

Intellipharmaceutics International Inc.  
Form 20-F  
February 18, 2014  
UNITED STATES

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549  
FORM 20-F

REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended November 30, 2013

OR

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

OR

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

Date of event requiring this shell company report .....

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File No. 0-53805

INTELLIPHARMACEUTICS INTERNATIONAL INC.  
(Exact name of registrant as specified in its charter)

Canada

(Jurisdiction of Incorporation or organization)

30 Worcester Road

Toronto, Ontario M9W 5X2

(Address of principal executive offices)

Shameze Rampertab, Vice President Finance and Chief Financial Officer, Intellipharmaceutics International Inc., 30 Worcester Road, Toronto, Ontario M9W 5X2, Telephone: (416) 798-3001, Fax: (416) 798-3007  
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

Title of each class  
Common shares, no par value

Name of each exchange  
on which registered  
NASDAQ  
TSX



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Securities registered or to be registered pursuant to Section 12(g) of the Act:  
None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:  
None

As of November 30, 2013, the registrant had 21,430,611 common shares outstanding.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes [ ] No [x]

If this report is an annual report or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Yes [ ] No [x]

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes [x] No [ ]

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes [x] No [ ]

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

Large accelerated filer [ ] Accelerated filer [ ] Non-accelerated filer [x]

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP [x] International Financial Reporting Standards as issued by  
the International Accounting Standards Board [ ] Other [ ]

If “Other” has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow:

Item 17 [ ] Item 18 [ ]

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes [ ] No [x]



## TABLE OF CONTENTS

	Page
<u>Part I.</u>	<u>2</u>
<u>Item 1. Identity of Directors, Senior Management and Advisors</u>	<u>2</u>
<u>Item 2. Offer Statistics and Expected Timetable</u>	<u>3</u>
<u>Item 3. Key Information</u>	<u>3</u>
<u>A. Selected Financial Data</u>	<u>3</u>
<u>B. Capitalization and Indebtedness</u>	<u>4</u>
<u>C. Reasons for the Offer and Use of Proceeds</u>	<u>4</u>
<u>D. Risk Factors</u>	<u>4</u>
<u>Item 4. Information on the Company</u>	<u>22</u>
<u>A. History and Development of the Company</u>	<u>22</u>
<u>B. Business Overview</u>	<u>22</u>
<u>C. Organizational Structure</u>	<u>34</u>
<u>D. Property, Plant and Equipment</u>	<u>35</u>
<u>Item 4A. Unresolved Staff Comments.</u>	<u>35</u>
<u>Item 5. Operating and Financial Review and Prospects</u>	<u>35</u>
<u>A. Operating Results</u>	<u>35</u>
<u>B. Liquidity and Capital Resources</u>	<u>42</u>
<u>C. Research and development, patents, and licenses, etc</u>	<u>44</u>
<u>D. Trend Information</u>	<u>44</u>
<u>E. Off-balance sheet arrangements</u>	<u>45</u>
<u>F. Tabular disclosure of contractual obligations</u>	<u>45</u>
<u>G. Safe Harbor</u>	<u>46</u>
<u>Item 6. Directors, Senior Management and Employees</u>	<u>46</u>
<u>A. Directors and Senior Management</u>	<u>46</u>
<u>B. Compensation</u>	<u>48</u>
<u>C. Board Practices</u>	<u>55</u>
<u>D. Employees</u>	<u>60</u>
<u>E. Share Ownership</u>	<u>60</u>
<u>Item 7. Major Shareholders and Related Party Transactions</u>	<u>68</u>
<u>A. Major Shareholders</u>	<u>68</u>
<u>B. Related Party Transactions</u>	<u>69</u>
<u>Item 8. Financial Information</u>	<u>69</u>
<u>A. Consolidated Statements and Other Financial Information</u>	<u>69</u>
<u>B. Significant changes</u>	<u>70</u>
<u>Item 9. The Offer and Listing</u>	<u>70</u>
<u>Item 10. Additional Information</u>	<u>71</u>
<u>A. Share Capital</u>	<u>71</u>
<u>B. Articles and By-laws</u>	<u>75</u>
<u>C. Material Contracts</u>	<u>76</u>
<u>D. Exchange Controls</u>	<u>76</u>
<u>E. Taxation</u>	<u>77</u>
<u>F. Dividends and Paying Agents</u>	<u>85</u>
<u>G. Statement by Experts</u>	<u>85</u>
<u>H. Documents on Display</u>	<u>86</u>
<u>I. Subsidiary Information</u>	<u>86</u>
<u>Item 11. Qualitative and Quantitative Disclosures about Market Risk</u>	<u>86</u>

<u>Item 12.</u>	<u>Description of Securities Other than Equity Securities</u>	<u>88</u>
<u>Part II.</u>		<u>88</u>
<u>Item 13.</u>	<u>Defaults, Dividends Arrearages and Delinquencies</u>	<u>88</u>
<u>Item 14.</u>	<u>Material Modifications to the Rights of Security Holders and Use of Proceeds</u>	<u>88</u>
<u>Item 15.</u>	<u>Controls and Procedures</u>	<u>88</u>
<u>Item</u>		
<u>16A.</u>	<u>Audit Committee Financial Expert</u>	<u>89</u>
<u>Item</u>		
<u>16B.</u>	<u>Code of Ethics</u>	<u>90</u>
<u>Item</u>		
<u>16C.</u>	<u>Principal Accountant Fees and Services</u>	<u>90</u>

---

TABLE OF CONTENTS  
(continued)

	Page
<u>Item 16D. Exemptions from the Listing Standards for Audit Committees</u>	<u>90</u>
<u>Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchases</u>	<u>90</u>
<u>Item 16F. Change in Registrant's Certifying Accountant</u>	<u>90</u>
<u>Item 16G. Corporate Governance</u>	<u>90</u>
<u>Item 16H. Mine Safety Disclosure</u>	<u>91</u>
<u>Part III.</u>	<u>91</u>
<u>Item 17 Financial Statements</u>	<u>91</u>
<u>Item 18 Financial Statements</u>	<u>91</u>
<u>Item 19 Exhibits</u>	<u>92</u>

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## DISCLOSURE REGARDING FORWARD-LOOKING INFORMATION

Certain statements in this annual report 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 expressed or implied regarding our plans, goals and milestones, status of developments 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 sales, revenues and profitability, projected costs and market penetration. In some cases, you can identify forward-looking statements by terminology such as “may”, “will”, “should”, “expects”, “plans”, “anticipates”, “believes”, “estimates”, “predicts”, “potential”, “continue”, “intends”, “could”, or the negative of such terms or other comparative terminology. We made a number of assumptions in the preparation of our forward-looking statements. You should not place undue reliance on our forward-looking statements, which are subject to a multitude of known and unknown risks and uncertainties that could cause actual results, future circumstances or events to differ materially from those stated in or implied by the forward-looking statements.

Risks, uncertainties and other factors that could affect our actual results include, but are not limited to, the estimated proceeds we may receive from any offering of our securities, our expected use of any proceeds from any offering, the effects of general economic conditions, securing and maintaining corporate alliances, our estimates regarding our capital requirements, and the effect of capital market conditions and other factors, including the current status of our product development programs, on capital availability, the potential dilutive effects of any future financing, our programs regarding research, development and commercialization of our product candidates, the timing of such programs, the timing, costs and uncertainties regarding obtaining regulatory approvals to market our product candidates, and the timing and amount of any available investment tax credits (“ITCs”). Other factors that could cause actual results to differ materially include but are not limited to:

- the actual or perceived benefits to users of our drug delivery technologies, products and product candidates as compared to others;
- our ability to establish and maintain valid and enforceable intellectual property rights in our drug delivery technologies, products and product candidates;
- the scope of protection provided by intellectual property for our drug delivery technologies, products and product candidates;
- the actual size of the potential markets for any of our products and product candidates compared to our market estimates;
- our selection and licensing of products and product candidates;
- our ability to attract distributors and collaborators with the ability to fund patent litigation and with acceptable development, regulatory and commercialization expertise and the benefits to be derived from such collaborative efforts;
- 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;
- our ability to create an effective direct sales and marketing infrastructure for products we elect to market and sell directly;
- the rate and degree of market acceptance of our products;
- the difficulty of predicting the impact of competitive products and pricing and the timing and success of product launches;



- the timing and amount of insurance reimbursement for our products;
- changes in the laws and regulations, including Medicare and Medicaid, affecting among other things, pricing and reimbursement of pharmaceutical products;
- the success and pricing of other competing therapies that may become available;
- our ability to retain and hire qualified employees;
- the availability and pricing of third-party sourced products and materials;
- difficulties or delays in manufacturing;
- the manufacturing capacity of third-party manufacturers that we may use for our products; and
- the successful compliance with United States Food and Drug Administration (“FDA”) and other governmental regulations applicable to us and our third party manufacturers’ facilities, products and/or businesses.

Additional risks and uncertainties relating to us and our business can be found in the “Risk Factors” section in Item 3.D below, as well as in our reports, public disclosure documents and other filings with the securities commissions and other regulatory bodies in Canada and the U.S., which are available on [www.sedar.com](http://www.sedar.com) and [www.sec.gov](http://www.sec.gov). The forward-looking statements reflect our current views with respect to future events, and are based on what we believe are reasonable assumptions as of the date of this document. 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.

Nothing contained in this document should be construed to imply that the results discussed herein will necessarily continue or that any conclusion reached herein will necessarily be indicative of actual operating results of the Company.

In this annual report, unless the context otherwise requires, the terms “we”, “us”, “our”, “Intellipharmaceutics” and the “Company” refer to Intellipharmaceutics International Inc. and its subsidiaries. Any reference in this annual report to our “products” includes a reference to our product candidates and future products we may develop. In this annual report, we refer to information regarding potential markets for our products, product candidates and other industry data. We believe that all such information has been obtained from reliable sources that are customarily relied upon by companies in our industry. However, we have not independently verified any such information.

Intellipharmaceutics™, Hypermatrix™, Drug Delivery Engine™, IntelliFoam™, IntelliGITransporter™, IntelliMatrix™, IntelliOsmotics™, IntelliPaste™, IntelliPellets™, IntelliShuttle™, Rexista™, nPODDDS™ and Regabatin™ are our trademarks. These trademarks are important to our business. Although we may have omitted the “TM” trademark designation for such trademarks in this annual report, all rights to such trademarks are nevertheless reserved. Unless otherwise noted, other trademarks used in this annual report are the property of their respective holders.

## PART I.

Item 1. Identity of Directors, Senior Management and Advisers

A. Directors and senior management

Not applicable.

B. Advisors

Not applicable.

C. Auditors

Not applicable.

Item 2. Offer Statistics and Expected Timetable

A. Offer statistics

Not applicable.

B. Method and expected timetable

Not applicable.

Item 3. Key Information

A. Selected Financial Data

The following selected financial data of Intellipharmaceuticals has been derived from the audited consolidated financial statements of the Company as at and for the years ended November 30, 2013, 2012, 2011 and 2010, and the eleven month period ended November 30, 2009. As a result of the IPC Arrangement Transaction (as defined and described in Item 4.A below) completed on October 22, 2009, we selected a November 30 year end. The comparative number of shares issued and outstanding, basic and diluted loss per share have been amended to give effect to this arrangement transaction. These statements were prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). All dollar amounts in this annual report are expressed in United States dollars ("U.S. dollars"), unless otherwise indicated.

	Periods ended				As at and for the eleven month period ended November 30, 2009
	As at and for the year ended November 30, 2013	As at and for the year ended November 30, 2012	As at and for the year ended November 30, 2011	As at and for the year ended November 30, 2010	
Revenue	1,527	107	502	1,459	630
Loss for the period	(11,495 )	(6,137 )	(4,880 )	(5,761 )	(1,839 )
Total assets	4,380	2,475	6,247	3,268	11,081
Total liabilities	10,335	4,243	9,340	3,175	6,449
Net assets	(5,955 )	(1,768 )	(3,093 )	93	4,632
Capital stock (1)	11,721	6,129	902	17	17
Loss per share - basic and diluted	(0.58 )	(0.36 )	(0.33 )	(0.53 )	(0.19 )
Dividends	Nil	Nil	Nil	Nil	Nil

Weighted average common shares	19,671	17,259	14,994	10,907	9,512
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-3-

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Notes:

(1) As restated for the year ended November 30, 2012 and 2011 and discussed in Items 5.A and 10.A

The following table sets forth the average exchange rate for one Canadian dollar expressed in terms of one U.S. dollar for the eleven month period ended November 30, 2009 and for fiscal years 2010, 2011, 2012 and 2013. The average rate is calculated using the average of the exchange rates on the last day of each month during the period.

AVERAGE	
2009 (11 months)	0.8696
2010	0.9673
2011	1.0123
2012	0.9977
2013	1.0241

The following table sets forth the high and low exchange rates for each month during the previous six months.

	LOW	HIGH
August 2013	0.9476	0.9712
September 2013	0.9494	0.9768
October 2013	0.9564	0.9724
November 2013	0.9435	0.9602
December 2013	0.9348	0.9454
January 2014	0.8952	0.9422
February 2014 (through February 14, 2014)	0.9011	0.9110

The exchange rates are based upon the noon buying rate as quoted by The Bank of Canada. At February 14, 2014, the exchange rate for one Canadian dollar expressed in terms of one U.S. dollar, as quoted by The Bank of Canada at 4 p.m. Eastern Time, equaled \$0.9105.

B. Capitalization and Indebtedness

Not Applicable.

C. Reasons for the Offer and Use of Proceeds

Not Applicable.

D. Risk Factors

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 annual report. The list of risks and uncertainties described below is not an exhaustive list. Additional risks and uncertainties not presently known to us or that we believe to be immaterial may also adversely affect our business. 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.

-4-

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## Risks related to our Company

Our business is capital intensive and requires significant investment to conduct research and development, clinical and regulatory activities necessary to bring our products to market, which capital may not be available in amounts or on terms acceptable to us, if at all.

Our business requires substantial capital investment in order 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. As of November 30, 2013, we had a cash balance of \$0.8 million. As of February 18, 2014, our cash balance was \$6.1 million, which we currently expect will fund our current operations through November 2014. We will need additional capital to fund our current operations commencing in November 2014, and to fund any significant expansion of our operations. Although there can be no assurances, such financing may come from revenues from proceeds of our at-the-market offering program (see “Prior Sales”, in Item 10, below for a further description of our at-the-market offering program) and from sales of our dexmethylphenidate hydrochloride extended-release products. Other potential sources of capital may include the collection of anticipated revenues resulting from future commercialization activities, development agreements or marketing license agreements, cost savings associated with managing operating expense levels, equity and/or debt financings, and/or new strategic partnership agreements funding some or all costs of development, although there can be no assurance that we will be able to obtain any such capital on terms or in amounts sufficient to meet our needs or at all. The availability of equity or debt financing will be affected by, among other things, the results of our research and development, our ability to obtain regulatory approvals, the market acceptance of our products, the state of the capital markets generally, strategic alliance agreements, and other relevant commercial considerations. In addition, if we raise additional funds by issuing equity securities, our then existing security holders will likely experience dilution, and the incurring of indebtedness would result in increased debt service obligations and could require us to agree to operating and financial covenants that would restrict our operations. In the event that we do not obtain additional capital, there may be substantial doubt about our ability to continue as a going concern and realize our assets and pay our liabilities as they become due. Any failure on our part to raise additional funds on terms favorable to us or at all, may require us to significantly change or curtail our current or planned operations in order to conserve cash until such time, if ever, that sufficient proceeds from operations are generated, and could result in our not taking advantage of business opportunities, in the termination or delay of clinical trials for one or more of our product candidates, in curtailment of our product development programs designed to identify new product candidates, in the sale or assignment of rights to our technologies, products or product candidates, and/or our inability to file abbreviated new drug applications (“ANDAs”) or new drug applications (“NDAs”) at all or in time to competitively market our products or product candidates.

Delays, suspensions and terminations in our preclinical studies and clinical trials could result in increased costs to us and delay our ability to generate product revenues.

The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites;
- manufacturing sufficient quantities of a drug candidate;
- obtaining institutional review board approval to conduct a clinical trial at a prospective clinical trial site;
- patient enrollment; and
- for controlled substances, obtaining specific permission to conduct a study, and obtaining import and export permits to ship study samples.



Once a clinical trial has begun, it may be delayed, suspended or terminated due to a number of factors, including:

- the number of patients that participate in the trial;
- the length of time required to enroll suitable subjects;
- the duration of patient follow-up;
- the number of clinical sites included in the trial;
- changes in regulatory requirements or regulatory delays or clinical holds requiring suspension or termination of the trials;
- delays, suspensions or termination of clinical trials due to the institutional review board overseeing the study at a particular site;
- failure to conduct clinical trials in accordance with regulatory requirements;
- unforeseen safety issues, including serious adverse events or side effects experienced by participants; and
- inability to manufacture, through third party manufacturers, adequate supplies of the product candidate being tested.

Based on results at any stage of product development, we may decide to repeat or redesign preclinical studies or clinical trials, conduct entirely new studies or discontinue development of products for one or all indications. In addition, our product candidates may not demonstrate sufficient safety and efficacy in pending or any future preclinical testing or clinical trials to obtain the requisite regulatory approvals. Even if such approvals are obtained for our products, they may not be accepted in the market as a viable alternative to other products already approved or pending approvals.

If we experience delays, suspensions or terminations in a preclinical study or clinical trial, the commercial prospects for our products will be harmed, and our ability to generate product revenues will be delayed or we may never be able to generate such revenues.

We have a history of operating losses, which may continue in the foreseeable future.

We have incurred net losses from inception through November 30, 2013 and had an accumulated deficit of \$41.6 million as of such date and have incurred additional losses since such date. As we engage in the development of products in our pipeline, we will continue to incur further 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 product candidates receive the approval of the FDA or other applicable regulatory agencies and we are able to successfully market approved products. We cannot be certain that we will be able to receive FDA approval for any of our current or future product candidates, or that we will reach the level of sales and revenues necessary to achieve and sustain profitability.

Loss of key scientists and failure to attract qualified personnel could limit our growth and negatively impact our operations.

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 employ other qualified scientists, Drs. Isa and Amina Odidi are our only employees with the knowledge and experience necessary for us to continue development of controlled-release products. We do not maintain key-person life insurance on any of our officers or employees. Although we have employment agreements with key members of our management team, each of our employees may terminate his or her employment at any time. 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 many new employees, and on our ability to develop and maintain important relationships with leading research and medical institutions and key distributors. If we lose the services of our executive officers or other qualified personnel or are unable to attract and retain qualified individuals to fill these roles or develop key relationships, our business, financial condition and results of operations could be



materially adversely affected.

-6-

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

We hold certain U.S., Canadian and foreign patents and have pending applications for additional patents outstanding. We intend to continue to seek patent protection for, or maintain as trade secrets, all of our commercially promising drug delivery platforms and technologies. Our success depends, in part, on our and our collaborative partners' ability to obtain and maintain patent protection for products and product candidates, maintain trade secret protection and operate without infringing the proprietary rights of third parties. Without patent and other similar protection, other companies could offer substantially identical products without incurring sizeable development costs which could diminish our ability to recover expenses of and realize profits on our developed products. If our pending patent applications are not approved, or if we are unable to obtain patents for additional developed technologies, the future protection for our technologies 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 or otherwise restricting our ability to do business in a particular area. If we are unable to obtain patents or otherwise protect our trade secrets or other intellectual property and operate without infringing on the proprietary rights of others, our business, financial condition and results of operations could be materially adversely affected.

We may be subject to intellectual property claims that could be costly and could disrupt our business.

Third parties may claim we have infringed their patents, trademarks, copyrights or other rights. We may be unsuccessful in defending against such claims, which could result in the inability to protect our intellectual property rights or liability in the form of substantial damages, fines or other penalties such as injunctions precluding our manufacture, importation or sales of products. The resolution of a claim could also require us to change how we do business or enter into burdensome royalty or license agreements. Insurance coverage may be denied or may not be adequate to cover every claim that third parties could assert against us. Even unsuccessful claims could result in significant legal fees and other expenses, diversion of management's time and disruptions in our business. Any of these claims could also harm our reputation.

We rely on maintaining as trade secrets our competitively sensitive know-how and other information. Intentional or unintentional disclosure of this information could impair our competitive position.

As to many technical aspects of our business, we have concluded that competitively sensitive information is either not patentable or that for competitive reasons it is not commercially advantageous to seek patent protection. In these circumstances, we seek to protect this know-how and other proprietary information by maintaining it in confidence as a trade secret. To maintain the confidentiality of our trade secrets, we generally enter into agreements that contain confidentiality provisions with our employees, consultants, collaborators, contract manufacturers and advisors upon commencement of their relationships with us. These provisions generally require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. We may not have these arrangements in place in all circumstances, and the confidentiality provisions in our favour may be breached. We may not become aware of, or have adequate remedies in the event of, any such breach. In addition, in some situations, the confidentiality provisions in our favour may conflict with, or be subject to, the rights of third parties with whom our employees, consultants, collaborators, contract manufacturers or advisors have previous employment or consulting relationships. To the extent that our employees, consultants, collaborators, contract manufacturers or advisors use trade secrets or know-how owned by others in their work for us, disputes may arise as to the ownership of relative inventions. Also, others may independently develop substantially equivalent trade secrets, processes and know-how, and competitors may be able to use this information to develop products that compete with our products, which could adversely impact our business. The disclosure of our trade secrets could impair our competitive position. Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information.



Approvals for our product candidates may be delayed or become more difficult to obtain if the FDA institutes changes to its approval requirements.

The FDA may institute changes to its ANDA approval requirements, which may make it more difficult or expensive for us to obtain approval for our new generic products. For instance, in July 2012, the Generic Drug Fee User Amendments of 2012 (“GDUFA”) were enacted into law. The GDUFA legislation implemented substantial fees for new ANDAs, Drug Master Files, product and establishment fees and a one-time fee for back-logged ANDAs pending approval as of October 1, 2012. Under GDUFA, generic product companies face significant penalties for failure to pay the new user fees, including rendering an ANDA not “substantially complete” until the fee is paid. It is currently uncertain the effect the new fees will have on our ANDA process and business. However, any failure by us or our suppliers to pay the fees or to comply with the other provisions of GDUFA may adversely impact or delay our ability to file ANDAs, obtain approvals for new generic products, generate revenues and thus may have a material adverse effect on our business, results of operations and financial condition.

We operate in a highly litigious environment.

From time to time, we are subject to legal proceedings. As of the date of this annual report, we are not aware of any pending or threatened litigation claims against us. Litigation to which we are, or may be, subject could relate to, among other things, our patent and other intellectual property rights, or such rights of others, business or licensing arrangements with other persons, product liability or financing activities. Such litigation could include an injunction against the manufacture or sale of one or more of our products or potential products 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 prevents 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 and have faced such challenges and may continue to do so in the future.

Brand-name pharmaceutical manufacturers routinely bring patent infringement litigation against ANDA applicants seeking FDA approval to manufacture and market generic forms of their branded products. We are routinely subject to patent litigation that can delay or prevent our commercialization of products, force us to incur substantial expense to defend, and expose us to substantial liability.

We cannot ensure the availability of raw materials.

Certain raw materials necessary for the development and subsequent commercial manufacture of our product candidates may be proprietary products of other companies. While we attempt to manage the risk associated with such proprietary raw materials, if our efforts fail, 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. In addition, many third party suppliers are subject to governmental regulation and, accordingly, we are dependent on the regulatory compliance of, as well as on the strength, enforceability and terms of our various contracts with, these third party suppliers.

Further, the FDA requires identification of raw material suppliers in applications for approval of drug products. If raw materials are unavailable from a specified supplier, the supplier does not give us access to its technical information for our application or the supplier is not in compliance with FDA or other applicable requirements, FDA approval of the supplier could delay the manufacture of the drug involved. 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.

Our product candidates may not be successfully developed or commercialized.

Successful development of our product candidates 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 or guidelines for the demonstration of bioequivalence;
- for NDA candidates, a product may not demonstrate acceptable large-scale clinical trial results, even though it demonstrated positive preclinical or initial clinical 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;
- difficulties may be encountered in formulating products, scaling up manufacturing processes or in getting approval for manufacturing;
- manufacturing costs, pricing or reimbursement issues, other competitive therapeutics, or other commercial factors may make the product uneconomical; and
- the proprietary rights of others, and their competing products and technologies, may prevent the product from being developed or commercialized.

Further, success in preclinical and early clinical trials does not ensure that large-scale clinical trials will be successful, nor does success in preliminary studies for ANDA candidates ensure that bioequivalence studies will be successful. Results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. The length of time necessary to complete bioequivalence studies or clinical trials and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly and may be difficult to predict.

As a result, there can be no assurance that any of our product candidates currently in development will ever be successfully commercialized.

Near-term revenue depends significantly on the success of our first filed ANDA (“lead”) product, our once daily dexamethylphenidate hydrochloride extended-release generic.

We have invested significant time and effort in the development of our lead product, our once daily generic dexamethylphenidate hydrochloride extended-release capsules, which has only recently received final FDA approval for the 15 and 30 mg strengths. Our 5, 10, 20 and 40 mg strengths were also tentatively FDA approved, subject to the right of another party or parties to 180 days of generic exclusivity from the date of first launch of such products by such parties. We believe that our development partner, Par Pharmaceutical, Inc. (“Par”), intends to launch these strengths immediately upon the expiry of those exclusivity periods but there can be no assurance as to when or if such launch will occur. There can be no assurance as to when or if final FDA approval will be received for the remaining product strengths we have applied for or that any of these strengths tentatively approved will ever be successfully commercialized. We depend significantly on the actions of our development partner Par in the prosecution, regulatory approval and commercialization of our generic dexamethylphenidate hydrochloride extended-release products and on their timely payment to us of the contracted quarterly payments as they come due. Our near term ability to generate significant revenue will depend upon successful commercialization of this product in the United States, where the branded Focalin XR® product is in the market. Although we have several other products in our pipeline, they are at earlier stages of development.



Our significant expenditures on research and development may not lead to successful product introductions.

We conduct research and development primarily to enable us to manufacture and market pharmaceuticals in accordance with FDA regulations. Typically, research expenses related to the development of innovative compounds and the filing of NDAs are significantly greater than those expenses associated with ANDAs. As we continue to develop new products, our research expenses will likely increase. We are required to obtain FDA approval before marketing our drug products and the approval process is costly and time consuming. Because of the inherent risk associated with research and development efforts in our industry, particularly with respect to new drugs, our research and development expenditures may not result in the successful introduction of FDA approved new pharmaceuticals.

We may not have the ability to develop or license, or otherwise acquire, and introduce new products on a timely basis.

Product development is inherently risky, especially for new drugs for which safety and efficacy have not been established and the market is not yet proven. Likewise, product licensing involves inherent risks including uncertainties due to matters that may affect the achievement of milestones, as well as the possibility of contractual disagreements with regard to terms such as license scope or termination rights. The development and commercialization process, particularly with regard to new drugs, also requires substantial time, effort and financial resources. The process of obtaining FDA or other regulatory approval to manufacture and market new and generic pharmaceutical products is rigorous, time consuming, costly and largely unpredictable. We, or a partner, may not be successful in obtaining FDA or other required regulatory approval or in commercializing any of the product candidates that we are developing or licensing.

We may not achieve our projected development goals in the time frames we announce and expect.

We set goals regarding the expected timing of meeting certain corporate objectives, such as the commencement and completion of clinical trials, anticipated regulatory approval and product launch dates. From time to time, we may make certain public statements regarding these goals. The actual timing of these events can vary dramatically due to, among other things, insufficient funding, delays or failures in our clinical trials or bioequivalence studies, the uncertainties inherent in the regulatory approval process, such as requests for additional information, delays in achieving manufacturing or marketing arrangements necessary to commercialize our product candidates and failure by our collaborators, marketing and distribution partners, suppliers and other third parties to fulfill contractual obligations.

Our products may not achieve expected levels of market acceptance, thereby limiting our potential to generate revenue.

Even if we are able to obtain regulatory approvals for our product candidates, the success of any of our products will be dependent upon market acceptance. Levels of market acceptance for any products marketed by us could be affected by several factors, including:

- the availability of alternative products from competitors;
- the prices of our products relative to those of our competitors;
- the timing of our market entry;
- the ability to market our products effectively at the retail level; and
- the acceptance of our products by government and private formularies.

Some of these factors are not within our control, and our proposed products may not achieve levels of market acceptance anticipated by us. Additionally, continuing and increasingly sophisticated studies of the proper utilization, safety and efficacy of pharmaceutical products are being conducted by the industry, government agencies and others which can call into question the utilization, safety and efficacy of our products and any product candidates we are



currently developing or may develop in the future. These studies could also impact a future product after it has been marketed. In some cases, studies have resulted, and may in the future result, in the discontinuance of product marketing or requirement of other risk management programs such as the need for a patient registry. The failure of our products and any of our product candidates, once approved, to achieve market acceptance would limit our ability to generate revenue and would adversely affect our results of operations.

-10-

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The risks and uncertainties inherent in conducting clinical trials could delay or prevent the development and commercialization of our own branded products, which could have a material adverse effect on our results of operations, liquidity, financial condition, and growth prospects.

There are a number of risks and uncertainties associated with clinical trials, which may be exacerbated by our relatively limited experience in conducting and supervising clinical trials and preparing NDAs. The results of initial clinical trials may not be indicative of results that would be obtained from large scale testing. Clinical trials are often conducted with patients having advanced stages of disease and, as a result, during the course of treatment these patients can die or suffer adverse medical effects for reasons that may not be related to the pharmaceutical agents being tested, but which nevertheless affect the clinical trial results. In addition, side effects experienced by the patients may cause delay of approval of our product candidates or a limited application of an approved product. Moreover, our clinical trials may not demonstrate sufficient safety and efficacy to obtain FDA approval.

Failure can occur at any time during the clinical trial process and, in addition, the results from early clinical trials may not be predictive of results obtained in later and larger clinical trials, and product candidates in later clinical trials may fail to show the desired safety or efficacy despite having progressed successfully through earlier clinical testing. A number of companies in the pharmaceutical industry have suffered significant setbacks in clinical trials, even in advanced clinical trials after showing positive results in earlier clinical trials. In the future, the completion of clinical trials for our product candidates may be delayed or halted for many reasons, including those relating to the following:

- delays in patient enrollment, and variability in the number and types of patients available for clinical trials;
- regulators or institutional review boards may not allow us to commence or continue a clinical trial;
- our inability, or the inability of our partners, to manufacture or obtain from third parties materials sufficient to complete our clinical trials;
- delays or failures in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective clinical trial sites;
- risks associated with trial design, which may result in a failure of the trial to show statistically significant results even if the product candidate is effective;
- difficulty in maintaining contact with patients after treatment commences, resulting in incomplete data;
- poor effectiveness of product candidates during clinical trials;
- safety issues, including adverse events associated with product candidates;
- the failure of patients to complete clinical trials due to adverse side effects, dissatisfaction with the product candidate, or other reasons;
- governmental or regulatory delays or changes in regulatory requirements, policy and guidelines; and
- varying interpretation of data by the FDA or other applicable foreign regulatory agencies.

In addition, our product candidates could be subject to competition for clinical study sites and patients from other therapies under development by other companies which may delay the enrolment in or initiation of our clinical trials. Many of these companies have significantly more resources than we do.

The FDA or other foreign regulatory authorities may require us to conduct unanticipated additional clinical trials, which could result in additional expense and delays in bringing our product candidates to market. Any failure or delay in completing clinical trials for our product candidates would prevent or delay the commercialization of our product candidates. There can be no assurance our expenses related to clinical trials will lead to the development of brand-name drugs which will generate revenues in the near future. Delays or failure in the development and commercialization of our own branded products could have a material adverse effect on our results of operations, liquidity, financial condition, and our growth prospects.



We rely on third parties to conduct clinical trials for our product candidates, and if they do not properly and successfully perform their legal and regulatory obligations, as well as their contractual obligations to us, we may not be able to obtain regulatory approvals for our product candidates.

We design the clinical trials for our product candidates, but rely on contract research organizations and other third parties to assist us in managing, monitoring and otherwise carrying out these trials, including with respect to site selection, contract negotiation and data management. We do not control these third parties and, as a result, they may not treat our clinical studies as their highest priority, or in the manner in which we would prefer, which could result in delays. Although we rely on third parties to conduct our clinical trials, we are responsible for confirming that each of our clinical trials is conducted in accordance with our general investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. The FDA enforces good clinical practices through periodic inspections of trial sponsors, principal investigators and trial sites. If we, our contract research organizations or our study sites fail to comply with applicable good clinical practices, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. There can be no assurance that, upon inspection, the FDA will determine that any of our clinical trials comply with good clinical practices. In addition, our clinical trials must be conducted with product manufactured under the FDA's current Good Manufacturing Practices ("cGMP") regulations. Our failure, or the failure of our contract manufacturers (if any are involved in the process) to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If third parties do not successfully carry out their duties under their agreements with us; if the quality or accuracy of the data they obtain is compromised due to failure to adhere to our clinical protocols or regulatory requirements; or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, our clinical trials may not meet regulatory requirements. If our clinical trials do not meet regulatory requirements or if these third parties need to be replaced, such clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of our product candidates, which could have a material adverse effect on our results of operations, financial condition and growth prospects.

Competition in our industry is intense, and developments by other companies could render our products and product candidates obsolete.

Many of our competitors, including medical technology, pharmaceutical or biotechnology and other companies, universities, government agencies, or research organizations, have substantially greater financial and technical resources and production and marketing capabilities than we have. They also may have greater experience in conducting bioequivalence studies, preclinical testing and clinical trials of pharmaceutical products, obtaining FDA and other regulatory approvals, and ultimately commercializing any approved products. Therefore, our competitors may succeed in developing and commercializing technologies and products that are more effective than the drug delivery technologies we have developed or we are developing or that will cause our technologies or products to become obsolete or non-competitive, and in obtaining FDA approval for products faster than we could. These developments could render our products obsolete and uncompetitive, which would have a material adverse effect on our business, financial condition and results of operations. Even if we commence further commercial sales of our products, we will be competing against the greater manufacturing efficiency and marketing capabilities of our competitors, areas in which we have limited or no experience.

We rely on collaborative arrangements with third parties that provide manufacturing and/or marketing support for some or all of our products and product candidates. Even if we find a potential partner, we may not be able to negotiate an arrangement on favourable terms or achieve results that we consider satisfactory. In addition, such

arrangements can be terminated under certain conditions and do not assure a product's success. We also face intense competition for collaboration arrangements with other pharmaceutical and biotechnology companies.

-12-

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Although we believe that our ownership of patents for some of our drug delivery products will limit direct competition with these products, we must also compete with established existing products and other promising technologies and other products and delivery alternatives that may be more effective than our products and proposed products. In addition, we may not be able to compete effectively with other commercially available products or drug delivery technologies.

We require regulatory approvals for any products that use our drug delivery technologies.

Our drug delivery technologies can be quite complex, with many different components. The development required to take a technology from its earliest stages to its incorporation in a product that is sold commercially can take many years and cost a substantial amount of money. Significant technical challenges are common as additional products incorporating our technologies progress through development.

Any particular technology such as our abuse-deterrent technology may not perform in the same manner when used with different therapeutic agents, and therefore this technology may not prove to be as useful or valuable as originally thought, resulting in additional development work.

If our efforts do not repeatedly lead to successful development of product candidates, we may not be able to grow our pipeline or to enter into agreements with marketing and distribution partners or collaborators that are willing to distribute or develop our product candidates. Delays or unanticipated increases in costs of development at any stage, or failure to solve a technical challenge, could adversely affect our operating results.

If contract manufacturers fail to devote sufficient time and resources to our concerns, or if their performance is substandard, the commercialization of our products could be delayed or prevented, and this may result in higher costs or deprive us of potential product revenues.

We rely on contract manufacturers for certain components and ingredients of our clinical trial materials, such as active pharmaceutical ingredients (“APIs”), and we may rely on such manufacturers for commercial sales purposes as well. Our reliance on contract manufacturers in these respects will expose us to several risks which could delay or prevent the commercialization of our products, result in higher costs, or deprive us of potential product revenues, including:

- Difficulties in achieving volume production, quality control and quality assurance, or technology transfer, as well as with shortages of qualified personnel;
- The failure to establish and follow cGMP and to document adherence to such practices;
- The need to revalidate manufacturing processes and procedures in accordance with FDA and other nationally mandated cGMPs and potential prior regulatory approval upon a change in contract manufacturers;
- Failure to perform as agreed or to remain in the contract manufacturing business for the time required to produce, store and distribute our products successfully;
- The potential for an untimely termination or non-renewal of contracts; and
- The potential for us to be in breach of our collaboration and marketing and distribution arrangements with third parties for the failure of our contract manufacturers to perform their obligations to us.

In addition, drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state and foreign agencies to ensure strict compliance with cGMP and other government regulations. While we may audit the performance of third-party contractors, we will not have complete control over their compliance with these regulations and standards. Failure by either our third-party manufacturers or by us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of applicable regulatory authorities to grant review of submissions or market approval of drugs, delays, suspension or withdrawal of approvals, product seizures or recalls, operating restrictions, facility closures and criminal

prosecutions, any of which could harm our business.

-13-

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We are subject to currency rate fluctuations that may impact our financial results.

A large majority of our expenses are payable in Canadian dollars and our financial results are reported in U.S. dollars. There may be instances where we have net foreign currency exposure. Any fluctuations in exchange rates will impact our financial results.

We have limited sales, marketing and distribution experience.

We have limited experience in the sales, marketing, and distribution of pharmaceutical products. There can be no assurance that, if required, we would be able to establish sales, marketing, and distribution capabilities or make arrangements with our collaborators, licensees, or others to perform such activities or that such efforts would be successful. If we fail to establish successful marketing and sales capabilities or to make arrangements with third parties, our business, financial condition and results of operations will be materially adversely affected.

Our significant shareholders have the ability to exercise significant influence over certain corporate actions.

Our principal shareholders, Drs. Amina and Isa Odidi, our President and Chief Operating Officer and our Chairman and Chief Executive Officer, respectively, and Odidi Holdings Inc., a privately-held company controlled by Drs. Amina and Isa Odidi, owned in the aggregate approximately 26.3% of our issued and outstanding common shares as of the date of this annual report (and collectively beneficially owned in the aggregate approximately 34.6% of our common shares, including common shares issuable upon the exercise of outstanding options and the conversion of the convertible debenture held by Drs. Amina and Isa Odidi that are exercisable or convertible within 60 days of the date hereof) . As a result, the principal shareholders have the ability to exercise significant influence over all matters submitted to our shareholders for approval whether subject to approval by a majority of holders of our common shares or subject to a class vote or special resolution requiring the approval of 66 % of the votes cast by holders of our common shares, in person or by proxy.

Our effective tax rate may vary.

Various internal and external factors may have favorable or unfavorable effects on our future effective tax rate. These factors include, but are not limited to, changes in tax laws, regulations and/or rates, changing interpretations of existing tax laws or regulations, future levels of research and development spending, the availability of tax credit programs for the reimbursement of all or a significant proportion of research and development spending, and changes in overall levels of pre-tax earnings. At present, we qualify in Canada for certain research tax credits for qualified scientific research and experimental development pertaining to our drug delivery technologies and drug products in research stages. If Canadian tax laws relating to research tax credits were substantially negatively altered or eliminated, or if a substantial portion of our claims for tax credits were denied by the relevant taxing authorities, pursuant to an audit or otherwise, it would have a material adverse effect upon our financial results.

#### Risks related to our Industry

Generic drug manufacturers will increase competition for certain products and may reduce our expected royalties.

Part of our product development strategy includes making NDA filings relating to product candidates involving the novel reformulation of existing drugs with active ingredients that are off-patent. Such NDA product candidates, if approved, are likely to face competition from generic versions of such drugs in the future. Regulatory approval for generic drugs may be obtained without investing in costly and time consuming clinical trials. Because of substantially reduced development costs, manufacturers of generic drugs are often able to charge much lower prices for their products than the original developer of a new product. If we face competition from manufacturers of generic drugs on products we may commercialize, such as our once-daily Rexista™ oxycodone product, the prices at which such of our



products are sold and the revenues we may receive could be reduced.

-14-

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Market acceptance of our products will be limited if users of our products are unable to obtain adequate reimbursement from third-party payers.

Government health administration authorities, private health insurers and other organizations generally provide reimbursement for products like ours, and our commercial success will depend in part on whether appropriate reimbursement levels for the cost of our products and related treatments are obtained from government authorities, private health insurers and other organizations, such as health maintenance organizations and managed care organizations. Even if we succeed in bringing any of our products to market, third-party payers may not provide reimbursement in whole or in part for their use.

Significant uncertainty exists as to the reimbursement status of newly approved health care products. Some of our product candidates, such as our once-daily Rexista™ abuse-deterrent oxycodone product, are intended to replace or alter existing therapies or procedures. These third-party payers may conclude that our products are less safe, less effective or less economical than those existing therapies or procedures. Therefore, third-party payers may not approve our products for reimbursement. We may be required to make substantial pricing concessions in order to gain access to the formularies of large managed-care organizations. If third party payers do not approve our products for reimbursement or fail to reimburse them adequately, sales will suffer as some physicians or their patients may opt for a competing product that is approved for reimbursement or is adequately reimbursed. Even if third-party payers make reimbursement available, these payers' reimbursement policies may adversely affect our ability and our potential marketing and distribution partners' ability to sell our products on a profitable basis.

We are subject to significant costs and uncertainties related to compliance with the extensive regulations that govern the manufacturing, labeling, distribution, and promotion of pharmaceutical products as well as environmental, safety and health regulations.

Governmental authorities in the United States and Canada regulate the research and development, testing and safety of pharmaceutical products. The regulations applicable to our existing and future products may change. Regulations require extensive clinical trials and other testing and government review and final approval before we can market our products. The cost of complying with government regulation can be substantial and may exceed our available resources, causing delay or cancellation of our product introductions.

Some abbreviated application procedures for controlled-release drugs and other products, including those related to our ANDA filings, or to the ANDA filings of unrelated third parties in respect of drugs similar to or chemically related to those of our ANDA filings, are or may become the subject of petitions filed by brand-name drug manufacturers or other ANDA filers seeking changes from the FDA in the interpretation of the statutory approval requirements for particular drugs as part of their strategy to thwart or advance generic competition. We cannot predict whether the FDA will make any changes to its interpretation of the requirements applicable to our ANDA applications as a result of these petitions, or whether unforeseen delays will occur in our ANDA filings while the FDA considers such petitions or changes or otherwise, or the effect that any changes may have on us. Any such changes in FDA interpretation of the statutes or regulations, or any legislated changes in the statutes or regulations, may make it more difficult for us to file ANDAs or obtain further approval of our ANDAs and generate revenues and thus may materially harm our business and financial results.

Any failure or delay in obtaining regulatory approvals could make it so that we are unable to market any products we develop and therefore adversely affect our business, results of operations, financial condition and cash flows. Even if product candidates are approved in the United States or Canada, regulatory authorities in other countries must approve a product prior to the commencement of marketing the product in those countries. The time required to obtain any such approval may be longer than in the United States or Canada, which could cause the introduction of our products in other countries to be cancelled or materially delayed.

The manufacturing, distribution, processing, formulation, packaging, labeling and advertising of our products are subject to extensive regulation by federal agencies, including in the United States, the FDA, Drug Enforcement Administration, Federal Trade Commission, Consumer Product Safety Commission and Environmental Protection Agency, among others. We are also subject to state and local laws, regulations and agencies. Compliance with these regulations requires substantial expenditures of time, money and effort in such areas as production and quality control to ensure full technical compliance. Failure to comply with FDA and other governmental regulations can result in fines, disgorgement, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production or distribution, suspension of the FDA's review of NDAs or ANDAs, enforcement actions, injunctions and civil or criminal prosecution.

Environmental laws have changed in recent years and we may become subject to stricter environmental standards in the future and face larger capital expenditures in order to comply with environmental laws. We are subject to extensive federal, state, provincial and local environmental laws and regulations which govern the discharge, emission, storage, handling and disposal of a variety of substances that may be used in, or result from, our operations. We are also subject periodically to environmental compliance reviews by environmental, safety, and health regulatory agencies and to potential liability for the remediation of contamination associated with both present and past hazardous waste generation, handling, and disposal activities. We cannot accurately predict the outcome or timing of future expenditures that we may be required to make in order to comply with the federal, state, local and provincial environmental, safety, and health laws and regulations that are applicable to our operations and facilities.

We are subject to product liability costs for which we may not have or be able to obtain adequate insurance coverage.

The testing and marketing of pharmaceutical products entails an inherent risk of product liability. Liability exposures for pharmaceutical products can be extremely large and pose a material risk. In some instances, we may be or may become contractually obligated to indemnify third parties for such liability. Our business may be materially and adversely affected by a successful product liability claim or claims in excess of any insurance coverage that we may have. Further, even if claims are not successful, the costs of defending such claims and potential adverse publicity could be harmful to our business.

While we currently have, and in some cases are contractually obligated to maintain, insurance for our business, property and our products as they are administered in bioavailability/bioequivalence studies, first and third party insurance is increasingly costly and narrow in scope. Therefore, we may be unable to meet such contractual obligations or we may be required to assume more risk in the future. If we are subject to third party claims or suffer a loss or damage in excess of our insurance coverage, we may be required to bear that risk in excess of our insurance limits. Furthermore, any first or third party claims made on our insurance policy may impact our ability to obtain or maintain insurance coverage at reasonable costs or at all in the future.

Our products involve the use of hazardous materials and waste, and as a result we are exposed to potential liability claims and to costs associated with complying with laws regulating hazardous waste.

Our research and development activities involve the use of hazardous materials, including chemicals, and are subject to Canadian federal, provincial and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. It is possible that accidental injury or contamination from these materials may occur. In the event of an accident, we could be held liable for any damages, which could exceed our available financial resources. Further, we may not be able to maintain insurance to cover these costs on acceptable terms, or at all. In addition, we may be required to incur significant costs to comply with environmental laws and regulations in the future.

Our operations may be adversely affected by risks associated with international business.

We may be subject to certain risks that are inherent in an international business, including:

- varying regulatory restrictions on sales of our products to certain markets and unexpected changes in regulatory requirements;
- tariffs, customs, duties, and other trade barriers;
- difficulties in managing foreign operations and foreign distribution partners;
- longer payment cycles and problems in collecting accounts receivable;
- political risks;



- foreign exchange controls that may restrict or prohibit repatriation of funds;
- export and import restrictions or prohibitions, and delays from customs brokers or government agencies;
- seasonal reductions in business activity in certain parts of the world; and
- potentially adverse tax consequences.

Depending on the countries involved, any or all of the foregoing factors could materially harm our business, financial condition and results of operations.

#### Risks related to our common shares

Our share price has been highly volatile and our shares could suffer a further decline in value.

The trading price of our common shares has been highly volatile and could continue to be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

- sales of our common shares, including any sales made in connection with future financings;
- announcements regarding new or existing corporate relationships or arrangements;
- announcements by us of significant acquisitions, joint ventures, or capital commitments;
- actual or anticipated period-to-period fluctuations in financial results;
- clinical and regulatory development regarding our product candidates;
- litigation or threat of litigation;
- failure to achieve, or changes in, financial estimates by securities analysts;
- comments or opinions by securities analysts or members of the medical community;
- announcements regarding new or existing products or services or technological innovations by us or our competitors;
- conditions or trends in the pharmaceutical and biotechnology industries;
- additions or departures of key personnel or directors;
- economic and other external factors or disasters or crises;
- limited daily trading volume; and
- developments regarding our patents or other intellectual property or that of our competitors.

In addition, the stock market in general and the market for drug development companies in particular have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Further, there has been significant volatility in the market prices of securities of life science companies. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. A securities class action suit against us could result in substantial costs, potential liabilities, and the diversion of management's attention and resources.

A large number of our common shares could be sold in the market in the near future, which could depress our stock price.

As of the date of this annual report, we had approximately 22.8 million common shares outstanding. In addition, a substantial portion of our shares are currently freely trading without restriction under the Securities Act of 1933, as amended ("U.S. Securities Act"), having been registered for resale or held by their holders for over one year and are eligible for sale under Rule 144. In addition, we may sell up to 5,305,484 of our common shares for up to an aggregate of \$16.8 million (or such lesser amount as may be permitted under applicable securities laws and regulations) through at-the-market issuances on NASDAQ or otherwise, of which 1,312,100 of our common shares have been sold for net proceeds to us of \$4,808,054 as of the date of this annual report. Roth Capital Partners, LLC ("Roth") received compensation of \$135,960 in connection with such sales.



On October 22, 2009, IntelliPharmaCeutics Ltd. (“IPC Ltd.”) and Vasogen Inc. (“Vasogen”) completed a plan of arrangement and merger (the “IPC Arrangement Agreement”), resulting in the formation of the Company. Our shareholders who received shares under the IPC Arrangement Agreement who were not deemed “affiliates” of either Vasogen, IPC Ltd. or us prior to the IPC Arrangement Agreement were able to resell the common shares that they received without restriction under the U.S. Securities Act. The common shares received by an “affiliate” after the IPC Arrangement Agreement or who were “affiliates” of either Vasogen, IPC Ltd. or us prior to the IPC Arrangement Agreement are subject to certain restrictions on resale under Rule 144.

As of the date of this annual report, there are currently common shares issuable upon the exercise of outstanding options and warrants and the conversion of an outstanding convertible debenture for an aggregate of approximately 7.5 million common shares. To the extent any of our options and warrants are exercised and the convertible debenture is converted, a shareholder’s percentage ownership will be diluted and our stock price could be further adversely affected. Moreover, as the underlying shares are sold, the market price could drop significantly if the holders of these restricted shares sell them or if the market perceives that the holders intend to sell these shares.

We have no history or foreseeable prospect of paying cash dividends.

We have not paid any cash dividends on our common shares and do not intend to pay cash dividends in the foreseeable future. We intend to retain future earnings, if any, for reinvestment in the development and expansion of our business. Dividend payments in the future may also be limited by loan agreements or covenants contained in other securities we may issue. Any future determination to pay cash dividends will be at the discretion of our board of directors and depend on our financial condition, results of operations, capital and legal requirements and such other factors as our board of directors deems relevant.

There may not be an active, liquid market for our common shares.

There is no guarantee that an active trading market for our common shares will be maintained on the NASDAQ Capital Market (“NASDAQ”) or the Toronto Stock Exchange (“TSX”). Investors may not be able to sell their shares quickly or at the latest market price if trading in our common shares is not active.

Future issuances of our shares could adversely affect the trading price of our common shares and could result in substantial dilution to shareholders.

We may need to issue substantial amounts of common shares in the future. In this regard, in November 2013, we entered into an at-the-market program pursuant to which we may, from time to time, sell up to 5,305,484 of our common shares for up to an aggregate of \$16.8 million (or such lesser amount as may be permitted under applicable securities laws and regulations) of our common shares on NASDAQ or otherwise. As of the date of this annual report, 1,312,100 of our common shares have been sold for net proceeds to us of \$4,808,054. There can be no assurance that any additional shares will be sold under our at-the-market program. To the extent that the market price of our common shares declines, we will need to issue an increasing number of common shares per dollar of equity investment. In addition to our common shares issuable in connection with the exercise of our outstanding warrants, our employees, and directors will hold rights to acquire substantial amounts of our common shares. In order to obtain future financing if required, it is likely that we will issue additional common shares or financial instruments that are exchangeable for or convertible into common shares. Also, in order to provide incentives to employees and induce prospective employees and consultants to work for us, we may offer and issue options to purchase common shares and/or rights exchangeable for or convertible into common shares. Future issuances of shares could result in substantial dilution to shareholders. Capital raising activities, if available, and dilution associated with such activities could cause our share price to decline. In addition, the existence of common share purchase warrants may encourage short selling by market participants. Also, in order to provide incentives to current employees and directors and induce prospective employees and consultants to work for us, we have historically granted options and deferred share units (“DSUs”), and intend to



continue to do so or offer and issue other rights exchangeable for or convertible into common shares. Future issuances of shares could result in substantial dilution to all our shareholders. In addition, future public sales by holders of our common shares could impair our ability to raise capital through any future equity offerings.

-18-

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We may in the future issue preference shares which could adversely affect the rights of holders of our common shares and the value of such shares.

Our board of directors has the ability to authorize the issue of an unlimited number of preference shares in series, and to determine the price, rights, preferences and privileges of those shares without any further vote or action by the holders of our common shares. Although we have no preference shares issued and outstanding, preference shares issued in the future could adversely affect the rights and interests of holders of our common shares.

Our common shares may not continue to be listed on the TSX.

Failure to maintain the applicable continued listing requirements of the TSX could result in our common shares being delisted from the TSX. The TSX will normally consider the delisting of securities if, in the opinion of the exchange, it appears that the public distribution, price, or trading activity of the securities has been so reduced as to make further dealings in the securities on TSX unwarranted. Specifically, participating securities may be delisted from the TSX if, among other things, the market value of an issuer's securities is less than C\$3,000,000 over any period of 30 consecutive trading days. In such circumstances, the TSX may place an issuer under a delisting review pursuant to which the issuer would be reviewed under the TSX's remedial review process and typically be granted 120 days to comply with all requirements for continued listing. If the market price of our common shares declines further or we are unable to maintain other listing requirements, the TSX could commence a remedial review process that could lead to the delisting of our common shares from the TSX. Further, if we complete a sale, merger, acquisition, or alternative strategic transaction, we will have to consider if the continued listing of our common shares on the TSX is appropriate, or possible.

If our common shares are no longer listed on the TSX, they may be eligible for listing on the TSX Venture Exchange. In the event that we are not able to maintain a listing for our common shares on the TSX or the TSX Venture Exchange, it may be extremely difficult or impossible for shareholders to sell their common shares in Canada. Moreover, if we are delisted from the TSX, but obtain a substitute listing for our common shares on the TSX Venture Exchange, our common shares will likely have less liquidity and more price volatility than experienced on the TSX.

Shareholders may not be able to sell their common shares on any such substitute exchange in the quantities, at the times, or at the prices that could potentially be available on a more liquid trading market. As a result of these factors, if our common shares are delisted from the TSX, the price of our common shares is likely to decline.

Our common shares may not continue to be listed on NASDAQ.

Failure to meet the applicable quantitative and/or qualitative maintenance requirements of NASDAQ could result in our common shares being delisted from NASDAQ. For continued listing, NASDAQ requires, among other things, that listed securities maintain a minimum bid price of not less than \$1.00 per share. If the bid price falls below the \$1.00 minimum for more than 30 consecutive trading days, an issuer will typically have 180 days to satisfy the \$1.00 minimum bid price, which must be maintained for a period of at least ten trading days in order to regain compliance.

If we are delisted from NASDAQ, our common shares may be eligible for trading on an over-the-counter market in the United States. In the event that we are not able to obtain a listing on another U.S. stock exchange or quotation service for our common shares, it may be extremely difficult or impossible for shareholders to sell their common shares in the United States. Moreover, if we are delisted from NASDAQ, but obtain a substitute listing for our common shares in the United States, it will likely be on a market with less liquidity, and therefore potentially more price volatility, than NASDAQ. Shareholders may not be able to sell their common shares on any such substitute U.S. market in the quantities, at the times, or at the prices that could potentially be available on a more liquid trading market. As a result of these factors, if our common shares are delisted from NASDAQ, the price of our common

shares is likely to decline. In addition, a decline in the price of our common shares will impair our ability to obtain financing in the future.

-19-

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Our common shares are listed for trading in the United States and may become subject to the Securities and Exchange Commission's penny stock rules.

Transactions in securities that are traded in the United States by companies with net tangible assets of \$5,000,000 or less and a market price per share of less than \$5.00 that are not traded on NASDAQ or on other securities exchanges may be subject to the "penny stock" rules promulgated under the Securities Exchange Act of 1934, as amended ("U.S. Exchange Act"). Under these rules, broker-dealers who recommend such securities to persons other than institutional investors must:

- make a special written suitability determination for the purchaser;
- receive the purchaser's written agreement to a transaction prior to sale;
- provide the purchaser with risk disclosure documents which identify risks associated with investing in "penny stocks" and which describe the market for these "penny stocks" as well as a purchaser's legal remedies; and
- obtain a signed and dated acknowledgment from the purchaser demonstrating that the purchaser has actually received the required risk disclosure document before a transaction in a "penny stock" can be completed.

As a result of these requirements, if our common shares are at such time subject to the "penny stock" rules, broker-dealers may find it difficult to effectuate customer transactions and trading activity in these shares in the United States may be significantly limited. Accordingly, the market price of the shares may be depressed, and investors may find it more difficult to sell the shares.

As a foreign private issuer in the United States, we are subject to different U.S. securities laws and rules than a domestic U.S. issuer.

As a foreign private issuer under U.S. securities laws we are not required to comply with all the periodic disclosure requirements of the U.S. Exchange Act applicable to domestic United States companies and therefore the publicly available information about us may be different or more limited than if we were a United States domestic issuer. In addition, our officers, directors, and principal shareholders are exempt from the "real time" reporting and "short swing" profit recovery provisions of Section 16 of the U.S. Exchange Act and the rules thereunder. Although under Canadian rules, our officers, directors and principal shareholders are generally required to file on SEDI ([www.sedi.ca](http://www.sedi.ca)) reports of transactions involving our common shares within five calendar days of such transaction, our shareholders may not know when our officers, directors and principal shareholders purchase or sell our common shares as timely as they would if we were a United States domestic issuer.

We are exposed to risks if we are unable to comply with laws and future changes to laws affecting public companies, including the Sarbanes-Oxley Act of 2002, and also to increased costs associated with complying with such laws.

Any future changes to the laws and regulations affecting public companies, as well as compliance with existing provisions of the Sarbanes-Oxley Act of 2002 ("SOX") in the United States and applicable Canadian securities laws, regulations, rules and policies, may cause us to incur increased costs to comply with such laws and requirements, including, among others, hiring additional personnel and increased legal, accounting and advisory fees. Delays, or a failure to comply with applicable laws, rules and regulations could result in enforcement actions, the assessment of other penalties and civil suits. The new laws and regulations may increase potential costs to be borne under indemnities provided by us to our officers and directors and may make it more difficult to obtain certain types of insurance, including liability insurance for directors and officers; as such, we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult to attract and retain qualified persons to serve on our board of directors, or as executive officers.



We are required annually to review and report on the effectiveness of our internal control over financial reporting in accordance with SOX Section 404 and Multilateral Instrument 52-109 – Certification of Disclosure in Issuer’s Annual and Interim Filings of the Canadian Securities Administrators. The results of this review are reported in our Annual Report on Form 20-F and in our Management Discussion and Analysis.

Management’s review is designed to provide reasonable, not absolute, assurance that all material weaknesses in our internal controls are identified. Material weaknesses represent deficiencies in our internal controls that may not prevent or detect a misstatement occurring which could have a material adverse effect on our quarterly or annual financial statements. In addition, there can be no assurance that any remedial actions we take to address any material weaknesses identified will be successful, nor can there be any assurance that further material weaknesses will not be identified in future years. Material errors, omissions or misrepresentations in our disclosures that occur as a result of our failure to maintain effective internal control over financial reporting could have a material adverse effect on our business, financial condition, results of operations, and the value of our common shares.

We may be classified as a “passive foreign investment company” or “PFIC” for U.S. income tax purposes, which could have significant and adverse tax consequences to U.S. investors.

The possible classification of our company as a passive foreign investment company (“PFIC”) for U.S. federal income tax purposes could have significant and adverse tax consequences for U.S. holders of our common shares and preference shares (collectively, “shares”). It may be possible for U.S. Holders (as defined in Item 10 below) of shares to mitigate certain of these consequences by making an election to treat us as a “qualified electing fund” or “QEF” under Section 1295 of the Code (a “QEF Election”) or a mark-to-market election under Section 1296 of the Internal Revenue Code of 1986, as amended (the “Code”). A non-U.S. corporation generally will be a PFIC if, for a taxable year (a) 75% or more of the gross income of such corporation for such taxable year consists of specified types of passive income or (b) on average, 50% or more of the assets held by such corporation either produce passive income or are held for the production of passive income, based on the fair market value of such assets (or on the adjusted tax basis of such assets, if such non-U.S. corporation is not publicly traded and either is a “controlled foreign corporation” under Section 957(a) of the Code, or makes an election to determine whether it is a PFIC based on the adjusted basis of the assets).

The determination of whether we are, or will be, a PFIC for a taxable year depends, in part, on the application of complex U.S. federal income tax rules, which are subject to various interpretations. Although the matter is not free from doubt, we believe that we were not a PFIC during our 2013 taxable year and may not be a PFIC during our 2014 taxable year. Because PFIC status is based on our income, assets and activities for the entire taxable year, and our market capitalization, it is not possible to determine whether we will be characterized as a PFIC for the 2014 taxable year until after the close of the taxable year. The tests for determining PFIC status are subject to a number of uncertainties. These tests are applied annually, and it is difficult to accurately predict future income, assets and activities relevant to this determination. In addition, because the market price of our common shares is likely to fluctuate, the market price may affect the determination of whether we will be considered a PFIC. There can be no assurance that we will not be considered a PFIC for any taxable year (including our 2014 taxable year). Absent one of the elections described above, if we are a PFIC for any taxable year during which a U.S. holder holds our shares, we generally will continue to be treated as a PFIC regardless of whether we cease to meet the PFIC tests in one or more subsequent years. Accordingly, no assurance can be given that we will not constitute a PFIC in the current (or any future) tax year or that the Internal Revenue Service (the “IRS”) will not challenge any determination made by us concerning our PFIC status.

If we are a PFIC, the U.S. federal income tax consequences to a U.S. holder of the ownership and disposition of our shares will depend on whether such U.S. holder makes a QEF or mark-to-market election. Unless otherwise provided by the IRS, a U.S. holder of our shares is generally required to file an informational return annually to report its ownership interest in the PFIC during any year in which we are a PFIC.

The foregoing does not purport to be a complete enumeration or explanation of the tax risks involved in an investment in our company. Prospective investors should read this entire annual report and consult with their own legal, tax and financial advisors before deciding to invest in our company.

It may be difficult to obtain and enforce judgments against us because of our Canadian residency.

We are governed by the laws of Canada. Most of our directors and officers are residents of Canada or other jurisdictions outside of the United States and all or a substantial portion of our assets and the assets of such persons may be located outside of the United States. As a result, it may be difficult for shareholders to effect service of process upon us or such persons within the United States or to realize in the United States on judgments of courts of the United States predicated upon the civil liability provisions of the U.S. federal securities laws or other laws of the United States. In addition, there is doubt as to the enforceability in Canada of liabilities predicated solely upon U.S. federal securities law against us, our directors, controlling persons and officers who are not residents of the United States, in original actions or in actions for enforcements of judgments of U.S. courts.

Item 4. Information on the Company

A. History and Development of the Company

The Company was incorporated under the Canada Business Corporations Act by certificate and articles of arrangement dated October 22, 2009.

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.

On October 19, 2009, the shareholders of IPC Ltd. and Vasogen approved the IPC Arrangement Agreement that resulted in the October 22, 2009 court-approved merger of IPC Ltd. and another U.S. subsidiary of Intellipharma Inc., coincident with an arrangement pursuant to which a predecessor of the Company combined 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 (the "IPC Arrangement Transaction"). The completion of the IPC Arrangement Transaction on October 22, 2009 resulted in the formation of the Company, which is incorporated under the laws of Canada. The common shares of the Company are traded on the TSX and NASDAQ.

For the years ended November 30, 2013, 2012 and 2011, we spent a total of \$5,060,853, \$5,992,417, and \$5,125,608, respectively, on research and development. Over the past three fiscal years and up to February 18, 2014, we have raised approximately \$24,696,800 in gross proceeds from the issuance of equity and convertible debt securities. Our common shares are listed on the TSX under the symbol "I" and on NASDAQ under the symbol "IPCI".

During the last and current financial year, we have not been aware of any indications of public takeover offers by third parties in respect of the Company's shares or by the Company in respect of other companies' shares.

For additional information on key events, see Item 4.B below.

B. Business Overview

We are a pharmaceutical company specializing in the research, development and manufacture of novel and generic controlled-release and targeted-release oral solid dosage drugs. Our patented Hypermatrix™ technology is a multidimensional controlled-release drug delivery platform that can be applied to the efficient development of a wide range of existing and new pharmaceuticals. Based on this technology platform, we have developed several drug delivery systems and a pipeline of products (our dexmethylphenidate hydrochloride extended-release capsules for the 15 and 30 mg strengths which recently received final FDA approval) and product candidates in various stages of development, including ANDAs filed with the FDA in therapeutic areas that include neurology, cardiovascular, gastrointestinal tract ("GIT"), diabetes and pain.



We were granted final FDA approval to market our dexamethylphenidate hydrochloride extended-release capsules for the 15 and 30 mg strengths on November 18, 2013. Commercial sales of these strengths were launched immediately by our commercialization partner in the United States, Par. As the first-filer for the drug product in the 15 mg strength, we will have 180 days of exclusivity of generic sales from the date of launch of such product in the United States by our partner, Par. Our 5, 10, 20 and 40 mg strengths were also tentatively FDA approved, subject to the right of another party or parties to 180 days of generic exclusivity from the date of first launch of such products by such parties. We believe that Par intends to launch these strengths immediately upon the expiry of those exclusivity periods, but there can be no assurance as to when or if any launch will occur. There can be no assurance as to when or if final FDA approval will be received for the remaining product strengths we have applied for or that any of these strengths tentatively approved will ever be successfully commercialized.

Our goal is to leverage our proprietary technologies and know-how in order to build a diversified portfolio of commercialized products that generate revenue. We intend to do this by advancing our products from the formulation stage through product development, regulatory approval and manufacturing. We believe that full integration of development and manufacturing should maximize the value inherent in our drug delivery technologies, products and product candidates and will create long term growth and value. Out-licensing sales and marketing to established organizations, when it makes economic sense to do so, should maximize revenues from our products while allowing us to focus on our core competencies.

### Our Strategy

We believe that our Hypermatrix™ technologies are a multidimensional controlled-release drug delivery platform that can be applied to the efficient development of a wide range of existing and new pharmaceuticals. We believe that the flexibility of these technologies allow us to develop complex drug delivery solutions within a relatively rapid timeframe. Based on this technology platform, we have developed several drug delivery systems and a pipeline of products (our dexamethylphenidate hydrochloride extended-release capsules for the 15 and 30 mg strengths which recently received final FDA approval) and product candidates in various stages of development, including ANDAs filed with the FDA. Certain, but not all, of the products in our pipeline may be developed from time to time for third parties pursuant to drug development agreements with those third parties, under which our development partner generally pays certain of 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.

The Hypermatrix™ technologies are applied to the development of both existing and new pharmaceuticals across a range of therapeutic classes. The competitive advantages of these technologies allow us to focus our development activities in two areas; difficult-to-develop controlled-release generic drugs, which follow an ANDA regulatory path; and improved current therapies through controlled release, which follow a NDA 505(b)(2) regulatory path.

The market we operate in is 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 we believe represent substantial opportunities for us to commercialize on our own or develop products or out-license our technologies and products:

- For existing controlled-release (once-a-day) products whose APIs are covered by drug molecule patents about to expire or already expired, or whose formulations are covered by patents about to expire, already expired or which we believe we do not infringe, we can seek to formulate generic products which are bioequivalent to the branded products. Our scientists have demonstrated a successful track record with such products, having previously developed several drug products which have been commercialized in the United States by their former employer/clients. The regulatory pathway for this approach requires ANDAs for the United States and corresponding pathways for other jurisdictions.
- For branded immediate-release (multiple-times-per-day) drugs, we can formulate improved replacement products, typically by developing new, potentially patentable, controlled-release once-a-day drugs. Among other out-licensing opportunities, these drugs can be licensed to and sold by the pharmaceutical company that made the original immediate-release product. These can potentially protect against revenue erosion in the brand by providing a clinically attractive patented product that competes favorably with the generic immediate-release competition that arises on expiry of the original patent(s). The regulatory pathway for this approach requires NDAs via a 505(b)(2) application for the U.S. or corresponding pathways for other jurisdictions where applicable. The 505(b)(2) pathway (which relies in part upon the approving agency's findings for a previously approved drug) both accelerates development timelines and reduces costs in comparison to NDAs for new chemical entities.



- Some of 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 aptly suited to developing abuse-deterrent pain medications. The regulatory pathway for this approach requires NDAs via a 505(b)(2) application for the U.S. or corresponding pathways for other jurisdictions where applicable.

We intend to collaborate in the development and/or marketing of one or more products with partners, when we believe that such collaboration may enhance the outcome of the project. We also plan to seek additional collaborations as a means of developing additional products. We believe that our business strategy enables us to reduce our risk by (a) having a diverse product portfolio that includes both branded and generic products in various therapeutic categories, and (b) building collaborations and establishing licensing agreements with companies with greater resources thereby allowing us to share costs of development and to improve cash-flow. There can be no assurance that we will be able to enter into additional collaborations or, if we do, that such arrangements will be beneficial.

We may also, from time to time, provide incidental consulting advice to other organizations regarding FDA standards.

### Our Drug Delivery Technologies

Our scientists have developed drug delivery technology systems, based on the Hypermatrix™ platform, that facilitate controlled-release delivery of a wide range of pharmaceuticals. These systems include several core technologies, which enable us to flexibly respond to a wide range of drug attributes and patient requirements, producing a desired controlled-release effect. Our technologies have been incorporated in drugs manufactured and sold by major pharmaceutical companies.

This group of drug delivery technology systems is based upon the drug active ingredient (“drug active”) being imbedded in, and an integral part of, a homogeneous (uniform), core and/or coatings consisting of one or more polymers which affect the release rates of drugs, other excipients (compounds other than the drug active), such as for instance lubricants which control handling properties of the matrix during fabrication, and the drug active itself. The Hypermatrix™ technologies are the core of our current marketing efforts and the technologies underlying our existing development agreements.

Our platform of Hypermatrix™ drug delivery technologies include, but are not limited to, IntelliFoam™, IntelliGITransporter™, IntelliMatrix™, IntelliOsmotics™, IntelliPaste™, IntelliPellets™, IntelliShuttle™ and nPODDDS™. Their key attributes are described below.

These technologies provide a broad range of release profiles, taking into account the physical and chemical characteristics of a drug product, the therapeutic use of the particular drug, and the optimal site for release of the API in the GIT. At present those technologies have been applied in the laboratory and/or in bioavailability/bioequivalence studies in man to such orally administered small molecule drugs as are used in the treatment of neurological, cardiovascular, GIT, diabetes, pain and other significant indications.

### The Hypermatrix™ Family of Technologies

#### IntelliFoam™

The IntelliFoam™ technology is based on the drug active being embedded in, but separate from a syntactic foam substrate, the properties of which are used to modulate the release of the drug active. The drug actives are embedded in a resin polymer matrix.



### IntelliGITransporter™

The IntelliGITransporter™ technology consists of an active drug immobilized in a homogeneous (uniform) matrix structure. A precise choice of mix ratios, polymers, and other ingredients imparts characteristics which protect the drug composition from mechanical degradation due to digestion, and/or from chemical degradation in the acidic stomach environment, and ensures that this technology allows control of release as well as releasing the medication at certain parts of the stomach or intestines without significant food effects or unintentional premature release of the entire drug dose. We believe that this technology is most useful for drug molecules with characteristics such as very low or very high potency, opiate analgesics (pain medications derived from the chemical compounds found in opium), or susceptibility to acid degradation. It is also useful for products where a zero-order (constant rate over time, independent of the amount of drug available for dissolution) release profile is desirable.

### IntelliMatrix™

The IntelliMatrix™ technology is a proprietary blend of several polymers. Depending on the constituents of the blend and the manner in which these interact, the use of the blend with a drug allows the drug to be released at predetermined rates, while imparting protective characteristics to both the drug and the GIT. This is most useful for drugs which require precisely controlled first-order release profiles, where the amount released with time is dependent on one component like the amount of drug available for dissolution.

### IntelliOsmotics™

The IntelliOsmotics™ technology is based upon the inclusion of multiple populations of polymers with distinct chemical bonding characteristics. These set up a complex matrix of hydrophilic (water attracting) and hydrophobic (water repelling) domains. When the tablet or bead is in an aqueous environment, like gastric contents, a “mixture” of water-soluble polymer and drug core is surrounded by gel layer(s) of water-insoluble polymer. Osmotic pressure drives the drug out when solvent passes through the gel layer while the polymer molecules remain. This permits control of the rate of release of the drug active by the variation of polymer ratios. This technology is most useful for drug molecules which require precisely controlled pseudo-first-order release profiles, where the rate of release is proportional to the amount available for dissolution as well as being proportional to one other component; however the effect of the amount of drug is overriding, so that the rate appears first-order. This type of release control can be useful when attempting to match difficult profiles for generic formulation.

### IntelliPaste™

The IntelliPaste™ technology is comprised of blends of multiple polymers, oils, excipients and drug active(s) which result in a paste-in-a-capsule dosage form. The physical attributes of the paste include that it is thixotropic, pseudoplastic and non-Newtonian or, in layman’s terms, like toothpaste. Typically, it is formulated as having very low solubility in water or oil, and low solubility in alcohol. These characteristics enable the resulting drug product to have tamper-deterrent properties, and to resist dissolution in even high concentrations of alcohol. As a result, IntelliPaste™ is the Company’s preferred delivery technology for the controlled delivery of opiates, narcotics and other central nervous system drug products which are susceptible to unlawful diversion or abuse.

### IntelliPellets™

The IntelliPellets™ technology consists of one or more type (population) of granule, bead, pellet, or tablet in a holding chamber or reservoir, such as a hard gelatin capsule. Each type (population) may be uniquely different from the other in the manner or rate it releases the drug. Our IntelliPellets™ technology is designed to control, prolong, delay or modify the release of drugs. It is particularly useful for the delivery of multiple drugs, for delayed, timed, pulsed or for chronotherapeutic drug delivery, designed to mimic our internal clocks for therapeutic optimization (the drug is

delivered in the right amount for the patient at the right time). This technology is most useful for the delivery of multiple-drug cocktails, or in situations where the timing of a single dose or the sequencing of multiple doses of the same drug is important.

-25-

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## IntelliShuttle™

The IntelliShuttle™ technology provides for drug release past the stomach, such as for drugs required for action beyond the stomach, for drugs which could be destroyed by the stomach environment, or for drugs which could harm the stomach itself. This technology “shuttles” the drug past the stomach to be released at predetermined times or sites where appropriate for optimum therapeutic effect. This technology is most useful for acid labile drug molecules (drugs that are destroyed in acid environment), such as the proton pump inhibitors, of which well-known omeprazole (Prilosec) and lansoprazole (Prevacid) are examples, or for drug molecules which may harm the stomach, of which the well-known aspirin is an example.

Each of the above-noted proprietary technologies was fully developed and ready for application to client drug delivery requirements from the date of our inception. Each of them has been utilized and applied to client drug delivery requirements under our existing and previous development contracts; in several instances more than one technology has been applied to a single drug development. We continue to develop all of our existing technologies and to conduct the necessary research to develop new products and technologies.

## nPODDDS™ (novel point of divergence drug delivery system)

The nPODDDS™ technology platform is designed to provide for certain unique drug delivery features in a product. These include the release of the active substance to show a divergence in a dissolution and/or bioavailability profile. The divergence represents a point or a segment in a release timeline where the release rate, represented by the slope of the curve, changes from an initial rate or set of rates to another rate or set of rates, the former representing the usually higher rate of release shortly after ingesting a dose of the drug, and the latter representing the rate of release over a later and longer period of time, being more in the nature of a controlled-release or sustained action. It is applicable for the delivery of opioid analgesics in which it is desired to discourage common methods of tampering associated with misuse and abuse of a drug, and also dose dumping in the presence of alcohol. It can potentially retard tampering without interfering with the bioavailability of the product.

## Our Products

The table below shows the present status of our ANDA and NDA product candidates that have been disclosed to the public.

Generic name	Brand	Indication	Stage of Development(1)	Regulatory Pathway	Market Size (in millions)(2)	Rights(3)
Dexamethylphenidate hydrochloride extended-release capsules	Focalin XR®	Attention deficit hyperactivity disorder	Received final approval for 15 and 30 mg, and tentative approval for 5, 10, 20 and 40 mg, strengths from FDA	ANDA	\$691	Intellipharmaceutics and Par
Venlafaxine hydrochloride extended-release capsules	Effexor XR®	Depression	ANDA application for commercialization approval for 3 strengths under review by FDA	ANDA	\$709	Intellipharmaceutics



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Pantoprazole  
sodium delayed-  
release tablets

Protonix® Conditions  
associated with  
gastroesophageal  
reflux disease

ANDA application ANDA  
for  
commercialization  
approval for 2  
strengths under  
review by FDA

\$330

Intellipharmaceuticals