Intellipharmaceutics International Inc.
Form 424B3
June 04, 2014
Filed pursuant to Rule 424(b)(3)

Registration No. 333-196112

SHORT FORM BASE SHELF PROSPECTUS

New Issue

INTELLIPHARMACEUTICS INTERNATIONAL INC.

U.S.$100,000,000

Common Shares
Preference Shares
Warrants
Subscription Receipts
Units

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Intellipharmaceutics International Inc. (the “Company”, “Intellipharmaceutics”, “we”, “us” or “our”) may offer and issue fr time to time common shares of the Company (“common shares”), preference shares of the Company (“preference shares”), warrants to purchase common shares or preference shares (“warrants”), subscription receipts (“subscription receipts”) and/or units comprised of one or more of the foregoing (“units” and together with the common shares, preference shares, warrants and subscription receipts, the “securities”) or any combination thereof for up to an aggregate initial offering price of U.S.$100,000,000 (or the equivalent thereof in other currencies) during the period that the registration statement of which this short form base shelf prospectus (the “prospectus”), including any amendments hereto, forms a part remains effective. Any offerings of the Company’s securities in Canada pursuant to this prospectus and any related filings with the securities commissions or other securities regulatory bodies in Canada shall be made only during the 25-month period commencing on the date hereof. Securities may be offered separately or together, in amounts, at prices and on terms to be determined based on market conditions at the time of sale and set forth in an accompanying prospectus supplement (a “prospectus supplement”).

The specific terms of the securities with respect to a particular offering will be set out in the applicable prospectus supplement and may include, where applicable (i) in the case of common shares, the number of common shares offered, the offering price, whether the common shares are being offered for cash, and any other terms specific to the common shares being offered, (ii) in the case of preference shares, the number of preference shares offered, the designation of a particular class or series, if applicable, the offering price, whether the preference shares are being offered for cash, the dividend rate, if any, any terms for redemption or retraction, any conversion rights, and any other terms specific to the preference shares being offered, (iii) in the case of warrants, the offering price, whether the warrants are being offered for cash, the designation, the number and the terms of the common shares or preference shares purchasable upon exercise of the warrants, any procedures that will result in the adjustment of these numbers, the exercise price, the dates and periods of exercise and any other terms specific to the warrants being offered, (iv) in the case of subscription receipts, the number of subscription receipts being offered, the offering price, whether the subscription receipts are being offered for cash, the procedures for the exchange of the subscription receipts for common shares, preference shares or warrants, as the case may be, and any other terms specific to the subscription receipts being offered and (v) in the case of units, the number of units offered, the offering price, and any other terms specific to the units being offered. Where required by statute, regulation or policy, and where securities are offered in currencies other than Canadian dollars, appropriate disclosure of foreign exchange rates applicable to the securities will be included in the prospectus supplement describing the securities.

All shelf information permitted under applicable law to be omitted from this prospectus will be contained in one or more prospectus supplements that will be delivered to purchasers together with this prospectus. Each prospectus supplement will be incorporated by reference into this prospectus for the purposes of securities legislation as of the date of the prospectus supplement and only for the purposes of the distribution of the securities to which the prospectus supplement pertains.

This prospectus constitutes a public offering of the securities only in those jurisdictions where they may be lawfully offered for sale and only by persons permitted to sell the securities in those jurisdictions. The Company may offer and sell securities to, or through, underwriters or dealers and also may offer and sell certain securities directly to other purchasers or through agents pursuant to exemptions from registration or qualification under applicable securities laws. A prospectus supplement relating to each issue of securities offered thereby will set forth the names of any underwriters, dealers, or agents involved in the offering and sale of the securities and will set forth the terms of the offering of the securities, the method of distribution of the securities including, to the extent applicable, the proceeds to the Company and any fees, discounts or any other compensation payable to underwriters, dealers or agents and any other material terms of the plan of distribution.

On June 3, 2014, the closing sale price of the common shares as reported by the TSX and NASDAQ was Cdn$4.03 and $3.72, respectively.

The Company’s registered office and head office is located at 30 Worcester Road, Toronto, Ontario, Canada, M9W 5X2.

We are a foreign private issuer under United States (“U.S.”) securities laws. The financial statements incorporated herein by reference have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”). The offering price of the securities being distributed under this prospectus will be stated in U.S. dollars.

Purchasers of any securities should be aware that the acquisition of the securities may have tax consequences both in the United States and in Canada. Such consequences for purchasers who are resident in, or citizens of, the United States or who are resident in Canada may not be described fully herein or in any applicable prospectus supplement. Purchasers of the securities should read any applicable tax discussion contained in the applicable prospectus supplement with respect to a particular offering of securities.

The enforcement by investors of civil liabilities under U.S. federal securities laws may be affected adversely by the fact that the Company is incorporated under the laws of Canada, that all of its officers and directors are residents of Canada, that some or all of the experts named in the registration statement are residents of a foreign country, and that a substantial portion of the assets of the Company and said persons are located outside the United States.

NEITHER THE U.S. SECURITIES AND EXCHANGE COMMISSION (THE "SEC") NOR ANY STATE SECURITIES COMMISSION OR CANADIAN SECURITIES REGULATOR HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

No underwriter has been involved in the preparation of this prospectus nor has any underwriter performed any review of the contents of this prospectus.

Investing in the securities involves certain risks. See "Risk Factors" beginning on page 4 of this prospectus. Prospective purchasers of the securities should carefully consider all the information in this prospectus and in the documents incorporated by reference in this prospectus.

The date of this prospectus is June 4, 2014

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You should rely only on the information contained in or incorporated by reference into this prospectus or any prospectus supplement. References to this "prospectus" include documents incorporated by reference therein. See "Documents Incorporated by Reference" at page 3 of this prospectus. The information in or incorporated by reference into this prospectus is current only as of its date. We have not authorized anyone to provide you with information that is different. This document may only be used where it is legal to offer these securities.

Any reference in this prospectus or any prospectus supplement to our "products" includes a reference to our product candidates and future products we may develop.

In this prospectus, any prospectus supplement, and/or the documents incorporated by reference herein or therein, 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.

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TRADEMARKS

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

CAUTIONARY NOTE REGARDING FORWARD-LOOKING INFORMATION

Certain statements included and incorporated by reference in this prospectus 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 such terms or other comparable 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 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. 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, or 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 of this prospectus, as well as in our other public filings incorporated by reference herein. 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 hereof, and we disclaim any intention and have no obligation or responsibility, except as required by law, to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

AVAILABLE INFORMATION

We file reports and other information with the securities commissions and similar regulatory authorities in each of the provinces and territories of Canada. These reports and information are available to the public free of charge on SEDAR at www.sedar.com.

We have filed with the SEC a registration statement on Form F-3 to register an indeterminable number of common shares, preference shares, warrants and subscription receipts as may from time to time be offered for sale by us, either individually or in units, at indeterminate prices (up to an aggregate maximum offering price for all such securities of U.S.$100,000,000. The information contained in this prospectus is not complete and may be changed. This prospectus provides you with some of the general terms that may apply to an offering of our securities. Each time we sell securities under this shelf registration we will provide a prospectus supplement that will contain specific information about the terms of that specific offering, including the number and price per security (or exercise price) of the securities to be offered and sold in that offering and the specific manner in which such securities may be offered. A prospectus supplement may also add to, update or change any of the information contained in this prospectus. If there is an inconsistency between the information in this prospectus and a prospectus supplement, you should rely on the information in the prospectus supplement. This prospectus, which constitutes a part of the registration statement, does not contain all of the information contained in the registration statement, certain items of which are contained in the exhibits to the registration statement as permitted by the rules and regulations of the SEC. Statements included in this prospectus or incorporated herein by reference about the contents of any contract, agreement or other documents referred to are not necessarily complete, and in each instance investors should refer to the exhibits for a more complete description of the matter involved. Each such statement is qualified in its entirety by such reference. Copies of the documents incorporated herein by reference may be obtained on request, orally or in writing, without charge, from Shameze Rampertab, our Chief Financial Officer, at 30 Worcester Road, Toronto, Ontario M9W 5X2, (416) 798-3001.

We are subject to the information requirements of the U.S. Securities Exchange Act of 1934, as amended, or the U.S. Exchange Act, relating to foreign private issuers and applicable Canadian securities legislation and, in accordance therewith, file reports and other information with the SEC and with the securities regulatory authorities in Canada. As a foreign private issuer, we are exempt from the rules under the U.S. Exchange Act prescribing the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the U.S. Exchange Act. In addition, we are not required to publish financial statements as promptly as U.S. companies.

Investors may read any document that we have filed with the SEC at the SEC's public reference room in Washington, D.C. Investors may also obtain copies of those documents from the public reference room of the SEC at 100 F Street, N.E., Washington, D.C. 20549 by paying a fee. Investors should call the SEC at 1-800-SEC-0330 or access its website at www.sec.gov for further information about the public reference rooms. Investors may read and download some of the documents we have filed with the SEC's Electronic Data Gathering and Retrieval system at www.sec.gov.

Readers should rely only on information contained or incorporated by reference in this prospectus and any applicable prospectus supplement. We have not authorized anyone to provide the reader with different information. We are not making an offer of any securities in any jurisdiction where the offer is not permitted. Readers should not assume that

the information contained in this prospectus is accurate as of any date other than the date on the front of this prospectus, unless otherwise noted herein or as required by law. It should be assumed that the information appearing in this prospectus and the documents incorporated herein by reference are accurate only as of their respective dates. Our business, financial condition, results of operations and prospects may have changed since those dates.

FINANCIAL INFORMATION

The financial statements of the Company incorporated herein by reference and in any prospectus supplement are reported in United States dollars and have been prepared in accordance with U.S. GAAP. References to "$" or "dollars" are to U.S. dollars, unless otherwise indicated.

EXCHANGE RATE INFORMATION

The following table sets out the high and low rates of exchange for one U.S. dollar expressed in Canadian dollars in effect at the end of each of the following periods; the average rate of exchange for those periods; and the rate of exchange in effect at the end of each of those periods, each based on the noon spot rate published by the Bank of Canada.

	Three months ended March 31, 2014	Years ended December 31,		
		2013	2012	2011
High	Cdn$1.1251	Cdn$1.0697	Cdn$1.0418	Cdn$1.0604
Low	Cdn$1.0614	Cdn$0.9839	Cdn$0.9710	Cdn$0.9449
Average for the Period	Cdn$1.1033	Cdn$1.0299	Cdn$0.9996	Cdn$0.9891
End of Period	Cdn$1.1053	Cdn$1.0636	Cdn$0.9949	Cdn$1.0170

On June 3, 2014, the noon spot rate for Canadian dollars in terms of the United States dollar, as reported by the Bank of Canada, was U.S.$1.00=Cdn$1.0910 or Cdn$1.00=U.S.$0.9166.

DOCUMENTS INCORPORATED BY REFERENCE

Information has been incorporated by reference in this prospectus from documents filed with securities commissions or similar authorities in each of the provinces and territories of Canada and filed with, or furnished to, the SEC. Copies of the documents incorporated herein by reference may be obtained on request without charge from our Chief Financial Officer at 30 Worcester Road, Toronto, Ontario, Canada, M9W 5X2, telephone (416) 798-3001. These documents are also available through the Internet on SEDAR, which can be accessed online at www.sedar.com, and on the SEC's Electronic Data Gathering and Retrieval System at www.sec.gov. The following documents filed or furnished by us with the various securities commissions or similar authorities in the provinces and territories of Canada and the SEC, as applicable, are specifically incorporated by reference into and form an integral part of this prospectus:

a) our annual report on Form 20-F for the fiscal year ended November 30, 2013, which was filed with the SEC on February 18, 2014, including our audited consolidated balance sheets as at November 30, 2013 and November 30, 2012, and the consolidated statements of operations and comprehensive loss, shareholders' equity (deficiency), and cash flows for each of the years in the three-year period ended November 30, 2013, as amended by our Form 20-F/A (Amendment No. 1) which was filed with the SEC on April 14, 2014;

b) our condensed unaudited interim consolidated financial statements and notes to the condensed unaudited interim consolidated financial statements for the three months ended February 28, 2014, which were included as Exhibit 99.2 to the Report on Form 6-K furnished to the SEC on April 14, 2014, together with the Management Discussion and Analysis of Financial Condition and Results of Operations for the three months ended February 28,2014, which was included as Exhibit 99.1 to the Report on Form 6-K furnished to the SEC on April 14, 2014;

c) our management proxy circular dated February 10, 2014 for the annual meeting of shareholders held on March 27, 2014, which was included as part of Exhibit 99.2 to our report on Form 6-K furnished to the SEC on February 26, 2014; and

d) our reports on Form 6-K furnished to the SEC on February 26, 2014, March 19, 2014, and March 31, 2014.

In addition, this prospectus shall also be deemed to incorporate by reference all subsequent annual reports filed on Form 20-F, Form 40-F or Form 10-K, and all subsequent filings on Forms 10-Q and 8-K filed by us pursuant to the U.S. Exchange Act after the effective time of the registration statement of which this prospectus forms a part and prior to the termination of the offering made by this prospectus. We may incorporate by reference into this prospectus any Form 6-K that is submitted to the SEC after the effective time of the registration statement of which this prospectus forms a part and before the date of termination of this offering. Any such Form 6-K that we intend to so incorporate shall state in such form that it is being incorporated by reference into the registration statement of which this prospectus forms a part. The documents

incorporated or deemed to be incorporated herein by reference contain meaningful and material information relating to us and the readers should review all information contained in this prospectus and the documents incorporated or deemed to be incorporated herein by reference.

Upon a new annual information form or annual report on Form 20-F and related annual consolidated financial statements being filed by us with the applicable securities regulatory authorities during the duration that this prospectus is effective, the previous annual information form or annual report on Form 20-F, the previous annual consolidated financial statements and all interim consolidated financial statements, and in each case the accompanying management's discussion and analysis, information circulars (to the extent the disclosure is inconsistent) and material change reports filed prior to the commencement of the financial year of the Company in which the new annual information form or annual report on Form 20-F is filed shall be deemed no longer to be incorporated into this prospectus for purposes of future offers and sales of securities under this prospectus. Upon interim consolidated financial statements and the accompanying management's discussion and analysis being filed by us with the applicable securities regulatory authorities during the duration that this prospectus is effective, all interim consolidated financial statements and the accompanying management's discussion and analysis filed prior to the new interim consolidated financial statements shall be deemed no longer to be incorporated into this prospectus for purposes of future offers and sales of securities under this prospectus.

A prospectus supplement containing the specific terms of an offering of securities and other information relating to the securities will be delivered to prospective purchasers of such securities together with this prospectus and will be deemed to be incorporated into this prospectus as of the date of such prospectus supplement only for the purpose of the offering of the securities covered by that prospectus supplement.

Any statement contained in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for the purposes of this prospectus, to the extent that a statement contained herein or in any other subsequently filed document which also is or is deemed to be incorporated by reference herein modifies or supersedes such statement. Any statement so modified or superseded shall not constitute a part of this prospectus, except as so modified or superseded. The modifying or superseding statement need not state that it has modified or superseded a prior statement or include any other information set forth in the document that it modifies or supersedes. The making of such a modifying or superseding statement shall not be deemed an admission for any purpose that the modified or superseded statement, when made, constituted a misrepresentation, an untrue statement of a material fact or an omission to state a material fact that is required to be stated or that is necessary to make a statement not misleading in light of the circumstances in which it was made.

RISK FACTORS

Prospective purchasers of securities should carefully consider the risk factors contained in and incorporated by reference in this prospectus (including subsequently filed documents incorporated by reference) and those described in a prospectus supplement relating to a specific offering of securities. Each of these risk factors could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our securities. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

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 or incorporated by reference in this prospectus or in any applicable prospectus supplement. 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, or those contained in any document incorporated by reference in this prospectus or in any applicable prospectus

supplement, occur, our business, financial condition and results of operations could be seriously harmed. Further, if we fail to meet the expectations of the public market in any given period, the market price of our common shares could decline. If any of the following risks actually occurs, our business, operating results, or financial condition could be materially adversely affected.

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

Risks related to our Company

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 June 3, 2014, our cash balance was $7.2 million, which we currently expect will fund our current operations through January 2015. We may need additional capital to fund our current operations commencing in January 2015, 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" beginning on page 27) 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. Our cash outflows are expected to consist primarily of internal and external research and development expenditures to advance our product pipeline in addition to general and administrative expenditures to support our corporate infrastructure. 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. Depending upon the results of our research and development programs and the availability of financial resources, we could decide to accelerate, terminate, reduce certain projects, or commence new ones. 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, or ANDAs, or new drug applications, or 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 February 28, 2014 and had an accumulated deficit of $39.4 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 whether 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.

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 favor 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 favor 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, or 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 prospectus, 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 o