INFINITY PHARMACEUTICALS, INC.
Form S-3/A
January 09, 2009
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As filed with the Securities and Exchange Commission on January 9, 2009

Registration No. 333-156246

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Pre-Effective

Amendment No. 1

to

FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

INFINITY PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

780 Memorial Drive

Cambridge, Massachusetts 02139

(617) 453-1000

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Gerald E. Quirk

Vice President and General Counsel

Infinity Pharmaceuticals, Inc.

780 Memorial Drive

Cambridge, Massachusetts 02139

(617) 453-1000

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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Approximate date of commencement of proposed sale to the public: From time to time after this registration statement becomes effective.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ¨

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. x

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨ _____

If this form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ¨

If this form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ¨

*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 the 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 x
Non-accelerated filer ¨	Smaller reporting company ¨

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be Registered	Proposed Maximum Offering Price Per Unit (1)	Proposed Maximum Aggregate Offering Price (1)	Amount of Registration Fee (2)
Common Stock, $0.001 par value per share	12,000,000	$7.25	$87,000,000	$3,419.10

(1) Pursuant to Rule 416 under the Securities Act, this Registration Statement also covers such additional number of additional shares of common stock issuable upon stock splits, stock dividends, dividends or other distribution, recapitalization or similar event with respect to the 12,000,000 shares of common stock being registered pursuant to this registration statement.

(2) Estimated solely for purposes of calculating the registration fee pursuant to Rule 457(c) under the Securities Act, based on average of high and low price per share of the common stock as reported on the NASDAQ Global Market on January 8, 2009. Of this amount, $1,021.01 was previously paid in connection with the initial filing of this Registration Statement with the Securities and Exchange Commission on December 17, 2008, where 4,000,000 shares of common stock were registered.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. The selling stockholders named in this prospectus may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and the selling stockholders named in this prospectus are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to completion, dated January 9, 2009

PROSPECTUS

INFINITY PHARMACEUTICALS, INC.

12,000,000 SHARES OF COMMON STOCK

This prospectus relates to resales of 6,000,000 shares of common stock held by Beacon Company, a Delaware general partnership, and Rosebay Medical Company L.P., a Delaware limited partnership, as transferees of Purdue Pharma L.P. and Purdue Pharmaceutical Products L.P., each a Delaware limited partnership, that were issued by Infinity Pharmaceuticals, Inc. in private placements completed on November 19, 2008 and January 7, 2009, and to resales of 6,000,000 shares of common stock issuable upon exercise of warrants held by Beacon Company and Rosebay Medical Company L.P., as transferees of Purdue Pharma L.P. and Purdue Pharmaceutical Products L.P., that were issued by Infinity Pharmaceuticals, Inc. in a private placement completed on January 7, 2009.

We will not receive any proceeds from the sale of the shares.

The selling stockholders identified in this prospectus, or their respective permitted pledgees, donees, transferees or other successors-in-interest, may offer the shares from time to time through public or private transactions at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices.

Our common stock is listed on the NASDAQ Global Market under the symbol INFI. On January 8, 2009, the reported last sale price of our common stock on the NASDAQ Global Market was $7.29 per share. You are urged to obtain current market quotations for our common stock.

Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page 5 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is January , 2009

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

Our website is located at *www.infi.com*. We regularly use our website to post information regarding our business, product development programs and governance, and we encourage you to use our website, particularly in the section entitled Investors/Media, as a source of information about us. We have not incorporated by reference into this prospectus the information on our website and you should not consider it to be a part of this document. Our website address is included as an inactive textual reference only.

Unless the context otherwise requires, references in this prospectus to Infinity, we, us, and our refer to Infinity Pharmaceuticals, Inc. and its subsidiaries.

We have not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus. The selling stockholders are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of common stock.

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PROSPECTUS SUMMARY

This summary highlights important features of this offering and the information included or incorporated by reference in this prospectus. This summary does not contain all of the information that you should consider before investing in our common stock. You should read the entire prospectus carefully, especially the risks of investing in our common stock discussed under Risk Factors.

INFINITY PHARMACEUTICALS, INC.

Our mission is to discover, develop, and deliver to patients best-in-class medicines for the treatment of cancer and related conditions. We combine our scientific expertise with a passion for developing novel small molecule drugs that target emerging cancer pathways with the goal of bringing better drugs to patients.

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

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

In December 2008, we reacquired from MedImmune, Inc., an affiliate of AstraZeneca plc, all worldwide development and commercialization rights for our Hsp90 program, which includes IPI-504 and IPI-493.

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

We also have a discovery program directed to fatty acid amide hydrolase, or FAAH, an emerging target for neuropathic pain. The enzyme FAAH degrades anandamide, which is an endogenous cannabanoid that produces an analgesic effect in response to pain. FAAH inhibition increases the duration of anandamide s analgesic effect, prolonging pain relief at the site of release. We expect to select a clinical candidate in our FAAH program by early 2009. We are pursuing our FAAH program in collaboration with Mundipharma and Purdue Pharmaceutical Products L.P., or Purdue.

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THE OFFERING

Common Stock offered by selling stockholders	12,000,000 shares
Use of proceeds	We will not receive any proceeds from the sale of the shares in the offering.
NASDAQ Global Market symbol	INFI

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RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below before purchasing our common stock. The risks and uncertainties described below are not the only ones facing our company. Additional risks and uncertainties may also impair our business operations. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer. In that case, the trading price of our common stock could fall, and you may lose all or part of the money you paid to buy our common stock.

Risks Related to Our Stage of Development as a Company

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

We have a limited operating history for you to evaluate our business. We have no approved products and have generated no product revenue. We have historically incurred operating losses. As of September 30, 2008, we had an accumulated deficit of $195.7 million, and our net losses for the nine months ended September 30, 2008 and the years ended December 31, 2007, 2006 and 2005 were $23.1 million, $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 IPI-504, IPI-493, IPI-926 and our other drug candidates. While we may have net income in future periods as the result of non-recurring collaboration revenue, we expect to incur substantial operating losses over the next several years as our clinical trial and drug manufacturing activities for our heat shock protein 90, or Hsp90, program increase and as we incur pre-commercialization expenses in anticipation of a potential commercial launch of IPI-504. As a result, our accumulated deficit will also increase significantly.

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

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

We will need substantial additional funds to support our planned operations. In the absence of additional funding and based on our current operating plans, we expect that our current cash, cash equivalents and available-for-sale securities, together with the $50 million line of credit that has been made available to us by entities associated with Purdue Pharmaceutical Products L.P., or Purdue, are sufficient to fund our planned operations through the end of 2012. We may, however, need to raise additional funds before that date if, for example, our research and development expenses exceed our current expectations or if we do not receive the 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 preclinical drug candidates than expected into early stage clinical trials;
- the cost of acquiring raw materials for, and of manufacturing, our drug candidates is higher than anticipated;
- we are required, or consider it advisable, to acquire or license intellectual property rights from one or more third parties;

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

Mundipharma or Purdue elects to discontinue its participation in a partnered program; or

we experience a loss in our investments due to general market conditions or other reasons.

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

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

This risk of failure of our current clinical candidates is high. To date, the data supporting our clinical development strategy for IPI-504, IPI-493, and IPI-926 are derived solely from laboratory and preclinical studies and, in the case of IPI-504, limited early-stage clinical trials. Later clinical trials, including our recently-commenced Phase 3 clinical trial of IPI-504 in refractory gastrointestinal stromal tumors, or GIST, may not show that IPI-504 is safe and effective in patients with this disease, in which case we would need to change our development strategy or abandon development of that drug candidate, either of which would result in delays and additional costs. It is impossible to predict when or if IPI-504, IPI-493, IPI-926 or any of our other drug candidates will prove safe or effective in humans or receive regulatory approval. These drug candidates may not demonstrate in patients the chemical and pharmacological properties ascribed to them in laboratory studies or early-stage clinical trials, and they may interact with human biological systems or other drugs in unforeseen, ineffective or harmful ways. If we are unable to discover or successfully develop drugs that are safe and effective in humans, we will not have a viable business.

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

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

terminates the agreement;

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

fails to successfully develop or manufacture any products arising out of our FAAH program or to commercialize any drug candidate under the alliance; or

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to the Development and Commercialization of Our Drug Candidates

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

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

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

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

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

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

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

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

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

- unexpected or unfavorable results of discussions with the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- delays in receiving, or the inability to obtain, required approvals from institutional review boards or other reviewing entities at clinical sites selected for participation in our clinical trials;
- delays in enrolling patients into clinical trials;
- a lower than anticipated retention rate of patients in clinical trials;
- the need to repeat clinical trials as a result of inconclusive or negative results or unforeseen complications in testing;
- inadequate supply or deficient quality of drug product or other materials necessary to conduct our clinical trials;
- unfavorable FDA inspection and review of a clinical trial site or records of any clinical or preclinical investigation;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials;
- a finding that the trial participants are being exposed to unacceptable health risks;

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

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

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

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

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

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

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

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

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

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

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

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in a delay of the affected trial and unplanned costs. If this were to occur, our efforts to obtain regulatory approval for and to commercialize our drug candidates may be delayed.

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

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

In September 2007, the Food and Drug Administration Amendments Act of 2007, or FDAAA, was enacted. The FDAAA grants a variety of new powers to the FDA, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. Under the FDAAA, companies that violate the new law are subject to substantial civil monetary penalties. While we expect the FDAAA to have a substantial effect on the biopharmaceutical industry, the extent of that effect is not yet known. As the FDA issues regulations, guidance and interpretations relating to the new legislation, the impact on the industry, as well as our business, will become clearer. The new requirements and other changes that the FDAAA imposes may make it more difficult, and likely more costly, to obtain approval of new medicines and to produce, market and distribute those products after approval.

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

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

To date, our drug candidates have been manufactured for preclinical testing and clinical trials primarily by third party manufacturers. If the FDA or other regulatory agencies approve IPI-504 or any of our other drug candidates for commercial sale, we expect that we would continue to rely, at least initially, on third party manufacturers to produce commercial quantities of our approved drug candidates. These manufacturers may not be able to successfully increase the manufacturing capacity for any approved drug candidates in a timely or economical manner, or at all. Significant scale-up of manufacturing might entail changes in the

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manufacturing process that have to be submitted to or approved by the FDA or other regulatory agencies. If contract manufacturers engaged by us are unable to successfully increase the manufacturing capacity for a drug candidate, or we are unable to establish our own manufacturing capabilities, the commercial launch of any approved products may be delayed or there may be a shortage in supply.

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

Even if IPI-504 or any of our other drug candidates obtains regulatory approval, that product may not gain market acceptance among physicians, patients and the medical community for a variety of reasons including:

- timing of market introduction of competitive drugs;
- lower demonstrated clinical safety and efficacy compared to other drugs;
- lack of cost-effectiveness;
- lack of reimbursement from managed care plans and other third-party payers;
- inconvenient or difficult administration;
- prevalence and severity of side effects;
- potential advantages of alternative treatment methods;
- safety concerns with similar drugs marketed by others;
- the reluctance of the target population to try new therapies and of physicians to prescribe those therapies; and
- ineffective sales, marketing and distribution support.

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

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

The FDA continues to review products even after they receive initial approval. If we receive approval to commercialize IPI-504 or any of our other drug candidates, the manufacturing, marketing and sale of these drugs will be subject to continuing regulation, including compliance with quality systems regulations, good manufacturing practices, adverse event requirements, and prohibitions on promoting a product for unapproved uses. Enforcement actions resulting from our failure to comply with government and regulatory requirements could result in fines, suspension of approvals, withdrawal of approvals, product recalls, product seizures, mandatory operating restrictions, criminal prosecution, civil penalties and other actions that could impair the manufacturing, marketing and sale of our drug candidates and our ability to conduct our business.

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

Even if we receive regulatory approval for IPI-504 or any of our other drug candidates, we will have tested them in only a small number of patients during our clinical trials. If our applications for marketing are approved and more patients begin to use our product, new risks and side effects associated with our products may be discovered.

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

Healthcare reform measures could adversely affect our business.

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

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

The Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA, expanded Medicare coverage for drug purchases by the elderly and disabled beginning in 2006. The new legislation uses formularies, preferred drug lists and similar mechanisms that may limit the number of drugs that will be covered in any therapeutic class or reduce the reimbursement for some of the drugs in a class. As a result of the expansion of legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce healthcare-related costs. Indeed, legislation that would permit the federal government to negotiate drug prices directly with manufacturers under the Medicare prescription drug programs is a major policy priority for many members of Congress and may be passed in the future. These cost reduction initiatives could decrease the coverage and price that we receive for our products in the future and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own reimbursement systems, and any limits on or reductions in reimbursement that occur in the Medicare programs may result in similar limits on or reductions in payments from private payers.

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

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

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

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

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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, Pfizer Inc. and Genentech, Inc. In addition to currently approved drugs, there are a significant number of drugs that are currently under development and may become available in the future for the treatment of various forms of cancer. We are also aware of a number of companies seeking to develop drug candidates directed to the same biological targets that our own drug candidates are designed to inhibit. Specifically, we are aware of numerous companies that have clinical development programs for compounds targeting Hsp90, which is the target of IPI-504 and IPI-493. These companies include, without limitation, Bristol-Myers Squibb (through its acquisition of Kosan Biosciences Incorporated), Biogen Idec Inc., Pfizer (through its acquisition of Serenex, Inc.), Vernalis plc (in collaboration with Novartis), Synta Pharmaceuticals Corp., Exelixis, Inc. and Astex Therapeutics Limited. In addition, Genentech (in collaboration with Curis, Inc.) and Exelixis, Inc. (in collaboration with Bristol-Myers Squibb) have collaborations under which drugs targeting the Hedgehog signaling pathway, which is also being targeted by IPI-926, are being developed.

Many of our competitors have:

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

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

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

We face exposure to significant product liability or other claims if any of our drug candidates is alleged to have caused harm. These risks are inherent in the testing, manufacturing and marketing of human medicinal products. Although we do not currently commercialize any products, claims could be made against us based on the use of our drug candidates in clinical trials. We currently have clinical trial insurance and will seek to obtain product liability insurance prior to the commercial launch of any of our drug candidates. Our insurance may not, however, provide adequate coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain current amounts of

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insurance coverage or obtain additional or sufficient insurance at a reasonable cost. If we are sued for any injury caused by our products or product candidates, our liability could exceed our insurance coverage and our total assets, and we would need to divert management attention to our defense. Claims against us, regardless of their merit or potential outcome, may also generate negative publicity or hurt our ability to recruit investigators and patients to our clinical trials, obtain physician acceptance of our products, or expand our business.

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

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

Risks Related to Intellectual Property

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

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

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

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

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

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

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

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

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

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

While we are not currently aware of any litigation or third party claims of intellectual property infringement related to our drug candidates, the biopharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents and claim that the use of our technologies infringes these patents or that we are employing

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their proprietary technology without authorization. We could incur substantial costs and diversion of management and technical personnel in defending against any claims that the manufacture and sale of our potential products or use of our technologies infringes any patents, or defending against any claim that we are employing any proprietary technology without authorization. The outcome of patent litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of the adverse party, especially in pharmaceutical patent cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. In the event of a successful claim of infringement against us, we may be required to:

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

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

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

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

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

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

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

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

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

Risks Associated with Our Common Stock

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

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

- the results of our current and any future clinical trials of IPI-504, IPI-493 and IPI-926 and our other drug candidates;
- the results of preclinical studies and planned clinical trials of our other discovery-stage programs;
- future sales of, and the trading volume in, our common stock;
- the entry into key agreements, including those related to the acquisition or in-licensing of new programs, or the termination of key agreements;
- the results and timing of regulatory reviews relating to the approval of our drug candidates;
- the initiation of, material developments in, or conclusion of litigation to enforce or defend any of our intellectual property rights;
- the initiation of, material developments in, or conclusion of litigation to defend products liability claims;
- the failure of any of our drug candidates, if approved, to achieve commercial success;
- the results of clinical trials conducted by others on drugs that would compete with our drug candidates;
- issues in manufacturing our drug candidates or any approved products;
- the loss of key employees;

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

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

changes in the structure of health care payment systems;

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

general and industry-specific economic conditions.

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

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

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

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

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

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

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

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

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

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

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

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

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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.

SPECIAL NOTE REGARDING FORWARD-LOOKING INFORMATION

This prospectus includes and incorporates forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements, other than statements of historical facts, included or incorporated in this prospectus regarding our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words anticipates, believes, estimates, expects, intends, may, plans, projects, will, would and similar expressions are intended to identify forward-looking stater although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included or incorporated in this prospectus, particularly under the heading Risk Factors , that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. Any such forward-looking statements represent management s views as of the date of the document in which such forward-looking statement is contained. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change.

USE OF PROCEEDS

We are filing the registration statement of which this prospectus is a part to permit holders of the shares of our common stock described in the section entitled Selling Stockholders to resell such shares. We will not receive any proceeds from the resale of shares by the selling stockholders. The selling stockholders will pay any underwriting discounts and commissions and expenses incurred by such selling stockholders for brokerage, accounting, tax or legal services or any other expenses incurred by such selling stockholders in disposing of the shares. We will bear all other costs, fees and expenses incurred in effecting the registration of the shares covered by this prospectus, including, without limitation, all registration and filing fees, NASDAQ Global Market listing fees and fees and expenses of our counsel and our auditors.

SELLING STOCKHOLDERS

On November 19, 2008, we sold 4,000,000 shares of our common stock in a private placement to Purdue Pharma L.P. and Purdue Pharmaceutical Products L.P. (the Initial Purchasers) in connection with our execution of a securities purchase agreement with such parties, which we refer to herein as the securities purchase agreement. Further, on January 7, 2009, we sold 2,000,000 shares of our common stock, and warrants to purchase 6,000,000 shares of our common stock, to the Initial Purchasers pursuant to the securities purchase agreement. All of such shares, as well as all of such warrants, were subsequently transferred through associated entities of the Initial Purchasers to the selling stockholders named in the table below. The table below also sets forth, to our knowledge, certain information about the selling stockholders as of January 8, 2009.

We do not know when or in what amounts the selling stockholders may offer shares for sale. The selling stockholders might not sell any or all of the shares offered by this prospectus. Because the selling stockholders may offer all or some of the shares pursuant to this offering and because there are currently no agreements or understandings with respect to the sale of any shares, we cannot estimate the number of shares that will be held by the selling stockholders after completion of this offering. However, for purposes of this table, we have assumed that, after completion of this offering, none of the shares covered by this prospectus will be held by the selling stockholders.

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Name of Selling Stockholders	Shares of Common Stock Beneficially Owned Prior to Offering		Number of Shares of Common Stock Being Offered	Shares of Common Stock to be Beneficially Owned After Offering	
	Number	Percentage		Number	Percentage
Beacon Company	6,000,000(1)	18.75%	6,000,000		
Rosebay Medical Company L.P.	6,000,000(1)	18.75%	6,000,000		

(1) Consists of 3,000,000 shares of common stock and 3,000,000 shares of common stock issuable upon exercise of currently-exercisable warrants.

Neither the selling stockholders nor any of their affiliates, officers, directors or holders of 5% or more of their respective share capital had held any position or office with us or any of our subsidiaries within the past three years. On November 19, 2008, we entered into strategic alliance agreements with Mundipharma International Corporation Limited, an independent associated company of the Initial Purchasers, and Purdue Pharmaceutical Products L.P. to develop and commercialize pharmaceutical products. On November 19, 2008, we also entered into a Line of Credit Agreement with the Initial Purchasers which provides for the borrowing by us from the Initial Purchasers of one or more unsecured loans up to an aggregate maximum principal amount of $50,000,000, subject to specified conditions.

PLAN OF DISTRIBUTION

The shares covered by this prospectus may be offered and sold from time to time by the selling stockholders. The term selling stockholders includes donees, pledgees, transferees or other successors-in-interest selling shares received after the date of this prospectus from the selling stockholders as a gift, pledge, distribution or other non-sale related transfer. The selling stockholders will act independently of us in making decisions with respect to the timing, manner and size of each sale. Such sales may be made on one or more exchanges or in the over-the-counter market or otherwise, at prices and under terms then prevailing or at prices related to the then current market price or in negotiated transactions. The selling stockholders may sell their shares by one or more of, or a combination of, the following methods:

purchases by a broker-dealer as principal and resale by such broker-dealer for its own account pursuant to this prospectus;

ordinary brokerage transactions and transactions in which the broker solicits purchasers;

an over-the-counter distribution in accordance with the rules of The Nasdaq Stock Market;

in privately negotiated transactions;

in options transactions;

to or through underwriters;

through dealers or agents;

a block trade in which the broker or dealer so engaged will attempt to sell the securities as an agent but may position and resell a portion of the block as a principal to facilitate the transaction;

through a combination of these methods; and

by any other legally available means.

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In addition, any shares that qualify for sale pursuant to Rule 144 may be sold under Rule 144 rather than pursuant to this prospectus.

To the extent required, this prospectus may be amended or supplemented from time to time to describe a specific plan of distribution. In connection with the distributions of shares or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions. In connection with such transactions, broker-dealers or other financial institutions may engage in short sales of the common stock in the course of hedging the positions they assume with the selling stockholders. The selling stockholders may enter into option or other transactions with broker-dealers or other financial institutions which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction). The selling stockholders may also pledge shares to a broker-dealer or other financial institution, and, upon a default, such broker-dealer or other financial institution, may effect sales of the pledged shares pursuant to this prospectus (as supplemented or amended to reflect such transaction).

In effecting sales, underwriters, broker-dealers or agents engaged by the selling stockholders may arrange for other underwriters or broker-dealers to participate. Underwriters, broker-dealers or agents may receive commissions, discounts or concessions from the selling stockholders in amounts to be negotiated immediately prior to the sale. Such discounts, concessions or commissions as to particular underwriters, broker-dealers or agents may be in excess of those customary on the types of transactions involved.

In offering the shares covered by this prospectus, the selling stockholders and any broker-dealers who execute sales for the selling stockholders may be deemed to be underwriters within the meaning of the Securities Act in connection with such sales. Any profits realized by the selling stockholders and the compensation of any broker-dealer may be deemed to be underwriting discounts and commissions. Some of the underwriters or deemed underwriters or agents and their associates may be customers of, engage in transactions with, and perform services for us in the ordinary course of business.

In order to comply with the securities laws of certain states, if applicable, the shares must be sold in such jurisdictions only through registered or licensed brokers or dealers. In addition, in certain states the shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

We have advised the selling stockholders that the anti-manipulation rules of Regulation M under the Exchange Act, may apply to sales of shares in the market and to the activities of the selling stockholders and their affiliates. In addition, we will make copies of this prospectus available to the selling stockholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The selling stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

At the time a particular offer of shares is made, if required, a prospectus supplement will be distributed that will set forth the number of shares being offered and the terms of the offering, including the name of any underwriter, dealer or agent, the purchase price paid by any underwriter, any discount, commission and other item constituting compensation, any discount, commission or concession allowed or reallowed or paid to any dealer, and the proposed selling price to the public.

We will pay all expenses of the registration of the shares of common stock pursuant to the securities purchase agreement, including, without limitation, Securities and Exchange Commission, or SEC, filing fees and expenses of compliance with state securities or blue sky laws; *provided, however,* that the selling stockholders will pay all underwriting discounts, commissions and concessions and brokers or agents commissions and concessions or selling commissions and concessions, if any. We have agreed to indemnify the selling stockholders against certain liabilities, including certain liabilities under the Securities Act. Underwriters, dealers and agents may be entitled to indemnification by us and the selling stockholders against specific civil liabilities, including liabilities under the Securities Act or to contribution with respect to payments which the underwriters or agents may be required to make in respect thereof, under underwriting or other agreements. The terms of any indemnification provisions will be set forth in a prospectus supplement.

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We have agreed with the selling stockholders to keep the registration statement of which this prospectus constitutes a part effective until such time as all of the shares covered by this prospectus may have been sold or may without volume restrictions pursuant to Rule 144.

LEGAL MATTERS

The validity of the shares offered by this prospectus has been passed upon by Wilmer Cutler Pickering Hale and Dorr LLP.

EXPERTS

The consolidated financial statements of Infinity Pharmaceuticals, Inc. appearing in Infinity Pharmaceuticals, Inc. s Annual Report (Form 10-K) for the year ended December 31, 2007, and the effectiveness of Infinity Pharmaceuticals, Inc. s internal control over financial reporting as of December 31, 2007 have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their reports thereon, included therein, and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such reports given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We file reports, proxy statements and other documents with the SEC. You may read and copy any document we file at the SEC s public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You should call 1-800-SEC-0330 for more information on the public reference room. Our SEC filings are also available to you on the SEC s Internet site at www.sec.gov.

This prospectus is part of a registration statement that we filed with the SEC. The registration statement contains more information than this prospectus regarding us and our common stock, including certain exhibits and schedules. You can obtain a copy of the registration statement from the SEC at the address listed above or from the SEC s Internet site.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC requires us to incorporate into this prospectus information that we file with the SEC in other documents. This means that we can disclose important information to you by referring to other documents that contain that information. The information incorporated by reference is considered to be part of this prospectus. Information contained in this prospectus and information that we file with the SEC in the future and incorporate by reference in this prospectus automatically updates and supersedes previously filed information. We incorporate by reference the documents listed below and any future filings we make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus and prior to the termination of this offering.

(1) Our Annual Report on Form 10-K for the year ended December 31, 2007, as filed with the SEC on March 14, 2008;

(2) Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, as filed with the SEC on May 9, 2008;

(3) Our Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, as filed with the SEC on August 6, 2008;

(4) Our Quarterly Report on Form 10-Q for the quarter ended September 30, 2008, as filed with the SEC on November 5, 2008;

(5) Our Current Report on Form 8-K, as filed with the SEC on January 7, 2008 (solely with respect to Item 8.01 therein);

(6) Our Current Report on Form 8-K, as filed with the SEC on March 18, 2008;

(7) Our Current Report on Form 8-K, as filed with the SEC on June 2, 2008;

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(8) Our Current Report on Form 8-K, as filed with the SEC on July 14, 2008;

(9) Our Current Report on Form 8-K, as filed with the SEC on October 28, 2008;

(10) Our Current Report on Form 8-K, as filed with the SEC on November 20, 2008;

(11) Our Current Report on Form 8-K, as filed with the SEC on December 9, 2008;

(12) Our Current Report on Form 8-K, as filed with the SEC on December 12, 2008;

(13) Our Current Report on Form 8-K, as filed with the SEC on January 8, 2009;

(14) Any other filings we make pursuant to the Exchange Act after the date of filing the initial registration statement and prior to effectiveness of the registration statement; and

(15) The description of our common stock contained in our Registration Statement on Form 8-A filed with the SEC on July 25, 2000 and our Registration Statement on Form 8-A filed with the SEC on February 24, 2003, as amended on November 20, 2008, including any amendments or reports filed for the purpose of updating those descriptions.

A statement contained in a document incorporated by reference into this prospectus shall be deemed to be modified or superceded for purposes of this prospectus to the extent that a statement contained in this prospectus, any prospectus supplement or in any other subsequently filed document which is also incorporated in this prospectus modifies or replaces such statement. Any statements so modified or superceded shall not be deemed, except as so modified or superceded, to constitute a part of this prospectus.

You may request a copy of these documents, which will be provided to you at no cost, by writing or telephoning us using the following contact information:

Infinity Pharmaceuticals, Inc.

780 Memorial Drive

Cambridge, Massachusetts 02139

Attention: Investor Relations

(617) 453-1000

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PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The following table sets forth the various expenses to be incurred in connection with the sale and distribution of the securities being registered hereby, all of which will be borne by Infinity (except any underwriting discounts and commissions and expenses incurred by the selling stockholders for brokerage, accounting, tax or legal services or any other expenses incurred by the selling stockholders in disposing of the shares). All amounts shown are estimates except the SEC registration fee.

SEC registration fee	$ 3,419
Legal fees and expenses	25,000
Accounting fees and expenses	10,000
Miscellaneous expenses	1,581
Total expenses	$ 40,000

Item 15. Indemnification of Directors and Officers.

Section 102 of the Delaware General Corporation Law, or the DGCL, allows a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. We have included such a provision in our Restated Certificate of Incorporation.

Section 145 of the DGCL empowers a corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he or she is or was a director, officer, employee or agent of the corporation or another enterprise if serving such enterprise at the request of the corporation. Depending on the character of the proceeding, a corporation may indemnify against expenses (including attorney s fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding if the person indemnified acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. In the case of an action by or in the right of the corporation, no indemnification may be made in respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine that despite the adjudication of liability, but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses that the court shall deem proper. Section 145 further provides that to the extent a director or officer of a corporation has been successful in the defense of any action, suit or proceeding referred to above, or in defense of any claim, issue or matter therein, he or she shall be indemnified against expenses (including attorney s fees) actually and reasonably incurred by him or her in connection therewith.

Our certificate of incorporation and bylaws provide that we shall, to the fullest extent authorized by the DGCL, indemnify our directors and executive officers; provided, however, that we may limit the extent of such indemnification by individual contracts with our directors and executive officers; and, provided, further, that we shall not be required to indemnify any director or executive officer in connection with any proceeding (or part thereof) initiated by such person or any proceeding by such person against us or our directors, officers, employees or other agents unless (i) such indemnification is expressly required to be made by law, (ii) the proceeding was authorized by the board of directors, and (iii) such indemnification is provided by us, in its sole discretion, pursuant to its powers under the DGCL.

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Until September 2012, we must advance expenses to and indemnify each former director and officer of Discovery Partners International, Inc. against costs and damages incurred as a result of such director or officer serving as a director or officer of Discovery Partners International, Inc. to the fullest extent permitted under the DGCL.

We have entered into agreements to indemnify certain of our directors and former executive officers. These agreements, among other things, provide for indemnification of such directors and executive officers for expenses specified in the agreements, including attorneys fees, judgments, fines and settlement amounts incurred by such directors or former executive officers in any action or proceeding arising out of that person s services as a director or executive officer of ours, any subsidiary of ours or any other entity to which the person provides or provided services at our request.

Our bylaws also permit us to maintain insurance to protect us and any director, officer, employee or agent against any liability with respect to which we would have the power to indemnify such persons under the DGCL. We maintain an insurance policy insuring our directors and officers against certain liabilities.

Item 16. Exhibits

EXHIBIT NUMBER	DESCRIPTION
4.1	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.
4.2	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.
4.3	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.
4.4	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.
4.5	Form of Common Stock Certificate. Previously filed as Exhibit 4.1 to the Registrant s Annual Report on Form 10-K filed on March 14, 2008 (File No. 000-31141) and incorporated herein by reference.
4.6	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.
4.7	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.

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4.8	Second Amendment to the Rights Agreement between the Registrant and American Stock Transfer & Trust Company dated November 19, 2008. Previously filed as Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed on November 20, 2008 (File No. 000-31141) and incorporated herein by reference.
5.1	Opinion of WilmerHale
23.1	Consent of Ernst & Young LLP (Independent Registered Public Accounting Firm)
23.2	Consent of WilmerHale, included in Exhibit 5.1 filed herewith.
24.1	Power of Attorney (Included in the signature page to the initial filing of this Registration Statement).

Item 17. Undertakings.

Item 512(a) of Regulation S-K. The undersigned Registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in the volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (i), (ii) and (iii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for purposes of determining liability under the Securities Act of 1933 to any purchaser:

(i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5) or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii) or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement

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relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

Item 512(b) of Regulation S-K. The undersigned registrant hereby undertakes that, for the purpose of determining any liability under the Securities Act of 1933, each filing of the registrant s annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan s annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

Item 512(h) of Regulation S-K. Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all the requirements for filing on Form S-3 and has duly caused this Pre-Effective Amendment No. 1 to its Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Cambridge, Commonwealth of Massachusetts, on January 9, 2009.

INFINITY PHARMACEUTICALS, INC.

By: /s/ Steven H. Holtzman
Steven H. Holtzman

Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, as amended, this Pre-Effective Amendment No. 1 to Registration Statement has been signed by the following persons in the capacities indicated on January 9, 2009.

Signature	Title
/s/ Steven H. Holtzman Steven H. Holtzman	Chairman and Chief Executive Officer (Principal Executive Officer)
/s/ Adelene Q. Perkins Adelene Q. Perkins	President and Chief Business Officer (Principal Financial Officer)
/s/ Christopher M. Lindblom Christopher M. Lindblom	Controller and Assistant Treasurer (Principal Accounting Officer)
* Martin Babler	Director
* Anthony B. Evnin, Ph.D.	Director
* Harry F. Hixson, Jr., Ph.D.	Director
* Eric S. Lander, Ph.D.	Director

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* Patrick P. Lee	Director
* Arnold J. Levine, Ph.D.	Director
* Franklin H. Moss, Ph.D.	Director
* Vicki L. Sato, Ph.D.	Director
* Ian F. Smith	Director
* James B. Tananbaum, M.D.	Director
* Michael C. Venuti, Ph.D.	Director

*By: /s/ Gerald E. Quirk
Gerald E. Quirk
As Attorney-in-Fact

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