IntelliPharmaCeutics International Inc.
Form F-3
March 11, 2011

As filed with the Securities and Exchange Commission on March 11, 2011
Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

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FORM F-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

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INTELLIPHARMACEUTICS INTERNATIONAL INC.
(Exact name of Registrant as specified in its charter)
(Translation of Registrant's name into English)

_____

Canada	N/A
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

30 Worcester Road
Toronto, Ontario M9W 5X2
(416) 798-3001
(Address and telephone number of Registrant's principal executive offices)

_____

Shameze Rampertab
Chief Financial Officer and
Vice President, Finance
Intellipharmaceutics International Inc.
30 Worcester Road
Toronto, Ontario M9W 5X2
(416) 798-3001
(Name, address, and telephone number of agent for service)

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With copies to:

Richard DiStefano, Esq.
Blank Rome LLP

405 Lexington Avenue
New York, New York 10174
Telephone: (212) 885-5000
Facsimile: (212) 885-5001

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Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this Registration Statement.

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, 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 filed pursuant to General Instruction I.C. 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.C. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under Securities Act, check the following box. ¨

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered(1)	Proposed maximum offering price per security(2)	Proposed maximum aggregate offering price	Amount of registration fee
Common shares, no par value per share (3)	4,800,000	$ 3.91	$ 18,768,000	$ 2,179
Common shares, no par value per share, issuable upon the exercise of warrants (4)	4,800,000	$ 3.91	$ 18,768,000	$ 2,179
Common shares, no par value per share, issuable upon the exercise of Placement Agent Warrants (5)	96,000	$ 3.91	$ 375,360	$ 44
Total registration fee	9,696,000		$ 37,911,360	$ 4,402

(1) Pursuant to Rule 416 of the Securities Act of 1933, there are also being registered hereunder additional common shares as may be issued to the selling shareholders because of any future stock dividends, stock distributions, stock splits, similar capital readjustments or other anti-dilution adjustments.

(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) of the Securities Act of 1933, based upon the average of the high and low sales prices of the common shares as reported on the Nasdaq Capital Market on March 7, 2011.

(3) Represents common shares of the Registrant being registered for resale for the accounts of selling shareholders who acquired such shares in a private transaction.

(4) Represents common shares of the Registrant's being registered for resale that have been or may be acquired upon the exercise of warrants that have been previously issued to selling shareholders who acquired such shares in a private transaction.

(5) Represents common shares of the Registrant being registered for resale that have been or may be acquired upon the exercise of warrants that have been previously issued to the placement agent in connection with a private transaction.

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 or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

SUBJECT TO COMPLETION, DATED MARCH 11, 2011

The information in this prospectus is not complete and may be changed. The selling shareholders 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 it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

INTELLIPHARMACEUTICS INTERNATIONAL INC.

9,696,000 Common Shares

This prospectus relates to up to 9,696,000 of our common shares, which have been registered for resale by some of our shareholders pursuant to this prospectus.

The common shares may be offered from time to time by the selling shareholders through ordinary brokerage transactions, in negotiated transactions or otherwise, at market prices prevailing at the time of sale or at negotiated prices and in other ways as described in the "Plan of Distribution." The common shares being offered include: (a) up to 4,800,000 common shares issued to investors in the Financing, as defined below, (b) 4,800,000 common shares issuable upon exercise of warrants issued to investors in the Financing, and (c) 96,000 common shares issuable upon exercise of warrants issued to the Placement Agent in connection with the Financing (the "Advisor Warrants"). We will not receive any of the proceeds from the sale of our common shares by the selling shareholders but we will receive funds from the exercise of the warrants held by the selling shareholders if and when any warrant holder pays the exercise price in cash rather than exercising on a cashless basis. We will utilize any proceeds through a cash exercise of such warrants for general corporate and working capital purposes.

Our common shares are listed for trading on the Toronto Stock Exchange under the symbol "I" and on the Nasdaq Capital Market under the symbol "IPCI". On March 2, 2011, the closing sale price of the common shares as reported by the Toronto Stock Exchange and the Nasdaq Capital Market were C$3.95 and $4.05, respectively.

An investment in the common shares is speculative and involves a high degree of risk. See "Risk Factors" beginning on Page 4. You should read this document and documents incorporated by reference into this prospectus before you invest.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is _____, 2011.

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You should rely only upon the information contained in, or incorporated by reference into, this document. We have not, and the selling shareholders have not, authorized any other person to provide you with different information. No other person is authorized to give any information or to represent anything not contained or incorporated by reference in this prospectus. You must not rely on any unauthorized information or representation. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. You should assume that the information appearing in this document is accurate only as of the date on the front cover of this document. Our business, financial condition, results of operations and prospects may have changed since that date.

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form F-3 that we filed with the United States Securities and Exchange Commission (SEC) with respect to 9,696,000 shares of our common stock which may be offered and sold from time to time in one or more offerings by the selling shareholders named under “Selling Shareholders”.

We may add to or modify in a prospectus supplement any of the information contained in this prospectus or in the documents that we have incorporated into this prospectus by reference. To the extent that any statement made in a prospectus supplement conflicts with statements made in this prospectus, the statements made in the prospectus supplement will be deemed to modify or supersede those made in this prospectus.

The rules of the SEC allow the Company to incorporate by reference certain information into this prospectus. See “Incorporation of Certain Information by Reference” for a description of the documents from which information is incorporated, and where you can get a copy of such documents.

You should read both this prospectus, especially the information discussed under “Risk Factors”, and any prospectus supplement together with the information described in this prospectus under “Where You Can Find More Information.”

References to “$” “U.S. $” or “dollars” are to U.S. dollars, unless otherwise indicated. Except as otherwise indicated, financial statements of, and information regarding, Intellipharmaceutics are presented in U.S. dollars.

Unless the context requires otherwise, reference in this prospectus to "we", "us", "our", "Intellipharmaceutics”, or "Company" refers to Intellipharmaceutics International Inc. and its subsidiaries.

Hypermatrix™, Drug Delivery Engine™, IntelliFoam™, IntelliGITransporter™, IntelliMatrix™, IntelliOsmotics™, IntelliPast IntelliPellets™, IntelliShuttle™ and Rexista™ are trademarks of Intellipharmaceutics and its wholly-owned subsidiaries. Other trademarks are the property of their respective holders. These trademarks are important to our business. Although we may have omitted the “TM” trademark designation for such trademarks in this prospectus, all rights to such trademarks are nevertheless reserved.

IMPORTANT INFORMATION REGARDING FORWARD-LOOKING INFORMATION

Certain statements in this document constitute “forward-looking statements” within the meaning of the United States Private Securities Litigation Reform Act of 1995 and/or “forward-looking information” under the Securities Act (Ontario). These statements include, without limitation, statements regarding the status of development, or expenditures relating to our business, plans to fund our current activities, statements concerning our partnering activities, health regulatory submissions, strategy, future operations, future financial position, future revenues and projected costs. In some cases, forward-looking statements can be identified by terminology such as “may”, “will”, “should”, “expects”, “plans”, “anticipates”, “believes”, “estimates”, “predicts”, “potential”, “continue”, “intends”, “could”, or the negativ terms or other comparable terminology. We made a number of assumptions in the preparation of these forward-looking statements that may change, thus causing actual future results or anticipated events to differ materially from those expressed or implied in any forward-looking information or statements. These assumptions include, but are not limited to, our ability to commercialize products, receipt of regulatory approvals, positive results of current and future clinical trials or bioequivalence studies, our ability to maintain and establish intellectual property rights in our drug delivery technologies and product candidates, our ability to obtain additional financing, existence of potential markets for our product candidates, our ability to attract distributors and collaborators with acceptable development, regulatory and commercialization expertise, sufficient working capital for the development and commercialization of product candidates, our ability to create an effective direct sales and marketing infrastructure for any products we may elect to market and sell directly, market acceptance of any products that we bring to market, our ability to retain and hire qualified employees, and general improvement of economic and capital market conditions in

Canada and the United States.

Forward-looking information involves known and unknown risks, uncertainties and other factors that could cause actual results to differ materially. Such factors include, but are not limited to, uncertainty regarding: the timing of our programs to research, develop and commercialize our products candidates; the timing and costs of obtaining regulatory approvals; the benefits of our drug delivery technologies and product candidates as compared to others; the scope of protection provided by intellectual property for our drug delivery technologies and product candidates; our estimates regarding our capital requirements and future revenues and profitability; our estimates of the size of the potential markets for our product candidates; our selection and licensing of product candidates; the benefits to be derived from collaborative efforts with distributors; sources of revenues and anticipated revenues, including contributions from distributors and collaborators, product sales, license agreements and other collaborative efforts for the development and commercialization of product candidates; the rate and degree of market acceptance of our products; the timing and amount of reimbursement of our products; the success and pricing of other competing therapies that may become available; the manufacturing capacity of third party manufacturers that we may use for our products; and other risk factors discussed from time to time in our reports, public disclosure documents and other filings with the securities commissions in Canada and the United States. Additional risks and uncertainties relating to the Company and our business can be found in the “Risk Factors” section of this prospectus, as well as in our other public filings. The forward-looking statements are made as of the date hereof, and we disclaim any intention and have no obligation or responsibility, except as required by law, to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

PROSPECTUS SUMMARY

The following summary highlights certain information contained elsewhere in this prospectus and in the documents incorporated by reference herein. It does not contain all the information that may be important to you. You should carefully read this prospectus and the documents incorporated by reference herein, before deciding to invest in our securities.

The Company

We were incorporated under the Canada Business Corporations Act by certificate and articles of arrangement dated October 22, 2009.

On October 19, 2009, the shareholders of Intellipharmaceutics Ltd. (“IPC Ltd.”) and Vasogen Inc. (“Vasogen”) approved the court approved plan of arrangement and merger (the “IPC Arrangement Agreement”) that resulted in the October 22, 2009 combination of IPC Ltd. and Intellipharmaceutics Corp. combining with 7231971 Canada Inc., a new Vasogen company that acquired substantially all of the assets and certain liabilities of Vasogen, including the proceeds from its non-dilutive financing transaction with Cervus LP as described further below. The completion of the IPC Arrangement Agreement on October 22, 2009, resulted in a new publicly-traded company, Intellipharmaceutics International Inc., incorporated under the laws of Canada and whose common shares are traded on the TSX and NASDAQ. IPC Ltd. shareholders were issued approximately 86% of the outstanding common shares of Intellipharmaceutics and Vasogen’s shareholders were issued approximately 14% of the outstanding common shares of Intellipharmaceutics.

Separately, Vasogen entered into an arrangement agreement with Cervus LP, an Alberta based limited partnership that resulted in Vasogen being reorganized prior to completion of the arrangement transaction with IPC Ltd. and provided gross proceeds to Vasogen of approximately C$7.5 million in non-dilutive capital.

Business Overview

We are a pharmaceutical company specializing in the research, development and manufacture of controlled and targeted novel oral solid drugs. Our patented Hypermatrix™ technology is a unique multidimensional controlled-release

drug delivery platform that can be applied to the development of a wide range of existing and new pharmaceuticals. Based on this technology, we have a pipeline of products in various stages of development in therapeutic areas that include neurology, cardiovascular, gastrointestinal tract, pain and infection. Certain products in our pipeline are being developed for third parties pursuant to drug development agreements with those third parties, under which our development partner generally pays the expenses of development, sometimes makes certain

milestone payments to us and receives a share of revenues or profits if the drug is developed successfully to completion, the control of which is generally in the discretion of our drug development partner.

We apply our technologies to the development of both existing and new pharmaceuticals across a range of therapeutic classes. We believe that our Hypermatrix™ technology allows us to focus our development activities in two areas; difficult-to-produce controlled-release generic drugs, which follow an abbreviated new drug application ("ANDA") regulatory path; and improved current therapies through controlled release, which follow a new drug application ("NDA") 505 (b)(2) regulatory path.

We operate in a market created by the expiration of drug product patents, challengeable patents and drug product exclusivity periods. There are three ways that we employ our controlled-release technologies, which represent substantial opportunities for us to license our technologies and products:

- For existing controlled-release (once-a-day) products covered by patents about to expire or already expired, we can seek to formulate generic products which are bioequivalent to the branded products. Our scientists have done so previously for several drug products, on a private contract basis with third party companies that cannot be disclosed because of confidentiality obligations of our scientists under their prior development agreements. Such products may be licensed to and sold by distributors of generic products.

- For branded immediate-release (multiple-times-per-day) products, we can seek to formulate improved replacement products, typically by developing a new, patentable, controlled-release (once-a-day) product. Such products may be licensed to and sold by the pharmaceutical company that made the original immediate-release product, thereby protecting the pharmaceutical company against revenue loss in the brand by providing a clinically attractive patented product that is expected to compete favorably with the generic immediate-release competition that arises on expiry of the original patent(s).

- Our technologies are also focused on the development of abuse-deterrent pain medications. The growing abuse and diversion of prescription "painkillers", specifically opioid analgesics, is well documented and is a major health and social concern. We believe that our technologies and know-how are uniquely suited to developing abuse-deterrent pain medications.

Corporate Information

Our registered principal office is located at 30 Worcester Road, Toronto, Ontario, Canada M9W 5X2. Our telephone number is (416) 798-3001 and our facsimile number is (416) 798-3007.

The Offering

Common Shares to be offered by the selling shareholders	9,696,000 shares, including 4,896,000 common shares that are issuable upon the exercise of warrants held by the selling shareholders.
Terms of the offering	The selling shareholders will determine when and how they will sell the securities offered in this prospectus.
Use of proceeds	We will not receive proceeds from the resale of shares by the selling shareholders. To the extent that the selling shareholders exercise, for cash rather than exercising on a cashless basis, all of

	the warrants covering the 9,696,000 common shares registered for resale under this prospectus, we would receive $12,300,000 in aggregate from such exercises. We intend to use such proceeds for working capital, research, product development and general corporate purposes.
Risk Factors	See “Risk Factors” beginning on page 4 and other information included in this prospectus for a discussion of factors you should consider before deciding to invest in our common shares.
Nasdaq Capital Market Symbol	IPCI
Toronto Stock Exchange Symbol	I

The Private Placement Offering

On February 1, 2011, we completed a private offering of investment units (the "Units") to certain accredited investors (the "Investors") for gross proceeds of $12,000,000 (the "Financing"), each Unit consisting of one common share, a five-year warrant to purchase one-half of a common share at an exercise price of $2.50 per whole share and a two-year warrant to purchase one-half of a common share at an exercise price of $2.50 per whole share.

The issuance of the securities was exempt from registration under the Securities Act of 1933, as amended, pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(2) of and Regulation D promulgated under the Securities Act.

In connection with the Financing, the Company agreed to file a registration statement on Form F-3 ("Registration Statement") within 40 days after the closing ("Filing Date") and use our best efforts to have it declared effective within 150 days after the closing ("Effective Date") to register (i) 100% of the common shares issued in the Financing; and (ii) 100% of the common shares underlying the investor warrants issued in the Financing (collectively, the "Registrable Securities"), or we will incur liquidated damages.

Ladenburg Thalmann & Co. Inc. acted as placement agent, along with certain co-agents (the "Placement Agent"), in connection with the Financing. For the Placement Agent's services, we paid a cash commission equal to 6.75% of the aggregate gross proceeds of the Units sold and issued three-year warrants to purchase 96,000 common shares, exercisable at any time at a price equal to $3.125 per share ("Agent Warrants").

We will use the net proceeds of the Financing:

- To advance clinical trials for our abuse resistant Rexista and/or other 505(b)(2) NDA opportunities;
- To file additional abbreviated new drug applications with the U.S. Food and Drug Administration;
- To establish additional partnerships to develop additional products; and
- For working capital and research, product development and general corporate purposes.

We are not permitted to use the proceeds for the satisfaction of any portion of the Company's debt (other than payment of trade payables in the ordinary course of the Company's business and prior practices), to pay any deferred salary accrued for any current or former Company employee, including any founders of the Company, for the redemption of any Common Shares or Common Share Equivalents, for the settlement of any outstanding litigation or in violation of FCPA or OFAC regulations.

RISK FACTORS

Set out below are certain risk factors that could materially adversely affect our future business, operating results or financial condition. Investors should carefully consider these risk factors and the other risk factors and information in this prospectus and our filings with the SEC, including our annual report on Form 20-F for the year ended November 30, 2009 filed with the SEC on June 1, 2010 and our report on Form 6-K filed with the SEC on March 1,

2011, each of which is incorporated by reference in this prospectus, and the other documents incorporated by reference in this prospectus, before making investment decisions involving our common shares.

RISKS RELATING TO OUR BUSINESS

Prospects for companies in the pharmaceutical industry generally may be regarded as uncertain given the research and development nature of the industry and uncertainty regarding the prospects of successfully commercializing product candidates and, accordingly, investments in companies such as ours should be regarded as very speculative. An investor should carefully consider the risks and uncertainties described below, as well as other information contained in this prospectus. If any one or more of the following risks occur, our business, financial condition and results of operations could be seriously harmed. Further, if we fail to meet the expectations of the public market in any given period, the market price of our common shares could decline. If any of the following risks actually occurs, our business, operating results, or financial condition could be materially adversely affected.

Our activities entail significant risks. In addition to the usual risks associated with a business, the following is a general description of certain significant risk factors which may be applicable to us.

Risks Related to our Company

We may require additional funds in our business that may be difficult to obtain when needed or on terms acceptable to us.

As of November 30, 2010, we had a cash balance of $0.8 million. On February 1, 2011, we completed a private offering of 4,800,000 units of the Company, each Unit consisting of one common share, a five-year warrant to purchase one-half of a common share at an exercise price of $2.50 per whole share and a two-year warrant to purchase one-half of a common share at an exercise price of $2.50 per whole share, for gross proceeds of $12,000,000. In the future, we will require substantial future capital in order to continue to conduct the research and development, clinical and regulatory activities necessary to bring our products to market and to establish commercial manufacturing, marketing and sales capabilities that may be difficult or impossible to obtain when needed or on terms acceptable to us.

In order to secure financing, if it is even available, it is likely that we would need to sell additional common shares or financial instruments that are exchangeable for or convertible into common shares and/or enter into development, distribution and/or licensing relationships, to fund all or a part of particular programs. Any future debt financing arrangements we enter into would likely contain restrictive covenants that would impose significant operating and, if any, financial restrictions on us.

Our ability to obtain funding will depend in part upon prevailing capital market conditions and our business performance. Any additional financing may not be obtained at favorable terms, if at all. Any future equity financing may also be dilutive to existing shareholders. If we cannot obtain adequate funding on reasonable terms, we may terminate or delay clinical trials for one or more of our product candidates, curtail significant product development programs that are designed to identify new product candidates, and/or sell or assign rights to our technologies, products or product candidates.

We have a history of losses.

We have incurred losses from inception through November 30, 2010. As at November 30, 2010, we had an accumulated deficit of $19.0 million. For the year ended November 30, 2010 we had a loss of $5.8 million. Our losses for the fiscal periods ended November 30, 2009, and December 31, 2008, and 2007, were $1.8 million, $3.8 million, $1.3 million, respectively. These historical financial losses and financial condition could make it more

difficult for us to obtain financing in the future or could reduce the value the market places on our common shares.

As we engage in the development of products in our pipeline, we will continue to incur losses. There can be no assurance that we will ever be able to achieve or sustain profitability or positive cash flow. Our ultimate success

will depend on whether our drug formulations receive the approval of the FDA or other applicable regulatory agencies needed to commercially market them and if we will be able to successfully market approved products. We cannot be certain that we will be able to receive FDA approval for any of our drug formulations, or that we will reach the level of sales and revenues necessary to achieve and sustain profitability.

We are dependent on key personnel.

We are dependent upon the scientific expertise of Dr. Isa Odidi, our Chairman and Chief Executive Officer, and Dr. Amina Odidi, our President and Chief Operating Officer. Although we now employ, and will in the future expect to continue to employ other qualified scientists, we are substantially dependent upon the efforts of Drs. Isa and Amina Odidi as they are our only employees who have the knowledge and know-how relating to the development of controlled-release products that we believe is necessary for us to continue development of our products.

The success of our business depends, in large part, on our continued ability to attract and retain highly qualified management, scientific, manufacturing and sales and marketing personnel, on our ability to successfully integrate large number of new employees into our corporate culture, and on our ability to develop and maintain important relationships with leading research and medical institutions and key distributors. Competition for these types of personnel and relationships is intense, and the failure to obtain and retain such personnel could have material adverse consequences.

Our intellectual property may not provide meaningful protection for our product candidates.

We hold U.S., Canadian and foreign patents and have pending applications for additional patents. We intend to continue to seek patent protection for, or maintain as trade secrets, all of the commercially promising drug delivery platforms and technologies that we have discovered, developed or acquired. Our success depends, in part, on our ability, and our collaborative partners' ability, to obtain and maintain patent protection for new product candidates, maintain trade secret protection and operate without infringing the proprietary rights of third parties. As with most pharmaceutical companies, our patent position is highly uncertain and involves complex legal and factual questions. Without patent and other similar protection, other companies could offer substantially identical products for sale without incurring the sizeable development costs that we have incurred. Our ability to recover these expenditures and realize profits upon the sale of products could be diminished. The process of obtaining patents can be time-consuming and expensive, with no certainty of success. Even if we spend the necessary time and money, a patent may not be issued or it may insufficiently protect the technology it was intended to protect. We can never be certain that we were first to develop the technology or that we were the first to file a patent application for the particular technology because of the time that elapses between patent filing and publication, and because publications in the scientific or patent literature lag behind actual discoveries. If our pending patent applications are not approved for any reason, or if we are unable to receive patent protection for additional proprietary technologies that we develop, the degree of future protection for our proprietary technology will remain uncertain. Furthermore, third parties may independently develop similar or alternative technologies, duplicate some or all of our technologies, design around our patented technologies or challenge our issued patents. Such third parties may have filed patent applications, or hold issued patents, relating to products or processes competitive with those we are developing. The patents of our competitors may impair our ability to do business in a particular area. Our success will depend, in part, on our ability to obtain patents, protect trade secrets and other proprietary information and operate without infringing on the proprietary rights of others.

We operate in a highly litigious environment.

The cost of commencing or defending litigation, if necessary, could be significant and could significantly drain our limited financial resources and disrupt our business operations. While there is no litigation pending or threatened against us other than as described under " Legal Proceedings and Regulatory Matters" in our Form 6-K filed on March

1, 2011, litigation to which we may be subjected could relate to, among other things, our patent and other intellectual property rights, licensing arrangements with other persons, product liability and financing activities. Such litigation could include an injunction against the manufacture or sale of a product or potential product or a significant monetary judgment, including a possible punitive damages award, or a judgment that certain of our patent or other intellectual property rights are invalid or unenforceable or infringe the intellectual property rights of

others. If such litigation is commenced, our business, results of operations, financial condition and cash flows could be materially adversely affected.

There has been substantial litigation in the pharmaceutical industry concerning the manufacture, use and sale of new products that are the subject of conflicting patent rights. When we file an ANDA for a bioequivalent version of a drug, we may, in some circumstances, be required to certify to the FDA that any patent which has been listed with the FDA as covering the branded product has expired, the date any such patent will expire, or that any such patent is invalid or will not be infringed by the manufacture, sale or use of the new drug for which the application is submitted. Approval of an ANDA is not effective until each listed patent expires, unless the applicant certifies that the patents at issue are not infringed or are invalid and so notifies the patent holder and the holder of the branded product. A patent holder may challenge a notice of non-infringement or invalidity by suing for patent infringement within 45 days of receiving notice. Such a challenge would prevent FDA approval for a period which ends 30 months after the receipt of notice, or sooner if an appropriate court rules that the patent is invalid or not infringed. From time to time, in the ordinary course of business, we face such challenges and may continue to do so in the future.

We have a reliance on key proprietary information.

We rely on trade secrets, know-how and other proprietary information as well as requiring our employees and other vendors and suppliers to sign confidentiality agreements. However, these confidentiality agreements may be breached, and they may not have adequate remedies for such breaches. Others may independently develop substantially equivalent proprietary information without infringing upon any proprietary technology. Third parties may otherwise gain access to our proprietary information and adopt it in a competitive manner.

We cannot ensure the availability of raw materials.

Certain raw materials, which may be necessary for the development and subsequent commercial manufacturing of our product candidates, may be proprietary products of other companies. We attempt to manage the risk associated with such proprietary raw materials by the imposition of contractual provisions in supply contracts that we believe are favorable to us, by management of inventories and by the continued search for alternative authorized suppliers of such materials or their equivalents. If this fails, or if there is a material shortage, contamination, and/or recall of such materials, the resulting scarcity could adversely affect our ability to develop or manufacture our product candidates.

The FDA requires identification of raw material suppliers in applications for approval of drug products. If raw materials were unavailable from a specified supplier or if the supplier does not give us access to its technical information in respect of our application or the supplier was not in compliance with FDA or other applicable requirements, the FDA approval of a new supplier could delay the manufacture of the drug involved. As a result, there is no guarantee we will always have timely and sufficient access to a required raw material or other product. Any inability to obtain raw materials on a timely basis, or any significant price increases which cannot be passed on to customers, could have a material adverse effect on our business, results of operations, financial condition and cash flows could be materially adversely affected.

Many third party suppliers are subject to governmental regulation and, accordingly, we are dependent on the regulatory compliance of these third parties. We also depend on the strength, enforceability and terms of our various contracts with our third party suppliers.

Our product candidates may not be successfully developed or commercialized.

Successful development of our products is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Products that appear promising in research or early phases of development may fail to reach later stages of development or the market for several reasons including:

· for ANDA candidates, bioequivalence studies results may not meet regulatory requirements for the demonstration of bioequivalence;

· for NDA candidates, a product may not demonstrate acceptable clinical trial results, even though it demonstrated positive preclinical trial results;

· for NDA candidates, a product may not be effective in treating a specified condition or illness;

· a product may have harmful side effects on humans;

· products may fail to receive the necessary regulatory approvals from the FDA or other regulatory bodies, or there may be delays in receiving such approvals. Among other things, such delays may be caused by slow enrolment in clinical studies, extended lengths of time to achieve study endpoints, additional time requirements for data analysis, discussions with the FDA, FDA requests for additional preclinical or clinical data, or unexpected safety, efficacy or manufacturing issues;

· difficulties may be encountered in formulating products, scaling up manufacturing processes or in getting approval for manufacturing;

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