treatment.

Preliminary data from the Phase 1 portion of this trial were presented at the American Association for Cancer Research-National Cancer Institute-European Organization for Research and Treatment of Cancer International Conference on Molecular Targets and Cancer Therapeutics in October 2007.

---

**Table of Contents**

Preliminary evidence of biological activity was reported in a heavily pretreated population of patients. In seven of nine evaluable patients, disease stabilization by RECIST was achieved over at least one cycle of administration. One patient with a mutation in EGFR and prior history of progression on targeted kinase inhibitors experienced stable disease for more than six months. In addition, four of four evaluated patients who underwent positron emission tomography imaging revealed a decrease in tumor metabolic activity in response to retaspimycin administration as measured by uptake of 18-fluorodeoxyglucose; two of these patients achieved a partial response using the EORTC's PET response criteria.

*Hormone Resistant Prostate Cancer.* Prostate cancer is the most common noncutaneous malignancy diagnosed in men in the United States. According to the American Cancer Society, more than 218,000 American men are diagnosed with prostate cancer annually. Prostate tumors that are growing despite the reduction of circulating testosterone to very low levels are characterized as hormone-resistant. The only therapy at this time proven to improve survival for men with HRPC, also known as castration-resistant prostate cancer, is docetaxel-based chemotherapy. Multiple cellular proteins or pathways have been linked to the progression of hormone refractory disease in patients with prostate cancer, including the androgen receptor, the Her-2 receptor, and Akt. These proteins are all client proteins of Hsp90, and in preclinical experiments these proteins are degraded in prostate cancer cells upon treatment with retaspimycin, leading to cancer cell death. This suggests that Hsp90 inhibition with retaspimycin is a promising area for clinical investigation in HRPC.

We are conducting a Phase 2 clinical trial evaluating retaspimycin in patients with advanced HRPC. The goal of this open-label, multi-center study is to determine the anti-tumor activity of retaspimycin in patients with HRPC and to correlate prior treatment status with clinical response. Initially, two groups of patients will be enrolled: one group having no prior treatment with cytotoxic chemotherapy, and one group having had prior treatment with a docetaxel-based chemotherapy. Evidence of biological activity in both groups of patients is being evaluated by RECIST, bone scans, and measurement of prostate-specific antigen levels. The trial is expected to enroll 30 patients initially (15 per group) and will expand to enroll an additional 10 patients in each trial arm if a response is observed in at least one patient in that arm. In this study, retaspimycin is being administered by intravenous infusion at the recommended Phase 2 dose of 400 mg/m<sup>2</sup> on a three-week cycle of therapy, consisting of twice-weekly treatment for two weeks followed by one week off treatment.

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

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

*IPI-493.* In parallel with the development of retaspimycin, we are pursuing development of IPI-493, a proprietary, orally available inhibitor of Hsp90. Like retaspimycin, 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. We are currently preparing our IND application for IPI-493 and expect to initiate clinical development of this compound in the second quarter of 2008.

## **Table of Contents**

Our Hsp90 program is being pursued in collaboration with MedImmune/AZ. For a description of this collaboration, see Strategic Alliances MedImmune/AZ below.

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

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

We have developed a novel, proprietary Hedgehog pathway inhibitor, IPI-926. IPI-926 is a semi-synthetic derivative of the natural product, cyclopamine, that inhibits the Hedgehog pathway by binding to the Smoothed receptor. When systemically administered in multiple preclinical animal models, IPI-926 has shown potent and selective inhibition of the Hedgehog pathway, anti-tumor activity, and attractive pharmacologic properties including oral bioavailability and extended half-life. We are currently completing preclinical toxicology studies on IPI-926 and anticipate commencing clinical development of this compound in 2008.

In November 2007, we regained from MedImmune/AZ all development and worldwide commercialization rights for our Hedgehog pathway program, including for IPI-926. Additionally, we have the right to opt-in to the development and commercialization of certain Hedgehog pathway programs being developed by AstraZeneca. In exchange for these rights, we waived the non-competition clause contained in our collaboration agreement with MedImmune/AZ applicable to AstraZeneca's independent work in the Hedgehog pathway.

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

Bcl-2 and the related protein Bcl-xL act as brakes on programmed cell death, or apoptosis, and are key regulators of this process. Many cancer cells have higher than normal levels of Bcl-2 and/or Bcl-xL. This allows them to evade apoptosis and potentially become resistant to chemotherapy. We are developing compounds that target Bcl-2 alone, and Bcl-2/Bcl-xL together, to inhibit their protective effect on cancer cells. Inhibitors of Bcl family proteins are expected to work as single agents in B-cell malignancies that are dependent on Bcl-2 for their survival, such as follicular lymphoma, chronic lymphocytic leukemia, and diffuse large B-cell lymphoma. Bcl inhibitors are also expected to work in combination with chemotherapies to sensitize a broad range of solid tumors to treatment with chemotherapy.

We have developed highly potent compounds that either selectively target Bcl-2 or target both Bcl-2 and Bcl-xL. In cells, these compounds disrupt the protein-protein interactions between Bcl-2 and its pro-apoptotic binding partners and selectively induce apoptosis in cancer cells that depend on Bcl-2 for survival. In preclinical studies in a variety of tumor types, antagonism of Bcl-2 using our compounds also results in synergy with multiple chemotherapeutic agents. These drug candidates are currently being optimized based on potency or specificity against Bcl-2, as well as for pharmaceutical properties such as solubility, metabolism and absorption, in collaboration with Novartis. For a description of our collaboration with Novartis, see Strategic Alliances Novartis below.

### ***Diversity Oriented Synthesis Technology***

Our diversity oriented synthesis chemistry technology consists of methods to create collections of novel, diverse, natural product-like compounds potentially able to interact with biological targets that have not been accessible to traditional synthetic chemistries. We have produced large libraries of structurally diverse and complex molecules for pharmaceutical screening. We believe these libraries embody all of the advantages of natural products, such as diversity and structural complexity, without the historic difficulties of synthesis and

## **Table of Contents**

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

### **Strategic Alliances**

Developing alliances has been a key strategic element in our evolution. Our alliances complement our expertise in small molecule drug discovery and development with important scientific, clinical, and business capabilities. We have developed significant alliances with leading pharmaceutical and biotechnology companies that enable us to drive forward our proprietary programs while retaining significant value in their downstream potential. These alliances have brought in over \$150 million in capital, allowing us to continue to advance our pipeline of novel small molecules and pursue potential additional product opportunities. Since our inception, all of our revenue has been derived from our strategic alliances. For the fiscal year ended December 31, 2007, our collaborations with Novartis accounted for 59% of our revenue and our collaboration with MedImmune/AZ accounted for 41% of our revenue.

**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 all development and worldwide commercialization rights under our Hedgehog pathway program.

Under the terms of this agreement, we share equally with MedImmune/AZ all development costs, as well as potential profits and losses, from any future marketed products. MedImmune/AZ made non-refundable, up-front payments totaling \$70 million to us in order to obtain co-exclusive rights to the Hsp90 and Hedgehog pathway development programs. Because we have continuing involvement in the development program, we are recognizing the up-front license fee as revenue on a straight-line basis over seven years, which is based on our estimate of the period under which product candidates would be developed by us under the collaboration. During the year ended December 31, 2007, we recognized \$10 million in revenue from such fee. In addition, we could receive up to \$215 million in milestone payments if certain late-stage development and sales objectives are achieved for products resulting from the Hsp90 program. Further, because the agreement is a cost-sharing arrangement rather than one in which research and development expenses are reimbursed, we record amounts reimbursable by MedImmune/AZ with respect to research and development as a reduction to research and development expense, and not as revenue. For the year ended December 31, 2007, we offset approximately \$13.7 million in amounts reimbursable by MedImmune/AZ against research and development expense.

We will retain primary responsibility for discovery and preclinical development of drug candidates targeting Hsp90. The parties will jointly lead clinical development through first product approval, if any. The parties will jointly develop a worldwide marketing and sales strategy for commercialized products, if any. MedImmune/AZ will have the initial right to market and sell such products worldwide, while we have the option to co-promote any future products in the United States, contributing up to 35% of the total promotional effort and with our promotional costs being included among those shared under the collaboration.

The parties will jointly own any invention and know-how that may be developed by either or both parties during the term of the agreement that is directed to the development, manufacture, use or sale of an active pharmaceutical ingredient of a product directed to Hsp90, or is developed in the course of performing activities under the research and development plan. The parties will also jointly own any patent rights that claim such an invention.

---

**Table of Contents**

The agreement with MedImmune/AZ will expire in August 2006. Either party may opt out of a project, as MedImmune/AZ did with respect to the Hedgehog pathway project in November 2007, by giving six months' written notice to the other party. If one party gives such notice, the other party has 20 days to also opt-out of the project, in which case the parties will seek to out-license or sell the project assets or seek to otherwise maximize the value of the project. We did not elect to opt out of the Hedgehog pathway project. Upon expiration of the six month notice period, the opting-out party is no longer obligated to perform work under the research and development plan and marketing plan for the project, nor pay development costs for the project. Thus, MedImmune/AZ's research and funding obligations with respect to the Hedgehog pathway project terminate in May 2008. An opting-out party is no longer entitled to share profits arising from the project; instead, such party is entitled to receive royalties at a rate based on when such party opted out. MedImmune/AZ agreed to waive these royalties in connection with its decision to opt-out of the Hedgehog pathway project. The collaboration agreement terminates with respect to a project if both parties opt out. If a party materially breaches the agreement with respect to a project and does not cure the breach within a specified period of time, the breaching party is deemed to have opted-out of such project. If a party which opted-out of a project materially breaches the agreement and does not cure the breach within a specified period of time, the breaching party shall no longer be entitled to royalties or milestones with respect to such project. In addition, either party is permitted to terminate the collaboration agreement with respect to a product if it believes there are safety concerns with respect to such product and the parties do not agree on the course of action to be taken, in which case the terminating party gives up all rights in such product.

**Novartis.** In February 2006, we entered into a collaboration agreement with Novartis to discover, develop and commercialize drugs targeting Bcl protein family members for the treatment of a broad range of cancers. Under the terms of this agreement, we granted to Novartis an exclusive, worldwide license to research, develop and commercialize pharmaceutical products that are based upon our proprietary Bcl inhibitors. Novartis paid us a \$15 million up-front license fee, an affiliate of Novartis made a \$5 million equity investment in us, and Novartis committed to provide us research funding of approximately \$10 million over the initial two-year research term, which expired in February 2008. Pursuant to this agreement, we conducted joint research with Novartis to identify molecules for clinical development. For the year ended December 31, 2007, we recognized \$3.75 million in revenue related to the amortization of the up-front license fee and \$4.8 million in revenue related to the reimbursable research and development services we performed for Novartis under the agreement.

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 these one-year extensions; thus, Novartis now has responsibility for further pre-clinical, clinical development and commercialization of any products based upon compounds discovered under the joint research program. We may request to participate in clinical development of any such products and, if such request is agreed upon by Novartis, Novartis will fund agreed-upon development costs that are incurred by us. We also have a non-exclusive right to detail Bcl-2 family inhibitor products in the United States, with our detailing costs to be reimbursed by Novartis.

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

## **Table of Contents**

### **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.

Retaspimycin and related molecules are protected by U.S. Patent No. 7,282,493, which expires in March 2025. This patent includes composition of matter, pharmaceutical composition, method of treatment, and synthetic method claims. IPI-926 is protected by U.S. Patent No. 7,230,004, which expires in October 2025. In addition, as of February 29, 2008 we had approximately 145 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 2028.

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:

Kosan Biosciences Incorporated, which we believe is conducting a Phase 3 and multiple Phase 2 clinical trials of tanespimycin and a Phase 2 and multiple Phase 1 clinical trials of alvespimycin;

Biogen Idec Inc., which we believe is conducting a Phase 2 clinical trial of BIIB021;

Vernalis plc, which we believe is conducting a Phase 1 clinical trial of an Hsp90 inhibitor in collaboration with Novartis;

Serenex, Inc., which we believe is conducting two Phase 1 clinical studies of SNX-5422;

Synta Pharmaceuticals Corp., which we believe is conducting two Phase 1 clinical studies of STA-9090; and

Astex Therapeutics Limited, which we believe is conducting a Phase 1 clinical trial of AT-13387 in collaboration with Novartis.





## **Table of Contents**

In addition, we believe that Curis, Inc., in collaboration with Genentech Inc., is intending to advance its Hedgehog pathway antagonist into Phase 2 clinical development in advanced solid tumors in 2008. Exelixis, Inc. and Bristol-Myers Squibb Co. are jointly conducting preclinical development of XL139, a Hedgehog pathway inhibitor.

Finally, we believe that Gemin-X Biosciences is conducting clinical trials of one or more Bcl-2 inhibitors in multiple cancer indications, that Abbott Laboratories, Inc. (in collaboration with Genentech) is conducting a Phase 1/2 clinical trial of its Bcl-2 inhibitor, ABT-263, and that Ascenta Therapeutics, Inc. is in Phase 2 clinical development of AT-101, also a Bcl-2 inhibitor.

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 29, 2008, our research and development group consisted of 99 individuals, of whom over 40 percent hold Ph.D. or M.D. degrees and over 64 percent hold advanced degrees. Our research and development group is focusing on drug discovery, preclinical research, clinical trials and manufacturing technologies. Our research and development expense for the years ended December 31, 2007, 2006 and 2005 was approximately \$33.8 million, \$35.8 million and \$31.5 million, respectively. Our strategic collaborator-sponsored research and development expenses totaled approximately \$18.5 million, \$8.1 million and \$0 for the years ended December 31, 2007, 2006 and 2005, respectively. In calculating strategic collaborator-sponsored research and development expenses, we have included net reimbursement for our research and development efforts, excluding license fees. Our remaining research and development expense is company-sponsored.

## **Manufacturing and Supply**

We rely primarily on third parties 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. We do not currently have relationships for redundant supply or a second source for any of our drug candidates.

## **Sales and Marketing**

We currently have no marketing, sales or distribution capabilities. We do, however, have the right to co-promote in the United States any products arising from our collaborations with MedImmune/AZ and Novartis. In order to participate in the commercialization of these drugs if and when they are approved for sale in the United States, we will need to, and we intend to, develop these capabilities.

## **Government Regulation**

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

## **Table of Contents**

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

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

preclinical laboratory and animal tests performed under the FDA's Good Laboratory Practices regulations;

submission and acceptance of an IND application, which must become effective before clinical trials may begin in the United States;

adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug candidate for its intended use;

development of manufacturing processes which conform to FDA-mandated current Good Manufacturing Practices, or cGMPs; and

FDA review and approval of a New Drug Application, or NDA, prior to any commercial sale or shipment of a product.

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

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

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

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

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

Phase 1: The drug candidate is initially introduced into healthy human subjects or patients and tested for safety, dosage tolerance, bioavailability, absorption, distribution, excretion and metabolism. For cancer drugs such as those we are developing, this phase of study is generally conducted in patients.

Phase 2: The drug candidate is introduced into a limited patient population to: (1) assess the efficacy of the candidate in specific, targeted indications; (2) assess dosage tolerance and optimal dosage; and (3) identify possible adverse effects and safety risks.



---

## **Table of Contents**

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

## **Table of Contents**

rights of inspection. Failure of third party manufacturers to comply with cGMP or other FDA requirements applicable to our products may result in, among other things, total or partial suspension of production, failure of the government to grant approval for marketing, and withdrawal, suspension, or revocation of marketing approvals.

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

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

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

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

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

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

In the United States, if a product that has Orphan Drug designation receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for seven years. In the European Union, the period of product exclusivity is ten years. Orphan Drug exclusivity, however, also could block the approval of one of our products in the United States for seven years for an Orphan Drug indication if a competitor obtains approval of the same drug, as defined by the FDA, for such Orphan Drug indication or if our product candidate is determined to be contained within the

**Table of Contents**

competitor's product for the same indication or disease. We have obtained Orphan Drug designation for retaspimycin for GIST in both the United States and the European Union and intend to seek Orphan Drug status for our other product candidates as appropriate. Orphan Drug designation may not, however, provide us with a material commercial advantage.

**Other Regulatory Matters**

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

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

**Employees**

We refer to our employees as citizen-owners. As of February 29, 2008, we had 125 full-time citizen-owners, 99 of whom were engaged in research and development and 26 of whom were engaged in management, administration and finance. Over 60 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 29, 2008:

<b>Name</b>	<b>Age</b>	<b>Position</b>
Steven H. Holtzman	54	President, Chair and Chief Executive Officer
Julian Adams, Ph.D.	53	President of Research & Development and Chief Scientific Officer
Adelene Q. Perkins	48	Executive Vice President and Chief Business Officer

## **Table of Contents**

*Steven H. Holtzman* has served as Chief Executive Officer and as Chair of our board of directors since September 2006, and as our President since October 2007. Mr. Holtzman was a co-founder of Old Infinity and served as its Chief Executive Officer and Chair of its board of directors from 2001 until the merger. Mr. Holtzman also served as President of Old Infinity from July 2001 to February 2006. From 1994 to 2001, Mr. Holtzman served as Chief Business Officer of Millennium Pharmaceuticals, Inc., a publicly traded pharmaceutical company. From 1996 to 2001, Mr. Holtzman served as a presidential appointee to the National Bioethics Advisory Commission, the principal advisory body to the President and Congress on ethical issues in the biomedical and life sciences. Prior to joining Millennium Pharmaceuticals, Inc., from 1986 to 1994, Mr. Holtzman was a founder and Executive Vice President of DNX Corporation, a publicly traded biotechnology company. Mr. Holtzman is a director of Anadys Pharmaceuticals, Inc., a publicly traded biopharmaceutical company, and a trustee of The Hastings Center for Ethics and the Life Sciences and 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 Old Infinity from February 2006 until the merger and as Chief Scientific Officer of Old Infinity from October 2003 until the merger. Prior to joining Old Infinity, Dr. Adams served as Senior Vice President, Drug Discovery and Development with Millennium Pharmaceuticals, Inc. from 1999 to 2001. Dr. Adams served as Senior Vice President, Research and Development with LeukoSite Inc., a private biopharmaceutical company, from July 1999 until its acquisition by Millennium in December 1999. Dr. Adams served as a director and Executive Vice President of Research and Development with ProScript, Inc., a private biopharmaceutical company, from 1994 until its acquisition by LeukoSite in 1999. Prior to joining ProScript, Dr. Adams held a variety of positions with Boehringer Ingelheim, a private pharmaceutical company, and Merck & Co., Inc., a publicly traded pharmaceutical company. Dr. Adams received a B.S. from McGill University and a Ph.D. from the Massachusetts Institute of Technology in the field of synthetic organic chemistry.

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

## **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.

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 incorporate information on our website into this document by reference.



## **Table of Contents**

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

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

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

In September 2006, we completed our merger with Old Infinity. Upon completion of the merger, the business of the combined company became the one operated by Old Infinity prior to the merger. As a result, the risk factors set forth below discuss the business of the combined company after the merger, which includes a discussion of the business of Old Infinity prior to the merger. For a further discussion of the merger, please see Business Corporate Information above.

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

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

We have a limited operating history for you to evaluate our business. We have no approved products and have generated no product revenue. We have incurred operating losses since our inception. As of December 31, 2007, we had an accumulated deficit of \$172.5 million, and our net losses for the years ended December 31, 2007, 2006 and 2005 were \$16.9 million, \$28.4 million and \$36.4 million, respectively. We have spent, and expect to continue to spend, significant resources to fund the research and development of retaspimycin and our other drug candidates. We expect to incur substantial and increasing operating losses over the next several years as our research, development, preclinical testing, clinical trial and drug manufacturing activities increase. As a result, our accumulated deficit will also increase significantly.

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

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

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

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

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

**Table of Contents**

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 costs of acquiring raw materials for, and of manufacturing, our drug candidates are higher than anticipated;

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

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

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

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

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

***If our strategic alliances with MedImmune/AZ and Novartis are unsuccessful, our operations may be negatively impacted.***

We have entered into alliances with MedImmune/AZ to jointly develop and commercialize novel drugs targeting Hsp90 and with Novartis to develop and commercialize Bcl-2 protein family members for the treatment of cancer. In these alliances, our collaborators have committed to provide substantial funding, as well as significant capabilities in clinical development, regulatory affairs, marketing and sales. The success of these alliances is largely dependent on the resources, efforts, technology and skills brought to them by our partners. 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 either of these alliances will be reduced or eliminated if our partner:

terminates the agreement;

## Table of Contents

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

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

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

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

Under our agreement with MedImmune/AZ, MedImmune/AZ may opt out of a project, as it did with the Hedgehog pathway project in November 2007, at any time by giving us six months' prior written notice, and has the right to terminate the agreement under other circumstances, including if it believes there are safety concerns with respect to a drug being developed under the collaboration. Under our alliance agreement with Novartis, Novartis may terminate the alliance at any time upon 60 days' notice to us. If either MedImmune/AZ or Novartis were to exercise its right to opt out of a program or to terminate the applicable alliance, we may not have sufficient financial resources or capabilities to continue development and commercialization of products from our Hsp90 or Bcl-2 programs and our ability to attract new alliance partners would be made more difficult.

Much of the potential revenue from our existing and future alliances will consist of contingent payments, such as payments for achieving development and commercialization milestones, royalties payable on sales of any successfully developed drugs, and profit-sharing arrangements. The milestone, royalty and other revenue that we may receive under these alliances will depend upon our, and our alliance partners', ability to successfully develop, introduce, market and sell new products. In some cases, we will not be involved in these processes and, accordingly, will depend entirely on our alliance partners. Our alliance partners may fail to develop or effectively commercialize products using our products or technologies because they:

decide not to devote the necessary resources because of internal constraints, such as limited personnel with the requisite scientific expertise, limited cash resources or specialized equipment limitations, or the belief that other drug development programs may have a higher likelihood of obtaining regulatory approval or may potentially generate a greater return on investment;

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

cannot obtain the necessary regulatory approvals.

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

If our alliance partners fail to develop or effectively commercialize our drug candidates, we may not be able to develop and commercialize that drug independently, and our financial condition and operations would be negatively impacted.

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

We are highly dependent on our management team, particularly Steve Holtzman, Julian Adams, Adelene Perkins and the other members of our executive leadership team. All of these individuals are employees-at-will,



## **Table of Contents**

which means that neither Infinity nor the employee is obligated to a fixed term of service and that the employment relationship may be terminated by either Infinity or the employee at any time, without notice, and whether or not cause or good reason exists for such termination. The loss of the services of any of these individuals might impede the achievement of our research, development and commercialization objectives. We do not maintain key person insurance on any of our employees.

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

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

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

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

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

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

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

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

To date, we have not obtained approval from the FDA or any foreign regulatory authority to market or sell any of our drug candidates. Our success depends primarily upon our, and our strategic alliance partners', ability to develop and commercialize our drug candidates successfully. Our most advanced drug candidate is retaspimycin, which is currently in early clinical trials and is the subject of a broad product development and commercialization agreement with MedImmune/AZ. Our other drug candidates are in various stages of preclinical development and discovery research.

## **Table of Contents**

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

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

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

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

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

Our analysis of data obtained from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unanticipated delays or increased costs due to changes in government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review.

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

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

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

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

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

**Table of Contents**

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

delays in enrolling patients into clinical trials;

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

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

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

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

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

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

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

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

Clinical trials require sufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the trial protocol, the number of clinical trial sites and the proximity of patients to those sites, the availability of effective treatments for the relevant disease, the eligibility criteria for the trial, the commitment of clinical investigators to identify eligible patients, and competing studies or trials. Delays in patient enrollment can result in increased costs and longer development times. Our failure to enroll patients in our clinical trials could delay the completion of the clinical trial beyond current expectations. In addition, the FDA could require us to conduct clinical trials with a larger number of subjects than has been projected for any of our drug candidates. As a result of these factors, we may not be able to enroll a sufficient number of patients in a timely or cost-effective manner.

Furthermore, enrolled patients may drop out of clinical trials, which could impair the validity or statistical significance of the clinical trials. A number of factors can influence the patient discontinuation rate, including, but not limited to: the inclusion of a placebo arm in a trial; possible inactivity or low activity of the drug candidate being tested at one or more of the dose levels being tested; adverse side effects experienced, whether or not related to the drug candidate; and the availability of numerous alternative treatment options that may induce patients to discontinue their participation in the trial. We may suspend, or the FDA or other applicable regulatory authorities may require us to suspend, clinical trials of a drug candidate at any time if we or they believe the patients participating in such clinical trials, or in independent third party clinical trials for drugs based on similar technologies, are being exposed to unacceptable health risks or for other reasons.

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

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

## Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-K

In September 2007, the Food and Drug Administration Amendments Act of 2007, or FDAAA, was enacted. The FDAAA grants a variety of new powers to the FDA, many of which are aimed at improving the safety of



---

**Table of Contents**

drug products before and after approval. Under the FDAAA, companies that violate the new law are subject to substantial civil monetary penalties. While we expect the FDAAA to have a substantial effect on the pharmaceutical industry, the extent of that effect is not yet known. As the FDA issues regulations, guidance and interpretations relating to the new legislation, the impact on the industry, as well as our business, will become clearer. The new requirements and other changes that the FDAAA imposes may make it more difficult, and likely more costly, to obtain approval of new pharmaceutical products and to produce, market and distribute products after approval.

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

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

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

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

Our drug candidates require precise, high quality manufacturing. The third party manufacturers on which we rely may not be able to comply with the FDA's current good manufacturing practices, or cGMPs, and other applicable government regulations and corresponding foreign standards. These regulations govern manufacturing processes and procedures and the implementation and operation of systems to control and assure the quality of products. The FDA may, at any time, audit or inspect a manufacturing facility to ensure compliance with cGMPs. Any failure by our contract manufacturers to achieve and maintain high manufacturing and quality control standards could result in, among other things, patient injury or death, product liability claims, penalties or other monetary sanctions, the failure of regulatory authorities to grant marketing approval of our drug candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of drug candidates or products, operating restrictions and/or criminal prosecution, any of which could significantly and adversely affect supply of our drug candidates and seriously hurt our business. Contract manufacturers may also encounter difficulties involving production yields or delays in performing their services. We do not have control over third party manufacturers' performance and compliance with these applicable regulations and standards. If, for some reason, our manufacturers cannot perform as agreed, we may be unable to replace such third party manufacturers in a timely manner and the production of our drug candidates would be interrupted, resulting in delays in clinical trials and additional costs. Switching manufacturers may be difficult because the number of potential manufacturers is limited and, depending on the type of material manufactured at the contract facility, the change in contract manufacturer must be submitted to and/or approved by the FDA and comparable regulatory authorities outside of the United States. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our drug candidates after receipt of regulatory approval. It may be difficult or impossible for us to find a replacement manufacturer on acceptable terms quickly, or at all.

## **Table of Contents**

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

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

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

timing of market introduction of competitive drugs;

lower demonstrated clinical safety and efficacy compared to other drugs;

lack of cost-effectiveness;

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

inconvenient or difficult administration;

prevalence and severity of side effects;

potential advantages of alternative treatment methods;

safety concerns with similar drugs marketed by others;

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

ineffective sales, marketing and distribution support.

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

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

The FDA continues to review products even after they receive initial approval. If we receive approval to commercialize retaspimycin or any of our other drug candidates, the manufacturing, marketing and sale of these drugs will be subject to continuing regulation, including compliance with quality systems regulations, good manufacturing practices, adverse event requirements, and prohibitions on promoting a product for

## Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-K

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.

## **Table of Contents**

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

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

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

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

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

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

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

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

The prices of some drugs are lower in other countries than in the United States because of government price regulation and market conditions. Under current law, importation of drugs into the United States is generally not permitted unless the drugs are approved in the United States and the entity that holds that approval consents to

---

## **Table of Contents**

the importation. Various proposals have been advanced to permit the importation of drugs from other countries to provide lower cost alternatives to the products available in the United States. If the laws or regulations are changed to permit more widespread importation of drugs into the United States than is currently permitted, such a change could have an adverse effect on our business by making available lower priced alternatives to our future products.

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

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

## **Risks Related to Our Field**

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

We seek to develop new drugs for cancer and related conditions. The cancer therapeutic segment of the pharmaceutical industry is highly competitive and rapidly changing. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations are pursuing the development of novel drugs that target various forms of cancer. We currently face, and expect to continue to face, intense and increasing competition as new products enter the market and advanced technologies become available. Moreover, there are a number of large pharmaceutical companies currently marketing and selling products to treat cancer, including Bristol-Myers Squibb Company, F. Hoffmann-La Roche Ltd., Novartis Pharma AG and Genentech, Inc. In addition to currently approved drugs, there are a significant number of drugs that are currently under development and may become available in the future for the treatment of various forms of cancer. We are also aware of a number of companies seeking to develop drug candidates directed to the same biological targets that our own drug candidates are designed to inhibit. Specifically, we are aware of numerous companies that have programs seeking to develop compounds that target Hsp90, which is the target of retaspimycin and IPI-493. These companies include, without limitation, Kosan Biosciences Incorporated, Biogen Idec Inc., Serenex, Inc., Vernalis plc (in collaboration with Novartis), Synta Pharmaceuticals Corp. and Astex Therapeutics Limited (in collaboration with Novartis). In addition, Curis, Inc. (in collaboration with Genentech) and Exelixis, Inc. (in collaboration with Bristol-Myers Squibb) have collaborations under which drugs targeting the Hedgehog signaling pathway, which is also being targeted by IPI-926, are being developed. Abbott Laboratories (in collaboration with Genentech), Gemin-X Biosciences and Ascenta Therapeutics are believed to be in early-stage development of compounds to target the Bcl-2 family of proteins, which is the target of one of our discovery programs.

Many of our competitors have:

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

## **Table of Contents**

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

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

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

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

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

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

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

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

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

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

We own or hold exclusive licenses to a number of U.S. and foreign patents and patent applications directed to our drug candidates. Our success depends on our ability to obtain patent protection both in the United States and in other countries for our drug candidates, their methods of manufacture and their methods of use. Our ability to protect our drug candidates from unauthorized or infringing use by third parties depends substantially on our ability to obtain and enforce our patents.

---

**Table of Contents**

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

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

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

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

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

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

---

## **Table of Contents**

For example, we are aware of third parties who are actively researching ansamycin analogs that are similar to our lead candidate, retaspimycin. These third parties have pending applications related to these analogs, but we have the first published application covering retaspimycin. It is possible that an interference proceeding could be declared between our application covering retaspimycin and one or more of these third party applications. An adverse decision in an interference proceeding may result in the loss of rights under a patent or patent application. In addition, the cost of interference proceedings could be substantial.

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

Our commercial success will depend on whether there are third party patents or other intellectual property relevant to our potential products that may block or hinder our ability to develop and commercialize our drug candidates. We may not have identified all U.S. and foreign patents or published applications that may affect our business either by blocking our ability to commercialize our drugs or by covering similar technologies that affect the applicable market. In addition, we may undertake research and development with respect to potential products, even when we are aware of third party patents that may be relevant to such potential products, on the basis that we may challenge or license such patents. For example, in our Hsp90 program, we have initiated a clinical trial evaluating the administration of retaspimycin in combination with Taxotere, and we may conduct additional trials with retaspimycin in combination with other therapeutic agents. We are aware of issued patents and published applications directed to combinations of Hsp90 inhibitors with a variety of other chemotherapeutic agents. We are also aware of patents and patent applications directed to methods of treating various disorders using a variety of Hsp90 inhibitors. We are in the process of evaluating the scope and validity of these patents and applications to determine whether we need to obtain one or more licenses. While we are not currently aware of any litigation or third party claims of intellectual property infringement related to our drug candidates, the pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents and claim that the use of our technologies infringes these patents or that we are employing their proprietary technology without authorization. We could incur substantial costs and diversion of management and technical personnel in defending against any claims that the manufacture and sale of our potential products or use of our technologies infringes any patents, or defending against any claim that we are employing any proprietary technology without authorization. The outcome of patent litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of the adverse party, especially in biotechnology related patent cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. In the event of a successful claim of infringement against us, we may be required to:

pay substantial damages;

stop developing, commercializing and selling the infringing drug candidates or approved products;

develop non-infringing products, technologies and methods; and

obtain one or more licenses from other parties, which could result in our paying substantial royalties or the granting of cross-licenses to our technologies.

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

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

Competitors may infringe our patents. To prevent infringement or unauthorized use, we may need to file infringement suits, which are expensive and time-consuming. In an infringement proceeding, a court may decide that one or more of our patents is not valid and/or enforceable. Even if the validity of our patents is upheld, a court may refuse to stop the other party from using the technology at issue on the ground that the other party s





## **Table of Contents**

activities are not covered by our patents. In this case, third parties may be able to use our patented technology without paying licensing fees or royalties. Policing unauthorized use of our intellectual property is difficult, and we may not be able to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States. In addition, third parties may affirmatively challenge our rights to, or the scope or validity of, our patent rights. We have not, however, received any communications from third parties challenging our patent applications covering our drug candidates.

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

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

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

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

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

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

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

### **Risks Associated with Our Common Stock**

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

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

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

**Table of Contents**

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

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

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

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

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

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

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

the results of clinical trials conducted by others on drugs that would compete with our drug candidates;

issues in manufacturing our drug candidates or any approved products;

the loss of key employees;

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

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

changes in the structure of health care payment systems; and

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

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

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

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

## Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-K

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

## **Table of Contents**

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

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

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

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

Our executive officers, directors, and other affiliates control approximately 27% 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 our company;

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

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

### **Item 1B. Unresolved Staff Comments**

There were no unresolved comments from the Staff of the U.S. Securities and Exchange Commission at December 31, 2007.

### **Item 2. Properties**

We lease a facility that contains approximately 67,000 square feet of laboratory and office space in Cambridge, Massachusetts. The lease has a term ending in December 2012. We currently sublease approximately 16,000 square feet of this space under a sublease agreement that expires in November 2009 and for which the subtenant has extension options through December 2012. Should we require additional space, we believe that a suitable facility would be available to accommodate expansion of our operations on commercially reasonable terms.

### **Item 3. Legal Proceedings**

We are not a party to any material legal proceedings.

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

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

No matters were submitted to a vote of our security holders, through solicitation of proxies or otherwise, during the last quarter of the year ended December 31, 2007.

**Table of Contents****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, all as adjusted for the 1-for-4 reverse stock split effected on September 12, 2006. Such quotations represent inter-dealer prices without retail mark up, mark down or commission and may not necessarily represent actual transactions.

	2007		2006	
	High	Low	High	Low
First quarter	\$ 15.00	\$ 10.66	\$ 10.96	\$ 9.36
Second quarter	12.07	10.37	11.36	9.36
Third quarter	11.42	8.48	17.05	10.32
Fourth quarter	10.84	8.94	15.74	11.58

 **Holders**

As of February 29, 2008, there were 135 holders of record of our common stock.

 **Dividends**

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

 **Use of Proceeds**

The registration statement (File No. 333-36638) for DPI's initial public offering was declared effective by the U.S. Securities and Exchange Commission on July 27, 2000. DPI received net proceeds from the offering of approximately \$94.7 million. From that date through the completion of the reverse merger on September 12, 2006, DPI used approximately \$18.5 million of the net proceeds for acquisitions of companies, \$6.0 million for prepaid  $\mu$ ARCS royalties, \$16.8 million for capital expenditures and \$4.3 million for costs associated with restructuring. From the completion of the merger through December 31, 2007, we used approximately \$23.2 million on our Hsp90 and Hedgehog pathway inhibitor programs and for general corporate purposes.

 **Comparative Stock Performance Graph**

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

The graph below shows a comparison of cumulative total stockholder returns from December 31, 2002 through December 31, 2007 for our common stock, the NASDAQ Stock Market (U.S. Companies) Index and the NASDAQ Biotechnology Index. The graph assumes that \$100 was invested in our common stock and in each index on December 31, 2002, and that all dividends were reinvested. No cash dividends have been declared or paid on our common stock.

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

**Table of Contents**

**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**

35



**Table of Contents****Item 6. Selected Financial Data**

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

	Year Ended December 31,				
	2007	2006	2005	2004	2003
<b>Statement of Operations Data:</b>					
Revenue	\$ 24,536	\$ 18,494	\$ 522	\$	\$ 152
Operating expenses:					
Research and development	33,793	35,792	31,460	28,396	24,405
General and administrative	14,034	9,464	5,530	5,290	7,777
Restructuring expenses					1,296
Total costs and expenses	47,827	45,256	36,990	33,686	33,478
Loss from operations	(23,291)	(26,762)	(36,468)	(33,686)	(33,326)
Interest income (expense), net	6,393	953	99	(402)	(524)
Debt extinguishment charge		(1,551)			
Loss before income taxes	(16,898)	(27,360)	(36,369)	(34,088)	(33,850)
Income taxes		(1,088)			
Net loss	\$ (16,898)	\$ (28,448)	\$ (36,369)	\$ (34,088)	\$ (33,850)
Basic and diluted net loss per common share(1)	\$ (0.87)	\$ (3.81)	\$ (17.01)	\$ (18.72)	\$ (26.33)
Basic and diluted weighted average number of common shares outstanding(1)	19,511,485	7,463,426	2,138,331	1,821,285	1,285,863

- (1) Basic and diluted net loss per common share and weighted average shares outstanding were impacted by the conversion of preferred stock and issuance of common stock in connection with the DPI merger on September 12, 2006.

	As of December 31,				
	2007	2006	2005	2004	2003
<b>Selected Balance Sheet Data:</b>					
Cash, cash equivalents and available-for-sale securities	\$ 114,189	\$ 101,697	\$ 10,946	\$ 44,548	\$ 52,517
Working capital	97,097	121,264	2,468	38,051	47,391
Total assets	129,725	154,648	24,451	61,966	67,756
Long-term debt and capital leases	20	374	2,041	4,047	5,763
Accumulated deficit	(172,546)	(155,305)	(126,857)	(90,488)	(56,400)
Total stockholders' equity	51,143	62,425	10,174	45,831	54,458

---

## **Table of Contents**

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

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

#### **DPI Merger**

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

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

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

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

#### **Business Overview**

Our mission is to discover, develop, and deliver to patients best-in-class medicines for the treatment of cancer and related conditions. A best-in-class drug refers to a drug, among all drugs within a class of drugs that operate through a particular target or molecular mechanism in the body to affect a particular disease, that is superior to all of the other drugs in the class by virtue of its superior efficacy, superior safety, ease of administration, or some combination of the foregoing. We have built a pipeline of innovative product candidates for multiple cancer indications, all of which represent proprietary applications of our expertise in small molecule

---

## **Table of Contents**

drug technologies. We believe that our small molecule discovery and development capabilities, strategic alliances, team of highly experienced management and scientists, and corporate culture form the basis of our potential long-term competitive advantage in seeking to deliver best-in-class medicines to patients.

Our lead product candidate, retaspimycin hydrochloride for injection (formerly known as IPI-504), or retaspimycin, is an intravenously administered small molecule inhibitor of heat shock protein 90, or Hsp90. Hsp90 is a molecule that maintains the structure and activity of specific proteins, known as client proteins of Hsp90; specific mutations in, or the aberrant expression of, these client proteins result in many types of cancer. Hsp90 enables the survival of the cancer cell by allowing the client protein to continue functioning. We believe that the inhibition of Hsp90 has broad therapeutic potential for patients with solid tumors and blood-related cancers, including those that are resistant to other drugs. As of February 29, 2008, retaspimycin is being evaluated as a single agent in three disease-focused clinical trials, including a Phase 1 trial in patients with metastatic and/or unresectable gastrointestinal stromal tumors (GIST) and other soft tissue sarcomas, the Phase 2 portion of a Phase 1/2 trial in patients with advanced non-small cell lung cancer (NSCLC), and a Phase 2 trial in patients with hormone-resistant prostate cancer (HRPC). We are also conducting a Phase 1b clinical trial of retaspimycin in combination with Taxotere® (docetaxel) in patients with advanced solid tumors. We currently expect to initiate additional clinical trials of retaspimycin during 2008, including a Phase 3 clinical trial in GIST in the third quarter of 2008 pending ongoing consultation with advisors and regulatory authorities and analysis of data from the ongoing Phase 1 trial, and one or more Phase 2 clinical trials in additional solid tumor indications. We also intend to begin a Phase 1 clinical trial of IPI-493, an orally available inhibitor of Hsp90, in the second quarter of 2008. We are pursuing our Hsp90 program in collaboration with MedImmune, Inc., a division of AstraZeneca plc. We use the term MedImmune/AZ to identify our Hsp90 collaborator.

Our next most advanced program is directed against the Hedgehog signaling pathway, or Hedgehog pathway. Normally, the Hedgehog pathway regulates tissue and organ formation during embryonic development. When abnormally activated during adulthood, however, the Hedgehog pathway is believed to play a central role in allowing the proliferation and survival of certain cancer-causing cells, and is implicated in many of the most deadly cancers. The lead candidate in our Hedgehog pathway program, IPI-926, has shown potent and selective inhibition of the Hedgehog pathway as well as anti-tumor activity in preclinical models. We intend to file an investigational new drug, or IND, application for IPI-926 by the third quarter of 2008 and to commence a Phase 1 clinical trial shortly thereafter.

We also have other research programs that target cancer and related conditions, including a program being conducted in collaboration with the Novartis Institutes for BioMedical Research, or Novartis, to identify small molecule compounds that inhibit the Bcl-2 family of proteins.

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

## **Collaboration Agreements**

In August 2006, we entered into a product development and commercialization agreement with MedImmune/AZ to jointly develop and commercialize cancer drugs targeting Hsp90 and the Hedgehog pathway. Under the terms of this agreement, we share equally with MedImmune/AZ all development costs, as well as potential profits and losses, from any future marketed products. MedImmune/AZ made non-refundable, up-front payments totaling \$70 million to us in order to obtain co-exclusive rights to the Hsp90 and Hedgehog pathway development programs. In November 2007, we regained from MedImmune/AZ all development and worldwide commercialization rights under our Hedgehog pathway program on a royalty-free basis, and

## **Table of Contents**

MedImmune/AZ's funding obligations under this program will end in May 2008. We continue to collaborate with MedImmune/AZ on our Hsp90 program, and could receive up to \$215 million in milestone payments if certain late-stage development and sales objectives are achieved for products resulting arising from that program. If any products are successfully developed under the collaboration, we have the right to co-promote these products in the United States, with our promotional costs being included among those that are shared under the collaboration. We may opt-out of the Hsp90 program, in which case we would receive a royalty on sales of any products arising from the program instead of profits and losses.

In February 2006, we entered into a collaboration agreement with Novartis to discover, develop and commercialize drugs targeting Bcl protein family members for the treatment of a broad range of cancers. Novartis paid us a \$15 million up-front license fee, an affiliate of Novartis made a \$5 million equity investment in us, and Novartis committed to provide us research funding of approximately \$10 million over the initial two-year research term, which expired in February 2008. Novartis had the right to extend the research term for up to two additional one-year terms, under which Novartis could have obligated us to provide up to five full-time equivalents, at Novartis' expense, to enable the full transition of the Bcl inhibitor program to Novartis. Novartis chose not to exercise its option for these one-year extensions; thus, the research term ended in February 2008 and we have no further performance obligations to Novartis. As a result, we expect to recognize \$8.1 million of the up-front license fee as revenue in the year ended December 31, 2008. 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. Once a clinical candidate is identified under the collaboration, we may request to participate in clinical development 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.

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

## **Financial Overview**

### ***Revenue***

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

## **Table of Contents**

### ***Research & Development Expense***

Since inception, we have focused on drug discovery and development programs, with particular emphasis on cancer drugs. Our primary research and development programs include:

Retaspimycin, an Hsp90 inhibitor that is currently in clinical development for metastatic and/or unresectable GIST, advanced NSCLC, hormone-resistant prostate cancer and malignant melanoma;

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

IPI-926, the lead candidate in our Hedgehog pathway inhibitor program, for which we have commenced IND-enabling studies, and

our Bcl-2 program.

Our Hsp90 program is being conducted in collaboration with MedImmune/AZ and our Bcl-2 program is being conducted in collaboration with Novartis. We previously had collaborated with MedImmune/AZ on our Hedgehog pathway inhibitor program, but MedImmune/AZ elected to opt out of participation in that program in November 2007.

Our research and development expense primarily consists of the following:

compensation of personnel associated with research activities, including consultants and contract research organizations;

laboratory supplies and materials;

manufacturing drug candidates for preclinical testing and clinical studies;

preclinical testing costs, including costs of toxicology studies;

fees paid to professional service providers for independent monitoring and analysis of our clinical trials;

depreciation of equipment; and

allocated costs of facilities.

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

### ***General & Administrative Expense***

## Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-K

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

### *Other Income & Expense*

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

## **Table of Contents**

### **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 drug development costs, assumptions in the valuation of stock-based compensation and income taxes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ from those estimates. We believe that the following accounting policies and estimates are most critical to aid you in understanding and evaluating our reported financial results.

#### ***Revenue Recognition***

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

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

We recognize revenues from non-refundable, up-front license fees on a straight-line basis over the contracted or estimated period of performance, which is typically the research or development term. We recognize research and development funding as earned over the period of effort. We regularly consider whether events warrant a change in the estimated period of performance under an agreement. Such a change would cause us to modify the period of time over which we recognize revenues from the up-front license fees paid to us under that agreement and would, in turn, result in changes in our quarterly and annual results. Through December 31, 2007, we have not made any such changes.

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

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

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.

---

**Table of Contents*****Research and Development Expense***

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

***Accrued Drug Development Costs***

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves identifying services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date. Examples of services for which we must estimate accrued expenses include service fees paid to contract manufacturers in conjunction with the production of clinical drug supplies and to contract research organizations and clinical trial sites in connection with preclinical studies and clinical trials. In connection with these service fees, our estimates are 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 underestimate 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 extent of services performed on or before a given date, and the cost of such services. We make these judgments based upon the facts and circumstances known to us. To date, we believe that have been able to reasonably estimate these costs. As the activities being performed by external service providers increase, such as for additional clinical trials and drug manufacturing activities, it will become increasingly difficult for us to estimate these costs, and our estimates of expenses for future periods may, consequently, be over- or underaccrued.

***Stock-Based Compensation***

We adopted Financial Accounting Standards Board Statement No. 123(R), *Share-Based Payment* ( SFAS No. 123(R) ), as of January 1, 2006 using the modified prospective method. SFAS No. 123(R) revises FAS Statement No. 123, *Accounting for Stock-Based Compensation* ( SFAS 123 ), supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees* ( APB 25 ), and amends FAS Statement No. 95, *Statement of Cash Flows*. SFAS No. 123(R) requires companies to expense the fair value of employee stock options and other equity compensation. Through December 31, 2005, we elected to follow APB 25 and related interpretations in accounting for our share-based compensation plans for employees, rather than the alternative fair value method provided for under SFAS No. 123. Accordingly, when options granted to employees had an exercise price equal to the fair market value on the date of grant, no compensation expense was recognized in our financial statements, and we disclosed in the notes to our financial statements pro forma disclosures in accordance with SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure* (an amendment of SFAS No. 123). Through December 31, 2005, we accounted for transactions in which services are received from non-employees in exchange for equity instruments based on the fair value of such services received or of the equity instruments issued, whichever is more reliably measured, in accordance with SFAS No. 123 and EITF Issue No. 96-18, *Accounting for Equity Instruments that Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*.



---

## **Table of Contents**

Accounting for equity instruments granted or sold by us under APB 25, SFAS No. 123, SFAS No. 123(R) and EITF Issue No. 96-18 requires fair value estimates of the equity instrument granted or sold. If our estimates of the fair value of these equity instruments are too high or too low, our expenses may be over- or understated.

Prior to the completion of the DPI merger in September 2006, our common stock had never been publicly traded. Prior to that date, the fair value of our common stock for accounting purposes was determined by Old Infinity's board of directors with input from management. Because we were not profitable and did not have significant revenue, we believed that a key factor in determining changes in the fair value of our common stock was the stage of, and changes in, our clinical pipeline. In the biotechnology and pharmaceutical industries, the progression of a drug candidate from preclinical development into clinical trials and the progression from one phase of clinical trials to the next may increase the enterprise's fair value. In addition to this factor, Old Infinity's board of directors determined the fair market value of our common stock based on other objective and subjective factors, including:

its knowledge and experience in valuing early-stage life sciences companies;

comparative values of public companies, discounted for the risk and limited liquidity provided for in the shares subject to the options we had issued;

pricing of private sales of our preferred stock;

prior valuations of stock grants;

the effect of events that had occurred between the times of such determinations; and

economic trends in the biotechnology and pharmaceutical industries specifically, and general economic trends.

From December 31, 2005 until the closing of the merger, in addition to the foregoing factors, the board of directors considered contemporaneous estimations of the fair value of our common stock using the Probability-Weighted Expected Return method, as of December 31, 2005, and again as of March 10, 2006 to estimate the increase in our value created by our collaboration with Novartis. These valuation analyses and the resulting estimates of our enterprise value were based on the market valuation method, specifically the guideline company approach. The enterprise value was allocated to the different classes of our equity instruments using the Probability-Weighted Expected Return method. Upon the announcement of the proposed merger with DPI on April 11, 2006, Old Infinity's board of directors began considering the price of DPI's common stock in determining fair market value.

We use our judgment in determining the fair value of stock options, including selecting the inputs we use in the Black-Scholes valuation model. Equity instrument valuation models are by their nature highly subjective. Any significant changes in any of our judgments, including those used to select the inputs for the Black-Scholes valuation model, could have a significant impact on the fair value of the equity instruments granted or sold and the associated compensation charge 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 the 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. Effective January 1, 2007, we adopted Financial Accounting Standards Board (FASB) Interpretation No. 48, *Accounting for Uncertainty in Income Taxes-an Interpretation of FASB Statement No. 109* (FIN 48). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, *Accounting for Income Taxes*, or SFAS 109. FIN 48 also prescribes a recognition threshold and measurement attribute for the financial statement



---

**Table of Contents**

recognition and measurement of each tax position taken or expected to be taken in a tax return. We consider many factors when evaluating and estimating our tax positions and tax benefits, which requires periodic adjustments and may not accurately forecast actual outcomes.

***New Accounting Pronouncements***

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

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

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

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

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

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

In December 2007, the FASB ratified the consensus reached by the EITF on EITF Issue 07-1, *Accounting for Collaborative Arrangements* ( EITF 07-1 ). EITF 07-1 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from, or made to, other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, EITF 07-1 clarified that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to EITF 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)*. EITF 07-1 will be effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. We are currently evaluating the effect of EITF 07-1 on our consolidated financial statements.

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

In February 2007, the EITF issued EITF 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* ( EITF 07-3 ). In EITF 07-3, the task force reached a consensus that nonrefundable advance payments for goods or services to be received in the future

**Table of Contents**

for use in research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services are performed. EITF 07-3 is effective for new contracts entered into during fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. We do not believe that EITF 07-3 will have a material impact on our financial position or results of operations.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, ( SFAS No. 157 ). SFAS No. 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS No. 157 codifies the definition of fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, clarifies the principle that fair value should be based on the assumptions market participants would use when pricing the asset or liability, and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007. We do not believe that SFAS No. 157 will have a material impact on our financial position or results of operations.

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

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

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

***Revenue***

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

\$10.0 million associated with the amortization of the up-front license fee received from MedImmune/AZ upon entry into our strategic alliance 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 under our technology access agreement.

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

\$3.3 million associated with the amortization of the up-front license fee received from MedImmune/AZ upon entry into our strategic alliance in August 2006;

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

\$2.5 million in license fees received upon the amendment of our technology access agreement with Amgen in July 2006;

**Table of Contents**

\$3.1 million related to the amortization of the non-refundable license fee, and \$4.1 million related to the reimbursable research and development services we performed, under our Bcl-2 collaboration entered into with Novartis in February 2006;

\$4.5 million related to the acceptance of compounds by Novartis International under our technology access agreement, and

\$1.0 million related to the acceptance of compounds to J&J under our technology access agreement.

*Research and Development Expense*

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

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

an increase of \$4.0 million in drug development costs as our Hsp90 and Hedgehog programs have advanced; and

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

The following table sets forth our estimates of research and development expenses, by program, over the last two years. These expenses primarily relate to payroll and related expenses for personnel working on the programs, drug development and manufacturing, preclinical toxicology studies and clinical trial costs. In addition, for the Hsp90 and Hedgehog pathway inhibitor programs, these expenses include credits of approximately \$13.7 million for the year ended December 31, 2007, and \$4.0 million for the year ended December 31, 2006, attributable to amounts reimbursable by MedImmune/AZ following entry into our collaboration agreement in August 2006. We did not track research and development expense by program in the year ended December 31, 2005. Those expenses were, however, largely related to our Hsp90 program.

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

We do not believe that the historical costs associated with our lead drug development programs are indicative of the future costs associated with these programs or represent what any other future drug development program we initiate may cost. We expect our Hsp90 program expenses to increase as we advance retaspimycin into additional, and later stage, clinical trials and as IPI-493 enters clinical development. In addition, we expect expenses for our Hedgehog pathway inhibitor program to increase as IPI-926 enters clinical development, and as a result of MedImmune/AZ not funding half of the expenses of this program after May 2008. Because of the risks inherent in drug discovery and development, we cannot reasonably estimate or know:

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

the anticipated completion dates of these programs; or

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

## **Table of Contents**

A further discussion of some of the risks and uncertainties associated with completing our drug development programs on schedule, or at all, and the potential consequences of failing to do so, are set forth in Part I of this report under the heading Risk Factors. Any failure by us or one of our strategic alliance partners to complete any stage of the development of any potential products in a timely manner could have a material adverse effect on our results of operations and financial position.

### *General and Administrative Expense*

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

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

an increase of \$1.3 million in patent costs, tax service expense, and miscellaneous tax expense, including state franchise taxes.

### *Interest Expense*

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

### *Interest and Investment Income*

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

### *Debt Extinguishment Charge*

In connection with the early retirement of our outstanding indebtedness to Oxford and Horizon in December 2006, we recorded a debt extinguishment charge of approximately \$1.6 million during the year ended December 31, 2006. This debt extinguishment charge represents the write-off of the unamortized portion of the warrants that we issued to Oxford and Horizon when we originally entered into these debt facilities, as well as a 4% prepayment penalty.

### *Income Taxes*

Our income tax expense of approximately \$1.1 million for the year ended December 31, 2006 relates to the alternative minimum tax driven by new collaborations we entered into during the year ended December 31, 2006. We did not incur any income tax expense in 2007, and we do not expect to incur income tax expense in 2008.



**Table of Contents****Comparison of the Years Ended December 31, 2006 and 2005**

The following table summarizes our results of operations for the years ended December 31, 2006 and 2005, in thousands, together with the change in each item in dollars and as a percentage.

	For the Years Ended December 31,			
	2006	2005	\$ Change	% Change
Revenue	\$ 18,494	\$ 522	\$ 17,972	3,443%
Research and development expense	(35,792)	(31,460)	(4,332)	14%
General and administrative expense	(9,464)	(5,530)	(3,934)	71%
Interest expense	(1,507)	(784)	(723)	92%
Interest and investment income	2,460	883	1,577	179%
Debt extinguishment charge	(1,551)		(1,551)	N/A
Income taxes	(1,088)		(1,088)	N/A

*Revenue*

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

\$3.3 million associated with the amortization of the up-front license fee received from MedImmune/AZ upon entry into our strategic alliance in August 2006;

\$2.5 million in license fees received upon the amendment of our technology access agreement with Amgen in July 2006;

\$3.1 million related to the amortization of the non-refundable license fee, and \$4.1 million related to the reimbursable research and development services we performed, under our Bcl-2 collaboration entered into with Novartis in February 2006;

\$4.5 million related to the acceptance of compounds by Novartis International under our technology access agreement, and

\$1.0 million related to the acceptance of compounds by J&J under our technology access agreement.

Our revenue during the year ended December 31, 2005 related entirely to the acceptance of compounds by J&J under our technology access agreement.

*Research and Development Expense*

Research and development expenses represented approximately 79% and 85% of our total operating expenses for the years ended December 31, 2006 and 2005, respectively.

The increase in research and development expenses for the year ended December 31, 2006 as compared to the year ended December 31, 2005 was primarily attributable to:

an increase of \$3.4 million in compensation and benefits, including SFAS No. 123(R) stock-based compensation, for our research and development personnel; and

## Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-K

an increase of \$3.3 million in external costs for toxicology studies and clinical trials of retaspimycin and our Hedgehog pathway inhibitor compounds.

During the year ended December 31, 2006, our research and development expense included a credit of approximately \$4.0 million attributable to amounts reimbursable by MedImmune/AZ under the cost-sharing provisions of our collaboration agreement, as well as a \$0.9 million asset impairment charge taken in the fourth quarter of 2006 with respect to certain laboratory equipment that we were no longer using.

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

The increases in general and administrative expense for the year ended December 31, 2006 as compared to year ended December 31, 2005 were primarily attributable to:

an increase of \$1.9 million in compensation and benefits, including SFAS No. 123(R) compensation expense for general and administrative employees, and new employees we hired in anticipation of becoming a public company; and

an increase of \$1.9 million in outside service fees, including audit, legal and consulting, primarily related to our becoming a public company and becoming compliant with Section 404 of the Sarbanes-Oxley Act.

*Interest Expense*

Interest expense increased in the year ended December 31, 2006 as compared to the year ended December 31, 2005 primarily as a result of borrowings made in 2006 under our debt facilities with Oxford and Horizon. We repaid in full all of our outstanding debt to Oxford and Horizon in December 2006.

*Interest and Investment Income*

Interest and investment income increased in the year ended December 31, 2006 as compared to the year ended December 31, 2005 primarily as a result of our higher balance of cash and available-for-sale securities at December 31, 2006. The increased cash and available-for-sale securities balance was primarily attributable to amounts we received upon completion of the merger, up-front license fees received from MedImmune/AZ and Novartis in connection with our collaborations, and proceeds from the issuance of preferred stock.

**Liquidity and Capital Resources**

We have not generated any revenue from the sale of drugs to date, and we do not expect to generate any such revenue for the next several years, if at all. We have instead relied on the proceeds from sales of equity securities, interest and income on cash, cash equivalents and available-for-sale securities, license fees, expense reimbursement under our collaborations, contract service payments and debt to fund our operations. Because our drug candidates are at an early stage of clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our drug candidates or whether, or when, we may achieve profitability.

Our cash, cash equivalents, available-for-sale securities and working capital are as follows:

	December 31, 2007	December 31, 2006
Cash, cash equivalents and available-for-sale securities	\$ 114,189,468	\$ 101,696,784
Working capital	97,097,370	121,264,233

	Years ended December 31,		
	2007	2006	2005
Cash provided by (used in):			
Operating activities	\$ 12,082,295	\$ 9,615,770	\$ (27,336,366)
Investing activities	(62,004,999)	13,479,706	15,576,370
Capital expenditures (included in investing activities above)	(2,405,677)	(946,565)	(2,348,250)
Financing activities	(1,060,054)	41,609,247	(3,431,127)

**Cash Flows**

The principal use of cash in operating activities in all of the periods presented was the funding of our net loss. Cash flows from operations can vary significantly due to various factors, including changes in accounts receivable and unbilled accounts receivable, as well as changes in

accounts payable, accrued expenses and deferred revenue.

---

**Table of Contents**

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

Cash flow from operations for the year ended December 31, 2006 included an increase of \$77.5 million in deferred revenue due to the collaboration agreements with MedImmune/AZ and Novartis. In September 2006, we received \$35.0 million from MedImmune/AZ, representing the first half of the up-front license fee related to our collaboration agreement. In February 2006, we received \$15.0 million from Novartis for the up-front license fee related to our collaboration agreement.

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

We believe that our cash, cash equivalents and available-for-sale securities at December 31, 2007 will be sufficient to support our current operating plan into 2010. Our currently-planned operating and capital requirements primarily include the need for working capital to, among other things:

continue clinical development of retaspimycin;

perform preclinical work on, and commence clinical development of, IPI-493;

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

advance our additional discovery programs.

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

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

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

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

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

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

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

we acquire or license rights to additional drug candidates or new technologies from one or more third parties. While we expect to seek additional funding through public or private financings of equity or debt securities, we may not be able to obtain financing on acceptable terms, or at all. In addition, the terms of our financings may be dilutive to, or otherwise adversely affect, holders of our common stock, or they may impact our ability to

**Table of Contents**

make capital expenditures or incur additional debt. We may also seek additional funds through arrangements with collaborators or other third parties, or through project financing. These arrangements would generally require us to relinquish or encumber rights to some of our technologies or drug candidates, and we may not be able to enter into such agreements on acceptable terms, if at all. If we are unable to obtain additional funding on a timely basis, we may be required to curtail or terminate some or all of our development programs, including some or all of our drug candidates.

**Contractual Obligations**

As of December 31, 2007, we had the following contractual obligations:

Contractual Obligations	Payments Due by Period (in thousands)						2013 and beyond
	Total	2008	2009	2010	2011	2012	
Equipment loans and capital leases, including interest	\$ 408	\$ 391	\$ 6	\$ 6	\$ 5	\$	\$
Software contract obligation	300	150	150				
Operating lease obligations	23,183	4,447	4,580	4,718	4,859	4,579	
Total contractual cash obligations	\$ 23,891	\$ 4,988	\$ 4,736	\$ 4,724	\$ 4,864	\$ 4,579	\$

In addition to the contractual obligations in the table above, long-term liabilities for unrecognized tax benefits and related accrued interest totaling approximately \$0.6 million at December 31, 2007 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, asset-backed securities, corporate obligations and U.S. government-sponsored enterprise obligations. We do not enter into investments for trading or speculative purposes. Our cash is deposited in and invested through highly rated financial institutions in North America. Our marketable securities are subject to interest rate risk and will fall in value if market interest rates increase.

A hypothetical 100 basis point increase in interest rates would result in an approximate \$322,742 decrease in the fair value of our investments as of December 31, 2007. We have the ability to hold our fixed income investments until maturity and, therefore, we do not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments.

**Table of Contents**

**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, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2007. 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, 2007 and 2006, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2 to the consolidated financial statements, effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123(R), *Share-Based Payment*. Additionally, as discussed in Note 2 to the consolidated financial statements, effective January 1, 2007, the Company adopted Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - an Interpretation of FASB Statement No. 109*, and Emerging Issues Task Force No. 06-2, *Accounting for Sabbatical Leave and Other Similar Benefits Pursuant to FASB Statement No. 43*.

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, 2007, 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, 2008 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Boston, Massachusetts

March 11, 2008



**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Consolidated Balance Sheets**

	December 31,	
	2007	2006
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 23,164,721	\$ 74,147,479
Available-for-sale securities	91,024,747	27,549,305
Accounts receivable	812,500	1,409,646
Unbilled accounts receivable	4,287,736	40,725,164
Notes receivable from employees	53,414	87,257
Prepaid expenses and other current assets	2,496,814	2,179,702
<b>Total current assets</b>	<b>121,839,932</b>	<b>146,098,553</b>
Property and equipment, net	5,984,711	6,539,930
Notes receivable from employees	47,928	104,642
Restricted cash	1,661,171	1,578,699
Other assets	190,862	326,058
<b>Total assets</b>	<b>\$ 129,724,604</b>	<b>\$ 154,647,882</b>
<b>Liabilities and stockholders equity</b>		
Current liabilities:		
Accounts payable	\$ 2,097,190	\$ 1,188,340
Accrued expenses	8,519,754	8,533,050
Deferred revenue	13,750,000	13,750,000
Current portion of long-term debt and capital leases	375,618	1,362,930
<b>Total current liabilities</b>	<b>24,742,562</b>	<b>24,834,320</b>
Deferred revenue, less current portion	51,041,667	64,791,667
Other liabilities	2,777,072	2,222,735
Long-term debt and capital leases, less current portion	20,400	374,205
<b>Total liabilities</b>	<b>78,581,701</b>	<b>92,222,927</b>
<b>Stockholders equity:</b>		
Preferred Stock, \$.001 par value; 1,000,000 shares authorized, no shares issued and outstanding at December 31, 2007 and 2006		
Common Stock, \$.001 par value; 100,000,000 shares authorized, and 19,710,773 shares issued and outstanding, at December 31, 2007; 100,000,000 shares authorized, and 19,523,243 shares issued and outstanding, at December 31, 2006	19,711	19,523
Additional paid-in capital	223,466,502	219,110,907
Treasury stock, at cost		(1,323,810)
Accumulated deficit	(172,546,266)	(155,305,106)
Accumulated other comprehensive income (loss)	202,956	(76,559)
<b>Total stockholders equity</b>	<b>51,142,903</b>	<b>62,424,955</b>
<b>Total liabilities and stockholders equity</b>	<b>\$ 129,724,604</b>	<b>\$ 154,647,882</b>

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



**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Consolidated Statements of Operations**

	Years Ended December 31,		
	2007	2006	2005
Collaborative research and development revenue	\$ 24,536,350	\$ 18,494,558	\$ 521,750
Operating expenses:			
Research and development	33,793,307	35,792,278	31,459,596
General and administrative	14,033,559	9,464,283	5,530,046
Total operating expenses	47,826,866	45,256,561	36,989,642
Loss from operations	(23,290,516)	(26,762,003)	(36,467,892)
Other income (expense):			
Interest expense	(188,035)	(1,507,102)	(784,290)
Debt extinguishment charge		(1,550,860)	
Interest and investment income	6,580,664	2,459,952	882,954
Total other income (expense)	6,392,629	(598,010)	98,664
Loss before income taxes	(16,897,887)	(27,360,013)	(36,369,228)
Income taxes		(1,087,960)	
Net loss	\$ (16,897,887)	\$ (28,447,973)	\$ (36,369,228)
Basic and diluted net loss per common share	\$ (0.87)	\$ (3.81)	\$ (17.01)
Basic and diluted weighted average number of common shares outstanding	19,511,485	7,463,426	2,138,331

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

**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Consolidated Statements of Cash Flows**

	Years Ended December 31,		
	2007	2006	2005
<b>Operating activities</b>			
Net loss	\$ (16,897,887)	\$ (28,447,973)	\$ (36,369,228)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation	2,753,560	3,416,774	3,746,238
Stock-based compensation including 401(k) match	5,223,224	1,974,731	172,042
Write-off of warrants associated with debt extinguishment		950,860	
Loan forgiveness	92,747	114,830	89,139
Loss (gain) on sale and disposals of property and equipment	25,446	16,518	(1,821)
Net accretion of available-for-sale securities	(3,597,182)	(39,937)	553,102
Impairment of available-for-sale securities	15,577		
Impairment of property and equipment	195,690	873,000	
Amortization of warrants	53,816	269,937	122,921
Interest income on restricted cash	(82,472)	(77,123)	(40,501)
Interest income on employee loans	(3,420)	(6,492)	(7,418)
Changes in operating assets and liabilities:			
Accounts receivable and unbilled accounts receivable	37,034,574	(42,134,810)	2,500,000
Prepaid expenses and other assets	(212,856)	(2,349,627)	31,660
Accounts payable, accrued expenses and other liabilities	1,231,478	(2,458,335)	2,389,250
Deferred revenue	(13,750,000)	77,513,417	(521,750)
Net cash provided by (used in) operating activities	12,082,295	9,615,770	(27,336,366)
<b>Investing activities</b>			
Purchases of property and equipment	(2,405,677)	(946,565)	(2,348,250)
Proceeds from sale of property and equipment	15,000		21,084
Purchases of available-for-sale securities	(208,173,692)	(1,705,437)	(17,462,464)
Sales and maturities of available-for-sale securities	148,559,370	16,131,708	35,366,000
Net cash (used in) provided by investing activities	(62,004,999)	13,479,706	15,576,370

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

	Years Ended December 31,		
	2007	2006	2005
<b>Financing activities</b>			
Cash proceeds from reverse acquisition of assets of DPI		40,113,005	
Proceeds from sale of Series C Convertible Preferred Stock, net of issuance costs			(13,546)
Proceeds from sale of Series D Convertible Preferred Stock		5,000,000	
Proceeds from issuances of common stock	342,151	864,614	342,401
Repurchase of common stock	(10,640)	(287,588)	(44,378)
Proceeds from equipment loan and other debt		15,000,000	1,959,622
Payments on equipment loan and other debt	(1,351,049)	(18,849,379)	(5,431,465)
Capital lease financing			43,371
Capital lease payments	(41,746)	(144,196)	(125,567)
Repayment of employee loans	11,230	7,791	20,435
New employee loans	(10,000)	(95,000)	(182,000)
Net cash (used in) provided by financing activities	(1,060,054)	41,609,247	(3,431,127)
Net (decrease) increase in cash and cash equivalents	(50,982,758)	64,704,723	(15,191,123)
Cash and cash equivalents at beginning of period	74,147,479	9,442,756	24,633,879
Cash and cash equivalents at end of period	\$ 23,164,721	\$ 74,147,479	\$ 9,442,756
<b>Supplemental cash flow disclosure</b>			
Interest paid	\$ 161,789	\$ 1,235,310	\$ 692,673
Income taxes paid	\$ 1,100,000	\$	\$
<b>Supplemental disclosure of noncash investing and financing activities</b>			
Equipment acquired under capital leases	\$ 28,800	\$	\$

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

**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Consolidated Statements of Stockholders' Equity**

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Common Stock		Additional Paid-in Capital		Treasury Stock	Accumulated Deficit	Accumulated Deferre Stock Compensation	Other Comprehensive Income (Loss)	Total Stockholders Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount							
Balance at December 31, 2004	1,597,510	\$ 1,598	5,279,428	\$ 5,279	2,894,972	\$ 2,895	2,525,317	\$ 2,525	\$ 136,435,502	\$	\$	(90,487,905)	\$ (81,446)	\$ (47,637)	\$ 45,830,811
Issuance of Series B warrants in connection with the equipment line									38,755						38,755
Issuance costs related to Series C Convertible Preferred Stock									(13,546)						(13,546)
Issuance of restricted stock and exercise of stock options							226,869	227	342,166						342,393
Restricted stock issued in prior years that vested in the year									171,533						171,533
Repurchase and retirement of common stock							(25,812)	(26)	(44,352)						(44,378)
Stock compensation expense modification of an award									1,046						1,046
Amortization of stock compensation expense													35,249		35,249
Compensation expense on variable stock awards									135,747						135,747
Comprehensive loss: Unrealized gain on marketable securities														45,596	45,596
Net loss												(36,369,228)			(36,369,228)
<b>Comprehensive loss</b>															<b>(36,323,632)</b>
Balance at December 31, 2005	1,597,510	\$ 1,598	5,279,428	\$ 5,279	2,894,972	\$ 2,895	2,726,374	\$ 2,726	\$ 137,066,851	\$	\$	(126,857,133)	\$ (46,197)	\$ (2,041)	\$ 10,173,978

**Table of Contents**

**INFINITY PHARMACEUTICALS, INC.**

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

Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series D Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Deferred Stock Compen- sation	Accu- mulate Other Compr hensiv Incom (Loss)
Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount					
597,510	\$ 1,598	5,279,428	\$ 5,279	2,894,972	\$ 2,895		\$	2,726,374	\$ 2,726	\$ 137,066,851	\$	\$ (126,857,133)	\$ (46,197)	\$ (2,041,511)
						266,313	266			4,999,734				
								133,152	133	864,481				
										127,047				
												(287,588)		
								(2,771)	(3)	(4,984)	4,987			
597,510	(1,598)	(5,279,428)	(5,279)	(2,894,972)	(2,895)	(266,313)	(266)	16,664,940	16,665	73,012,884	(1,041,209)			
										1,974,731				
										1,116,360				
								1,548	2					
													(46,197)	46,197
														(74,511)
														(28,447,973)

\$ \$ \$ \$ 19,523,243 \$ 19,523 \$ 219,110,907 \$ (1,323,810) \$ (155,305,106) \$ \$ (76,5



**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Consolidated Statements of Stockholders Equity (Continued)**

	Common Stock			Treasury Stock	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders Equity
	Shares	Amount	Additional Paid-in Capital				
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							(16,618,372)
Balance at December 31, 2007	19,710,773	\$ 19,711	\$ 223,466,502	\$	\$ (172,546,266)	\$ 202,956	\$ 51,142,903

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

---

**Table of Contents**

**INFINITY PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements**

**1. Organization**

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

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

Since former Old Infinity security holders owned, immediately following the merger, approximately 69% of the combined company on a fully-diluted basis and as a result of certain other factors, including that former Old Infinity directors constituted a majority of the combined company's board of directors and all members of the combined company's executive management were from Old Infinity, Old Infinity was deemed to be the acquiring company for accounting purposes and the transaction was accounted for as a reverse acquisition of assets and a recapitalization in accordance with accounting principles generally accepted in the United States. These financial statements reflect the historical results of Old Infinity prior to the merger and that of the combined company following the merger, and do not include the historical financial results of DPI prior to the completion of the merger. Stockholders' equity has been retroactively restated to reflect the number of shares of common stock received by former Old Infinity security holders in the merger, after giving effect to the difference between the par values of the capital stock of Old Infinity and Infinity common stock, with the offset to additional paid-in capital. In addition, the pre-merger financial information has been restated to reflect the 1-for-4 reverse split of DPI common stock that became effective immediately prior to the closing of the merger, the closing of the merger, and the related conversion of all of the capital stock of Old Infinity into Infinity common stock. See Note 12 for a discussion of the conversion of such stock in the merger.

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

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

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

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

**Table of Contents**

**INFINITY PHARMACEUTICALS, INC.**

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

ongoing basis, we evaluate our estimates, including those related to revenue recognition and related allowances. 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 prior year amounts in accrued liabilities, other long-term liabilities, working capital, net cash provided by operating activities and net cash used in investing activities have been reclassified to conform to the current year presentation. This reclassification has no impact on previously reported net loss or cash flows.

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

Cash equivalents and short-term available-for-sale marketable securities primarily consist of money market funds, asset-backed securities, corporate obligations and U.S. government-sponsored enterprise obligations. We consider all highly liquid investments with maturities of three months or less at the time of purchase to be cash equivalents. Cash equivalents, which consist primarily of money market funds, are stated at cost, which approximates fair value.

We determine the appropriate classification of available-for-sale securities at the time of purchase and reevaluate such designation at each balance sheet date. We have classified all of our marketable securities at December 31, 2007 and 2006 as available-for-sale. We carry available-for-sale securities at fair value, with the unrealized gains and losses reported in accumulated other comprehensive income (loss), which is a separate component of stockholders' equity. The fair value of these securities is based on quoted market prices.

We adjust the cost of available-for-sale debt securities for amortization of premiums and accretion of discounts to maturity. Realized gains and losses and declines in value, if any, that we judge to be other-than-temporary on available-for-sale securities are reported in interest and investment income. The cost of securities sold is based on the specific identification method. We include interest and dividends on securities classified as available-for-sale in investment income. Realized gains or losses from the sales of securities for the years ended December 31, 2007, 2006 and 2005 were immaterial.

**Concentration of Risk**

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

Cash and cash equivalents are primarily maintained with two major financial institutions in the United States. Deposits at banks may exceed the insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal risk. Financial instruments that potentially subject us to concentration of credit risk primarily consist of available-for-sale securities. Available-for-sale securities consist of investment grade corporate obligations, asset backed securities and U.S. government-sponsored enterprise obligations. Our investment policy, which has been approved by our Board of Directors, limits the amount that we may invest in one type of investment, thereby reducing credit risk concentrations. Accounts receivable include amounts due under strategic alliances for which we do not obtain collateral.

---

**Table of Contents**

**INFINITY PHARMACEUTICALS, INC.**

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

**Segment Information**

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

All of our revenues to date have been generated under research collaboration agreements. During the year ended December 31, 2007:

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

Revenues associated with the up-front license fee we received from MedImmune, Inc., a division of AstraZeneca plc, or MedImmune/AZ, accounted for approximately 41% of our revenue.

During the year ended December 31, 2006:

Revenues associated with the up-front license fee, reimbursable research and development services and compound acceptance fees we received from Novartis and Novartis International accounted for approximately 63% of our revenue;

Revenues associated with the up-front license fee we received from MedImmune/AZ accounted for approximately 18% of our revenue; and

Revenues associated with the license fee we received from Amgen Inc., or Amgen, accounted for approximately 14% of our revenue. During 2005, all of our revenue was associated with a non-exclusive worldwide license with Johnson & Johnson Pharmaceutical Research & Development, a division of Janssen Pharmaceutica N.V., or J&J, to use certain of our small molecules in J&J's drug discovery efforts.

Payments due from Novartis represented 100% of our accounts receivable balance as of December 31, 2007 and 32% of our accounts receivable balance as of December 31, 2006. Payments due from MedImmune/AZ represented 68% of our accounts receivable balance at December 31, 2006. Payments due from MedImmune/AZ represented 90% of our unbilled accounts receivable balance as of December 31, 2007 and 93% of our unbilled accounts receivable balance at December 31, 2006. Payments due from Novartis represented the remaining unbilled accounts receivable balance in both periods. We did not have an allowance for doubtful accounts for the years ended December 31, 2007 and 2006.

**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements (Continued)****Property and Equipment**

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

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

**Impairment of Long-Lived Assets**

Consistent with SFAS No. 144, *Accounting for the Impairment of Long-Lived Assets and Long-Lived Assets to be Disposed Of*, when impairment indicators exist, we evaluate our long-lived assets for potential impairment. Potential impairment is assessed when there is evidence that events or changes in circumstances have occurred that indicate that the carrying amount of a long-lived asset may not be recovered. Recoverability of these assets is assessed based on undiscounted expected future cash flows from the assets, considering a number of factors, including past operating results, budgets and economic projections, market trends, and product development cycles. An impairment in the carrying value of each asset is assessed when the undiscounted expected future cash flows derived from the asset are less than its carrying value. Impairments, if any, are recognized in earnings. An impairment loss would be recognized in an amount equal to the excess of the carrying amount over the undiscounted expected future cash flows. See Note 5 for discussion on impairment charges recognized during the years ended December 31, 2007 and 2006.

**Fair Value of Financial Information**

Cash and cash equivalents, accounts payable and accrued liabilities are carried at cost, which management believes approximates fair value. The carrying amount reported in our balance sheets for long-term debt and capital lease obligations approximate their fair value.

**Revenue Recognition**

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

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

**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements (Continued)**

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

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

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

**Income Taxes**

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

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

**Basic and Diluted Net Loss per Common Share**

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

	At December 31,		
	2007	2006	2005
Stock options	3,876,004	1,889,572	980,445
Warrants	246,629	246,629	181,716
Unvested restricted shares	54,954	190,359	381,608

---

**Table of Contents**

**INFINITY PHARMACEUTICALS, INC.**

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

**Comprehensive Income (Loss)**

SFAS No. 130, *Reporting Comprehensive Income*, requires us to display comprehensive income (loss) and its components as part of our full set of financial statements. Comprehensive income is comprised of net income (loss) and other comprehensive (loss) income. Other comprehensive (loss) income includes unrealized holding gains and losses on available-for-sale securities.

**Stock-Based Compensation Expense**

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

**Research and Development Expense**

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

**Accounting for Sabbatical Leave**

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

---

**Table of Contents**

**INFINITY PHARMACEUTICALS, INC.**

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

**New Accounting Pronouncements**

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

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

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

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

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

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

In December 2007, the FASB ratified the consensus reached by the EITF on EITF Issue 07-1, *Accounting for Collaborative Arrangements* ( EITF 07-1 ). EITF 07-1 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from, or made to, other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, EITF 07-1 clarified that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to EITF 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)*. EITF 07-1 will be effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. We are currently evaluating the effect of EITF 07-1 on our consolidated financial statements.

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

In February 2007, the EITF issued EITF 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* ( EITF 07-3 ). In EITF 07-3, the task force reached a consensus that nonrefundable advance payments for goods or services to be received in the future for use in research and development activities should be deferred and capitalized. The capitalized amounts should





**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements (Continued)**

be expensed as the related goods are delivered or the services are performed. EITF 07-3 is effective for new contracts entered into during fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. We do not believe that EITF 07-3 will have a material impact on our financial position or results of operations.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, ( SFAS No. 157 ). SFAS No. 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS No. 157 codifies the definition of fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, clarifies the principle that fair value should be based on the assumptions market participants would use when pricing the asset or liability, and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007. We do not believe that SFAS No. 157 will have a material impact on our financial position or results of operations.

**3. Stock-Based Compensation****2000 Stock Incentive Plan**

Our 2000 Stock Incentive Plan (the 2000 Plan ) provides for the grant of stock options intended to qualify as incentive stock options under the Internal Revenue Code or as nonqualified stock options, as well as restricted stock. As of December 31, 2007, an aggregate of 4,962,379 shares of our common stock are reserved for issuance under the 2000 Plan, of which 432,887 shares of common stock remained available for future grant. The number of shares of our common stock available for issuance under the 2000 Plan automatically increases on the first trading day of each calendar year by an amount equal to 4% of the total number of shares of our common stock that are outstanding on the last trading day of the preceding calendar year, but in no event may this increase exceed 2,000,000 shares. The exercise price of all options granted under the discretionary option grant program of the 2000 Plan must equal at least the fair value of our common stock on the date of grant. Outstanding options granted under the 2000 Plan are exercisable as the options vest, which is generally over a four-year period. All options granted under the 2000 Plan expire no later than ten years after the date of grant.

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

**2001 Stock Incentive Plan**

In connection with the merger, we assumed awards that were granted by Old Infinity under Old Infinity's 2001 Stock Incentive Plan (now known as the Infinity Pharmaceuticals, Inc. Pre-Merger Stock Incentive Plan) (the 2001 Plan ), which provided for the grant of incentive and non-statutory options and restricted stock awards. Under the 2001 Plan, stock awards were granted to Old Infinity's employees, officers, directors and consultants. Incentive stock options were granted at a price not less than fair value of the common stock on the date of grant. The board of directors of Old Infinity determined the vesting of the awards. For grants made to new employees upon commencement of employment, awards typically provided for vesting of 25% of shares at the end of the first year of service with the remaining 75% vesting ratably on a monthly basis over the following three-year period. Annual grants to existing employees typically provided for monthly vesting over four years. The maximum contractual term of stock options granted under the 2001 Plan was ten years. As of December 31, 2007, an aggregate of 1,145,516 shares of our common stock are reserved for issuance upon the exercise of outstanding assumed awards. The 2001 Plan was not assumed by us following the merger; therefore, no further grants may be made under the 2001 Plan.

**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements (Continued)**

All stock options granted under the 2001 Plan contained provisions allowing for the early exercise of such options. All shares of common stock issued upon exercise of these options contain certain provisions that allow us to repurchase unvested shares at their original purchase price, such as upon termination of employment. The repurchase provisions for unvested shares issued upon the exercise of options granted as part of an employee's initial employment generally lapse as follows: 25% at the end of the first year of service with the remaining 75% lapsing ratably on a monthly basis over the following three-year period. The repurchase provisions for unvested shares issued upon exercise of options granted as part of annual grants to existing employees generally lapse on a monthly basis over a four-year period; however, Old Infinity granted 190,287 shares during 2005 with a repurchase provision lapsing on a monthly basis over a six-year period.

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

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

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

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

	Year Ended December 31, 2007	Year Ended December 31, 2006
Research and development	\$ 2,558,655	\$ 1,112,602
General and administrative	2,664,569	862,129

As of December 31, 2007, there was \$15,678,589 of total unrecognized compensation cost, net of estimated forfeitures, related to unvested options and restricted stock, including \$23,845 of unrecognized compensation expense associated with the forgiveness of the nonrecourse loans. The unrecognized compensation cost is expected to be recognized over a weighted-average period of 3.1 years.

As a result of the adoption of SFAS No. 123(R), our basic and diluted loss per share for the year ended December 31, 2006 was greater by \$0.26.

**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements (Continued)****SFAS No. 123(R) Valuation Assumptions**

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

	2007	2006
Risk-free interest rate	4.35%	4.73%
Expected annual dividend yield		
Expected stock price volatility	60.99%	63.42%
Expected term of options	5.1 years	5.2 years

The valuation assumptions were determined as follows:

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

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

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

*Expected term of options:* The expected term of the awards represents the period of time that the awards are expected to be outstanding. We use historical data and expectations for the future to estimate employee exercise and post-vest termination behavior. For the year ended December 31, 2006, we believed that all groups of employees exhibited similar exercise and post-vest termination behavior and therefore did not stratify employees into multiple groups. For the year ended December 31, 2007, we stratified employees into two groups, which we considered a change in accounting estimate per SFAS No. 154, *Accounting Changes and Error Corrections*. This change in accounting estimate did not have a material effect in the period of change.

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

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

**Determination of Fair Value**

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



**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements (Continued)**

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

its knowledge and experience in valuing early-stage life sciences companies;

comparative values of public companies, discounted for the risk and limited liquidity provided for in the shares subject to the options we had issued;

pricing of private sales of our preferred stock;

prior valuations of stock grants;

the effect of events that had occurred between the times of such determinations; and

economic trends in the biotechnology and pharmaceutical industries specifically, and general economic trends.

From December 31, 2005 until the closing of the merger, in addition to the foregoing factors, the board of directors considered contemporaneous estimations of the fair value of our common stock using the Probability-Weighted Expected Return method, as of December 31, 2005, and again as of March 10, 2006 to estimate the increase in our value created by our collaboration with Novartis. These valuation analyses and the resulting estimates of our enterprise value were based on the market valuation method, specifically the guideline company approach. The enterprise value was allocated to the different classes of our equity instruments using the Probability-Weighted Expected Return method.

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

A summary of our stock option activity for the year ended December 31, 2007 is as follows:

	Stock Options	Weighted-Average Exercise Price	Weighted-Average Contractual Life (years)	Aggregate Intrinsic Value (in millions)
Outstanding at January 1, 2007	1,889,572	\$ 7.47		
Granted	2,277,464	11.90		
Exercised	(182,461)	2.06		
Forfeited	(108,571)	9.31		
Outstanding at December 31, 2007	3,876,004	10.24	8.70	\$ 6.8
Vested or expected to vest at December 31, 2007	3,780,849	\$ 10.22	8.69	\$ 6.7

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

Exercisable at December 31, 2007(1)	1,701,070	\$	7.95	7.82	\$	6.8
-------------------------------------	-----------	----	------	------	----	-----

(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, 2007, 2006 and 2005 were \$6.82, \$6.88, and \$1.45, respectively.

**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements (Continued)**

The aggregate intrinsic value of options outstanding at December 31, 2007 was calculated based on the positive difference between the closing fair market value of our common stock on December 31, 2007 and the exercise price of the underlying options. The aggregate intrinsic value of options exercised during the years ended December 31, 2007, 2006 and 2005 was \$1,651,508, \$495,129, and \$4,567, respectively. The total cash received from employees and non-employees as a result of stock option exercises during the year ended December 31, 2007 was approximately \$342,151.

A summary of the status of unvested restricted stock as of December 31, 2007, and changes during the year then ended, is presented below:

	Restricted Stock	Weighted-Average Grant Date Fair Value
Unvested at January 1, 2007	190,359	\$ 1.80
Granted		
Vested	(130,016)	1.67
Repurchased	(5,389)	2.02
Unvested at December 31, 2007	54,954*	\$ 1.99

\* Includes 4,245 unvested restricted shares related to the nonrecourse loans forgiven on March 31, 2006.

During the year ended December 31, 2007, we repurchased an aggregate of 5,389 unvested restricted shares of our common stock from employees who ceased employment with us. These repurchases were made at the original purchase prices, totaling \$10,893. During the year ended December 31, 2006, we repurchased an aggregate of 2,769 unvested restricted shares of our common stock from employees who ceased employment with us. These repurchases were made at the original purchase prices, totaling \$4,989. During the year ended December 31, 2005, we repurchased an aggregate of 25,812 unvested restricted shares of our common stock from employees who ceased employment with us. These repurchases were made at the original purchase prices totaling \$44,378. The total fair value of the shares vested during the years ended December 31, 2007, 2006, and 2005 (measured on the date of vesting) was \$1,451,346, \$2,685,758 and \$594,167, respectively.

No related income tax benefits were recorded during the years ended December 31, 2007, 2006 or 2005.

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

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

During the year ended December 31, 2006, two employees whose employment terminated, but who entered into consulting agreements with us, retained unvested awards even though they would not provide any continuing substantive service as a non-employee. These awards continued to vest over the term of the consulting agreements. In connection with such termination of employment, we recognized \$125,912 in additional stock-based compensation expense during the year ended December 31, 2006.





**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements (Continued)****Prior to the adoption of SFAS No. 123(R)**

Through December 31, 2005, we accounted for awards under the 2001 Plan under SFAS No. 123, electing to use the intrinsic value recognition and measurement principles of APB 25, and related interpretations as provided by SFAS No. 123 and enhanced disclosures as required by SFAS No. 148, *Stock-Based Compensation Transition and Disclosure*. Stock-based employee compensation cost of \$122,160 is reflected in our net loss for 2005 for options granted that were subject to variable accounting.

We have applied the recognition provisions of SFAS No. 123 and EITF No. 96-18 for all stock option grants to non-employees. Stock-based non-employee compensation cost of \$49,882 is reflected in net loss for the year ended December 31, 2005 for awards made under the 2001 Plan.

The following table illustrates the effect on net loss as if we had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation for the year ended December 31, 2005:

Net loss, as reported	\$ (36,369,228)
Add: total employee stock-based compensation expense included in net loss	122,160
Deduct: total employee stock-based compensation expense determined under fair value-based method for all awards	(553,221)
Pro forma net loss	\$ (36,800,289)
Basic and diluted net loss per common share, as reported	\$ (17.01)
Basic and diluted net loss per common share, pro forma	\$ (17.21)

The fair value of the options was estimated at the date of grant using the Black-Scholes valuation model using the following weighted-average assumptions as follows for the year ended December 31, 2005:

	<b>2005</b>
Risk-free interest rate	4.50%
Expected annual dividend yield	
Expected stock price volatility	70.00%
Expected term of options	9.0 years

For purposes of pro forma disclosures, the estimated fair value of options is amortized over the service or vesting period on a straight-line basis.

**4. Available-for-Sale Securities**

The following is a summary of available-for-sale securities:

	Cost	December 31, 2007		Estimated Fair Value
		Gross Unrealized Gains	Gross Unrealized Losses	
Corporate bonds due in one year or less	\$ 64,067,447	\$ 199,633	\$ (17,551)	\$ 64,249,529
Asset backed securities				
Due in one year or less	2,477,892	5,158		2,483,050

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

Due in one to five years	23,362,884	32,712		23,395,596
Due after ten years	219,473		(16,996)	202,477
U.S. government-sponsored enterprise obligations due after ten years	694,095			694,095
	\$ 90,821,791	\$ 237,503	\$ (34,547)	\$ 91,024,747

**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements (Continued)**

		<b>December 31, 2006</b>		
	<b>Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Estimated Fair Value</b>
Corporate bonds due in one year or less	\$ 12,211,749	\$ 2,786	\$ (19,954)	\$ 12,194,581
Asset backed securities				
Due in one to five years	11,750,271	922	(59,699)	11,691,494
Due in six to ten years	226,242		(11)	226,231
Due after ten years	316,315	16		316,331
Certificates of deposit due in one year or less	359,085			359,085
U.S. government-sponsored enterprise obligations				
Due in one year or less	1,999,220	160		1,999,380
Due after ten years	762,982		(779)	762,203
	\$ 27,625,864	\$ 3,884	\$ (80,443)	\$ 27,549,305

All investments as of December 31, 2007 have been in an unrealized loss position for less than 12 months. The following is a summary of the gross unrealized losses and the fair value of our investments in an unrealized loss position that are not deemed to be other-than-temporarily impaired, aggregated by investment category:

	<b>December 31, 2007</b>	
	<b>Total Fair Value</b>	<b>Unrealized Losses</b>
Corporate bonds	\$ 14,441,604	\$ (17,551)
Asset-backed securities	202,497	(16,996)
<b>Total</b>	<b>\$ 14,644,101</b>	<b>\$ (34,547)</b>

The unrealized losses on investments in corporate bonds and asset-backed securities at December 31, 2007 were generated from ten securities. The unrealized losses were primarily caused by interest rate increases, and not credit quality issues. To determine whether an other-than-temporary impairment exists, we considered whether we have the ability and intent to hold the investment until a market price recovery, and considered whether evidence indicating the recoverability of the cost of the investment outweighed evidence to the contrary. Since the decline in market value was primarily attributable to changes in interest rates 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, 2007.

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.

**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements (Continued)****5. Property and Equipment**

Property and equipment consist of the following:

	December 31,	
	2007	2006
Laboratory equipment	\$ 13,825,219	\$ 13,001,874
Computer hardware and purchased software	5,011,159	4,577,799
Office equipment and furniture and fixtures	554,698	585,024
Leasehold improvements	4,118,903	3,413,251
	23,509,979	21,577,948
Less accumulated depreciation	(17,525,268)	(15,038,018)
	\$ 5,984,711	\$ 6,539,930

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

During the year ended December 31, 2007, we leased office equipment under capital lease arrangements, totaling \$28,800; related accumulated amortization at December 31, 2007 was \$1,800. The lease is for 48 months, with an annual interest rate of 8.2%. The lease equipment secures the lease.

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

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

During 2005, we disposed of certain laboratory and computer equipment, which had a cost of \$35,432 and accumulated depreciation of \$16,169 for proceeds of \$21,084, resulting in a gain on the sale of \$1,821.

**6. Restricted Cash**

We held \$1,661,171 in restricted cash as of December 31, 2007 and \$1,578,699 in restricted cash as of December 31, 2006. 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. In February 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 approximately \$565,000.

**7. Accrued Expenses**

Accrued expenses consisted of the following:

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

	December 31,	
	2007	2006
Accrued payment to strategic alliance partner	\$	\$ 1,020,050
Accrued drug manufacturing costs	2,072,916	1,274,276
Accrued toxicology studies	623,567	536,211
Accrued compensation and benefits	3,248,123	2,399,709
Accrued software license fees	189,988	189,988
Unvested restricted stock	73,526	198,386
Accrued tax liability	92,000	1,087,960
Other	2,219,634	1,826,470
<b>Total accrued expenses</b>	<b>\$ 8,519,754</b>	<b>\$ 8,533,050</b>

**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements (Continued)****8. Other Long-Term Liabilities**

Other long-term liabilities consisted of the following:

	December 31,	
	2007	2006
Deferred rent	\$ 1,748,848	\$ 1,838,603
Accrued tax liability	636,338	
Other	391,886	384,132
 Total other long-term liabilities	 \$ 2,777,072	 \$ 2,222,735

**9. Commitments and Contingencies****Facility Lease**

We lease our office and laboratory space under a noncancelable facility lease agreement that expires in December 2012. We have the right to extend this 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 lease by giving the landlord notice nine months before the term of the lease expires.

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

	Facility Lease
Years Ending December 31:	
2008	\$ 4,446,728
2009	4,580,130
2010	4,717,534
2011	4,859,060
2012	4,579,070
Thereafter	
 Total minimum lease payments	 \$ 23,182,522

Rent expense of \$4,334,575, \$4,339,610, and \$4,321,507, before considering sublease income, was incurred during the years ended December 31, 2007, 2006, and 2005, respectively. During the years ended December 31, 2007, 2006, and 2005, we subleased a portion of our facility space for total sublease income of \$551,025, \$549,678, and \$498,240, respectively. We record sublease payments as an offset to rental expense in our statement of operations. Future minimum sublease income under noncancelable leases is \$518,691 for the year ended December 31, 2008.

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

In December 2001, we secured an equipment loan agreement with two banks allowing for borrowings of up to an aggregate amount of \$5 million to finance the purchase of certain equipment. Interest was charged at the U.S. Treasury note yield plus 6.5%. Amounts borrowed under this agreement were collateralized by the equipment financed through the respective loans. There are no borrowings available under the equipment loan agreement at December 31, 2007. In connection with the entry of this agreement, we issued warrants. See Note 12 for a further

discussion of warrants.



**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements (Continued)**

In September 2002, we secured an equipment loan agreement with a finance company allowing for borrowings of up to an aggregate of \$5 million to finance the purchase of certain equipment. The line was increased by \$500,000 during 2003 under the same terms. Interest was charged between 9.91% and 10.26% depending on whether the note was for laboratory or other equipment. Amounts borrowed under this agreement were collateralized by the equipment financed through the respective loans. There are no borrowings available under the equipment loan agreement at December 31, 2007. In connection with the entry of this agreement, we issued warrants. See Note 12 for a further discussion of warrants.

In December 2002, we secured an equipment financing agreement with a finance company allowing for financings of up to an aggregate of \$6 million to finance the acquisition of certain equipment. Interest was charged between 8% and 10% and fluctuated depending on whether the note is for laboratory or other equipment and when the funds were drawn down by us. Amounts borrowed under this agreement were collateralized by the equipment financed through the respective loans. In March 2004, the equipment line was increased to \$9 million. In January 2005, the equipment line was increased to \$12 million. On August 11, 2004, we executed a master lease agreement with the finance company allowing for leases to be created for equipment financing under the total equipment line of \$12 million. No borrowings remain available to be drawn under the equipment loan and master lease agreement at December 31, 2007. In connection with the entry of this agreement, we issued warrants. See Note 12 for a further discussion of warrants.

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

Capital leases obligations and equipment loan maturities are as follows:

Years Ended December 31:	
2008	\$ 390,753
2009	5,953
2010	6,459
2011	5,489
Total	408,654
Less amount representing interest	(12,636)
Amounts excluding interest	396,018
Less current portion	(375,618)
Capital lease obligations and equipment debt long term portions	\$ 20,400

We had the following capital lease obligations and equipment loans at December 31, 2007 and 2006:

	<b>2007</b>	<b>2006</b>
Total capital lease obligations and equipment loans	\$ 396,018	\$ 1,737,135
Less current portion	(375,618)	(1,362,930)
Total long-term capital lease obligations and equipment loans	\$ 20,400	\$ 374,205

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

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

equipment and property. We amended this agreement on March 31, 2006 (as so amended, the Oxford Agreement ) to allow for us to borrow up to \$7.5 million for use in operations. Under the Oxford Agreement, we had borrowed an aggregate principal amount of

---

**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements (Continued)**

\$7.5 million from Oxford pursuant to promissory notes dated as of March 31, 2006 and June 30, 2006 (the Oxford Notes ). The Oxford Notes bore interest at a rate of 11.26% and 11.75% per annum, respectively, and were payable in 39 consecutive monthly installments, the first nine of which were interest only, beginning in May 2006. The Oxford Notes could be prepaid upon payment of a pre-payment penalty of up to 4% of the outstanding principal balance. Further, in connection with the execution of the March 2006 amendment to the Oxford Agreement, we issued warrants. See Note 12 for a further discussion of warrants.

On June 30, 2006, we entered into a venture loan and security agreement (the Horizon Agreement ) with Horizon Technology Funding Company LLC ( Horizon ) under which we borrowed an aggregate principal amount of \$7.5 million pursuant to the terms of two promissory notes, each dated as of June 30, 2006 (the Horizon Notes ). The Horizon Notes bore interest at a rate equal to 11.93% per annum and were payable in 39 consecutive monthly installments, the first nine of which were interest only, beginning in July 2006. The Horizon Notes could be prepaid upon payment of a pre-payment penalty of up to 4% of the outstanding principal balance. Further, in connection with the execution of the Horizon Agreement, we issued warrants. See Note 12 for a further discussion of warrants.

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

**10. Collaboration Agreements****MedImmune/AZ**

In August 2006, we entered into a product development and commercialization agreement with MedImmune/AZ to jointly develop and commercialize cancer drugs targeting Hsp90 and the Hedgehog pathway. Under the terms of this agreement, we share equally with MedImmune/AZ all development costs, as well as potential profits and losses, from any future marketed products. 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. Because we have continuing involvement in the development program, we are recognizing the up-front license fee as revenue on a straight-line basis over seven years, which is based on our estimate of the period under which product candidates would be developed by us under the collaboration. During the year ended December 31, 2007, we recognized \$10.0 million in revenue from such fee, and during the year ended December 31, 2006, we recognized \$3.3 million in revenue from such fee. In November 2007, we regained from MedImmune/AZ all development and worldwide commercialization rights under our Hedgehog pathway program on a royalty-free basis, and MedImmune/AZ's funding obligation under this program will end in May 2008. We continue to collaborate with MedImmune/AZ on our Hsp90 program, and could receive up to \$215 million in milestone payments if certain late-stage development and sales objectives are achieved for products resulting arising from that program. Further, because we share development costs equally, we record any payments from MedImmune/AZ with respect to research and development costs that we incur as a reduction to research and development expense, and not as revenue. During the years ended December 31, 2007 and 2006, we offset against research and development expense approximately \$13.7 million and \$4.0 million, respectively, that is reimbursable from MedImmune/AZ for sharing of costs that we incurred for research and development under the collaboration.

---

**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements (Continued)****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 expect to recognize \$8.1 million of the up-front license fee as revenue in the year ended December 31, 2008. 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, 2007 and 2006, we recognized \$3.75 million and \$3.1 million, respectively, in revenue related to the amortization of the non-refundable license fee and \$4.8 million and \$4.1 million, respectively, in revenue related to the reimbursable research and development services we performed for Novartis under the *Novartis Product Development Agreement*.

In November 2004, we entered into a collaboration and option agreement (the *Novartis Collaboration Agreement*) with Novartis International. Pursuant to the *Novartis Collaboration Agreement*, we and Novartis International agreed to jointly design a collection of novel small molecules that would be synthesized by us using our diversity oriented synthesis chemical technology platform. Under the *Novartis Collaboration Agreement*, Novartis International may use the resulting compound collection in its independent drug discovery efforts. We have certain rights to use the resulting compound collection in our own drug discovery efforts, and Novartis International has the option to license from us on an exclusive worldwide basis specified lead compounds for further development and commercialization. In the event that Novartis International exercises its option to license specified lead compounds, it will pay us milestone payments and royalties on net sales of certain drug products incorporating such compounds. In addition, Novartis International has paid us \$10.5 million for the successful acceptance of compounds. During the years ended December 31, 2007 and 2006, we recognized \$6.0 million and \$4.5 million, respectively, as revenue for acceptance of compounds under the *Novartis Collaboration Agreement*.

**Amgen**

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

**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements (Continued)****J&J**

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

**11. Income Taxes**

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

Our effective income tax rate for the years ended December 31, 2007, 2006 and 2005 differed from the expected US federal statutory income tax rate as set forth below:

	2007	2006	2005
Expected federal tax expense (benefit)	\$ (5,745,282)	\$ (9,302,405)	\$ (12,365,538)
Permanent differences	698,537	290,788	11,606
State taxes, net of deferral benefit	(1,059,498)	(1,715,473)	(2,280,351)
Tax credits and related adjustments	559,720	(3,457,466)	(1,258,641)
Alternative minimum tax		1,087,960	
Other		(43,724)	(48,248)
Change in valuation allowance	5,546,523	14,228,280	15,941,172
Income tax provision	\$	\$ 1,087,960	\$

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

	Year Ended December 31,	
	2007	2006
Deferred tax assets:		
Net operating loss carryforwards	\$ 35,891,924	\$ 27,817,546
Tax credits	8,465,672	8,430,898
Deferred revenue	26,091,604	31,628,729
Accrued expenses	1,300,175	1,532,689
Amortization	678,040	656,367
Other	1,686,882	639,520
Valuation allowance	(73,931,930)	(70,331,818)
Total deferred tax assets	182,367	373,931
Deferred tax liabilities:		
Depreciation	(182,367)	(373,931)

Net deferred tax asset	\$	\$
------------------------	----	----

**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements (Continued)**

We have recorded a valuation allowance against our deferred tax assets in each of the years ended December 31, 2007 and 2006 because management believes that it is more likely than not that these assets will not be realized. The valuation allowance increased by \$3,600,112 during the year ended December 31, 2007 primarily as a result of unbenefited losses.

At December 31, 2007, we have federal and state net operating loss carryforwards for income tax purposes of approximately \$118,311,000 and \$123,561,000, respectively, to offset future taxable income. We also have federal and state tax credits to offset future tax liabilities of approximately \$5,307,000 and \$3,884,000, respectively. Our net operating losses and tax credits each begin to expire in 2021 for federal purposes and each began expiring in 2006 for state purposes. These tax attributes will continue to expire through 2027 if not utilized. Additionally, our net operating loss carryforwards and tax credits are limited as a result of certain ownership changes, as defined under Sections 382 and 383 of the Internal Revenue Code. This limits the annual amount of these tax attributes that can be utilized to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on our value immediately prior to an ownership change. Subsequent ownership changes may further affect the limitation in future years. The net operating losses and tax credits that will expire unused in the future as a result of Section 382 and 383 limitations have been eliminated as of December 31, 2007 from the amounts disclosed above.

During the twelve month period ended December 31, 2007, we recorded an increase to our liability for unrecognized tax benefits of approximately \$13,644,000 and \$30,000 of interest expense, which relates to positions taken during the current period. We have a total of \$30,000 of interest and penalties accrued as of December 31, 2007. If the tax benefits are ultimately recognized, the effective tax rates in any future periods would be favorably affected by approximately \$624,000, the balance will have no impact to our effective tax rate as a result of our full valuation allowance. We anticipate that our liability for unrecognized tax benefits will decrease by approximately \$13,050,000 over the next 12 month period as the uncertainty about the timing of such deductibility will reverse over the period.

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

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

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

**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements (Continued)****12. Stockholders Equity**

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

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

**Convertible Preferred Stock**

In February 2006, we issued 266,313 shares of Series D Convertible Preferred Stock, \$.001 par value, to Novartis International at a price of \$18.77 per share. Proceeds from this stock issuance were \$5,000,000. All of these shares of preferred stock were converted into common stock in connection with the merger. Immediately prior to the effective time of the merger, DPI completed a 1-for-4 reverse stock split. In addition, all outstanding Series A, Series B, Series C and Series D Convertible Preferred Stock was converted into common stock in the merger. No shares of convertible preferred stock were outstanding at December 31, 2007.

**Stockholder Rights Agreement**

We have a stockholder rights agreement that provides for a dividend distribution of one preferred share purchase right for each outstanding share of our common stock held of record at the close of business on February 24, 2003. The rights are not currently exercisable. Under certain conditions involving an acquisition or proposed acquisition by any person or group holding 15% or more of our outstanding common stock, 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. We retired 22,060, 2,771 and 25,812 shares of treasury stock during the years ended December 31, 2007, 2006, and 2005, respectively. These were all non-cash transactions, with the offset to additional paid-in capital.

**Warrants**

In connection with various loan and financing agreements during the period from December 2001 through December 2006, including our agreements with Horizon and Oxford, we issued warrants to purchase shares of convertible preferred stock, which became warrants to purchase common stock as a result of the merger. The fair value of the warrants was estimated using the Black-Scholes valuation model assuming no expected dividends, a volatility ranging from 64% to 95%, a contractual life of ten years, and a risk-free interest rate ranging from 3.05% to 5.50%. 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.





**Table of Contents**

**INFINITY PHARMACEUTICALS, INC.**

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

In July 2002, we issued warrants to purchase shares of convertible preferred stock, which became warrants to purchase common stock as a result of the 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 both December 31, 2007 and 2006. These warrants are currently exercisable and expire on dates ranging from February 28, 2012 to June 30, 2016 and have exercise prices ranging from \$7.64 to \$13.35 per share.

**Notes Receivable From Stock Purchase Agreements**

In 2002, we loaned four employees \$202,500 and one consultant \$45,000 to effect the purchase of shares of our restricted common stock. The loans were considered nonrecourse and nonsubstantive; therefore, we did not record the loans on our balance sheet and consequently continued to account for these awards as stock options for accounting purposes. The unvested portion of the shares were subject to repurchase by us, at our option, at the original issuance price. The repurchase restriction lapsed as follows: 20 to 25% at the end of the first year of service with the remaining 75 to 80% lapsing ratably on a monthly basis over the following four- to five-year period, as applicable. Interest on the loans accrued at various rates from 4.5% to 5.0%. On certain notes, the principal and accrued interest were forgiven ratably or repaid over approximately 48 months provided that the employees remained employed by us. In the event of termination, the unforgiven principal plus accrued interest was due. Options that were exercised using proceeds from the loans were subject to variable accounting. We recorded \$0, \$58,464 and \$50,197 of variable stock compensation expense during the years ended December 31, 2007, 2006 and 2005, respectively, related to these shares. During 2003, two of the four employees who entered into notes receivable from stock purchase agreements with us ceased to be employed by us. These loans plus accrued interest were repaid by the individuals in accordance with the original terms for all vested shares. These payments were accounted for as stock option exercises.

In 2003, we loaned two employees a total of \$341,985 to effect the purchase of shares of restricted common stock pursuant to the 2001 Plan. The loans were nonrecourse and nonsubstantive; therefore, we did not record the loans on our balance sheet and consequently accounted for these awards as stock options for expense purposes. The unvested portions of the shares were subject to repurchase by us, at our option, at the original issuance price. The repurchase restriction lapsed as follows: 25% at the end of the first year of service with the remaining 75% lapsing ratably on a monthly basis over the following three-year period. Interest on the loans accrued at 3.65%. The principal of the note and accrued interest became due upon an event that resulted in the underlying shares becoming publicly traded or if the person left our employ. In the event of termination, the unforgiven principal plus accrued interest became due. The stock purchases were subject to variable accounting until they vested. We recorded \$38,044, \$144,583 and \$17,460, in variable stock compensation expense during the years ended December 31, 2007, 2006 and 2005, respectively, related to these shares.

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

---

**Table of Contents**

**INFINITY PHARMACEUTICALS, INC.**

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

We recorded \$17,429, \$198,151 and \$20,546, in variable stock compensation expense during the years ended December 31, 2007, 2006 and 2005, respectively, related to these shares. The loan was secured by the common stock purchased.

In 2005, we loaned two employees a total of \$85,378 to effect the exercise of stock options pursuant to the 2001 Plan. The loans were nonrecourse and nonsubstantive; therefore, we did not record the loans on our balance sheet and consequently continued to account for those awards as stock options for expense purposes. These unvested shares were subject to repurchase by us, at our option or upon certain events, at the original issuance price. The repurchase restriction lapsed ratably on a monthly basis over a four-year period. Interest on the loan accrued at 4.20%. The principal on the note and accrued interest were repaid or forgiven depending upon certain future events, provided that the employee remained employed by us. In the event of termination, the unforgiven principal plus accrued interest became due. The stock purchases were subject to variable accounting. We recorded \$12,383, \$23,964 and \$1,002 in variable stock compensation expense during the years ended December 31, 2007, 2006 and 2005, respectively, related to these shares. The loan was secured by the common stock purchased.

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

**13. Notes Receivable from Employees**

During 2002, we established a First Time Homebuyer Assistance Program under which our employees can apply for a forgivable loan for \$10,000 or \$16,000, depending on when they were hired, towards the purchase of their first home. The loans are forgiven over a period of three to four years. In the event of termination, the unforgiven principal of the note, plus interest accrued at a rate of between 3.06% and 4.6% per year, will be due and payable within 30 days. We may also provide loans to new employees to assist with relocation.

**14. Related-Party Transactions**

We paid consulting fees of approximately \$25,000 to \$75,000 per year per individual to five of our former board members and one of our scientific founders in connection with service on our scientific advisory board. Our scientific advisory board disbanded in December 2006. Total consulting fees paid to these individuals for the years ended December 31, 2006 and 2005 were approximately \$209,142 and \$220,824, respectively.

**15. 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 year ended December 31, 2007, we matched 50% of the first six percent of participant contributions with our common stock. The cost of our matching contributions during the year ended December 31, 2007 was \$370,698. We did not contribute to this plan during the years ended December 31, 2006 and 2005.

**16. Accounting for Sabbatical Leave**

On January 1, 2007, we adopted EITF 06-2 to account for sabbatical leaves. All of our full-time employees are eligible to receive four paid weeks of sabbatical leave after five years of continuous employment. The cumulative effect of a change in accounting principle as a result of adoption of EITF 06-2 was \$343,273, which

**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements (Continued)**

was recorded to accumulated deficit and accrued expenses as of January 1, 2007. We recorded additional compensation expense of \$96,075 during the year ended December 31, 2007. Prior to the adoption of EITF 06-2, we did not accrue for sabbatical leaves.

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

	Quarter Ended March 31, 2007	Quarter Ended June 30, 2007 (In Thousands, Except Per Share Amounts)	Quarter Ended September 30, 2007	Quarter Ended December 31, 2007
Collaborative research and development revenue	\$ 6,116	\$ 5,654	\$ 7,507	\$ 5,259
Operating expenses:				
Research and development	7,476	8,187	8,166	9,964
General and administrative	3,294	3,237	2,899	4,604
<b>Total operating expenses</b>	<b>10,770</b>	<b>11,424</b>	<b>11,065</b>	<b>14,568</b>
Loss from operations	(4,654)	(5,770)	(3,558)	(9,309)
Other (expense)/income:				
Interest expense	(102)	(30)	(30)	(26)
Interest and investment income	1,866	1,640	1,590	1,485
Total other income	1,764	1,610	1,560	1,459
<b>Net loss</b>	<b>\$ (2,890)</b>	<b>\$ (4,160)</b>	<b>\$ (1,998)</b>	<b>\$ (7,850)</b>
Basic and diluted net loss per common share	\$ (0.15)	\$ (0.21)	\$ (0.10)	\$ (0.40)
Basic and diluted weighted average number of common shares outstanding	19,388,131	19,505,672	19,576,199	19,628,653

	Quarter Ended March 31, 2006	Quarter Ended June 30, 2006 (In Thousands, Except Per Share Amounts)	Quarter Ended September 30, 2006	Quarter Ended December 31, 2006
Collaborative research and development revenue	\$ 719	\$ 2,819	\$ 5,997	\$ 8,959
Operating expenses:				
Research and development	9,678	8,825	8,267	9,022
General and administrative	1,973	1,385	2,453	3,653
<b>Total operating expenses</b>	<b>11,651</b>	<b>10,210</b>	<b>10,720</b>	<b>12,675</b>
Loss from operations	(10,932)	(7,391)	(4,723)	(3,716)
Other (expense)/income:				

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

Interest expense	(142)	(213)	(551)	(601)
Debt extinguishment charge				(1,551)
Interest and investment income	194	210	525	1,531
<b>Total other (expense)/income</b>	<b>52</b>	<b>(3)</b>	<b>(26)</b>	<b>(621)</b>
Loss before income taxes	(10,880)	(7,394)	(4,749)	(4,337)
Income taxes				(1,088)
Net loss	\$ (10,880)	\$ (7,394)	\$ (4,749)	\$ (5,425)
<b>Basic and diluted net loss per common share(1)</b>	<b>\$ (4.55)</b>	<b>\$ (3.04)</b>	<b>\$ (0.83)</b>	<b>\$ (0.28)</b>
Basic and diluted weighted average number of common shares outstanding(1)	2,393,401	2,435,095	5,740,124	19,270,605

- (1) Basic and diluted net loss per common share and weighted average shares outstanding were impacted by the conversion of the preferred stock and the issuance of common stock in connection with the DPI merger on September 12, 2006.

---

**Table of Contents**

**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 chief executive officer and chief 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, 2007. In designing and evaluating our disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our chief executive officer and chief financial officer concluded that as of December 31, 2007, our disclosure controls and procedures were (1) designed to ensure that material information relating to us is made known to our chief executive officer and chief financial officer by others, particularly during the period in which this report was prepared and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

**Internal Control Over Financial Reporting**

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

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

Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;

Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and

Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2007. 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 our assessment, management believes that, as of December 31, 2007, our internal control over financial reporting is effective based on those criteria.

---

**Table of Contents**

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

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

The Board of Directors and Shareholders of

Infinity Pharmaceuticals, Inc.

We have audited Infinity Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2007, 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, 2007, 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, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2007 of Infinity Pharmaceuticals, Inc. and our report dated March 11, 2008 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Boston, Massachusetts

March 11, 2008

**Table of Contents**

***(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, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information**

Not applicable.

**PART III**

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

The sections titled Proposal 1 Election of Directors, Board Meetings and Attendance, Board Committees, Section 16(a) Beneficial Ownership Reporting Compliance and Code of Business Conduct and Ethics appearing in the definitive proxy statement we will file in connection with our Annual Meeting of Stockholders to be held on May 22, 2008 are incorporated herein by reference. The information required by this item relating to executive officers may be found in Part I, Item 1 of this report under the heading Business Executive Officers.

**Item 11. Executive Compensation**

The section titled Compensation of Executive Officers and Directors appearing in the definitive proxy statement we will file in connection with our Annual Meeting of Stockholders to be held on May 22, 2008 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 22, 2008 are incorporated herein by reference.

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

The sections titled Transactions with Related Persons and Board Determination of Independence appearing in the definitive proxy statement we will file in connection with our Annual Meeting of Stockholders to be held on May 22, 2008 are incorporated herein by reference.

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

The section titled Auditors Fees appearing in the definitive proxy statement we will file in connection with our Annual Meeting of the Stockholders to be held on May 22, 2008 is incorporated herein by reference.



**Table of Contents**

**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

	<b>Page number</b>
<u>Report of Independent Registered Public Accounting Firm on Financial Statements</u>	52
<u>Consolidated Balance Sheets at December 31, 2007 and 2006</u>	53
<u>Consolidated Statements of Operations for the years ended December 31, 2007, 2006, and 2005</u>	54
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2007, 2006, and 2005</u>	55
<u>Consolidated Statements of Stockholders' Equity for the years ended December 31, 2007, 2006 and 2005</u>	57
<u>Notes to Consolidated Financial Statements</u>	60
<b>(a)(2) Financial Statement Schedules</b>	

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.

**Table of Contents****SIGNATURES**

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

**INFINITY PHARMACEUTICALS, INC.**

Date: March 13, 2008

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ STEVEN H. HOLTZMAN  <b>Steven H. Holtzman</b>	Chair & Chief Executive Officer  <i>(Principal Executive Officer)</i>	March 13, 2008
/s/ ADELENE Q. PERKINS  <b>Adelene Q. Perkins</b>	Executive Vice President & Chief Business Officer <i>(Principal Financial Officer)</i>	March 13, 2008
/s/ CHRISTOPHER M. LINDBLOM  <b>Christopher M. Lindblom</b>	Controller & Assistant Treasurer  <i>(Principal Accounting Officer)</i>	March 13, 2008
/s/ D. RONALD DANIEL  <b>D. Ronald Daniel</b>	Director	March 13, 2008
/s/ ANTHONY B. EVNIN, PH.D.  <b>Anthony B. Evnin, Ph.D.</b>	Director	March 13, 2008
/s/ HARRY F. HIXSON, JR., PH.D.  <b>Harry F. Hixson, Jr., Ph.D.</b>	Director	March 13, 2008
/s/ ERIC S. LANDER, PH.D.  <b>Eric S. Lander, Ph.D.</b>	Director	March 13, 2008
/s/ PATRICK P. LEE  <b>Patrick P. Lee</b>	Director	March 13, 2008

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

/s/ ARNOLD J. LEVINE, PH.D.	Director	March 13, 2008
<b>Arnold J. Levine, Ph.D.</b>		
/s/ FRANKLIN H. MOSS, PH.D.	Director	March 13, 2008
<b>Franklin H. Moss, Ph.D.</b>		
/s/ VICKI L. SATO, PH.D.	Director	March 13, 2008
<b>Vicki L. Sato, Ph.D.</b>		
/s/ JAMES B. TANANBAUM, M.D.	Director	March 13, 2008
<b>James B. Tananbaum, M.D.</b>		
/s/ MICHAEL C. VENUTI, PH.D.	Director	March 13, 2008
<b>Michael C. Venuti, Ph.D.</b>		

**Table of Contents**

**EXHIBIT INDEX**

<b>Exhibit</b>	<b>Description</b>
3.1	Restated Certificate of Incorporation of the Registrant. Previously filed as Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (File No. 000-31141) and incorporated herein by reference.
3.2	Bylaws of the Registrant. Previously filed as Exhibit 3.4 to the Registrant's Registration Statement on Form S-1 filed on June 23, 2000 (File No. 333-36638) and incorporated herein by reference.
3.3	Amendment to the Registrant's Amended and Restated Bylaws. Previously filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
3.4	Second Amendment to the Registrant's Amended and Restated Bylaws. Previously filed as Exhibit 3.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (File No. 000-31141) and incorporated herein by reference.
4.1	Form of Common Stock Certificate. Filed herewith.
4.2	Rights Agreement between the Registrant and American Stock Transfer & Trust Company dated February 13, 2003, which includes the form of Certificate of Designation for the Series A junior participating preferred stock as Exhibit A, the form of Rights Certificate as Exhibit B and the Summary of Rights to Purchase Series A junior participating preferred stock as Exhibit C. Previously filed as Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed on February 24, 2003 (File No. 000-31141) and incorporated herein by reference.
4.3	First Amendment to the Rights Agreement between the Registrant and American Stock Transfer & Trust Company dated April 11, 2006. Previously filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on April 12, 2006 (File No. 000-31141) and incorporated herein by reference.
10.1	License Agreement, dated as of July 7, 2006, by and between Infinity Discovery Inc. (formerly known as Infinity Pharmaceuticals, Inc.) ( IDI ) and Amgen Inc. Previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.2	Collaboration and Option Agreement, dated as of November 16, 2004, by and between IDI and Novartis International Pharmaceutical Ltd. Previously filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.3	Collaboration Agreement, dated as of February 24, 2006, by and between IDI and Novartis Institutes for BioMedical Research, Inc. Previously filed as Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.4	Collaboration and License Agreement, dated as of December 22, 2004, by and between IDI and Johnson & Johnson Pharmaceutical Research & Development, a division of Janssen Pharmaceutica N.V., as amended by Amendment No. 1 effective as of March 2, 2006. Previously filed as Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.5	Collaboration Agreement, dated as of August 25, 2006, by and between MedImmune, Inc. and IDI. Previously filed as Exhibit 10.1 to MedImmune's Quarterly Report on Form 10-Q for the quarter ended September 30, 2006 (File No. 0-19131) and incorporated herein by reference.
10.6	Master Security Agreement between IDI and General Electric Capital Corporation ( GE ) dated December 6, 2002, as amended on December 6, 2002, together with Promissory Notes in favor of GE. Previously filed as Exhibit 10.6 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.

**Table of Contents**

<b>Exhibit</b>	<b>Description</b>
10.7	Lease Agreement dated July 2, 2002 between IDI and ARE-770/784/790 Memorial Drive LLC (the Lease ), as amended by First Amendment to Lease dated March 25, 2003, Second Amendment to Lease dated April 30, 2003, Third Amendment to Lease dated October 30, 2003 and Fourth Amendment to Lease dated December 15, 2003. Previously filed as Exhibit 10.36 to the Registrant s Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.8	Sublease dated August 24, 2004 between IDI and Hydra Biosciences, Inc, together with Consent to Sublease dated September 16, 2004 by ARE-770/784/790 Memorial Drive LLC, IDI and Hydra Biosciences, Inc., as amended by First Amendment to Sublease dated October 17, 2005, together with Consent to Amendment to Sublease dated as of October 31, 2005 by ARE-770/784/790 Memorial Drive LLC and Second Amendment to Sublease dated as of January 9, 2006, together with Consent to Amendment to Sublease dated as of January 26, 2006 by ARE-770/784/790 Memorial Drive LLC, IDI and Hydra Biosciences, Inc. Previously filed as Exhibit 10.37 to the Registrant s Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.9*	Offer Letter between IDI and Steven Holtzman dated as of August 1, 2001. Previously filed as Exhibit 10.9 to the Registrant s Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.10*	Amendment to Offer Letter between IDI and Steven Holtzman dated as of October 25, 2007. Previously filed as Exhibit 99.3 to the Registrant s Current Report on Form 8-K filed on October 30, 2007 (File No. 000-31141) and incorporated herein by reference.
10.11*	Offer Letter between IDI and Julian Adams dated as of August 19, 2003. Previously filed as Exhibit 10.10 to the Registrant s Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.12*	Amendment to Offer Letter between IDI and Julian Adams dated as of October 25, 2007. Previously filed as Exhibit 99.4 to the Registrant s Current Report on Form 8-K filed on October 30, 2007 (File No. 000-31141) and incorporated herein by reference.
10.13*	Offer Letter between IDI and Adelene Perkins dated as of February 6, 2002. Previously filed as Exhibit 10.11 to the Registrant s Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.14*	Amendment to Offer Letter between IDI and Adelene Perkins dated as of October 25, 2007. Previously filed as Exhibit 99.5 to the Registrant s Current Report on Form 8-K filed on October 30, 2007 (File No. 000-31141) and incorporated herein by reference.
10.15*	Letter Agreement between IDI and Steven Holtzman dated effective as of March 31, 2006. Previously filed as Exhibit 10.12 to the Registrant s Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.16*	Letter Agreement between IDI and Julian Adams dated effective as of March 31, 2006. Previously filed as Exhibit 10.13 to the Registrant s Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.17*	Letter Agreement between IDI and Adelene Perkins dated effective as of March 31, 2006. Previously filed as Exhibit 10.14 to the Registrant s Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.18	Pre-Merger Stock Incentive Plan. Previously filed as Exhibit 10.18 to the Registrant s Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.

**Table of Contents**

<b>Exhibit</b>	<b>Description</b>
10.19*	Form of Restricted Stock Agreement entered into with each of the directors identified on the schedule thereto. Previously filed as Exhibit 10.19 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.20*	Form of Nonstatutory Stock Option Agreement entered into with each of the directors identified on the schedule thereto. Previously filed as Exhibit 10.20 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.21*	Form of Stock Restriction Agreement entered into with each of the directors identified on the schedule thereto. Previously filed as Exhibit 10.21 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.22*	Stock Restriction Agreement entered into with Franklin H. Moss on August 14, 2001. Previously filed as Exhibit 10.22 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.23*	Form of Restricted Stock Agreement entered into with each of the officers and directors identified on the schedule thereto. Previously filed as Exhibit 10.23 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.24*	Form of Restricted Stock Agreement entered into with each of the officers and directors identified on the schedule thereto. Previously filed as Exhibit 10.24 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.25*	Form of Incentive Stock Agreement entered into with each of the officers identified on the schedule thereto. Previously filed as Exhibit 10.25 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.26*	Restricted Stock Agreement entered into with Adelene Perkins on March 19, 2002. Previously filed as Exhibit 10.26 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.27*	Form of Nonstatutory Stock Option Agreement entered into with each of the officers identified on the schedule thereto. Previously filed as Exhibit 10.27 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.28*	Restricted Stock Agreement entered into with Julian Adams on October 6, 2003. Previously filed as Exhibit 10.28 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.29*	Form of Restricted Stock Agreement entered into with Steven Holtzman on each of the dates specified on the schedule thereto. Previously filed as Exhibit 10.29 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.30*	Nonstatutory Stock Option Agreement entered into with Steven Holtzman on March 25, 2004. Previously filed as Exhibit 10.30 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.31*	Restricted Stock Agreement entered into with Steven Holtzman on August 14, 2001. Previously filed as Exhibit 10.31 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.32	2000 Stock Incentive Plan. Previously filed as Exhibit 10.59 to the Registrant's Registration Statement on Form S-1 filed on May 9, 2000 (File No. 333-36638) and incorporated herein by reference.

**Table of Contents**

<b>Exhibit</b>	<b>Description</b>
10.33	Amendment No. 1 to 2000 Stock Incentive Plan; Amendment No. 2 to 2000 Stock Incentive Plan; Amendment No. 3 to 2000 Stock Incentive Plan. Previously filed as Exhibit 10.32 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.34	Amendment No. 4 to 2000 Stock Incentive Plan. Previously filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (File No. 000-31141) and incorporated herein by reference.
10.35	Form of Incentive Stock Option Agreement under 2000 Stock Incentive Plan. Previously filed as Exhibit 10.33 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.36	Form of Nonstatutory Stock Option Agreement under 2000 Stock Incentive Plan. Previously filed as Exhibit 10.34 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.37	Form of Restricted Stock Agreement under 2000 Stock Incentive Plan. Previously filed as Exhibit 10.35 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
21.1	Subsidiaries of the Registrant. Filed herewith.
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm. Filed herewith.
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended. Filed herewith.
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended. Filed herewith.
32.1	Statement of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Filed herewith.
32.2	Statement of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Filed herewith.

\* Indicates management contract or compensatory plan  
 Confidential treatment has been requested and/or granted as to certain portions, which portions have been filed separately with the Securities and Exchange Commission.