Intellipharmaceutics International Inc.
Form 20-F
February 28, 2019

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

[X]

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

For the fiscal year ended November 30, 2018

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)

Greg Powell, 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	Name of each exchange on which registered
Common shares, no par value	NASDAQ TSX

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, 2018, the registrant had 18,252,243 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 every Interactive Data File required to be submitted 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 such files).

Yes [X] No [_]

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

Large accelerated filer [_] Accelerated filer [_] Non-accelerated filer [X] Emerging growth company [_]

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act. [_]

† The term “new or revised financial accounting standard” refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

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 theInternational 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]

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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 expectations, plans, goals and milestones, status of developments or expenditures relating to our business, plans to fund our current activities, and 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 “appear”, “unlikely”, “target”, “may”, “will”, “should”, “expects”, “plans”, “plans to”, “anticipates”, “believes”, “estimates”, “predicts”, “confident”, “prospects”, “potential” “intends”, “look forward”, “could”, “would”, “projected”, “goals”, “set to”, “seeking” or the negative of such terms or other co 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, capital availability, the estimated proceeds (and the expected use of any proceeds) we may receive from any offering of our securities, the potential dilutive effects of any future financing, potential liability from and costs of defending pending or future litigation, our ability to comply with the Nasdaq Stock Market LLC (“Nasdaq”) and the Toronto Stock Exchange (“TSX”) continued listing standards and our ability to develop and implement a plan of compliance with the Nasdaq continued listing standards acceptable to a Nasdaq Hearings Panel (the “Nasdaq Panel”), 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 difficulty in predicting the timing and results of any product launches, the timing and amount of profit-share payments from our commercial partners, and the timing and amount of any available investment tax credits, 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 rights for our drug delivery technologies, products and product candidates, recent and future legal developments in the United States and elsewhere that could make it more difficult and costly for us to obtain regulatory approvals for our product candidates and negatively affect the prices we may charge, increased public awareness and government scrutiny of the problems associated with the potential for abuse of opioid based medications, pursuing growth through international operations could strain our resources, our limited manufacturing, sales, marketing or distribution capability and our reliance on third parties for such, 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/or commercial partners with the ability to fund patent litigation and with acceptable product 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 commercial partners, 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, delays in product approvals that may be caused by changing regulatory requirements, the difficulty in predicting the timing of regulatory approval and launch of competitive products, the difficulty in predicting the impact of competitive products on sales volume, pricing, rebates and other allowances, the number of competitive product entries, and the nature and extent of any aggressive pricing and rebate activities that may follow, the inability to forecast wholesaler demand and/or wholesaler buying patterns, seasonal fluctuations in the number of prescriptions written for our generic Focalin XR® capsules, which may produce substantial fluctuations in revenue, the timing and amount of insurance reimbursement regarding our products,

changes in laws and regulations affecting the conditions required by the United States Food and Drug Administration ("FDA") for approval, testing and labeling of drugs including abuse or overdose deterrent properties, and changes affecting how opioids are regulated and prescribed by physicians, changes in laws and regulations, including Medicare and Medicaid, affecting among other things, pricing and reimbursement of pharmaceutical products, the effect of recent changes in U.S. federal income tax laws, including but not limited to, limitations

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on the deductibility of business interest, limitations on the use of net operating losses and application of the base erosion minimum tax, on our U.S. corporate income tax burden, 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, challenges related to the development, commercialization, technology transfer, scale-up, and/or process validation of manufacturing processes for our products or product candidates, the manufacturing capacity of third-party manufacturers that we may use for our products, potential product liability risks, the recoverability of the cost of any pre-launch inventory, should a planned product launch encounter a denial or delay of approval by regulatory bodies, a delay in commercialization, or other potential issues, the successful compliance with FDA, Health Canada and other governmental regulations applicable to us and our third party manufacturers' facilities, products and/or businesses, our reliance on commercial partners, and any future commercial partners, to market and commercialize our products and, if approved, our product candidates, difficulties, delays, or changes in the FDA approval process or test criteria for Abbreviated New Drug Applications ("ANDAs") and New Drug Applications ("NDAs"), challenges in securing final FDA approval for our product candidates, including our oxycodone hydrochloride extended release tablets ("Oxycodone ER") product candidate, in particular, if a patent infringement suit is filed against us with respect to any particular product candidates (such as in the case of Oxycodone ER), which could delay the FDA's final approval of such product candidates, healthcare reform measures that could hinder or prevent the commercial success of our products and product candidates, the risk that the FDA may not approve requested product labeling for our product candidate(s) having abuse-deterrent properties and targeting common forms of abuse (oral, intra-nasal and intravenous), risks associated with cyber-security and the potential vulnerability of our digital information or the digital information of a current and/or future drug development or commercialization partner of ours, and risks arising from the ability and willingness of our third-party commercialization partners to provide documentation that may be required to support information on revenues earned by us from those commercialization partners.

Additional risks and uncertainties relating to us and our business can be found in the "Risk Factors" section in Item 3.D below, the "Risk Factors" sections of our latest annual information form and our latest registration statements on Form F-1 and F-3 (including any documents forming a part thereof or incorporated by reference therein), as amended, 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 and 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 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.

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

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. Whenever we refer to any of our current product candidates (including additional product strengths of products we are currently marketing) and future products we may develop, no assurances can be given that we, or any of our strategic partners, will successfully commercialize or complete the development of any of such product candidates or future products under development or proposed for development, that regulatory approvals will be granted for any such product candidate or future product, or that any approved product will be produced in commercial quantities or sold profitably.

Unless stated otherwise, all references to "$", "U.S.$", or "U.S. Dollars" are to the lawful currency of the United States and all references to "C$" are to the lawful currency of Canada. 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™, nPODDDS™, PODRAS™ and Regabatin™ are our tradem 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.

Unless the context otherwise requires, references in this document to (i) share amounts, per share data, share prices, exercise prices and conversion rates have been adjusted to reflect the effect of the 1-for-10 reverse split (the "reverse split") which became effective on each of Nasdaq and TSX at the open of market on September 14, 2018, and (ii) "consolidation" or "share consolidation" are intended to refer to such reverse split.

PART I.

Item 1. Identity of Directors, Senior Management and Advisers

A. Directors and Senior Management

Not applicable.

B. Advisers

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 the Company has been derived from the audited consolidated financial statements of the Company as at and for the years ended November 30, 2018, 2017, 2016, 2015, and 2014. 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 U.S. dollars, unless otherwise indicated.

(in thousands of U.S. dollars, except for per share data)

	As at and for the year ended November 30, 2018	As at and for the year ended November 30, 2017	As at and for the year ended November 30, 2016	As at and for the year ended November 30, 2015	As at and for the year ended November 30, 2014
	$	$	$	$	$
Revenue	1,713	5,504	2,247	4,094	8,770
Loss for the year	(13,747)	(8,857)	(10,144)	(7,436)	(3,856)
Total assets	11,474	7,397	7,975	5,224	7,875
Total liabilities	7,372	7,010	6,858	5,362	2,966
Net assets	4,102	386	1,116	(138)	4,909
Capital stock	44,328	35,290	29,831	21,481	18,941
Loss per share - basic and diluted	(2.89)	(2.86)	(3.80)	(3.13)	(1.67)
Dividends	Nil	Nil	Nil	Nil	Nil
Weighted average common shares	4,762	3,101	2,670	2,377	2,305

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 (“R&D”) 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.

Risks related to our Company

Our business is capital intensive and requires significant investment to conduct the 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 R&D, clinical and regulatory activities and to defend against patent litigation claims in order to bring our products to market and to establish commercial manufacturing, marketing and sales capabilities. As of November 30, 2018, we had a cash balance of $6.6 million. As of February 28, 2019, our cash balance was $3.0 million. While we expect to satisfy short term operational needs from cash on hand and profit transfer payments from our commercial partners, we need to obtain additional funding as we further the development of our product candidates. Potential sources of capital may include payments from licensing agreements, cost savings associated with managing operating expense levels, other equity and/or debt financings, and/or new strategic partnership agreements which fund some or all costs of product development. We intend to utilize the equity markets to bridge any funding shortfall and to provide capital

to continue to advance our most promising product candidates. Our future operations are highly dependent upon our ability to source additional capital to support advancing our product pipeline through continued R&D activities and to fund any significant expansion of our operations. Our ultimate success will depend on whether our product candidates receive approval by the FDA, Health Canada, and the regulatory authorities of other countries in which are products are proposed to be sold and whether we are able to successfully market our approved products. We cannot be certain that we will receive FDA, Health Canada, or such other regulatory approval for any of our current or future product candidates, that we will reach the level of sales and revenues necessary to achieve and sustain profitability or that we can secure other capital sources on terms or in amounts sufficient to meet our needs, or at all. Our cash requirements for R&D during any period depend on the number and extent of the R&D activities we focus on. At present, we are working principally on our Oxycodone ER 505(b)(2), PODRAS™ technology (as defined in Item 4.B. below), additional 505(b)(2) product candidates for development in various areas, and selected generic product candidate development projects. Our development of Oxycodone ER will require significant expenditures, including costs to defend against the Purdue litigation (as described below). For our Regabatin™ XR 505(b)(2) product candidate, Phase III clinical trials can be capital intensive, and will only be undertaken consistent with the availability of funds and a prudent cash management strategy. We anticipate some investment in fixed assets and equipment over the next several months, the extent of which will depend on cash availability.

Effective October 1, 2018, the maturity date for the 2013 Debenture (as defined below) was extended to April 1, 2019. The Company currently expects to repay the current outstanding principal amount of $1,050,000 on or about April 1, 2019, if the Company then has cash available. In addition, the 2018 Debenture (as defined below) will mature on September 1, 2020.

The availability of equity or debt financing will be affected by, among other things, the results of our R&D, our ability to obtain regulatory approvals, our success in commercializing approved products with our commercial partners and 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 sufficient additional capital, it will raise substantial doubt about our ability to continue as a going concern, realize our assets, and pay our liabilities as they become due. Our cash outflows are expected to consist primarily of internal and external R&D, legal and consulting expenditures to advance our product pipeline and selling, general and administrative expenses to support our commercialization efforts. Depending upon the results of our R&D programs, the impact of the litigation against us and the availability of financial resources, we could decide to accelerate, terminate, or reduce certain projects, or commence new ones. Any failure on our part to successfully commercialize approved products or 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 us not taking advantage of business opportunities, in the termination or delay of clinical trials or us not taking any necessary actions required by the FDA or Health Canada 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 ANDAs, Abbreviated New Drug Submissions (“ANDSs”) 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. We had an accumulated deficit of $85,620,939 as of November 30, 2018 and have incurred additional losses since such date. As we engage in the development of products in our pipe line, we may 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. In addition to the other factors described in this annual report, our ultimate success will depend on how many of our product candidates receive approval by the FDA, Health Canada, and the regulatory authorities of the other countries in which are products are proposed to be sold and whether we are able to successfully market approved products. We cannot be certain that we will be able to receive FDA, Health Canada or such other regulatory 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. If we are unsuccessful in commercializing our products and/or securing sufficient financing, we may need to cease or curtail our operations.

Loss of key scientists and/or 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, Chief Executive Officer and Co-Chief Scientific Officer, and Dr. Amina Odidi, our President, Chief Operating Officer and Co-Chief Scientific 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 the 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 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; provided, however, we may not be able to obtain the necessary licenses on acceptable terms, or at all. 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. Any of the foregoing may have a material adverse effect upon our business and financial condition.

We are a defendant in litigation and are at risk of additional similar litigation in the future that could divert management's attention and adversely affect our business and could subject us to significant liabilities.

We are a defendant in the litigation matters described below and under Item 8.A. The defense of such litigation may increase our expenses and divert our management's attention and resources, and any unfavorable outcome could have a material adverse effect on our business and results of operations. Any adverse determination in such litigation, or any settlement of such litigation matters could require that we make significant payments. In addition, we may be the target of other litigation in the future. Any negative outcome in any ongoing or future litigation may have a material adverse effect on our business and financial condition.

Recent and future legal developments could make it more difficult and costly for us to obtain regulatory approvals for our product candidates and negatively affect the prices we may charge.

In the United States and elsewhere, recent and proposed legal and regulatory changes to healthcare systems could prevent or delay our receipt of regulatory approval for our product candidates, restrict or regulate our post-approval marketing activities, and adversely affect our ability to profitably sell our products. We do not know whether additional legislative changes will be enacted, or whether the FDA's regulations, guidance or interpretations will be changed, or what impact any such changes will have, if any, on our ability to obtain regulatory approvals for our

product candidates. Further, the U.S. Centers for Medicare and Medicaid Services, or CMS, frequently changes product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Also, increased scrutiny by the U.S. Congress of the FDA's approval process could significantly delay or prevent our receipt of regulatory approval for our product candidates and subject us to more stringent product labeling and post-marketing testing and other requirements.

We operate in a highly litigious environment.

From time to time, we may be exposed to claims and legal actions in the normal course of business. As of the date of this annual report, we are not aware of any pending or threatened material litigation claims against us other than as described below and under Item 8.A below. 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 or 505(b)(2) NDA 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.

In November 2016, we filed an NDA for our Oxycodone ER product candidate, relying on the 505(b)(2) regulatory pathway, which allowed us to reference data from the file of Purdue Pharma L.P.(“Purdue”) for its OxyContin® extended-release oxycodone hydrochloride. Our Oxycodone ER application was accepted by the FDA for further review in February 2017. We certified to the FDA that we believed that our Oxycodone ER product candidate would not infringe any of the OxyContin® patents listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the “Orange Book”, or that such patents are invalid, and so notified Purdue and the other owners of the subject patents listed in the Orange Book of such certification. On April 7, 2017, we received notice that Purdue, Purdue Pharmaceuticals L.P., The P.F. Laboratories, Inc., or collectively the Purdue parties, Rhodes Technologies, and Grünenthal GmbH, or collectively the Purdue litigation plaintiffs or plaintiffs, had commenced patent infringement proceedings, or the Purdue litigation, against us in the U.S. District Court for the District of Delaware (docket number 17-392) in respect of our NDA filing for Oxycodone ER, alleging that our proposed Oxycodone ER infringes 6 out of the 16 patents associated with the branded product OxyContin®, or the OxyContin® patents, listed in the Orange Book. The complaint seeks injunctive relief as well as attorneys’ fees and costs and such other and further relief as the Court may deem just and proper. An answer and counterclaim have been filed.

Subsequent to the above-noted filing of lawsuit, 4 further such patents were listed and published in the Orange Book. We then similarly certified to the FDA concerning such further patents. On March 16, 2018, we received notice that the Purdue litigation plaintiffs had commenced further such patent infringement proceedings against us adding the 4 further patents. This lawsuit is also in the District of Delaware federal court under docket number 18-404.

As a result of the commencement of the first of these legal proceedings, the FDA is stayed for 30 months from granting final approval to our Oxycodone ER product candidate. That time period commenced on February 24, 2017,

when the Purdue litigation plaintiffs received notice of our certification concerning the patents, and will expire on August 24, 2019, unless the stay is earlier terminated by a final declaration of the courts that the patents are invalid, or are not infringed, or the matter is otherwise settled among the parties.

On or about June 26, 2018, the court issued an order to sever 6 “overlapping” patents from the second Purdue case, but ordered litigation to proceed on the 4 new (2017-issued) patents. An answer and counterclaim was filed on July 9, 2018. The existence and publication of additional patents in the Orange Book, and litigation arising therefrom, is an ordinary and to be expected occurrence in the course of such litigation.

On July 6, 2018, the court issued a so-called “Markman” claim construction ruling on the first case and the October 22, 2018 trial date remained unchanged. We believe that we have non-infringement and/or invalidity defenses to all of the asserted claims of the subject patents in both of the cases and will vigorously defend against these claims.

On July 24, 2018, the parties to the case mutually agreed to and did have dismissed without prejudice the infringement claims related to the Grünenthal ‘060 patent. The Grünenthal ‘060 patent is one of the six patents included in the original litigation case, however, the dismissal does not by itself result in a termination of the 30-month litigation stay.

On October 4, 2018, the parties mutually agreed to postpone the scheduled court date pending a case status conference scheduled for December 17, 2018. At that time, further trial scheduling and other administrative matters were postponed pending the Company’s anticipated resubmission of the Oxycodone ER NDA to the FDA, which is due no later than February 28, 2019.

In July 2017, three complaints were filed in the U.S. District Court for the Southern District of New York that were later consolidated under the caption Shanawaz v. Intellipharmaceutics Int’l Inc., et al., No. 1:17-cv-05761 (S.D.N.Y.). The lead plaintiffs filed a consolidated amended complaint on January 29, 2018. In the amended complaint, the lead plaintiffs assert claims on behalf of a putative class consisting of purchasers of our securities between May 21, 2015 and July 26, 2017. The amended complaint alleges that the defendants violated Sections 10(b) and 20(a) of the U.S. Securities Exchange Act of 1934, as amended (the “U.S. Exchange Act”) and Rule 10b-5 promulgated thereunder by making allegedly false and misleading statements or failing to disclose certain information regarding our NDA for Oxycodone ER abuse-deterrent oxycodone hydrochloride extended-release tablets. The complaint seeks, among other remedies, unspecified damages, attorneys’ fees and other costs, equitable and/or injunctive relief, and such other relief as the court may find just and proper. On March 30, 2018, the Company and the other defendants filed a motion to dismiss the amended complaint for failure to state a valid claim. The defendants’ motion to dismiss was granted in part, and denied in part, in an Order dated December 17, 2018. In its Order, the court dismissed certain of the plaintiffs’ securities claims, to the extent that the claims were based upon statements describing the Oxycodone ER product’s abuse-deterrent features and its bioequivalence to OxyContin. However, the court allowed the claims to proceed to the extent plaintiffs challenged certain public statements describing the contents of the Company’s Oxycodone ER NDA. Defendants filed an answer to the amended complaint on January 7, 2019, and discovery is ongoing. We intend to vigorously defend against the remainder of the claims asserted in the consolidated action.

On February 21, 2019, the Company and its CEO, Dr. Isa Odidi, received a Statement of Claim concerning an action against them in the Superior Court of Justice of Ontario under the caption Victor Romita, plaintiff, and Intellipharmaceutics International Inc. and Isa Odidi, defendants. The action seeks certification as a class action and alleges that certain public statements made by the Company in the period February 29, 2016 to July 26, 2017 knowingly or negligently contained or omitted material facts concerning the Company’s NDA for Oxycodone ER abuse-deterrent oxycodone hydrochloride extended release tablets. The plaintiff alleges that he suffered loss and damages as a result of trading in the Company’s shares on TSX during the above-noted period. The claim seeks, among other remedies, unspecified damages, legal fees and court and other costs as the court may permit. At this time, the action has not been certified as a class action. The Company intends to vigorously defend against the claims asserted in this action.

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 changes 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 User Fee Amendments of 2012, or GDUFA, was enacted into law. The GDUFA legislation implemented substantial fees for new ANDAs, Drug Master Files, product and establishment fees. In return, the program is intended to provide faster and more predictable ANDA reviews by the FDA and more timely inspections of drug facilities. For the FDA's fiscal year 2019, the user fee rate is $178,799 for new ANDAs. For the FDA's fiscal year 2019, the FDA will also charge an annual facility user fee of $226,305 plus a new general program fee of $186,217. 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 and generate revenues and thus may have a material adverse effect on our business, results of operations and financial condition.

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 through contractual provisions in supply contracts, by management of inventory and by continuing to search for alternative authorized suppliers of such materials or their equivalents, 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 our 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;

changes in the approval process of the FDA or other regulatory bodies during the development period or changes in regulatory review for each submitted product application may also cause delays in the approval or result in rejection of an application;

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

difficulties may be encountered in the manufacture and/or packaging of our products;

once manufactured, our products may not meet prescribed quality assurance and stability tests;

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 commercialized product, our once daily generic Focalin XR® (dexmethylphenidate hydrochloride extended-release), and our second commercialized product, generic Seroquel XR® (quetiapine fumarate extended release).

We have invested significant time and effort in the development of our first ANDA product, our once daily generic Focalin XR® capsules, for which we received final approval from the FDA in November 2013 under the Company ANDA (as defined in Item 4.B. below) to launch the 15 and 30 mg strengths. Commercial sales of these strengths were launched immediately by our commercialization partner in the U.S., Par Pharmaceutical, Inc. (“Par”). Our 5, 10, 20 and 40 mg strengths were also then tentatively FDA approved, subject to the right of Teva Pharmaceuticals USA, Inc. (“Teva”) to 180 days of generic exclusivity from the date of first launch of such products. Teva launched its own 5, 10, 20 and 40 mg strengths of generic Focalin XR® capsules on November 11, 2014, February 2, 2015, June 22, 2015 and November 19, 2013, respectively. In January 2017, Par launched the 25 and 35 mg strengths of its generic Focalin XR® capsules in the U.S., and in May 2017, Par launched the 10 and 20 mg strengths, complementing the 15 and 30

mg strengths of our generic Focalin XR® marketed by Par. The FDA granted final approval under the Par ANDA (as defined in Item 4.B. below) for its generic Focalin XR® capsules in the 5, 10, 15, 20, 25, 30, 35 and 40 mg strengths. As the first filer of an ANDA for generic Focalin XR® in the 25 and 35 mg strengths, Par had 180 days of U.S. generic marketing exclusivity for those strengths. In November 2017, Par launched the remaining 5 and 40 mg strengths of generic Focalin XR®, complementing the 10, 15, 20, 25, 30 and 35 mg strengths previously launched and marketed by Par and providing us with the full line of general Focalin XR® strengths available in the U.S. market. Under a license and commercialization agreement we entered into with Par in November 2015, as amended on August 12, 2011 and September 24, 2013 (the “Par agreement”), we receive calendar quarterly profit-share payments on Par’s U.S. sales of generic Focalin XR®. There can be no assurance whether any strengths will be successfully commercialized. We depend significantly on the actions of our marketing partner Par in the prosecution, regulatory approval and commercialization of our generic Focalin XR® capsules and on their timely payment to us of the contracted calendar quarterly payments as they come due.

We have also invested significant time and effort in the development of our second ANDA product, our generic Seroquel XR® tablets in the 50, 150, 200, 300 and 400 mg strengths, and in May 2017 our ANDA received final FDA approval for all of these strengths. Our approved product is a generic equivalent for the corresponding strengths of the branded product Seroquel XR® sold in the U.S. by AstraZeneca Pharmaceuticals LP ("AstraZeneca"). The Company manufactured and shipped commercial quantities of all strengths of generic Seroquel XR® to our marketing and distribution partner Mallinckrodt LLC ("Mallinckrodt"), and Mallinckrodt launched all strengths in June 2017. In October 2016, we announced a license and commercial supply agreement with Mallinckrodt, granting Mallinckrodt an exclusive license to market, sell and distribute in the U.S. the following extended release drug product candidates (the "licensed products") which have either been launched (generic Seroquel XR®) or for which we have ANDAs filed with the FDA (the "Mallinckrodt agreement"):

Quetiapine fumarate extended-release tablets (generic Seroquel XR®) – Approved by FDA and launched

Desvenlafaxine extended-release tablets (generic Pristiq®) – ANDA Under FDA Review (tentatively approved)

Lamotrigine extended-release tablets (generic Lamictal® XR™) – ANDA Under FDA Review

Under the terms of the 10-year agreement, we received a non-refundable upfront payment of $3 million in October 2016. In addition, the agreement also provides for a long-term profit sharing arrangement with respect to these licensed products (which includes up to $11 million in cost recovery payments that are payable on future sales of licensed product). We have agreed to manufacture and supply the licensed products exclusively for Mallinckrodt on a cost plus basis. The Mallinckrodt agreement contains customary terms and conditions for an agreement of this kind, and is subject to early termination in the event we do not obtain FDA approvals of the Mallinckrodt licensed products by specified dates, or pursuant to any one of several termination rights of each party. There can be no assurance whether any strengths of our generic Seroquel XR® will be successfully commercialized. We depend significantly on the actions of our marketing partner Mallinckrodt in the commercialization of our generic Seroquel XR® tablets and on their timely payment to us of the contracted payments as they come due.

Our near term ability to generate significant revenue will depend upon successful commercialization of our products in the U.S., where the branded Focalin XR® product and the branded Seroquel XR® product are in the market. Although we have several other products in our pipeline, and received final approval from the FDA for our generic Keppra XR® (levetiracetam extended-release tablets) for the 500 and 750 mg strengths and final approval from the FDA for our metformin hydrochloride extend release tablets in the 500 and 750 mg strengths, the majority of the products in our pipeline are at earlier stages of development. We will be exploring licensing and commercial alternatives for our generic Keppra XR® product strengths that have been approved by the FDA. We are also actively evaluating options to realize commercial returns from the approval of our generic Glucophage® XR.

Our significant expenditures on R&D may not lead to successful product introductions.

We conduct R&D 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 R&D efforts in our industry, particularly with respect to new drugs, our R&D 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.

Our business and operations are increasingly dependent on information technology and accordingly we would suffer in the event of computer system failures, cyber-attacks or a deficiency in cyber-security.

Our internal computer systems, and those of our vendors and current and/or future drug development or commercialization partners of ours, may be vulnerable to damage from cyber-attacks, computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures. The risk of a security breach or disruption, particularly through cyber-attacks, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions have increased. If such an event were to occur and cause interruptions in our operations or those of a drug development or commercialization partner, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur significant liability and damage to our reputation. In addition, further development of our drug candidates could be adversely affected.

In addition, the unauthorized dissemination of sensitive personal information could expose us or other third parties to regulatory fines or penalties, litigation and potential liability, or otherwise harm our business.

Our business can be impacted by wholesaler buying patterns, increased generic competition and, to a lesser extent, seasonal fluctuations, which may cause our operating results to fluctuate.

We believe that the revenues derived from our generic Focalin XR® capsules and generic Seroquel XR® tablets are subject to wholesaler buying patterns, increased generic competition negatively impacting price, margins and market share consistent with industry post-exclusivity experience and, to a lesser extent, seasonal fluctuations in relation to generic Focalin XR® capsules (as these products are indicated for conditions including attention deficit hyperactivity disorder which we expect may see increases in prescription rates during the school term and declines in prescription rates during the summer months). Accordingly, these factors may cause our operating results to fluctuate.

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 failure to secure appropriate product labeling approvals, 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. In addition, the possibility of a patent infringement suit regarding one or more of our product candidates could delay final FDA approval of such candidates. If we fail to achieve one or more of these planned goals, the price of our common shares could decline.

We have limited manufacturing, sales, marketing or distribution capability and we must rely upon third parties for such.

While we have our own manufacturing facility in Toronto, we rely on third-party manufacturers to supply pharmaceutical ingredients, and we will be reliant upon a third-party manufacturer to produce certain of our products and product candidates. Third-party manufacturers may not be able to meet our deadlines or adhere to quality standards and specifications. Our reliance on third parties for the manufacture of pharmaceutical ingredients and

finished products creates a dependency that could severely disrupt our research and development, our clinical testing, and ultimately our sales and marketing efforts if such third party manufacturers fail to perform satisfactorily, or do not adequately fulfill their obligations. If our manufacturing operation or any contracted manufacturing operation is unreliable or unavailable, we may not be able to move forward with our intended business operations and our entire business plan could fail. There is no assurance that our manufacturing operation or any third-party manufacturers will be able to meet commercialized scale production requirements in a timely manner or in accordance with applicable standards or current Good Manufacturing Process.

If our manufacturing facility is unable to manufacture our product(s) or the manufacturing process is interrupted due to failure to comply with regulations or for other reasons, it could have a material adverse impact on our business.

If our manufacturing facility fails to comply with regulatory requirements or encounter other manufacturing difficulties, it could adversely affect our ability to supply products. All facilities and manufacturing processes used for the manufacture of pharmaceutical products are subject to inspection by regulatory agencies at any time and must be operated in conformity with the current Good Manufacturing Practices (“cGMP”) regulations. Compliance with FDA and Health Canada cGMP requirements applies to both drug products seeking regulatory approval and to approved drug products. In complying with cGMP requirements, pharmaceutical manufacturing facilities must continually expend significant time, money and effort in production, record-keeping and quality assurance and control so that their products meet applicable specifications and other requirements for product safety, efficacy and quality. Failure to comply with applicable legal requirements subjects our manufacturing facility to possible legal or regulatory action, including

shutdown, which may adversely affect our ability to manufacture product. Were we not able to manufacture products at our manufacturing facility because of regulatory, business or any other reasons, the manufacture and marketing of these products would be interrupted. This could have a material adverse impact on our business, results of operations, financial condition, cash flows and competitive position.

The use of legal and regulatory strategies by competitors with innovator products, including the filing of citizen petitions, may delay or prevent the introduction or approval of our product candidates, increase our costs associated with the introduction or marketing of our products, or significantly reduce the profit potential of our product candidates.

Companies with innovator drugs often pursue strategies that may serve to prevent or delay competition from alternatives to their innovator products. These strategies include, but are not limited to:

filing “citizen petitions” with the FDA that may delay competition by causing delays of our product approvals;

seeking to establish regulatory and legal obstacles that would make it more difficult to demonstrate a product’s bioequivalence or “sameness” to the related innovator product;

filing suits for patent infringement that automatically delay FDA approval of products seeking approval based on the Section 505(b)(2) pathway;

obtaining extensions of market exclusivity by conducting clinical trials of innovator drugs in pediatric populations or by other methods;

persuading the FDA to withdraw the approval of innovator drugs for which the patents are about to expire, thus allowing the innovator company to develop and launch new patented products serving as substitutes for the withdrawn products;

seeking to obtain new patents on drugs for which patent protection is about to expire; and

initiating legislative and administrative efforts in various states to limit the substitution of innovator products by pharmacies.

These strategies could delay, reduce or eliminate our entry into the market and our ability to generate revenues from our products and product candidates.

Our products and product candidates, if approved for sale, may not gain acceptance among physicians, patients and the medical community, 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 by physicians, healthcare professionals and third-party payers and our profitability and growth will depend on a number of factors, including:

demonstration of safety and efficacy;

changes in the practice guidelines and the standard of care for the targeted indication;

relative convenience and ease of administration;

the prevalence and severity of any adverse side effects;

the availability of alternative products from competitors;

the prices of our products relative to those of our competitors;

pricing, reimbursement and cost effectiveness, which may be subject to regulatory control;

the number of competitive product entries, and the nature and extent of any aggressive pricing and rebate activities that may follow;

the timing of our market entry;

the ability to market our products effectively at the retail level;

the acceptance of our products by government and private formularies; and

the availability of adequate third-party insurance coverage or reimbursement.

If any product candidate that we develop does not provide a treatment regimen that is as beneficial as, or is perceived as being as beneficial as, the current standard of care or otherwise does not provide patient benefit, that product candidate, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance. Our ability to effectively promote and sell any approved products will also depend on pricing and cost-effectiveness, including our ability to produce a product at a competitive price and our ability to obtain sufficient

third-party coverage or reimbursement. If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, patients and third-party payers, our ability to generate revenues from that product would be substantially reduced. In addition, our efforts to educate the medical community and third-party payers on the benefits of our product candidates may require significant resources, may be constrained by FDA rules and policies on product promotion, and may never be successful.

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 enrollment 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 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. In addition, such competitors may obtain FDA approval for products faster than us. Any of the foregoing 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 favorable 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.

Although we believe that our ownership of patents for some of our drug delivery products will limit direct competition for such products, we must also compete with established existing products and other technologies, 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.

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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.

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

Although our financial results are reported in U.S. dollars and our revenues are payable in U.S. dollars, a majority of our expenses are payable in Canadian dollars. Our financial condition may be affected by movements of the U.S. dollar against the Canadian dollar. There may be instances where we have net foreign currency exposure. Any fluctuations in exchange rates may have an adverse effect on our financial results.

We are exposed to risks arising from the ability and willingness of our third-party commercialization partners to provide documentation that may be required to support information on revenues earned by us from those commercialization partners.

If our third-party commercialization partners, from whom we receive revenues, are unable or unwilling to supply necessary or sufficient documentation to support the revenue numbers in our financial statements in a timely manner to the satisfaction of our auditors, this may lead to delays in the timely publication of our financial results, our ability to obtain an auditor's report on our financial statements and our possible inability to access the financial markets during the time our results remain unpublished.

We rely on commercial partners, and may rely on future commercial partners, to market and commercialize our products and, if approved, our product candidates, and one or more of those commercial partners may fail to develop and effectively commercialize our current, and any future, products.

Our core competency and strategic focus is on drug development and we now, and may in the future, utilize strategic commercial partners to assist in the commercialization of our products and our product candidates, if approved by the FDA. If we enter into strategic partnerships or similar arrangements, we will rely on third parties for financial resources and for commercialization, sales and marketing. Our commercial partners may fail to develop or effectively commercialize our current, and any future products, for a variety of reasons, including, among others, intense competition, lack of adequate financial or other resources or focus on other initiatives or priorities. Any failure of our third-party commercial partners to successfully market and commercialize our products and product candidates would diminish our revenues.

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 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 R&D spending, the availability of tax credit programs for the reimbursement of all or a significant proportion of R&D 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.

The effect of U.S. federal income tax law changes enacted in 2017 on the U.S. corporate income tax burden on our future U.S. operations cannot be predicted. Although such legislation reduced the maximum corporate income tax rate from 35% to 21%, it also introduced several changes that could increase our effective rate of tax on our net operating income. For example, if our operations are highly leveraged, the new limitations on business interest deductions may prevent us from being able to reduce our corporate income tax base by a significant amount of interest incurred on debt necessary to fund operations. In addition, newly enacted limitations on a corporation's ability to reduce its taxable

income by net operating loss carryovers may prevent us from using prior year accumulated losses fully to offset taxable income earned in profitable years. Finally, if we make significant payments for interest, royalties, services and otherwise deductible items to our foreign affiliates, the base erosion minimum tax enacted in 2017 may apply to increase our effective rate of U.S. corporate income tax.

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 Oxycodone ER product candidate, the prices at which such of our products are sold and the revenues we may receive could be reduced.

Revenues from generic pharmaceutical products typically decline as a result of competition, both from other pharmaceutical companies and as a result of increased governmental pricing pressure.

Our generic drugs face intense competition. Prices of generic drugs typically decline, often dramatically, especially as additional generic pharmaceutical companies (including low-cost generic producers based in China and India) receive approvals and enter the market for a given product and competition intensifies. Consequently, our ability to sustain our sales and profitability on any given product over time is affected by the number of new companies selling such product and the timing of their approvals.

In addition, intense pressure from government healthcare authorities to reduce their expenditures on prescription drugs could result in lower pharmaceutical pricing, causing decreases in our revenues.

Furthermore, brand pharmaceutical companies continue to defend their products vigorously. For example, brand companies often sell or license their own generic versions of their products, either directly or through other generic pharmaceutical companies (so-called “authorized generics”). No significant regulatory approvals are required for authorized generics, and brand companies do not face any other significant barriers to entry into such market. Brand companies may seek to delay introductions of generic equivalents through a variety of commercial and regulatory tactics. These actions may increase the costs and risks of our efforts to introduce generic products and may delay or prevent such introduction altogether.

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 the use of such products.

Significant uncertainty exists as to the reimbursement status of newly approved health care products. Some of our product candidates, such as our once-daily Oxycodone ER, 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, cross-border imports 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, cross-border importation and advertising of our products are subject to extensive regulation by federal agencies, including the FDA, Drug Enforcement Administration, Federal Trade Commission, Consumer Product Safety Commission and Environmental Protection Agency in the United States, and Health Canada and Canada Border Services Agency in Canada, 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 Health Canada 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 or Health Canada’s review of NDAs, ANDAs or ANDSs, as the case may be, 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.

There has been an increased public awareness of the problems associated with the potential for abuse of opioid-based medications.

There has been increasing legislative attention to opioid abuse in the U.S., including passage of the 2016 Comprehensive Addiction and Recovery Act and the 21st Century Cures Act, which, among other things, strengthens state prescription drug monitoring programs and expands educational efforts for certain populations. These laws could result in fewer prescriptions being written for opioid drugs, which could impact future sales of our Oxycodone ER and related opioid product candidates.

Federal, state and local governmental agencies have increased their level of scrutiny of commercial practices of companies marketing and distributing opioid products, resulting in investigations, litigation and regulatory intervention affecting other companies. A number of counties and municipalities have filed lawsuits against pharmaceutical wholesale distributors, pharmaceutical manufacturers and retail chains related to the distribution of prescription opioid pain medications. Policy makers and regulators are seeking to reduce the impact of opioid abuse on families and communities and are focusing on policies aimed at reversing the potential for abuse. In furtherance of those efforts, the FDA has developed an Action Plan and has committed to enhance safety labeling, require new data, strengthen post-market requirements, update the Risk Evaluation and Mitigation Strategy program, expand access to and encourage the development of abuse-deterrent formulations and alternative treatments, and re-examine the risk-benefit profile of opioids to consider the wider public health effects of opioids, including the risk of misuse. Several states also have passed laws and have employed other clinical and public health strategies to curb prescription drug abuse, including prescription limitations, increased physician education requirements, enhanced monitoring programs, tighter restrictions on access, and greater oversight of pain clinics. This increasing scrutiny and related governmental and private actions, even if not related to a product that we intend to manufacture and commercialize, could have an unfavorable impact on the overall market for opioid-based products such as our Oxycodone ER product candidate, or otherwise negatively affect our business.

Healthcare reform measures could hinder or prevent the commercial success of our products and product candidates.

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could affect our future revenues and potential profitability. Federal and state lawmakers regularly propose and, at times, enact legislation that results in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. An example of this is the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or, collectively, the Affordable Care Act. In addition, other legislative changes have been proposed and adopted in the U.S. since the Affordable Care Act was enacted.

Members of the U. S. Congress and the Trump administration have expressed an intent to pass legislation or adopt executive orders to fundamentally change or repeal parts of the Affordable Care Act.

The cost of prescription pharmaceuticals has also been the subject of considerable discussion in the U.S. Members of Congress and the Trump administration have indicated that they will address such costs through new legislative and administrative measures. To date, there have been several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, Congress and the Trump administration have each indicated that it will continue to pursue new legislative and/or administrative measures to control drug costs. The Trump administration has proposed a plan to reduce the cost of drugs. The Trump administration’s plan contains certain measures that the U.S. Department of Health and Human Services is already working to implement. For example, on October 25, 2018, CMS issued an Advanced Notice of Proposed Rulemaking, or ANPRM, indicating it is considering issuing a proposed rule in the Spring of 2019 on a model called the International Pricing Index. This model would utilize a basket of other countries’ prices as a reference for the Medicare program to use in reimbursing for drugs covered under Part B. The ANPRM also included an updated version of the Competitive Acquisition Program, as an alternative to current “buy and bill” payment methods for Part B drugs. Such a proposed rule could limit our product pricing and have material adverse effects on our business.

Individual state legislatures in the U.S. have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing. Some of these measures include price or patient reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure and

transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and which could result in reduced demand for our products once approved or additional pricing pressures, and may adversely affect our operating results.

Our ability to market and promote our Oxycodone ER product candidate and its abuse-deterrent features will be determined by FDA-approved labeling requirements.

The commercial success of our Oxycodone ER product candidate will depend upon our ability to obtain requested FDA-approved labeling describing its abuse-deterrent features. Our failure to achieve FDA approval of requested product labeling containing such information will prevent us from advertising and promoting the abuse-deterrent features of our product candidate in a way to differentiate it from competitive products. This would make our product candidate less competitive in the market. Moreover, FDA approval is required in order to make claims that a product has an abuse-deterrent effect.

In April 2015, the FDA published final guidance with respect to the evaluation and labeling of abuse-deterrent opioids. The guidance provides direction as to the studies and data required for obtaining abuse-deterrent claims in a product label. If a product is approved by the FDA to include such claims in its label, the applicant may use the approved labeling information about the abuse-deterrent features of the product in its marketing efforts to physicians.

Although we intend to provide data to the FDA to support approval of abuse-deterrence label claims for Oxycodone ER, there can be no assurance that Oxycodone ER or any of our other product candidates will receive FDA-approved labeling that describes the abuse-deterrent features of such products. The FDA may find that our studies and data do not support our requested abuse-deterrent labeling or that our product candidate does not provide substantial abuse-deterrence benefits because, for example, its deterrence mechanisms do not address the way it is most likely to be abused. Furthermore, the FDA could change its guidance, which could require us to conduct additional studies or generate additional data. If the FDA does not approve our requested abuse-deterrent labeling, we will be limited in our ability to promote Oxycodone ER based on its abuse-deterrent features and, as a result, our business may suffer.

We may be subject to product liability claims 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. Any of the foregoing may have a material adverse effect on our business and financial condition.

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 R&D 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.

In the event we pursue growth through international operations, such growth could strain our resources, and if we are unable to manage any growth we may experience, we may not be able to successfully implement our business plan.

In connection with any geographic expansion we may pursue, international operations would involve substantial additional risks, including, among others: difficulties complying with the U.S. Foreign Corrupt Practices Act and other applicable anti-bribery laws. difficulties maintaining compliance with the various laws and regulations of multiple jurisdictions that may be applicable to our business, many of which may be unfamiliar to us. more complexity in our regulatory and accounting compliance. differing or changing obligations regarding taxes, duties or other fees. limited intellectual property protection in some jurisdictions. risks associated with currency exchange and convertibility,

including vulnerability to appreciation and depreciation of foreign currencies. uncertainty related to developing legal and regulatory systems and standards for economic and business activities in some jurisdictions. trade restrictions or barriers, including tariffs or other charges and import-export regulations, changes in applicable laws or policies. the impact of and response to natural disasters. and the potential for war, civil or political unrest and economic and financial instability. The occurrence of any of these risks could limit our ability to pursue international expansion, increase our costs or expose us to fines or other legal sanctions, any of which could negatively impact our business, reputation and financial condition.

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.. Litigation of this type has been instituted 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 February 28, 2019, we had approximately 21,925,577 common shares outstanding. In addition, a substantial portion of our shares are currently freely trading without restriction under the U.S. Securities Act of 1933, as amended ("U.S. Securities Act"), having been registered for resale or held by their holders for over six months and are eligible for sale under Rule 144.

On July 17, 2017, the Company's most recent registration statement on Form F-3 (the "Shelf Registration Statement") was declared effective by the Securities and Exchange Commission ("SEC"). The Shelf Registration Statement allows for, subject to securities regulatory requirements and limitations, the potential offering of up to an aggregate of US$100 million of the Company's common shares, preference shares, warrants, subscription receipts, subscription rights and units, or any combination thereof, from time to time in one or more offerings, and are intended to give the Company the flexibility to take advantage of financing opportunities when, and if, market conditions are favorable to the Company. The specific terms of such future offerings, if any, would be established, subject to the approval of the Company's board of directors (the "Board"), at the time of such offering and will be described in detail in a prospectus supplement filed at the time of any such offering. To the extent any securities of the Company are issued by the Company under the Shelf Registration Statement or the shelf prospectus, a shareholder's percentage ownership will be diluted and our stock price could be further adversely affected. As of February 28, 2019, the Company has issued 1,246,969 common shares using the Shelf Registration Statement, and there can be no assurance that any additional securities will be sold under the Shelf Registration Statement or the shelf prospectus.

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 February 28, 2019, there are currently common shares issuable upon the exercise of outstanding options and warrants and DSUs and the conversion of the Debentures for an aggregate of approximately 22,762,481 common shares. To the extent any of our options and warrants is 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 and depend on our financial condition, results of operations, capital and legal requirements and such other factors as our Board 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 Nasdaq or 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.

There may be future sales or other dilution of our equity, which may adversely affect the market price of our common shares.

The Company may, from time to time, issue additional common shares, including any securities that are convertible into or exchangeable for, or that represent the right to receive, common shares. The market price of our common shares could decline as a result of sales of common shares or securities that are convertible into or exchangeable for, or that represent the right to receive, common shares after this offering or the perception that such sales could occur.

Future sales of our common shares may cause the prevailing market price of our common shares to decrease.

We have registered a substantial number of outstanding common shares and common shares that are issuable upon the exercise of outstanding warrants. If the holders of our registered common shares choose to sell such shares in the public market or if holders of our warrants exercise their purchase rights and sell the underlying common shares in the public market, or if holders of currently restricted common shares choose to sell such shares in the public market, the prevailing market price for our common shares may decline. The sale of shares issued upon the exercise of our warrants (and options) could also further dilute the holdings of our then existing shareholders. In addition, future public sales by holders of our common shares could impair our ability to raise capital through equity offerings.

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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. There can be no assurance that we will be able to sell any additional shares. 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.

On July 17, 2017, the Shelf Registration Statement was declared effective by the SEC. The Shelf Registration Statement allows for, subject to securities regulatory requirements and limitations, the potential offering of up to an aggregate of $100 million of the Company’s common shares, preference shares, warrants, subscription receipts, subscription rights and units, or any combination thereof, from time to time in one or more offerings, and are intended to give the Company the flexibility to take advantage of financing opportunities when, and if, market conditions are favorable to the Company. The specific terms of such future offerings, if any, would be established, subject to the approval of the Company’s Board, at the time of such offering and will be described in detail in a prospectus supplement filed at the time of any such offering. As of February 28, 2019, the Company has issued 1,246,969 common shares using the Shelf Registration Statement, and there can be no assurance that any additional securities will be sold under the Shelf Registration Statement. In March 2018, the Company terminated its continuous offering under the prospectus supplement dated July 18, 2017 and prospectus dated July 17, 2017 in respect of its at-the-market program.

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 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. For example, participating securities may be delisted from the TSX if, among other things, the market value of an issuer’s securities that are listed on the TSX is less than C$3,000,000 over any period of 30 consecutive trading days. In such circumstances, the TSX may notify an issuer that it is under

delisting review and the issuer will normally be given up to 120 days from the date of such notification to correct the fall in market value and such other deficiencies noted by the TSX. At any time prior to the end of the delisting review period, the TSX will provide the issuer with an opportunity to be heard where the issuer may present submissions to satisfy the TSX that all deficiencies identified in the TSX's notice have been rectified. If at the conclusion of the hearing the issuer cannot satisfy the TSX that the deficiencies identified have been rectified and that no other delisting criteria are then applicable to the issuer, the TSX will determine whether to delist the issuer's securities.

If the market price of our common shares declines further or we are unable to maintain other listing requirements, the TSX may determine to delist our common shares. 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 experience potentially more price volatility than experienced on 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.

We are currently not in compliance with the requirements for the continued listing of our common shares on Nasdaq. As described below, if we are not in compliance with those requirements by March 7, 2019, a Nasdaq Panel will determine whether we will be provided with an extension of time for that purpose.

In September 2017, we were notified by Nasdaq that we were not in compliance with the minimum market value of listed securities required for continued listing on Nasdaq. Nasdaq Listing Rule 5550(b) requires listed securities to maintain a minimum market value of $35.0 million, among other alternatives, including minimum stockholders' equity of $2.5 million. A failure to meet the minimum market value requirement exists if the deficiency continues for a period of 30 consecutive business days. Based on the market value of our common shares for the 30 consecutive business days from August 8, 2017, we did not satisfy the minimum market value of listed securities requirement. By rule, we were provided 180 calendar days, or until March 19, 2018, to regain compliance with that requirement. To regain compliance, our common shares were required to have a market value of at least $35.0 million for a minimum of 10 consecutive business days prior to March 19, 2018, which they did not. In the alternative, if the minimum market value requirement for continued listing is not met, an issuer may maintain continued listing under Nasdaq Listing Rule 5550(b) if it has stockholders' equity of at least $2.5 million.

On April 20, 2018, we received notice that the Nasdaq Listings Qualification staff (the "Nasdaq Staff") had determined to delist our common shares as a result of our failure to meet either the minimum market value of listed securities requirement or the minimum stockholders' equity requirement for continued listing. However, any delisting action by the Nasdaq Staff was stayed pending the ultimate conclusion of our hearing before the Nasdaq Panel.

In addition to not meeting the minimum market value of listed securities or minimum stockholders' equity requirements, we were separately notified in December 2017 that our common shares no longer satisfied the minimum $1.00 per share bid requirement under Nasdaq Listing Rule 5550(a)(2).

We attended a hearing before the Nasdaq Panel on May 17, 2018, and subsequently received formal notice that the Nasdaq Panel had granted our request for continued listing provided that by September 28, 2018, we (i) comply with Nasdaq's $1.00 bid price requirement by having a closing bid price of over $1.00 for ten consecutive trading days, (ii) have stockholders' equity position of over $2.5 million, and (iii) provide the Nasdaq Panel with updated financial projections demonstrating our ability to maintain compliance with the stockholders' equity rule for the coming year. Following receipt of shareholder approval for a reverse stock split (known as a share consolidation under Canadian law) at our August 15, 2018 shareholders meeting, on September 12, 2018, we filed articles of amendment to effectuate a 1-for-10 reverse split, and our common shares began trading on each of Nasdaq and TSX on a post-reverse split basis on September 14, 2018. As a result of the closing bid price of our common shares exceeding $1.00 for the period from September 14, 2018 to September 27, 2018, we received a letter from Nasdaq Listing Qualification notifying us that we had regained compliance with Nasdaq's minimum bid price requirement. On September 29, 2018, we were advised that the Nasdaq Panel granted an extension through October 17, 2018 for us to regain compliance with Nasdaq's stockholders' equity continued listing requirement.

On October 17, 2018, we filed with the SEC a report on Form 6-K reporting that we believed we had regained compliance with Nasdaq's stockholders' equity requirement after giving effect to the proceeds from the October 2018 offering.

On October 26, 2018, we announced that we had regained compliance with Nasdaq's stockholders' equity requirement and that the Nasdaq Panel determined that we would remain subject to a "Panel Monitor" until October 22, 2019.

In November 2018, we received written notification from Nasdaq notifying us that the minimum bid price per share for our common shares was below $1.00 for a period of 30 consecutive business days and that, as a result, we were not in compliance with Nasdaq's minimum bid price requirement.

In December 2018, we received written notification from Nasdaq notifying us that a hearing with a Nasdaq Panel had been scheduled for January 10, 2019.

At a hearing held on January 10, 2019, we presented to the Nasdaq Panel our plan to regain and maintain compliance with Nasdaq's continued listing requirements.

On January 28, 2019, we announced that we had received notice from the Nasdaq Panel extending the continued listing of our common shares until March 7, 2019, subject to certain conditions, while we work to regain compliance with Nasdaq's requirements. Following the March 7, 2019 deadline, the Nasdaq Panel will determine whether a further extension period is warranted in the event we have not regained compliance. However, there can be no assurance that the Nasdaq Panel will grant such an extension. Moreover, there can be no assurance that we will be able to regain compliance with Nasdaq's requirements or, if we do, that we will be able to maintain compliance with all applicable requirements for continued listing on Nasdaq over the long term. The Nasdaq Panel's determination requires us to promptly notify Nasdaq of any significant events that occur during the extension period that may affect our compliance with Nasdaq requirements.

There is no assurance that the Company will be able to regain compliance with Nasdaq's listing requirements, or if it does, that the Company will be able to maintain compliance with Nasdaq's listing requirements. If we are unable to maintain compliance with Nasdaq's continued listing requirements, our common shares may no longer be listed on Nasdaq or another U.S. national securities exchange and the liquidity and market price of our common shares may be adversely affected. If our common shares are delisted from Nasdaq, they may trade in the U.S. on the over-the-counter market, which is a less liquid market. In such case, our shareholders' ability to trade, or obtain quotations of the market value of, our common shares would be severely limited because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask prices for our securities. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, employees and fewer business development opportunities.

If our common shares are not listed on a national securities exchange, compliance with applicable state securities laws may be required for subsequent offers, transfers and sales of the common shares.

Because our common shares are currently listed on Nasdaq, we are not required to register or qualify in any state the subsequent offer, transfer or sale of the common shares. If our common shares are delisted from Nasdaq and are not eligible to be listed on another national securities exchange, subsequent transfers of our common shares by U.S. holders may not be exempt from state securities laws. In such event, it will be the responsibility of the holder of common shares to register or qualify the common shares for any subsequent offer, transfer or sale in the United States or to determine that any such offer, transfer or sale is exempt under applicable state securities laws.

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If our common shares are not listed on a national securities exchange, they may become subject to the SEC'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 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) reports of transactions involving our common shares within five calendar days of such transaction, our principal shareholders may not know when our officers, directors and 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 ("SOX"), 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 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, 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" 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 (as defined below) of our common shares and warrants. It may be possible for U.S. Holders of common shares, but not holders of warrants with respect to periods prior to exercise, 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 Internal Revenue Code (the "Code") (a "QEF Election") or a mark-to-market election under Section 1296 of 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 2018 taxable year and will not likely be a PFIC during our 2019 taxable year. Because PFIC status is based on the composition of our income and assets and the nature of our activities for the entire taxable year, and on our market capitalization, it is not possible to determine whether we will be characterized as a PFIC for the 2019 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 for any given year. There can be no assurance that we will not be considered a PFIC for any taxable year (including our 2019 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 common shares, we generally will continue to be treated as a PFIC with respect to such holder's proportionate share of our income arising in any year in which we are 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 United States 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 common shares will depend on whether such U.S. Holder makes a QEF or mark-to-market election. A U.S. Holder may only make a QEF election if we agree to provide certain tax information to such holder annually. At this time, we do not intend to provide U.S. Holders with such information as may be required to make a QEF election effective.

Unless otherwise provided by the IRS, a U.S. holder of our common shares is generally required to file an informational return annually to report its ownership interest in the Company during any year in which we are a PFIC.

If we are a PFIC for one or more years in which a U.S. Holder holds a warrant prior to exercise, it is possible that such holder could recognize gain on the sale, exchange or disposition of that warrant that it would not otherwise recognize if we were not a PFIC. Any U.S. income tax imposed on the holder with respect to the inclusion of such gain or the inclusion of a pro rata share of our income in his, her or its income following exercise of such warrant could result in an interest charge payable on such holder's tax liability that is calculated back to the first year in which such holder held that warrant in which we were considered to be a PFIC.

The foregoing only speaks to the United States federal income tax considerations as to the Code in effect on the date of this annual report.

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. All of our directors and officers are residents of Canada 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, Intellipharmaceutics International Inc., was incorporated under the Canada Business Corporations Act (the “CBCA”) 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.

Our agent for service in the United States is Corporation Service Company at 1090 Vermont Avenue N.W., Washington, D.C. 20005.

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 Intellipharmaceutics 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 and governed by the CBCA. The common shares of the Company are traded on the TSX and Nasdaq.

For the years ended November 30, 2018, 2017 and 2016, we spent a total of $10,827,293, $9,271,353, and $8,166,736, respectively, on research and development. Over the past three fiscal years and up to February 28, 2019, we have raised approximately $36,095,962 in gross proceeds from the issuance of equity and convertible debt securities. Our common shares are listed on the TSX 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.

For information on the availability of, and access to, information regarding the Company filed with the SEC or presented on the Company's website, see Item 10.H. below.

B. Business Overview

Corporate Developments

In February 2019, we received tentative approval from the FDA for our ANDA for desvenlafaxine extended-release tablets in the 50 and 100 mg strengths. This product is a generic equivalent of the branded product Pristiq® sold in the U.S. by Wyeth Pharmaceuticals, LLC.

As more fully described below (under “NASDAQ NOTICES AND NASDAQ HEARINGS PANEL GRANT OF REQUEST FOR CONTINUED LISTING”), in January 2019, we announced that we had received notice from the Nasdaq Panel extending the continued listing of our common shares until March 7, 2019, subject to certain conditions, while we work to regain compliance with Nasdaq’s requirements.

In January 2019, we announced that we had commenced a R&D program of pharmaceutical cannabidiol (“CBD”) based products. As part of this R&D program, we filed provisional patent applications with the United States Patent and Trademark Office pertaining to the delivery and application of cannabinoid-based therapeutics, began talks with potential commercialization partners in the cannabidiol industry, and identified a potential supplier of CBD. We hold a Health Canada Drug Establishment License and a dealer's license under the Narcotics Control Regulations (“NCR”). Under the NCR license, we are currently authorized to possess, produce, sell and deliver drug products containing various controlled substances, including CBD, in Canada.

In November 2018, we announced that we had received final approval from the FDA for our ANDA for venlafaxine hydrochloride extended-release capsules in the 37.5, 75 and 150 mg strengths. The approved product is a generic equivalent of the branded product Effexor® XR sold in the U.S. by Wyeth Pharmaceuticals, LLC. We are actively exploring the best approach to maximize our commercial returns from this approval.

In November 2018, we announced that we had submitted an investigational new drug (“IND”) application to the FDA for our oxycodone hydrochloride immediate release (“IPCI006”) tablets in the 5, 10, 15, 20 and 30 mg strengths. This novel drug formulation incorporates our Paradoxical OverDose Resistance Activating System (“PODRAS™”) delivery technology and our novel Point Of Divergence Drug Delivery System (“nPODDDS™”) technology. IPCI006 is designed to prevent, delay or limit the release of oxycodone hydrochloride when more intact tablets than prescribed are ingested, thus delaying or preventing overdose and allowing for sufficient time for a rescue or medical intervention to take place. It is also intended to present a significant barrier to abuse by snorting, "parachuting," injecting or smoking finely crushed oxycodone hydrochloride immediate release tablets.

In November 2018, we announced that we had entered into an exclusive licensing and distribution agreement for our abuse resistant Oxycodone ER product candidate and four generic drug products with a pharmaceutical distributor in the Philippines. A Philippines-based pharmaceutical distributor was granted the exclusive right, subject to regulatory approval, to import and market our first novel drug formulation, abuse-deterrent Oxycodone ER, in the Philippines. Additionally, this distributor was granted, subject to regulatory approval, the exclusive right to import and market our generic Seroquel XR®, Focalin XR®, Glucophage® XR, and Keppra XR® in the Philippines. Under the terms of the agreement, the distributor will be required to purchase a minimum yearly quantity of all products included in the agreement and we will be the exclusive supplier of these products.

In November 2018, we announced that we had entered into two exclusive licensing and distribution agreements with pharmaceutical distributors in Malaysia and Vietnam:

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A Malaysian pharmaceutical distribution company was granted the exclusive right, subject to regulatory approval, to import and market our generic Seroquel XR® (quetiapine fumarate extended-release) in Malaysia. Under the terms of the agreement, four strengths (50, 200, 300 and 400 mg) of generic Seroquel XR® will be manufactured and supplied by us for distribution in Malaysia. We are also in discussions to include other products in the agreement with this distributor, who will be required to purchase a minimum yearly quantity of all products included in the agreement.

o
A Vietnamese pharmaceutical distributor was granted the exclusive right, subject to regulatory approval, to import and market our generic Seroquel XR®, Glucophage® XR, and Keppra XR® in Vietnam. Under the terms of the agreement, two strengths (500 and 750mg) of generic Glucophage® XR, three strengths (50, 150 and 200mg) of generic Seroquel XR® and one strength (500 mg) of generic Keppra XR® will be manufactured and supplied by us for distribution in Vietnam. The Vietnamese distributor will be required to purchase a minimum yearly quantity of all products included in the agreement.

In October 2018, we completed an underwritten public offering in the United States, resulting in the sale to the public of 827,970 Units at $0.75 per Unit, which were comprised of one common share and one warrant (the “2018 Unit Warrants”) exercisable at $0.75 per share. We concurrently sold an additional 1,947,261 common shares and warrants to purchase 2,608,695 common shares exercisable at $0.75 per share (the “2018 Option Warrants”) pursuant to the over-allotment option exercised in part by the underwriter. The price for the common shares issued in connection with exercise of the overallotment option was $0.74 per share and the price for the warrants issued in connection with the exercise of the overallotment option was $0.01 per warrant, less in each case the underwriting discount. In addition, we issued 16,563,335 pre-funded units (“2018 Pre-Funded Units”), each 2018 Pre-Funded Unit consisting of one pre-funded warrant (a “2018 Pre-Funded Warrant”) to purchase one common share and one warrant (a “2018 Warrant”, and together with the 2018 Unit Warrants and the 2018 Option Warrants, the “2018 Firm Warrants”) to purchase one common share. The 2018 Pre-Funded Units were offered to the public at $0.74 each and a 2018 Pre-Funded Warrant is exercisable at $0.01 per share. Each 2018 Firm Warrant is exercisable immediately and has a term of five years and each 2018 Pre-Funded Warrant is exercisable immediately and until all 2018 Pre-Funded Warrants are exercised. We also issued warrants to the placement agents to purchase 1,160,314 common shares at an exercise price of $0.9375 per share (the “October 2018 Placement Agent Warrants”), which were exercisable immediately upon issuance. In aggregate, we issued 2,775,231 common shares, 16,563,335 2018 Pre-Funded Warrants and 20,000,000 2018 Firm Warrants in addition to 1,160,314 October 2018 Placement Agent Warrants.

In October 2018, we announced that we had completed the clinical portion of our Category 2 and 3 human abuse liability studies for our Oxycodone ER product candidate to support its abuse-deterrent label claims for both the oral and intranasal route of administration. Bioanalytical samples and statistical analysis for such studies are pending. Results from the studies will be included in our response to the FDA Complete Response Letter which is due no later than February 28, 2019.

In September 2018, we announced a one-for-ten share consolidation (reverse split). The reverse split was implemented in order to qualify for continued listing on Nasdaq, whereby we have to meet certain continued listing criteria, including a closing bid price of at least $1.00 for a minimum of 10 consecutive business days. On September 12, 2018, we filed articles of amendment which implemented the reverse split, and our shares began trading on each of Nasdaq and TSX on a post-split basis under our existing trade symbol “IPCI” at the market open on September 14, 2018. The reverse split reduced the number of outstanding common shares from approximately 43.5 million to approximately 4.35 million at that time.

In September 2018, we announced that we issued in a private placement financing (the “2018 Debenture Financing”) an unsecured convertible debenture in the principal amount of $0.5 million (the “2018 Debenture”), which will mature on September 1, 2020. The 2018 Debenture bears interest at a rate of 10% per annum, payable monthly, is pre-payable at any time at our option, and is convertible at any time into common shares at a conversion price of $3.00 per common share at the option of the holder. The 2018 Debenture Financing was non-brokered and the net proceeds were used for working capital and general corporate purposes.

In July 2018, we announced that infringement claims related to one of the six original patents included in the Purdue litigation were dismissed without prejudice (as described below). As previously announced, in April 2017, we had received notice that Purdue, Purdue Pharmaceuticals L.P., The P.F. Laboratories, Inc., Rhodes Technologies, and another party had commenced patent infringement proceedings against us in the U.S. District Court for the District of Delaware in respect of our NDA filing for Oxycodone ER. The parties to the case mutually agreed to and did have dismissed without prejudice the infringement claims related to the Grünenthal ‘060 patent (which is one of the six patents included in the original litigation case). On October 4, 2018, the parties mutually agreed to postpone the scheduled court date pending a case status conference scheduled for December 17, 2018. At that time, further trial scheduling and other administrative matters were postponed pending the Company’s anticipated resubmission of the Oxycodone ER NDA to the FDA, which is due no later than February 28, 2019.

In March 2018, we announced the closing of two registered direct offerings. The first offering consisted of 583,333 common shares at a price of $6.00 per share for gross proceeds of approximately $3.5 million. We also issued to the investors unregistered warrants to purchase an aggregate of 291,666 common shares at an exercise price of $6.00 per share. The warrants became exercisable six months following the closing date and will expire 30 months after the date they became exercisable. After commissions and offering expenses, we received net proceeds of approximately $3.0 million. We also issued to the placement agents warrants to purchase 29,166 common shares at an exercise price of $7.50 per share. In the second registered direct offering, we issued 300,000 common shares at a price of $6.00 per share for gross proceeds of $1.8 million. We also issued to the investors unregistered warrants to purchase an aggregate of 150,000 common shares at an exercise price of $6.00 per share. The warrants became exercisable six months following the closing date and will expire 30 months after the date they became exercisable. After commissions and offering expenses, we received net proceeds of approximately $1.6 million. We also issued to the placement agents warrants to purchase 15,000 common shares at an exercise price of $7.50 per share.

In February 2018, we met with the FDA to discuss a previously-announced Complete Response Letter (“CRL”) for Oxycodone ER, including issues related to the blue dye in the product candidate. Based on those discussions, the product candidate will no longer include the blue dye. The blue dye was intended to act as an additional deterrent if Oxycodone ER is abused and serve as an early warning mechanism to flag potential misuse or abuse. The FDA confirmed that the removal of the blue dye is unlikely to have any impact on formulation quality and performance. As a result, we will not be required to repeat in vivo bioequivalence studies and pharmacokinetic studies submitted in the Oxycodone ER NDA. The FDA also indicated that, from an abuse liability perspective, Category 1 studies will not have to be repeated on Oxycodone ER with the blue dye removed.

There can be no assurance that our products will be successfully commercialized or produce significant revenues for us. Also, there can be no assurance that we will not be required to conduct further studies for our Oxycodone ER product candidate, that the FDA will approve any of our requested abuse-deterrence label claims or that the FDA will ultimately approve the NDA for the sale of our Oxycodone ER product candidate in the U.S. market that we will be successful in submitting any additional ANDAs or NDAs with the FDA or ANDSs with Health Canada, that the FDA or Health Canada will approve any of our current or future product candidates for sale in the U.S. market and Canadian market, that any of our products or product candidates will receive regulatory approval for sale in other jurisdictions (including the Philippines, Malaysia and Vietnam) that our desvenlafaxine extended-release will receive final FDA approval or that any of our products will ever be successfully commercialized and produce significant revenue for us. Furthermore, there can be no assurances regarding our ability to comply with the Nasdaq continued listing standards acceptable to a Nasdaq Panel, as described below. Moreover, there can be no assurance that any of our provisional patent applications will successfully mature into patents, or that any cannabidiol-based product candidates we develop will ever be successfully commercialized or produce significant revenue for us.

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NASDAQ NOTICES AND NASDAQ HEARINGS PANEL GRANT OF REQUEST FOR CONTINUED LISTING

We are currently not in compliance with the requirements for the continued listing of our common shares on Nasdaq. As described below, if we are not in compliance with those requirements by March 7, 2019, a Nasdaq Panel will determine whether we will be provided with an extension of time for that purpose.

In September 2017, we were notified by Nasdaq that we were not in compliance with the minimum market value of listed securities required for continued listing on Nasdaq. Nasdaq Listing Rule 5550(b) requires listed securities to maintain a minimum market value of $35.0 million, among other alternatives, including minimum stockholders' equity of $2.5 million. A failure to meet the minimum market value requirement exists if the deficiency continues for a period of 30 consecutive business days. Based on the market value of our common shares for the 30 consecutive business days from August 8, 2017, we did not satisfy the minimum market value of listed securities requirement. By rule, we were provided 180 calendar days, or until March 19, 2018, to regain compliance with that requirement. To regain compliance, our common shares were required to have a market value of at least $35.0 million for a minimum of 10 consecutive business days prior to March 19, 2018, which they did not. In the alternative, if the minimum market value requirement for continued listing is not met, an issuer may maintain continued listing under Nasdaq Listing Rule 5550(b) if it has stockholders' equity of at least $2.5 million.

On April 20, 2018, we received notice that the Nasdaq Staff had determined to delist our common shares as a result of our failure to meet either the minimum market value of listed securities requirement or the minimum stockholders' equity requirement for continued listing. However, any delisting action by the Nasdaq Staff was stayed pending the ultimate conclusion of our hearing before the Nasdaq Panel.

In addition to not meeting the minimum market value of listed securities or minimum stockholders' equity requirements, we were separately notified in December 2017 that our common shares no longer satisfied the minimum $1.00 per share bid requirement under Nasdaq Listing Rule 5550(a)(2).

We attended a hearing before the Nasdaq Panel on May 17, 2018, and subsequently received formal notice that the Nasdaq Panel had granted our request for continued listing provided that by September 28, 2018, we (i) comply with Nasdaq's $1.00 bid price requirement by having a closing bid price of over $1.00 for ten consecutive trading days, (ii) have stockholders' equity position of over $2.5 million, and (iii) provide the Nasdaq Panel with updated financial projections demonstrating our ability to maintain compliance with the stockholders' equity rule for the coming year. Following receipt of shareholder approval for a reverse stock split (known as a share consolidation under Canadian law) at our August 15, 2018 shareholders meeting, on September 12, 2018, we filed articles of amendment to effectuate a 1-for-10 reverse split, and our common shares began trading on each of Nasdaq and TSX on a post-reverse split basis on September 14, 2018. As a result of the closing bid price of our common shares exceeding $1.00 for the period from September 14, 2018 to September 27, 2018, we received a letter from Nasdaq Listing Qualification notifying us that we had regained compliance with Nasdaq's minimum bid price requirement. On September 29, 2018, we were advised that the Nasdaq Panel granted an extension through October 17, 2018 for us to regain compliance with Nasdaq's stockholders' equity continued listing requirement.

On October 17, 2018, we filed with the SEC a report on Form 6-K reporting that we believed we had regained compliance with Nasdaq's stockholders' equity requirement after giving effect to the proceeds from the October 2018 offering.

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On October 26, 2018, we announced that we had regained compliance with Nasdaq's stockholders' equity requirement and that the Nasdaq Panel determined that we would remain subject to a "Panel Monitor" until October 22, 2019.

In November 2018, we received written notification from Nasdaq notifying us that the minimum bid price per share for our common shares was below $1.00 for a period of 30 consecutive business days and that, as a result, we were not in compliance with Nasdaq's minimum bid price requirement.

In December 2018, we received written notification from Nasdaq notifying us that a hearing with a Nasdaq Panel had been scheduled for January 10, 2019.

At a hearing held on January 10, 2019, we presented to the Nasdaq Panel our plan to regain and maintain compliance with Nasdaq's continued listing requirements.

On January 28, 2019, we announced that we had received notice from the Nasdaq Panel extending the continued listing of our common shares until March 7, 2019, subject to certain conditions, while we work to regain compliance with Nasdaq's requirements. Following the March 7, 2019 deadline, the Nasdaq Panel will determine whether a further extension period is warranted in the event we have not regained compliance. However, there can be no assurance that the Nasdaq Panel will grant such an extension. Moreover, there can be no assurance that we will be able to regain compliance with Nasdaq's requirements or, if we do, that we will be able to maintain compliance with all applicable requirements for continued listing on Nasdaq over the long term. The Nasdaq Panel's determination requires us to promptly notify Nasdaq of any significant events that occur during the extension period that may affect our compliance with Nasdaq requirements.

NEW LITIGATION

On February 21, 2019, the Company and its CEO, Dr. Isa Odidi, received a Statement of Claim concerning an action against them in the Superior Court of Justice of Ontario under the caption Victor Romita, plaintiff, and Intellipharmaceutics International Inc. and Isa Odidi, defendants. The action seeks certification as a class action and alleges that certain public statements made by the Company in the period February 29, 2016 to July 26, 2017 knowingly or negligently contained or omitted material facts concerning the Company's NDA for Oxycodone ER abuse-deterrent oxycodone hydrochloride extended release tablets. The plaintiff alleges that he suffered loss and damages as a result of trading in the Company's shares on TSX during the above-noted period. The claim seeks, among other remedies, unspecified damages, legal fees and court and other costs as the court may permit. At this time, the action has not been certified as a class action. The Company intends to vigorously defend against the claims asserted in this action.

Our Company

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 (some of which have received FDA approval) and product candidates in various stages of development, including ANDAs filed with the FDA (and one ANDS filed with Health Canada) and

one NDA filing, in therapeutic areas that include neurology, cardiovascular, gastrointestinal tract ("GIT"), diabetes and pain.

In November 2005, we entered into the Par agreement (as amended on August 12, 2011 and September 24, 2013), pursuant to which we granted Par an exclusive, royalty-free license to make and distribute in the U.S. all strengths of our generic Focalin XR® (dexmethylphenidate hydrochloride extended-release) capsules for a period of 10 years from the date of commercial launch (which was November 19, 2013) Under the Par agreement, we made a filing with the FDA for approval to market generic Focalin XR® capsules in various strengths in the U.S. (the "Company ANDA"), and are the owner of that Company ANDA, as approved in part by the FDA. We retain the right to make and distribute all strengths of the generic product outside of the U.S. Calendar quarterly profit-sharing payments for its U.S. sales under the Company ANDA are payable by Par to us as calculated pursuant to the Par agreement. Within the purview of the Par agreement, Par also applied for and owns an ANDA pertaining to all marketed strengths of generic Focalin XR® (the "Par ANDA"), and is now approved by the FDA, to market generic Focalin XR® capsules in all marketed strengths in the U.S. As with the Company ANDA, calendar quarterly profit-sharing payments are payable by Par to us for its U.S. sales of generic Focalin XR® under the Par ANDA as calculated pursuant to the Par agreement.

We received final approval from the FDA in November 2013 under the Company ANDA to launch the 15 and 30 mg strengths of our generic Focalin XR® capsules. Commercial sales of these strengths were launched immediately by our commercialization partner in the U.S., Par. In January 2017, Par launched the 25 and 35 mg strengths of its generic Focalin XR® capsules in the U.S., and in May 2017, Par launched the 10 and 20 mg strengths, complementing the 15 and 30 mg strengths of our generic Focalin XR® marketed by Par. The FDA granted final approval under the Par ANDA for its generic Focalin XR® capsules in the 5, 10, 15, 20, 25, 30, 35 and 40 mg strengths, and subsequently Par launched the remaining 5 and 40 mg strengths. Under the Par agreement, we receive quarterly profit share payments on Par's U.S. sales of generic Focalin XR®. We currently expect revenues from sales of the generic Focalin XR® capsules to continue to be impacted by ongoing competitive pressures in the generic market. There can be no assurance whether revenues from this product will improve going forward or that any recently launched strengths will be successfully commercialized. We depend significantly on the actions of our marketing partner Par in the prosecution, regulatory approval and commercialization of our generic Focalin XR® capsules and on its timely payment to us of the contracted calendar quarterly payments as they come due.

In February 2019, we received tentative approval from the FDA for our ANDA for desvenlafaxine extended-release tablets in the 50 and 100 mg strengths. This product is a generic equivalent of the branded product Pristiq® sold in the U.S. by Wyeth Pharmaceuticals, LLC. There can be no assurance that our desvenlafaxine extended-release tablets in the 50 and 100 mg strengths will receive final FDA approval or, if approved, that they will be successfully commercialized and produce significant revenue for us. We previously announced that we had entered into a license and commercial supply agreement with Mallinckrodt, which granted Mallinckrodt, subject to its terms, an exclusive license to market, sell and distribute in the U.S. the Company's desvenlafaxine extended-release tablets (generic Pristiq®). Among other things, the agreement provides for the Company to have a long-term profit sharing arrangement with respect to the licensed product. Intellipharmaceutics has agreed to manufacture and supply the licensed product exclusively for Mallinckrodt on a cost-plus basis, and Mallinckrodt has agreed that Intellipharmaceutics will be its sole supplier of the licensed product marketed in the U.S.

In November 2018, we received final approval from the FDA for our ANDA for venlafaxine hydrochloride extended-release capsules in the 37.5, 75 and 150 mg strengths. The approved product is a generic equivalent of the branded product Effexor® XR sold in the U.S. by Wyeth Pharmaceuticals, LLC. We are actively exploring the best approach to maximize our commercial returns from this approval. There can be no assurance that our generic Effexor XR® for the 37.5, 75 and 150 mg strengths will be successfully commercialized and produce significant revenue for us.

In February 2017, we received final approval from the FDA for our ANDA for metformin hydrochloride extended release tablets in the 500 and 750 mg strengths, a generic equivalent for the corresponding strengths of the branded product Glucophage® XR sold in the U.S. by Bristol-Myers Squibb. The Company is aware that several other generic versions of this product are currently available that serve to limit the overall market opportunity for this product. We have been continuing to evaluate options to realize commercial returns on this product, particularly in international markets. In November 2018, we announced that we entered into two exclusive licensing and distribution agreements with pharmaceutical distributors in Vietnam and the Philippines pursuant to which the distributors were granted the exclusive right, subject to regulatory approval, to import and market our generic Glucophage® XR in Vietnam and the Philippines, respectively. There can be no assurance as to when and if such product will receive regulatory approval for the sale in Vietnam or the Philippines. Moreover, there can be no assurance that our metformin hydrochloride extended release tablets will be successfully commercialized and produce significant revenues for us.

In February 2016, we received final approval from the FDA of our ANDA for generic Keppra XR® (levetiracetam extended-release) tablets for the 500 and 750 mg strengths. Our generic Keppra XR® is a generic equivalent for the corresponding strengths of the branded product Keppra XR® sold in the U.S. by UCB, Inc., and is indicated for use in the treatment of partial onset seizures associated with epilepsy. We are aware that several other generic versions of

this product are currently available that serve to limit the overall market opportunity. We have been actively exploring the best approach to maximize our commercial returns from this approval and have been looking at several international

markets where, despite lower volumes, product margins are typically higher than in the U.S. In November 2018, we announced that we entered into two exclusive licensing and distribution agreements with pharmaceutical distributors in Vietnam and the Philippines pursuant to which the distributors were granted the exclusive right, subject to regulatory approval, to import and market our generic Keppra XR® in Vietnam and the Philippines, respectively. There can be no assurance as to when and if such product will receive regulatory approval for the sale in Vietnam or the Philippines. Moreover, there can be no assurance that our generic Keppra XR® for the 500 and 750 mg strengths will be successfully commercialized and produce significant revenues for us.

In May 2017, we received final approval from the FDA for our ANDA for quetiapine fumarate extended-release tablets in the 50, 150, 200, 300 and 400 mg strengths. Our approved product is a generic equivalent for the corresponding strengths of the branded product Seroquel XR® sold in the U.S. by AstraZeneca. Pursuant to a settlement agreement between us and AstraZeneca dated July 30, 2012, we were permitted to launch our generic versions of the 50, 150, 200, 300 and 400 mg strengths of generic Seroquel XR®, on November 1, 2016, subject to FDA final approval of our ANDA for those strengths. The Company manufactured and shipped commercial quantities of all strengths of generic Seroquel XR® to our marketing and distribution partner Mallinckrodt, and Mallinckrodt launched all strengths in June 2017.

In October 2016, we announced a license and commercial supply agreement with Mallinckrodt, granting Mallinckrodt an exclusive license to market, sell and distribute in the U.S, as licensed products, the following extended release drug product candidates which have either been launched (generic Seroquel XR) or for which we have ANDAs filed with the FDA:

Quetiapine fumarate extended-release tablets (generic Seroquel XR®) – Approved and launched

Desvenlafaxine extended-release tablets (generic Pristiq®) – ANDA Under FDA Review (tentatively approved)

Lamotrigine extended-release tablets (generic Lamictal® XR™) – ANDA under FDA Review

Under the terms of the 10-year agreement with Mallinckrodt, we received a non-refundable upfront payment of $3 million in October 2016. In addition, the agreement also provides for a long-term profit sharing arrangement with respect to these licensed products (which includes up to $11 million in cost recovery payments that are payable on future sales of licensed product). We have agreed to manufacture and supply the licensed products exclusively for Mallinckrodt on a cost plus basis. The Mallinckrodt agreement contains customary terms and conditions for an agreement of this kind and is subject to early termination in the event we do not obtain FDA approvals of the Mallinckrodt licensed products by specified dates, or pursuant to any one of several termination rights of each party. Upon the expiration of the initial term, and absent any early termination actions, the Mallinckrodt agreement will be automatically renewed for additional and consecutive terms of one year (the 12-month period coinciding with Mallinckrodt’s regularly established fiscal months), absent notice of non-renewal given by one party to the other at least 180 days prior to the end of the initial or renewal term.

Our goal is to leverage our proprietary technologies and know-how in order to build a diversified portfolio of revenue generating commercial products. 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 will help maximize the value of our drug delivery technologies, products and product candidates. We also believe that out-licensing sales and marketing to established organizations, when it makes economic sense, will improve our return from our products while allowing us to focus on our core competencies. We expect our expenditures for the purchase of production, laboratory and computer equipment and the expansion of manufacturing and warehousing capability to be higher as we prepare for the commercialization of ANDAs, one NDA and one

ANDS that are pending FDA and Health Canada approval, respectively.

Our Strategy

Our Hypermatrix™ technologies are central to the development and manufacture of novel and generic controlled-release and targeted-release oral solid dosage drugs. The Hypermatrix™ technologies are a multidimensional controlled-release drug delivery platform that we believe can be applied to the efficient development of a wide range of existing and new pharmaceuticals. We believe that the flexibility of these technologies allows us to develop complex drug delivery solutions within an industry-competitive timeframe. Based on this technology platform, we have developed several drug delivery systems and a pipeline of products (some of which have received FDA approval) and product candidates in various stages of development, including ANDAs filed with the FDA (and one ANDS filed with Health Canada) and one NDA filing, in therapeutic areas that include neurology, cardiovascular, GIT, diabetes and pain. We expect that 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 commercialization partner may pay certain of the expenses of development, make certain milestone payments to us and receive a share of revenues or profits if the drug is developed successfully to completion, the control of which would generally be in the discretion of our drug development partner.

The principal focus of our development activities previously targeted difficult-to-develop controlled-release generic drugs which follow an ANDA regulatory path. Our current development effort is increasingly directed towards improved difficult-to-develop controlled-release drugs which follow an NDA 505(b)(2) regulatory pathway. We have increased our R&D emphasis towards specialty new product development, facilitated by the 505(b)(2) regulatory pathway, by advancing the product development program for both Oxycodone ER and RegabatinTM. We have also identified several additional 505(b)(2) product candidates for development in various indication areas including cardiovascular, dermatology, pulmonary disease and oncology. The technology that is central to our abuse deterrent formulation of our Oxycodone ER is the nPODDDS™, or novel Point of Divergence Drug Delivery System. nPODDDS™ 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.

In addition, our PODRAS™ or Paradoxical OverDose Resistance Activating System delivery technology was initially introduced to enhance our Oxycodone ER (abuse deterrent oxycodone hydrochloride extended release tablets) product candidate. The PODRASTM delivery technology platform was designed to prevent overdose when more pills than prescribed are swallowed intact. Preclinical studies of prototypes of oxycodone with PODRAS™ technology suggest that, unlike other third-party abuse-deterrent oxycodone products in the marketplace, if more tablets than prescribed are deliberately or inadvertently swallowed, the amount of drug active ingredient (“drug active”) released over 24 hours may be substantially less than expected. However, if the prescribed number of pills is swallowed, the drug release should be as expected. Certain aspects of our PODRAS™ technology are covered by U.S. Patent Nos. 9,522,119, 9,700,515, 9,700,516 and 9,801,939 and Canadian Patent No. 2,910,865 issued by the U.S. Patent and Trademark Office and the Canadian Intellectual Property Office in respect of “Compositions and Methods for Reducing Overdose” in December 2016, July 2017 and October 2017, respectively. The issuance of these patents provides us with the opportunity to accelerate our PODRAS™ development plan by pursuing proof of concept studies in humans. We intend to incorporate this technology in future product candidates, including Oxycodone ER and other similar pain products, as well as pursuing out-licensing opportunities. The Company is currently working on the development of an Oxycodone immediate-release (IR) product incorporating this technology.

The NDA 505(b)(2) pathway (which relies in part upon the FDA’s findings for a previously approved drug) both accelerates development timelines and reduces costs in comparison to NDAs for new chemical entities. An advantage of our strategy for development of NDA 505(b)(2) drugs is that our product candidates can, if approved for sale by the FDA, potentially enjoy an exclusivity period which may provide for greater commercial opportunity relative to the generic ANDA route.

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 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.

Some of our technologies are also focused on the development of abuse-deterrent and overdose preventive 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.

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 U.S. by their former employer/clients. The regulatory pathway for this approach requires ANDAs for the U.S. and ANDSs for Canada.

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 commercially viable or beneficial.

Our Drug Delivery Technologies

Hypermatrix™

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 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.

nPODDDS™

In addition to continuing efforts with Hypermatrix™ as a core technology, our scientists continue to pursue novel research activities that address unmet needs. Oxycodone ER (abuse deterrent oxycodone hydrochloride extended release tablets) is an NDA candidate, with a unique long acting oral formulation of oxycodone intended to treat moderate-to-severe pain. The formulation is intended to present a significant barrier to tampering when subjected to various forms of physical and chemical manipulation commonly used by abusers. It is also designed to prevent dose dumping when inadvertently co-administered with alcohol. The technology that supports our abuse deterrent formulation of oxycodone is the nPODDDS™ Point of Divergence Drug Delivery System. The use of nPODDDS™ does not interfere with the bioavailability of oxycodone. We intend to apply the nPODDDS™ technology platforms to other

extended release opioid drug candidates (e.g., oxymorphone, hydrocodone, hydromorphone and morphine) utilizing the 505(b)(2) regulatory pathway.

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PODRAS™

Our Paradoxical OverDose Resistance Activating System (PODRAS™) delivery technology is designed to prevent overdose when more pills than prescribed are swallowed intact. Preclinical studies of prototypes of oxycodone with PODRAS™ technology suggest that, unlike other third-party abuse-deterrent oxycodone products in the marketplace, if more tablets than prescribed are deliberately or inadvertently swallowed, the amount of drug active released over 24 hours may be substantially less than expected. However, if the prescribed number of pills is swallowed, the drug release should be as expected. We are currently working on an alternate Oxycodone ER product candidate incorporating our PODRAS™ delivery technology. In April 2015, the FDA published Guidance for Industry: Abuse-Deterrent Opioids — Evaluation and Labeling, which cited the need for more efficacious abuse-deterrence technology. In this Guidance, the FDA stated, "opioid products are often manipulated for purposes of abuse by different routes of administration or to defeat extended-release properties, most abuse-deterrent technologies developed to date are intended to make manipulation more difficult or to make abuse of the manipulated product less attractive or less rewarding. It should be noted that these technologies have not yet proven successful at deterring the most common form of abuse—swallowing a number of intact capsules or tablets to achieve a feeling of euphoria." The FDA reviewed our request for Fast Track designation for our abuse deterrent Oxycodone ER development program incorporating PODRAS™, and in May 2015 notified us that the FDA had concluded that we met the criteria for Fast Track designation. Fast Track is a designation assigned by the FDA in response to an applicant's request which meets FDA criteria. The designation mandates the FDA to facilitate the development and expedite the review of drugs intended to treat serious or life threatening conditions and that demonstrate the potential to address unmet medical needs.

In December 2016, July 2017 and October 2017, U.S. Patent Nos. 9,522,119, 9,700,515, 9,700,516 and 9,801,939 and Canadian Patent No. 2,910,865 were issued by the U.S. Patent and Trademark Office and the Canadian Intellectual Property Office in respect of "Compositions and Methods for Reducing Overdose". The issued patents cover aspects of the PODRAS™ delivery technology. The issuance of these patents represents a significant advance in our abuse deterrence technology platform. The PODRAS™ platform has the potential to positively differentiate our technology from others of which we are aware, and may represent an important step toward addressing the FDA's concern over the ingestion of a number of intact pills or tablets. In addition to its use with opioids, the PODRASTM platform is potentially applicable to a wide range of drug products, inclusive of over-the-counter drugs, that are intentionally or inadvertently abused and cause harm by overdose to those who ingest them. We intend to apply the PODRAS™ technology platforms to other extended release opioid drug candidates (e.g., oxymorphone, hydrocodone, hydromorphone and morphine) utilizing the 505(b)(2) regulatory pathway.

The Hypermatrix™ Family of Technologies

Our platform of Hypermatrix™ drug delivery technologies include, but are not limited to, IntelliFoam™, IntelliGITransporter™, IntelliMatrix™, IntelliOsmotics™, IntelliPaste™, IntelliPellets™, IntelliShuttle™, nPODDDS™ and PODRAS™. Some of 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.

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 our 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.

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.

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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.

Our Products and Product Candidates

The table below shows the present status of our ANDA, ANDS and NDA products and 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)
Dexmethylphenidate hydrochloride extended-release capsules	Focalin XR®	Attention deficit hyperactivity disorder	Received final approval for 5, 10,15, 20, 25, 30, 35 and 40 mg strengths from FDA(4)	ANDA	$851	Intellipharmaceutics and Par (US) Philippines rights subject to licensing and distribution agreement Intellipharmaceutics
Levetiracetam extended-release tablets	Keppra XR®	Partial onset seizures for epilepsy	Received final approval for the 500 and 750 mg strengths from FDA	ANDA	$126	Philippines and Vietnamese rights subject to licensing and distribution agreements
Venlafaxine hydrochloride extended-release capsules	Effexor XR®	Depression	Received final approval for 37.5, 75 and 150 mg strengths from FDA	ANDA	$774	Intellipharmaceutics
Pantoprazole sodium delayed-release tablets	Protonix®	Conditions associated with gastroesophageal reflux disease	ANDA application for commercialization approval for 2 strengths under review by FDA	ANDA	$367	Intellipharmaceutics
Metformin hydrochloride extended-release tablets	Glucophage® XR	Management of type 2 diabetes	Received final approval for 500 and 750 mg strengths from FDA	ANDA	$388 (500 and 750 mg only)	Intellipharmaceutics Philippines and Vietnamese rights subject to licensing and distribution agreements
Quetiapine fumarate extended-release tablets	Seroquel XR®	Schizophrenia, bipolar disorder & major depressive disorder	Received final FDA approval for all 5 strengths. ANDS under review by Health Canada	ANDA	$190	Intellipharmaceutics and Mallinckrodt (US)

						Philippines, Malaysian and Vietnamese rights subject to licensing and distribution agreements
Lamotrigine extended-release tablets	Lamictal® XR™	Anti-convulsant for epilepsy	ANDA application for commercialization approval for 6 strengths under review by FDA	ANDA	$525	Intellipharmaceutics and Mallinckrodt (US)
Desvenlafaxine extended-release tablets	Pristiq®	Depression	Received tentative approval for the 50 and 100 mg strengths from FDA	ANDA	$279	Intellipharmaceutics and Mallinckrodt (US)
Trazodone hydrochloride extended-release tablets	Oleptro™	Depression	ANDA application for commercialization approval for 2 strengths under review by FDA	ANDA	N/A(5)	Intellipharmaceutics
Carvedilol phosphate extended- release capsules	Coreg CR®	Heart failure, hypertension	Late-stage development	ANDA	$66	Intellipharmaceutics
Oxycodone hydrochloride controlled-release capsules	OxyContin®	Pain	NDA application accepted February 2017 and under review by FDA	NDA 505(b)(2)	$1,471	Intellipharmaceutics Philippines rights subject to licensing and distribution agreement
Pregabalin extended-release capsules	Lyrica®	Neuropathic pain	IND application submitted in August 2015	NDA 505(b)(2)	$5,425	Intellipharmaceutics
Ranolazine extended-release tablets	Ranexa®	Chronic angina	ANDA application for commercialization approval for 2 strengths under review by FDA	ANDA	$1,013	Intellipharmaceutics
Oxycodone hydrochloride immediate release tablets (IPCI006)	Roxicodone®	Pain	IND application submitted in November 2018	NDA 505(b)(2)	$653	Intellipharmaceutics

Notes:

(1)
There can be no assurance as to when, or if at all, the FDA or Health Canada will approve any product candidate for sale in the U.S. or Canadian markets.

(2)
Represents sales for all strengths, unless otherwise noted, for the 12 months ended January 2019 in the U.S., including sales of generics in TRx MBS Dollars, which represents projected new and refilled prescriptions representing a standardized dollar metric based on manufacturer's published catalog or list prices to wholesalers, and does not represent actual transaction prices and does not include prompt pay or other discounts, rebates or reductions in price. Source: Symphony Health Solutions Corporation. The information attributed to Symphony Health Solutions Corporation herein is provided as is, and Symphony makes no representation and/or warranty of any kind, including but not limited to, the accuracy and/or completeness of such information.

(3)
For information regarding the Par agreement, the Mallinckrodt agreement and the licensing and distribution agreements with pharmaceutical distributors in Malaysia, Vietnam and the Philippines, see "Our Company" and "Other Potential Products and Markets". There can be no assurance as to when, or if at all, any of our products or product candidates, as the case may be, will receive regulatory approval for sale in the Philippines, Malaysia or Vietnam. For unpartnered products, we are exploring licensing agreement opportunities or other forms of distribution. While we believe that licensing agreements are possible, there can be no assurance that any can be secured.

(4)
Includes a Company ANDA final approval for our 15 and 30 mg strengths, and a Par ANDA final approval for their 5, 10, 15, 20, 25, 30, 35 and 40 mg strengths. Profit sharing payments to us under the Par agreement are the same irrespective of the ANDA owner.

(5)
Trazodone Hydrochloride extended release tablets are not currently being marketed in the United States.

We typically select products for development that we anticipate could achieve FDA or Health Canada approval for commercial sales several years in the future. However, the length of time necessary to bring a product to the point where the product can be commercialized can vary significantly and depends on, among other things, the availability of funding, design and formulation challenges, safety or efficacy, patent issues associated with the product, and FDA and Health Canada review times.

Dexmethylphenidate Hydrochloride – Generic Focalin XR® (a registered trademark of the brand manufacturer)

Dexmethylphenidate hydrochloride, a Schedule II restricted product (drugs with a high potential for abuse) in the U.S., is indicated for the treatment of attention deficit hyperactivity disorder. In November 2005, we entered into the Par agreement pursuant to which we granted Par an exclusive, royalty-free license to make and distribute in the U.S. all of our FDA approved strengths of our generic Focalin XR® (dexmethylphenidate hydrochloride extended-release) capsules for a period of 10 years from the date of commercial launch (which was November 19, 2013). We retain the right to make and distribute all strengths of the generic product outside of the U.S. Calendar quarterly profit-sharing payments for its U.S. sales of all strengths of generic Focalin XR® are payable by Par to us as calculated pursuant to the Par agreement.

We received final approval from the FDA in November 2013 under the Company ANDA to launch the 15 and 30 mg strengths of our generic Focalin XR® capsules. Commercial sales of these strengths were launched immediately by our commercialization partner in the U.S., Par. Our 5, 10, 20 and 40 mg strengths were also then tentatively FDA approved, subject to the right of Teva to 180 days of generic exclusivity from the date of first launch of such products. In January 2017, Par launched the 25 and 35 mg strengths of its generic Focalin XR® capsules in the U.S., and in May 2017, Par launched the 10 and 20 mg strengths, complementing the 15 and 30 mg strengths of our generic Focalin XR® marketed by Par. In November 2017, Par launched the remaining 5 and 40 mg strengths providing us with the full line of generic Focalin XR® strengths available in the U.S. market.

In November 2018, we announced that we entered into an exclusive licensing and distribution agreement with a pharmaceutical distributor in the Philippines pursuant to which the distributor was granted the exclusive right, subject to regulatory approval, to import and market our generic Focalin XR® in the Philippines. Under the terms of the agreement, the distributor will be required to purchase a minimum yearly quantity of our generic Focalin XR® and we will be the exclusive supplier of such product. This multi-year agreement is subject to early termination. There can be no assurance as to when and if such product will receive regulatory approval for the sale in the Philippines or that, if so approved, the product will be successfully commercialized there and produce significant revenues for us.

Levetiracetam – Generic Keppra XR® (a registered trademark of the brand manufacturer)

We received final approval from the FDA in February 2016 for the 500 and 750 mg strengths of our generic Keppra XR® (levetiracetam extended-release) tablets. Keppra XR®, and the drug active levetiracetam, are indicated for use in the treatment of partial onset seizures associated with epilepsy. We are aware that several other generic versions of this product are currently available and serve to limit the overall market opportunity. We have been actively exploring the best approach to maximize our commercial returns from this approval and have been looking at several international markets where, despite lower volumes, product margins are typically higher than in the U.S.

In November 2018, we announced that we entered into two exclusive licensing and distribution agreements with pharmaceutical distributors in Vietnam and the Philippines pursuant to which the distributors were granted the exclusive right, subject to regulatory approval, to import and market our generic Keppra XR® in Vietnam and the Philippines, respectively. Under the terms of the agreements, the distributors will be required to purchase a minimum yearly quantity of our generic Keppra XR®. These multi-year agreements are each subject to early termination.

There can be no assurance that the Company's generic Keppra XR® for the 500 and 750 mg strengths will be successfully commercialized. Further, there can be no assurance as to when and if such product will receive regulatory approval for the sale in Vietnam or the Philippines or that, if so approved, the product will be successfully commercialized there and produce significant revenues for us.

Metformin hydrochloride – Generic Glucophage® XR (a registered trademark of the brand manufacturer)

We received final approval from the FDA in February 2017 for the 500 and 750 mg strengths of our generic Glucophage® XR (metformin hydrochloride extended release) tablets. Glucophage® XR, and the drug active metformin, are indicated for use in the management of type 2 diabetes treatment. The Company is aware that several other generic versions of this product are currently available and serve to limit the overall market opportunity, however, we are continuing to evaluate options to realize commercial returns on this product, particularly in international markets.

In November 2018, we announced that we entered into two exclusive licensing and distribution agreements with pharmaceutical distributors in the Vietnam and the Philippines pursuant to which the distributors were granted the exclusive right, subject to regulatory approval, to import and market our generic Glucophage® XR in Vietnam and the Philippines, respectively. Under the terms of the agreements, the distributors will be required to purchase a minimum yearly quantity of our generic Glucophage® XR. These multi-year agreements are each subject to early termination.

There can be no assurance that our generic Glucophage® XR for the 500 and 750 mg strengths will be successfully commercialized. Further, there can be no assurance as to when and if such product will receive regulatory approval for the sale in Vietnam or the Philippines or that, if so approved, the product will be successfully commercialized there and produce significant revenues for us.

Venlafaxine hydrochloride – Effexor XR® (a registered trademark of the brand manufacturer)

We received final approval from the FDA in November 2018 for our ANDA for venlafaxine hydrochloride extended-release capsules in the 37.5, 75 and 150 mg strengths. The approved product is a generic equivalent of the branded product Effexor® XR sold in the U.S. by Wyeth Pharmaceuticals, LLC. Effexor® XR, and the drug active venlafaxine hydrochloride, are indicated for the treatment of major depressive disorder, or MDD. We are actively exploring the best approach to maximize our commercial returns from this approval. We are aware that several other generic versions of this product are currently available and serve to limit the overall market opportunity. There can be no assurance that the Company's venlafaxine hydrochloride extended-release capsules for the 37.5 mg, 75 mg, and 150 mg will be successfully commercialized and produce significant revenue for us.

Oxycodone ER (Abuse Deterrent Oxycodone Hydrochloride Extended-Release Tablets)

One of our non-generic products under development is our Oxycodone ER (abuse deterrent oxycodone hydrochloride extended release tablets) product candidate, intended as an abuse and alcohol-deterrent controlled-release oral formulation of oxycodone hydrochloride for the relief of pain. Our Oxycodone ER is a new drug candidate, with a unique long acting oral formulation of oxycodone intended to treat moderate-to-severe pain when a continuous, around the clock opioid analgesic is needed for an extended period of time. The formulation is intended to present a significant barrier to tampering when subjected to various forms of physical and chemical manipulation commonly used by abusers. It is also designed to prevent dose dumping when inadvertently co-administered with alcohol. Dose dumping is the rapid release of an active ingredient from a controlled-release drug into the blood stream that can result in increased toxicity, side effects, and a loss of efficacy. Dose dumping can result by consuming the drug through crushing, taking with alcohol, extracting with other beverages, vaporizing or injecting. In addition, when crushed or pulverized and hydrated, the proposed extended release formulation is designed to coagulate instantaneously and entrap the drug in a viscous hydrogel, which is intended to prevent syringing, injecting and snorting. Our Oxycodone ER formulation is difficult to abuse through the application of heat or an open flame, making it difficult to inhale the active ingredient from burning.

In March 2015, we announced the results of three definitive open label, blinded, randomized, cross-over, Phase I pharmacokinetic clinical trials in which our Oxycodone ER was compared to the existing branded drug OxyContin® (extended release oxycodone hydrochloride) under single dose fasting, single dose steady-state fasting and single dose fed conditions in healthy volunteers. We had reported that the results from all three studies showed that Oxycodone ER met the bioequivalence criteria (90% confidence interval of 80% to 125%) for all matrices, i.e., on the measure of maximum plasma concentration or Cmax, on the measure of area under the curve time (AUCt) and on the measure of area under the curve infinity (AUCinf).

In May 2015, the FDA provided us with notification regarding our IND submission for Oxycodone ER indicating that we would not be required to conduct Phase III studies if bioequivalence to OxyContin® was demonstrated based on pivotal bioequivalence studies.

In January 2016, we announced that pivotal bioequivalence trials of our Oxycodone ER, dosed under fasted and fed conditions, had demonstrated bioequivalence to OxyContin® extended release tablets as manufactured and sold in the U.S. by Purdue. The study design was based on FDA recommendations and compared the lowest and highest strengths of exhibit batches of our Oxycodone ER to the same strengths of OxyContin®. The results show that the ratios of the pharmacokinetic metrics, Cmax, AUC0-t and AUC0-f for Oxycodone ER vs OxyContin®, are within the interval of 80% - 125% required by the FDA with a confidence level exceeding 90%.

In July 2016, we announced the results of a food effect study conducted on our behalf for Oxycodone ER. The study design was a randomized, one-treatment two periods, two sequences, crossover, open label, laboratory-blind bioavailability study for Oxycodone ER following a single 80 mg oral dose to healthy adults under fasting and fed conditions. The study showed that Oxycodone ER can be administered with or without a meal (i.e., no food effect). Oxycodone ER met the bioequivalence criteria (90% confidence interval of 80% to 125%) for all matrices, involving maximum plasma concentration and area under the curve (i.e., Cmax ratio of Oxycodone ER taken under fasted conditions to fed conditions, and AUC metrics taken under fasted conditions to fed conditions). We believe that Oxycodone ER is well differentiated from currently marketed oral oxycodone extended release products.

In November 2016, we filed an NDA seeking authorization to market our Oxycodone ER in the 10, 15, 20, 30, 40, 60 and 80 mg strengths, relying on the 505(b)(2) regulatory pathway which allowed us to reference data from Purdue’s file for its OxyContin®. In February 2017, the FDA accepted for filing our NDA, and set a Prescription Drug User Fee Act, or PDUFA, target action date of September 25, 2017. Our submission is supported by pivotal pharmacokinetic studies that demonstrated that Oxycodone ER is bioequivalent to OxyContin®. The submission also includes abuse-deterrent studies conducted to support abuse-deterrent label claims related to abuse of the drug by various pathways, including oral, intra-nasal and intravenous, having reference to the FDA's "Abuse-Deterrent Opioids - Evaluation and Labeling" guidance published in April 2015.

Our NDA was filed under Paragraph IV of the Hatch-Waxman Act, as amended. We certified to the FDA that we believed that our Oxycodone ER product candidate would not infringe any of the OxyContin® patents listed in the FDA’s Orange Book, or that such patents are invalid, and so notified all holders of the subject patents of such certification. On April 7, 2017, we received notice that Purdue, Purdue Pharmaceuticals L.P., The P.F. Laboratories, Inc., or collectively the Purdue parties, Rhodes Technologies, and Grünenthal GmbH, or collectively the Purdue litigation plaintiffs, had commenced patent infringement proceedings, or the Purdue litigation, against us in the U.S. District Court for the District of Delaware (docket number 17-392) in respect of our NDA filing for Oxycodone ER, alleging that our proposed Oxycodone ER infringes 6 out of the 16 patents associated with the branded product OxyContin®, or the OxyContin® patents, listed in the Orange Book. The complaint seeks injunctive relief as well as attorneys' fees and costs and such other and further relief as the Court may deem just and proper. An answer and counterclaim have been filed.

Subsequent to the above-noted filing of lawsuit, 4 further such patents were listed and published in the Orange Book. We then similarly certified to the FDA concerning such further patents. On March 16, 2018, we received notice that the Purdue litigation plaintiffs had commenced further such patent infringement proceedings adding the 4 further patents. This lawsuit is also in the District of Delaware federal court under docket number 18-404.

As a result of the commencement of the first of these legal proceedings, the FDA is stayed for 30 months from granting final approval to our Oxycodone ER product candidate. That time period commenced on February 24, 2017, when the Purdue litigation plaintiffs received notice of our certification concerning the patents, and will expire on

August 24, 2019, unless the stay is earlier terminated by a final declaration of the courts that the patents are invalid, or are not infringed, or the matter is otherwise settled among the parties.

On or about June 26, 2018, the court issued an order to sever 6 “overlapping” patents from the second Purdue case, but ordered litigation to proceed on the 4 new (2017-issued) patents. An answer and counterclaim was filed on July 9, 2018. The existence and publication of additional patents in the Orange Book, and litigation arising therefrom, is an ordinary and to be expected occurrence in the course of such litigation.

On July 6, 2018, the court issued a so-called “Markman” claim construction ruling on the first case and the October 22, 2018 trial date remained unchanged. We believe that we have non-infringement and/or invalidity defenses to all of the asserted claims of the subject patents in both of the cases and will vigorously defend against these claims.

On July 24, 2018, the parties to the case mutually agreed to and did have dismissed the infringement claims related to the Grünenthal ‘060 patent. The Grünenthal ‘060 patent is one of the six patents included in the original litigation case, however, the dismissal does not by itself result in a termination of the 30-month litigation stay.

On October 4, 2018, the parties mutually agreed to postpone the scheduled court date pending a case status conference scheduled for December 17, 2018.At that time, further trial scheduling and other administrative matters were postponed pending the Company’s anticipated resubmission of the Oxycodone ER NDA to the FDA, which is due no later than February 28, 2019.

In June 2017, we announced that a joint meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and Drug Safety and Risk Management Advisory Committee of the FDA (together, the “Advisory Committees”) meeting was scheduled for July 26, 2017 to review our NDA for Oxycodone ER. The submission requested that our Oxycodone ER product candidate include product label claims to support the inclusion of language regarding abuse-deterrent properties for the intravenous route of administration.
In July 2017, the Company announced that the FDA Advisory Committees voted 22 to 1 in finding that the Company’s NDA for Oxycodone ER should not be approved at this time. The Advisory Committees also voted 19 to 4 that the Company had not demonstrated that Oxycodone ER has properties that can be expected to deter abuse by the intravenous route of administration, and 23 to 0 that there was not sufficient data for Oxycodone ER to support inclusion of language regarding abuse-deterrent properties in the product label for the intravenous route of administration. The Advisory Committees expressed a desire to review the additional safety and efficacy data for Oxycodone ER that may be obtained from human abuse potential studies for the oral and intranasal routes of administration.

In September 2017, the Company received a CRL from the FDA for the Oxycodone ER NDA. In its CRL, the FDA provided certain recommendations and requests for information, including that Intellipharmaceutics complete Category 2 and Category 3 studies to assess the abuse-deterrent properties of Oxycodone ER by the oral and nasal routes of administration. The FDA also requested additional information related to the inclusion of the blue dye in the Oxycodone ER formulation, which is intended to deter abuse. The FDA also requested that Intellipharmaceutics submit an alternate proposed proprietary name for Oxycodone ER. The FDA determined that it could not approve the application in its present form. The FDA has granted our request for an extension to February 28, 2019 to resubmit our NDA for Oxycodone ER under section 505(b)(2) of the U.S. Federal Food, Drug and Cosmetic Act.

In February 2018, the Company met with the FDA to discuss the above-referenced CRL for Oxycodone ER, including issues related to the blue dye in the product candidate. Based on those discussions, the product candidate will no longer include the blue dye. The blue dye was intended to act as an additional deterrent if Oxycodone ER is abused and serve as an early warning mechanism to flag potential misuse or abuse. The FDA confirmed that the removal of the blue dye is unlikely to have any impact on formulation quality and performance. As a result, the Company will not be required to repeat in vivo bioequivalence studies and pharmacokinetic studies submitted in the Oxycodone ER NDA. The FDA also indicated that, from an abuse liability perspective, Category 1 studies will not have to be repeated on Oxycodone ER with the blue dye removed.

The abuse liability studies for the intranasal route of abuse commenced in May 2018 with subject screening, while the studies to support abuse-deterrent label claims for the oral route of abuse commenced in June 2018. The clinical part of both studies has now been completed. Bioanalytical testing and statistical analysis for such studies are pending.

There can be no assurance that the studies will be adequate, that we will not be required to conduct further studies for Oxycodone ER, that the FDA will approve any of the Company's requested abuse-deterrence label claims or that the FDA will ultimately approve our NDA for the sale of Oxycodone ER in the U.S. market, or that it will ever be successfully commercialized and produce significant revenue for us

In November 2018, we announced that we entered into an exclusive licensing and distribution agreement with a pharmaceutical distributor in the Philippines pursuant to which the distributor was granted the exclusive right, subject to regulatory approval, to import and market Oxycodone ER in the Philippines. Under the terms of the agreement, the distributor will be required to purchase a minimum yearly quantity of our Oxycodone ER and we will be the exclusive supplier of our Oxycodone ER. This multi-year agreement is subject to early termination. There can be no assurance as to when and if such product candidate will receive regulatory approval for the sale in the Philippines or that, if so approved, the product will be successfully commercialized there and produce significant revenues for us.

Oxycodone Hydrochloride IR Tablets (IPCI006) (Abuse Deterrent and Overdose Resistant Oxycodone Hydrochloride Immediate Release Tablets) – ROXICODONE®

In November 2018, we announced that we had submitted an IND application to the FDA for our IPCI006 oxycodone hydrochloride immediate release tablets in the 5, 10, 15, 20 and 30 mg strengths. This novel drug formulation incorporates the Company's PODRAS™, or Paradoxical OverDose Resistance Activating System, delivery technology and its nPODDDS™, or novel Point Of Divergence Drug Delivery System, technology. IPCI006 is designed to prevent, delay or limit the release of oxycodone hydrochloride when more intact tablets than prescribed are ingested, thus delaying or preventing overdose and allowing for sufficient time for a rescue or medical intervention to take place. It is also intended to present a significant barrier to abuse by snorting, "parachuting," injecting or smoking finely crushed oxycodone hydrochloride immediate release tablets. The data generated from the studies conducted under this IND is expected to form part of an NDA seeking FDA approval for IPCI006 tablets.

If approved, IPCI006 may be the first immediate release formulation of oxycodone hydrochloride intended to simultaneously prevent or delay overdose and prevent abuse by intranasal or intravenous routes.

There can be no assurance that we will be successful in submitting any NDA with the FDA, that the FDA will approve the Company's IPCI006 product candidate for sale in the U.S. market or any related abuse-deterrent label claims, or that it will ever be successfully commercialized and produce significant revenue for us.

Quetiapine fumarate extended-release tablets - Generic Seroquel XR® (a registered trademark of the brand manufacturer)

In May 2017, we received final approval from the FDA for our ANDA for quetiapine fumarate extended-release tablets in the 50, 150, 200, 300 and 400 mg strengths. Our approved product is a generic equivalent for the corresponding strengths of the branded product Seroquel XR® sold in the U.S. by AstraZeneca. Pursuant to a settlement agreement between us and AstraZeneca dated July 30, 2012, we were permitted to launch our generic versions of the 50, 150, 200, 300 and 400 mg strengths of generic Seroquel XR®, on November 1, 2016, subject to FDA final approval of our ANDA for those strengths. Our final FDA approval followed the expiry of 180-day exclusivity periods granted to the first filers of generic equivalents to the branded product, which were shared by Par and Accord Healthcare. The Company manufactured and shipped commercial quantities of all strengths of generic Seroquel XR® to our marketing and distribution partner Mallinckrodt, and Mallinckrodt launched all strengths in June 2017.

In November 2018, we announced that we entered into three exclusive licensing and distribution agreements with pharmaceutical distributors in Malaysia, Vietnam and the Philippines pursuant to which the distributors were granted the exclusive right, subject to regulatory approval, to import and market our generic Seroquel XR® in Malaysia, Vietnam and the Philippines, respectively. Under the terms of the agreements, the distributors will be required to purchase a minimum yearly quantity of our generic Seroquel XR®. The multi-year agreements are each subject to early termination. There can be no assurance as to when and if such product will receive regulatory approval for the sale in Malaysia, Vietnam or the Philippines or that, if so approved, the product will be successfully commercialized there and produce significant revenues for us.

Desvenlafaxine succinate extended-release tablets – Generic Pristiq® (a registered trademark of the brand manufacturer)

In February 2019, we received tentative approval from the FDA for our ANDA for desvenlafaxine extended-release tablets in the 50 and 100 mg strengths. This product is a generic equivalent of the branded product Pristiq® sold in the U.S. by Wyeth Pharmaceuticals, LLC. There can be no assurance that our desvenlafaxine extended-release tablets in

the 50 and 100 mg strengths will receive final FDA approval or, if approved, that they will be successfully commercialized and produce significant revenue for us. We previously announced that we had entered into a license and commercial supply agreement with Mallinckrodt, which granted Mallinckrodt, subject to its terms, an exclusive license to market, sell and distribute in the U.S. the Company's desvenlafaxine extended-release tablets (generic Pristiq®). Among other things, the agreement provides for the Company to have a long-term profit sharing arrangement with respect to the licensed product. Intellipharmaceutics has agreed to manufacture and supply the licensed product exclusively for Mallinckrodt on a cost-plus basis, and Mallinckrodt has agreed that Intellipharmaceutics will be its sole supplier of the licensed product marketed in the U.S.

Regabatin™ XR (Pregabalin Extended-Release)

Another Intellipharmaceutics non-generic controlled-release product under development is Regabatin™ XR, pregabalin extended-release capsules. Pregabalin is indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy, postherpetic neuralgia, spinal cord injury and fibromyalgia. A controlled-release version of pregabalin should reduce the number of doses patients take, which could improve patient compliance, and therefore possibly enhance clinical outcomes. Lyrica® pregabalin, twice-a-day ("BID") dosage and three-times-a-day ("TID") dosage, are drug products marketed in the U.S. by Pfizer Inc. In October 2017, Pfizer also received approval for a Lyrica® CR, a controlled-release version of pregabalin. In 2014, we conducted and analyzed the results of six Phase I clinical trials involving a twice-a-day formulation and a once-a-day formulation. For formulations directed to certain indications which include fibromyalgia, the results suggested that Regabatin™ XR 82.5 mg BID dosage was comparable in bioavailability to Lyrica® 50 mg (immediate-release pregabalin) TID dosage. For formulations directed to certain other indications which include neuropathic pain associated with diabetic peripheral neuropathy, the results suggested that Regabatin™ XR 165 mg once-a-day dosage was comparable in bioavailability to Lyrica® 75 mg BID dosage.

In March 2015, the FDA accepted a Pre-Investigational New Drug (or Pre-IND) meeting request for our once-a-day Regabatin™ XR non-generic controlled release version of pregabalin under the NDA 505(b)(2) regulatory pathway, with a view to possible commercialization in the U.S. at some time following the December 30, 2018 expiry of the patent covering the pregabalin molecule. Regabatin™ XR is based on our controlled release drug delivery technology platform which utilizes the symptomatology and chronobiology of fibromyalgia in a formulation intended to provide a higher exposure of pregabalin during the first 12 hours of dosing. Based on positive feedback and guidance from the FDA, we submitted an IND application for RegabatinTM XR in August 2015. The FDA completed its review of the IND application and provided constructive input that we will use towards further development of the program. We believe our product candidate has significant additional benefits to existing treatments and are currently evaluating strategic options to advance this opportunity.

There can be no assurance that any additional Phase I or other clinical trials we conduct will meet our expectations, that we will have sufficient capital to conduct such trials, that we will be successful in submitting an NDA 505(b)(2) filing with the FDA, that the FDA will approve this product candidate for sale in the U.S. market, or that it will ever be successfully commercialized.

Other Potential Products and Markets

We are continuing our efforts to identify opportunities internationally, particularly in China, that could if effectuated provide product distribution alternatives through partnerships and therefore would not likely require an investment or asset acquisition by us. Discussions toward establishing a partnership to facilitate future development activities in China are ongoing. We have not at this time entered into and may not ever enter into any such arrangements.

In addition, we are seeking to develop key relationships in several other international jurisdictions where we believe there may be substantial demand for our generic products. These opportunities could potentially involve out-licensing of our products, third-party manufacturing supply and more efficient access to pharmaceutical ingredients and therefore assist with the development of our product pipeline.

In November 2018, we announced that we had entered into an exclusive licensing and distribution agreement for our abuse resistant Oxycodone ER product candidate and four generic drug products with a pharmaceutical distributor in the Philippines. Under the terms of the agreement the distributor was granted the exclusive right, subject to regulatory approval, to import and market our first novel drug formulation, abuse-deterrent Oxycodone ER, in the Philippines. Additionally, this distributor was granted, subject to regulatory approval, the exclusive right to import and market our generic Seroquel XR®, Focalin XR®, Glucophage® XR, and Keppra XR® in the Philippines. Under the terms of the

agreement, the distributor will be required to purchase a minimum yearly quantity of all products included in the agreement and we will be the exclusive supplier of said products. The multi-year agreement with the Philippines distributor is subject to early termination. Financial terms of the agreement have not been disclosed. There can be no assurance as to when or if any of our products or product candidates will receive regulatory approval for sale in the Philippines or that, if so approved, any such products will be successfully commercialized there and produce significant revenues for us. Moreover, there can be no assurance that we will not be required to conduct further studies for Oxycodone ER, that the FDA will approve any of our requested abuse-deterrent label claims or that the FDA will ultimately approve the NDA for the sale of Oxycodone ER in the U.S. market, or that it will ever be successfully commercialized.

In November 2018, we announced that we had entered into two exclusive licensing and distribution agreements with pharmaceutical distributors in Malaysia and Vietnam.

A Malaysian pharmaceutical distribution company was granted the exclusive right, subject to regulatory approval, to import and market our generic Seroquel XR® (quetiapine fumarate extended-release) in Malaysia. Under the terms of the agreement, four strengths (50, 200, 300 and 400 mg) of generic Seroquel XR® will be manufactured and supplied by us for distribution in Malaysia. We are also in discussions to include other products in the agreement with said distributor, who will be required to purchase a minimum yearly quantity of all products included in the agreement.

A Vietnamese pharmaceutical distributor was granted the exclusive right, subject to regulatory approval, to import and market our generic Seroquel XR®, Glucophage® XR, and Keppra XR® in Vietnam. Under the terms of the agreement, two strengths (500 and 750 mg) of generic Glucophage® XR, three strengths (50, 150 and 200 mg) of generic Seroquel XR® and one strength (500 mg) of generic Keppra XR® will be manufactured and supplied by us for distribution in Vietnam. The Vietnamese distributor will be required to purchase a minimum yearly quantity of all products included in the agreement.

The multi-year agreements with the Malaysian and Vietnamese distributors are each subject to early termination. Financial terms of the agreements have not been disclosed. There can be no assurance as to when or if any of our products will receive regulatory approval for sale in Malaysia or Vietnam or that, if so approved, the products will be successfully commercialized there and produce significant revenues for the Company.

Additionally, in January 2018, we announced we had commenced a R&D program for CBD based products. As part of this R&D program, we filed multiple provisional patent applications with the United States Patent and Trademark Office pertaining to the delivery and application of cannabinoid-based therapeutics, began talks with potential commercialization partners in the cannabidiol industry, and identified a potential supplier of CBD. The patent filings, together with certain of our already issued drug delivery patents, are intended to form the basis of the development of a pipeline of novel controlled-release product candidates with CBD as the main active ingredient.

COMPETITIVE ENVIRONMENT

We are engaged in a business characterized by extensive research efforts, rapid technological developments and intense competition. Our competitors include medical technology, pharmaceutical, biotechnology and other companies, universities and research institutions. All of these competitors currently engage in, have engaged in or may engage in the future, in development, manufacturing, marketing and commercialization of new pharmaceuticals and existing pharmaceuticals, some of which may compete with our present or future products and product candidates.

Our drug delivery technologies may compete with existing drug delivery technologies, as well as new drug delivery technologies that may be developed or commercialized in the future. Any of these drugs and drug delivery technologies may receive government approval or gain market acceptance more rapidly than our products and product candidates. As a result, our products and product candidates may become non-competitive or obsolete.

We believe that our ability to successfully compete will depend on, among other things, the efficacy, safety and reliability of our products and product candidates, the timing and scope of regulatory approval, the speed at which we develop product candidates, our, or our commercialization partners', ability to manufacture and sell commercial quantities of a product to the market, product acceptance by physicians and other professional healthcare providers, the quality and breadth of our technologies, the skills of our employees and our ability to recruit and retain skilled employees, the protection of our intellectual property, and the availability of substantial capital resources to fund development and commercialization activities.

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MANUFACTURING

We have internal manufacturing capabilities consisting of current Good Laboratory Practices ("cGLP") research laboratories and a cGMP manufacturing plant for solid oral dosage forms at our 30 Worcester Road Facility (as defined in Item 4.D. below). Raw materials used in manufacturing our products are available from a number of commercial sources and the prices for such raw materials are generally not particularly volatile. In October 2014, the FDA provided us with written notification that the 30 Worcester Road Facility had received an "acceptable" classification. Such inspections are carried out on a regular basis by the FDA and an "acceptable" classification is necessary to permit us to be in a position to receive final approvals for ANDAs and NDAs and to permit manufacturing of drug products intended for commercial sales in the United States after any such approvals. Similarly, Health Canada completed an inspection of our 30 Worcester Road Facility in September 2015 which resulted in a "compliant" rating. Once we have completed certain renovations to our newly-leased 22 Worcester Road Facility (as defined in Item 4.D. below), we plan to request an inspection by regulatory agencies which will determine compliance of the facility with cGMP.

INTELLECTUAL PROPERTY

Proprietary rights are an important aspect of our business. These include know-how, trade secrets and patents. Know-how and trade secrets are protected by internal company policies and operating procedures, and where necessary, by contractual provisions with development partners and suppliers. We also seek patent protection for inventive advances which form the basis of our drug delivery technologies. With respect to particular products, we may seek patent protection on the commercial composition, our methods of production and our uses, to prevent the unauthorized marketing and sale of competitive products.

Patents which relate to and protect various aspects of our Hypermatrix™ family of drug delivery technologies include the following United States, Japanese, Chinese, Indian, Canadian and European patents which have been issued to us:

Country	Issue Date	Issue No.	Title
U.S.A.	October 31, 2017	9,801,939	Compositions and Methods For Reducing Overdose
U.S.A.	July 11, 2017	9,700,516	Compositions and Methods For Reducing Overdose
U.S.A.	July 11, 2017	9,700,515	Compositions and Methods For Reducing Overdose
U.S.A.	Dec 20, 2016	9,522,119	Compositions and Methods For Reducing Overdose
U.S.A.	July 14, 2015	9,078,827	Pharmaceutical Composition Having Reduced Abuse Potential
U.S.A.	Aug 12, 2014	8,802,139	Proton Pump-Inhibitor-Containing Capsules Which Comprise Subunits Differently Structured For A Delayed Release Of The Active Ingredient
U.S.A.	Dec 10, 2013	8,603,520	Oral Multi-functional Pharmaceutical Capsule Preparations of Proton Pump Inhibitors
U.S.A.	Mar 12, 2013	8,394,409	Controlled Extended Drug Release Technology
U.S.A.	Mar 15, 2011	7,906,143	Controlled Release Pharmaceutical Delivery Device and Process for Preparation Thereof
U.S.A.		7,858,119	Extended Release Pharmaceuticals

	Dec 28, 2010		
U.S.A.	Aug 15, 2006	7,090,867	Controlled Release Delivery Device for Pharmaceutical Agents Incorporating Microbial Polysaccharide Gum
U.S.A.	Oct 5, 2004	6,800,668	Syntactic Deformable Foam Compositions and Methods for Making
U.S.A.	Nov 25, 2003	6,652,882	Controlled Release Formulation Containing Bupropion
U.S.A.	Aug 19, 2003	6,607,751	Novel Controlled Release Delivery Device for Pharmaceutical Agents Incorporating Microbial Polysaccharide Gum
U.S.A.	Nov 12, 2002	6,479,075	Pharmaceutical Formulations for Acid Labile Substances
U.S.A.	Oct 2, 2001	6,296,876	Pharmaceutical Formulations for Acid Labile Substances
Japan	Aug 28, 2015	5,798,293	Pharmaceutical Composition Having Reduced Abuse Potential
Japan	Jan 17, 2014	5,457,830	Controlled Release Delivery Device Comprising An Organosol Coat
Japan	Aug 8, 2014	5,592,547	Drug Delivery Composition
Japan	Aug 30, 2013	5,349,290	Drug Delivery Composition
India	Feb 10, 2015	265,141	Pharmaceutical Composition Having Reduced Abuse Potential
Europe	Nov 26, 2014	2,007,360	Controlled Release Delivery Device Comprising an Organosol Coat
Canada	May 26, 2015	2,579,382	Controlled Release Composition Using Transition Coating, And Method Of Preparing Same/ Controlled Release Delivery Device
Canada	Jan 28, 2014	2,571,897	Controlled Extended Drug Release Technology
Canada	Apr 8, 2014	2,576,556	/Drug Delivery Device
Canada	Mar 11, 2014	2,648,280	Controlled Release Delivery Device Comprising an Organosol Coat
Canada	Jun 19, 2012	2,626,558	Pharmaceutical Composition having Reduced Abuse Potential
Canada	Sep 25, 2012	2,529,984	Oral Multi-Functional Pharmaceutical Capsule Preparations of Proton Pump Inhibitors
Canada	Feb 22, 2011	2,459,857	Combinatorial Type Controlled Release Drug Delivery Device
Canada	Mar 15, 2005	2,435,276	Syntactic Deformable Foam Compositions and Methods for Making

In addition to these issued patents, we have several U.S. patent applications, and corresponding foreign applications pending, including Patent Cooperation Treaty - national stage processing and entry applications, relating to various aspects of our HyperMatrixTM drug delivery technologies, including methods and compositions for coating of tablets and beads, compositions incorporating disintegrants to assist in controlled release, compositions incorporating multiple drug actives, and compositions directed to classes of drug actives designed as therapies for specific indications and compositions intended to enhance deterrence of willful abuse of narcotic compositions.

REGULATORY REQUIREMENTS

We focus on the development of both branded drug products (which require NDAs) and generic drug products (which require ANDAs). The research and development, manufacture and marketing of controlled-release pharmaceuticals are subject to regulation by U.S., Canadian and other governmental authorities and agencies. Such national agencies and other federal, state, provincial and local entities regulate the testing, manufacturing, safety and promotion of our products. The regulations applicable to our products may change as the currently limited number of approved controlled-release products increases and regulators acquire additional experience in this area.

United States Regulation

New Drug Application

We will be required by the FDA to comply with NDA procedures for our branded products prior to commencement of marketing by us or our licensees. New drug compounds and new formulations for existing drug compounds which cannot be filed as ANDAs, but follow a 505(b)(2) regulatory pathway, are subject to NDA procedures.

These procedures for a new drug compound include (a) preclinical laboratory and animal toxicology tests; (b) scaling and testing of production batches; (c) submission of an IND, and subsequent approval is required before any human clinical trials can commence; (d) adequate and well controlled replicate human clinical trials to establish the safety and efficacy of the drug for its intended indication; (e) the submission of an NDA to the FDA; and (f) FDA approval of an NDA prior to any commercial sale or shipment of the product, including pre-approval and post-approval inspections of our manufacturing and testing facilities. If all of this data in the product application is owned by the applicant, the FDA will issue its approval without regard to patent rights that might be infringed or exclusivity periods that would affect the FDA’s ability to grant an approval if the application relied upon data which the applicant did not own.

Preclinical laboratory and animal toxicology tests may have to be performed to assess the safety and potential efficacy of the product. The results of these preclinical tests, together with information regarding the methods of manufacture of the products and quality control testing, are then submitted to the FDA as part of an IND requesting authorization to initiate human clinical trials. Once the IND notice period has expired, clinical trials may be initiated, unless an FDA hold on clinical trials has been issued.

A new formulation for an existing drug compound requires a 505(b)(2) application. This application contains full reports of investigations of safety and effectiveness but at least some information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. A 505(b)(2) application is submitted when some specific information necessary for approval is obtained from: (1) published literature and/or (2) the FDA findings of safety and effectiveness for an approved drug. The FDA has implemented this approach to encourage innovation in drug development without requiring duplicative studies while protecting the patent and exclusivity rights for the approved drug. A 505(b)(2) application can be submitted for a new chemical entity, a new molecular entity or any changes to previously approved drugs such as dosage form, strength, route of administration, formulation, indication, or bioinequivalence where the application may rely on the FDA’s

finding on safety and effectiveness of the previously approved drug. In addition, the applicant may also submit a 505(b)(2) application for a change in drug product that is eligible for consideration pursuant to a suitability petition. For example, a 505(b)(2) application would be appropriate for a controlled-release product that is bioinequivalent to a reference listed drug where the proposed product is at least as bioavailable and the pattern of release is at least as favorable as the approved pharmaceutically equivalent product. A 505(b)(2) application may be granted three years of exclusivity if one or more clinical investigations, other than bioavailability/bioequivalence studies, was essential to the approval and conducted or sponsored by the applicant; five years of exclusivity is granted if it is for a new chemical entity. A 505(b)(2) application may also be eligible for orphan drug and pediatric exclusivity.

A 505(b)(2) application must contain the following: (1) identification of those portions of the application that rely on the information the applicant does not have a right of reference, (2) identification of any or all listed drugs by established name, proprietary name, dosage form, strength, route of administration, name of the listed drug's sponsor, and the application number if application relies on the FDA's previous findings of safety and effectiveness for a listed drug, (3) information with respect to any patents that claim the drug or the use of the drug for which approval is sought, (4) patent certifications or statement with respect to any relevant patents that claim the listed drug, (5) if approval for a new indication, and not for the indications approved for the listed drug, a certification so stating, (6) a statement as to whether the listed drug has received a period of marketing exclusivity, (7) bioavailability/bioequivalence studies comparing the proposed product to the listed drug (if any) and (8) studies necessary to support the change or modification from the listed drugs or drugs (if any). Before submitting the application, the applicant should submit a plan to identify the types of bridging studies that should be conducted and also the components of application that rely on the FDA's findings of safety and effectiveness of a previously approved drug product. We intend to generate all data necessary to support FDA approval of the applications we file. A 505(b)(2) application must provide notice of certain patent certifications to the NDA holder and patent owner, and approval may be delayed due to patent or exclusivity protections covering an approved product.

Clinical trials involve the administration of a pharmaceutical product to individuals under the supervision of qualified medical investigators who are experienced in conducting studies under "Good Clinical Practice" guidelines. Clinical studies are conducted in accordance with protocols that detail the objectives of a study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol is submitted to the FDA and to an institutional review board prior to the commencement of each clinical trial. Clinical studies are typically conducted in three sequential phases, which may overlap. In Phase I, the initial introduction of the product into human subjects, the compound is tested for absorption, safety, dosage, tolerance, metabolic interaction, distribution, and excretion. Phase II involves studies in a limited patient population with the disease to be treated to (1) determine the efficacy of the product for specific targeted indications, (2) determine optimal dosage and (3) identify possible adverse effects and safety risks. In the event Phase II evaluations demonstrate that a pharmaceutical product is effective and has an acceptable safety profile, Phase III clinical trials are undertaken to further evaluate clinical efficacy of the product and to further test its safety within an expanded patient population at geographically dispersed clinical study sites. Periodic reports on the clinical investigations are required.

We, or the FDA, may suspend clinical trials at any time if either party believes the clinical subjects are being exposed to unacceptable health risks. The results of the product development, analytical laboratory studies and clinical studies are submitted to the FDA as part of an NDA for approval of the marketing and commercialization of a pharmaceutical product.

Abbreviated New Drug Application

In certain cases, where the objective is to develop a generic version of an approved product already on the market in controlled-release dosages, an ANDA may be filed in lieu of filing an NDA. Under the ANDA procedure, the FDA waives the requirement to submit complete reports of preclinical and clinical studies of safety and efficacy and instead requires the submission of bioequivalency data; that is, demonstration that the generic drug produces the same effect in the body as its brand-name counterpart and has the same pharmacokinetic profile, or change in blood concentration over time. The ANDA procedure is available to us for a generic version of a drug product approved by the FDA. In certain cases, an ANDA applicant may submit a suitability petition to the FDA requesting permission to submit an ANDA for a drug product that differs from a previously approved reference drug product (the "Listed Drug") when the change is one authorized by statute. Permitted variations from the Listed Drug include changes in: (1) route of administration, (2) dosage form, (3) strength and (4) one of the active ingredients of the Listed Drug when the Listed Drug is a combination product. The FDA must approve the petition before the ANDA may be submitted. An applicant is not permitted to petition for any other kinds of changes from Listed Drugs. The information in a suitability petition

must demonstrate that the change from the Listed Drug requested for the proposed drug product may be adequately evaluated for approval without data from investigations to show the proposed drug product's safety or effectiveness. The advantages of an ANDA over an NDA include reduced R&D costs associated with bringing a product to market, and generally a shorter review and approval time at the FDA.

GDUFA implemented substantial fees for new ANDAs, Drug Master Files, product and establishment fees. In return, the program is intended to provide faster and more predictable ANDA reviews by the FDA and more timely inspections of drug facilities. For the FDA's fiscal year 2019, the user fee rate is $178,799 . For the FDA's fiscal year 2019, the FDA will also charge an annual facility user fee of $226,305 plus a new general program fee of $186,217. 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.

Patent Certification and Exclusivity Issues

ANDAs and/or NDAs filed under Paragraph IV of the Hatch Waxman Act which seek approval by a non-brand owner to market a generic version of a branded drug product prior to the expiry of patents owned or listed in the Orange Book (the "Listed Patents") as applicable to the brand owner's product, are required to include certifications pursuant to Paragraph IV that either the Listed Patents are invalid or that the applicant's drug product does not infringe the Listed Patents. In such circumstances, the owner of the branded drug and/or the holder of the patents may commence patent infringement litigation against the applicant. In such a case, the FDA is not empowered to approve such pending ANDA or NDA until the expiry of 30 months from the commencement of such litigation, unless within such 30 month period the said patents are found to be invalid, or the drug product covered by the ANDA or NDA is finally found by a court not to infringe such patents.

Under the U.S. Food, Drug and Cosmetic Act ("FDC Act"), the first filer of an ANDA (but not an NDA) with a "non-infringement" certification is entitled, if its drug product is approved, to receive 180 days of market exclusivity. Subsequent filers of generic products, if non-infringing and approved by the FDA, are entitled to market their products six months after the first commercial marketing of the first filer's generic product. A company having FDA approval and permission from the original brand owner is able to market an authorized generic at any time. The 180-day exclusivity period can be forfeited if the first applicant withdraws its application or the FDA considers the application to have been withdrawn, the first applicant amends or withdraws Paragraph IV Certification for all patents qualifying for 180 day exclusivity, or the first applicant fails to obtain tentative approval within 30 months after the date filed, unless failure is due to a change in review requirements. The preservation of the 180 day exclusivity period related to the first-to-file status of a drug not approved within 30 months after the date filed, generally requires that an application be made to the FDA for extension of the time period where the delay has been due to a change in the review requirements for the drug. The approval of the continued first-to-file status in such circumstances is subject to the discretion of the FDA. There can be no assurance that the FDA would accede to such a request if made.

Patent expiration refers to expiry of U.S. patents (inclusive of any extensions) on drug compounds, formulations and uses. Patents outside the United States may differ from those in the United States. Under U.S. law, the expiration of a patent on a drug compound does not create a right to make, use or sell that compound. There may be additional patents relating to a person's proposed manufacture, use or sale of a product that could potentially prohibit such person's proposed commercialization of a drug compound.

The FDC Act contains other market exclusivity provisions that offer additional protection to pioneer drug products which are independent of any patent coverage that might also apply. Exclusivity refers to the fact that the effective date of approval of a potential competitor's ANDA for a generic of the pioneer drug may be delayed or, in certain

cases, an ANDA may not be submitted until the exclusivity period expires. Five years of exclusivity are granted to the first approval of a “new chemical entity”. Three years of exclusivity may apply to products which are not new chemical entities, but for which new clinical investigations are essential to the approval. For example, a new indication for use, or a new dosage strength of a previously approved product, may be entitled to exclusivity, but only with respect to that indication or dosage strength. Exclusivity only offers protection against a competitor entering the market via the ANDA route, and does not operate against a competitor that generates all of its own data and submits a full NDA.

If applicable regulatory criteria are not satisfied, the FDA may deny approval of an NDA or an ANDA or may require additional testing. Product approvals may be withdrawn if compliance with current or future regulatory standards is not maintained or if problems occur after the product reaches the market. The FDA may require further testing and surveillance programs to monitor the pharmaceutical product that has been commercialized. Non-compliance with applicable requirements can result in additional penalties, including product seizures, injunction actions and criminal prosecutions.

Canadian Regulation

The requirements for selling pharmaceutical drugs in Canada are substantially similar to those of the United States described above.

Investigational New Drug Application

Before conducting clinical trials of a new drug in Canada, we must submit a Clinical Trial Application to the Therapeutic Products Directorate ("TPD"). This application includes information about the proposed trial, the methods of manufacture of the drug and controls, preclinical laboratory and animal toxicology tests on the safety and potential efficacy of the drug, and information on any previously executed clinical trials with the new drug. If, within 30 days of receiving the application, the TPD does not notify us that our application is unsatisfactory, we may proceed with clinical trials of the drug. The phases of clinical trials are the same as those described above under "United States Regulation – New Drug Application".

New Drug Submission

Before selling a new drug in Canada, we must submit a New Drug Submission ("NDS") or Supplemental New Drug Submission ("sNDS") to the TPD and receive a Notice of Compliance ("NOC") from the TPD to sell the drug. The submission includes information describing the new drug, including its proper name, the proposed name under which the new drug will be sold, a quantitative list of ingredients in the new drug, the methods of manufacturing, processing, and packaging the new drug, the controls applicable to these operations, the tests conducted to establish the safety of the new drug, the tests to be applied to control the potency, purity, stability and safety of the new drug, the results of bio-pharmaceutics and clinical trials as appropriate, the intended indications for which the new drug may be prescribed and the effectiveness of the new drug when used as intended. The TPD reviews the NDS or sNDS. If the submission meets the requirements of Canada's Food and Drugs Act and Regulations, the TPD will issue an NOC for the new drug.

Where the TPD has already approved a drug for sale in controlled-release dosages, we may seek approval from the TPD to sell an equivalent generic drug through an ANDS. In certain cases, the TPD does not require the manufacturer of a proposed drug that is claimed to be equivalent to a drug that has already been approved for sale and marketed, to conduct clinical trials; instead, the manufacturer must satisfy the TPD that the drug is bioequivalent to the drug that has already been approved and marketed.

The TPD may deny approval or may require additional testing of a proposed new drug if applicable regulatory criteria are not met. Product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Contravention of Canada's Food and Drugs Act and Regulations can result in fines and other sanctions, including product seizures and criminal prosecutions.

Proposals have recently been made that, if implemented, would significantly change Canada's drug approval system. In general, the recommendations emphasize the need for efficiency in Canadian drug review. Proposals include establishment of a separate agency for drug regulation and modeling the approval system on those found in European

Union countries. There is no assurance, however, that such changes will be implemented or, if implemented, will expedite the approval of new drugs.

The Canadian government has regulations which can prohibit the issuance of an NOC for a patented medicine to a generic competitor, provided that the patentee or an exclusive licensee has filed a list of its Canadian patents covering that medicine with the Minister of Health and Welfare. After submitting the list, the patentee or an exclusive licensee can commence a proceeding to obtain an order of prohibition directed to the Minister prohibiting him or her from issuing an NOC. The minister may be prohibited from issuing an NOC permitting the importation or sale of a patented medicine to a generic competitor until patents on the medicine expire or the waiver of infringement and/or validity of the patent(s) in question is resolved by litigation in the manner set out in such regulations. There may be additional patents relating to a company's proposed manufacture, use or sale of a product that could potentially prohibit such company's proposed commercialization of a drug compound.

Certain provincial regulatory authorities in Canada have the ability to determine whether the consumers of a drug sold within such province will be reimbursed by a provincial government health plan for that drug by listing drugs on formularies. The listing or non-listing of a drug on provincial formularies may affect the prices of drugs sold within provinces and the volume of drugs sold within provinces.

Additional Regulatory Considerations

Sales of our products by our licensees outside the United States and Canada will be subject to regulatory requirements governing the testing, registration and marketing of pharmaceuticals, which vary widely from country to country.

Under the U.S. Generic Drug Enforcement Act, ANDA applicants (including officers, directors and employees) who are convicted of a crime involving dishonest or fraudulent activity (even outside the FDA regulatory context) are subject to debarment. Debarment is disqualification from submitting or participating in the submission of future ANDAs for a period of years or permanently. The Generic Drug Enforcement Act also authorizes the FDA to refuse to accept ANDAs from any company which employs or uses the services of a debarred individual. We do not believe that we receive any services from any debarred person.

In addition to the regulatory approval process, pharmaceutical companies are subject to regulations under provincial, state and federal law, including requirements regarding occupational safety, laboratory practices, environmental protection and hazardous substance control, and may be subject to other present and future local, provincial, state, federal and foreign regulations, including possible future regulations of the pharmaceutical industry. We believe that we are in compliance in all material respects with such regulations as are currently in effect.

Before medicinal products can be distributed commercially, a submission providing detailed information must be reviewed and approved by the applicable government or agency in the jurisdiction in which the product is to be marketed. The regulatory review and approval process varies from country to country.

C. Organizational Structure

The following chart shows the corporate relationship structure of Intellipharmaceutics and its three wholly-owned subsidiaries, including jurisdictions of incorporation, as of February 28, 2019.

D. Property, Plant and Equipment

On December 1, 2015, we entered into a lease agreement for a 25,000 square foot facility located at 30 Worcester Road Toronto, Ontario, Canada M9W 5X2 (“30 Worcester Road Facility”), as well as a 40,000 square foot facility on the adjoining property located at 22 Worcester Road, Toronto, Ontario, Canada M9W 5X2, both of which are owned indirectly by the same landlord (“22 Worcester Road Facility”, and together with 30 Worcester Road Facility, the “Combined Properties”) for a five-year term with a five-year renewal option. Basic rent over the five-year term is C$240,000 per annum for the Combined Properties, subject to an annual consumer price inflation adjustment, and we are responsible for utilities, municipal taxes and operating expenses for the leased property. With these two leased premises, we now have use of 65,000 square feet of commercial space to accommodate our growth objectives over the next several years. We also have an option to purchase the Combined Properties after March 1, 2017 until November 30, 2020 based on a fair value purchase formula. We use our 30 Worcester Road Facility as a cGLP research laboratory, office space, and cGMP scale-up and small to medium-scale manufacturing plant for solid oral dosage forms. The 30 Worcester Road Facility consists of approximately 4,900 square feet for administrative space, 4,300 square feet for R&D, 9,200 square feet for manufacturing, and 3,000 square feet for warehousing. The 22 Worcester Road Facility provides approximately 35,000 square feet of warehouse space and approximately 5,000 square feet of office space. The current lease also provides us with a right of first refusal to purchase the Combined Properties. The landlord is required to provide us with at least 60 days prior written notice and the desired sale price for the Combined Properties prior to offering the premises to a third party or on the open market. We have five business days to accept such offer and purchase price for a transaction to close within 60 days of the notice. If we decline the offer, the landlord is entitled to offer and sell the properties for a purchase price of not less than the price offered to us for a period of 180 days, after which time the landlord is again obliged to offer the properties to us before offering them to a third party or on the open market. On September 17, 2018, the Company entered into a lease default agreement with the landlord with respect to past-due amounts owing under the lease. Pursuant to the terms of the agreement, the Company has acknowledged the amounts owing and agreed to payment terms beginning October 31, 2018. In return, the landlord has agreed to forbear from enforcing any rights or remedies under the agreement, subject to payments being made as scheduled. The Company subsequently paid all past due amounts and currently is not in default of the lease.

We continually monitor our facility requirements in the context of our needs and we expect these requirements to change commensurately with our activities.

Item 4A. Unresolved Staff Comments

Not applicable.

Item 5. Operating and Financial Review and Prospects

The following discussion and analysis should be read in conjunction with the audited annual consolidated financial statements of the Company and notes thereto. See “Item 18. Financial Statements”. The consolidated financial statements have been prepared in accordance with U.S. GAAP. All amounts are expressed in United States dollars unless otherwise noted. Annual references are to the Company’s fiscal years, which ended on November 30, 2018, 2017 and 2016.

A. Operating Results

Our results of operations have fluctuated significantly from period to period in the past and are likely to do so in the future. We anticipate that our quarterly and annual results of operations will be impacted for the foreseeable future by several factors, including the timing of approvals to market our product candidates in various jurisdictions and any resulting licensing revenue, milestone revenue, product sales, the number of competitive products and the extent of any aggressive pricing activity, wholesaler buying patterns, the timing and amount of payments received pursuant to our current and future collaborations with third parties, the existence of any first-to-file exclusivity periods, and the progress and timing of expenditures related to our research, development and commercialization efforts. Due to these fluctuations, we presently believe that the period-to-period comparisons of our operating results are not a reliable indication of our future performance.

The following are selected financial data for the years ended November 30, 2018, 2017 and 2016.

	For the years ended						
	November 30, 2018	November 30, 2017	November 30, 2016	Change 2018 vs 2017		Change 2017 vs 2016	
	$	$	$	$	%	$	%
Revenue:							
Licensing	1,370,607	5,025,350	2,209,502	(3,654,743)	-73%	2,815,848	127%
Up-front fees	342,124	479,102	37,500	(136,978)	-29%	441,602	1178%
	1,712,731	5,504,452	2,247,002	(3,791,721)	-69%	3,257,450	145%
Cost of goods sold	124,870	704,006	-	(579,136)	-82%	704,006	N/A

Gross Margin	1,587,861	4,800,446	2,247,002	(3,212,585)	-67%	2,553,444	114%
Expenses:							
Research and development	10,827,293	9,271,353	8,166,736	1,555,940	17%	1,104,617	14%
Selling, general and administrative	3,476,450	3,287,914	3,546,132	188,536	6%	(258,218)	-7%
Depreciation	610,384	506,961	385,210	103,423	20%	121,751	32%
	14,914,127	13,066,228	12,098,078	1,847,899	14%	968,150	8%
Loss from operations	(13,326,266)	(8,265,782)	(9,851,076)	(5,060,484)	61%	1,585,294	-16%
Net foreign exchange (loss) gain	8,592	(80,093)	(22,470)	88,685	-111%	(57,623)	256%
Interest income	227	15,037	207	(14,810)	-98%	14,830	7164%
Interest expense	(255,231)	(389,239)	(270,238)	134,008	-34%	(119,001)	44%
Financing cost	(174,802)	(137,363)	-	(37,439)	27%	(137,363)	N/A
Net loss and comprehensive loss	(13,747,480)	(8,857,440)	(10,143,577)	(4,890,040)	55%	1,286,137	-13%

Year Ended November 30, 2018 Compared to the Year Ended November 30, 2017

Revenue

The Company recorded revenues of $1,712,731 for the year ended November 30, 2018 versus $5,504,452 for the year ended November 30, 2017. Such revenues consisted primarily of licensing revenues from commercial sales of the 15, 25, 30 and 35 mg strengths of our generic Focalin XR® under the Par agreement. The decrease in revenues in the year ended November 30, 2018 compared to year ended November 30, 2017 is primarily due to considerably lower profit share payments from sales of generic Focalin XR® capsules in the U.S. Beginning in early 2018, we began to see a significant impact from aggressive pricing by competitors, resulting in a marked increase in gross-to-net deductions such as wholesaler rebates, chargebacks and pricing adjustments. While the gross-to-net deductions fluctuate on a quarter over quarter basis, profit share payments for the last several quarters have shown decline over the same period in the prior year.

Revenues from generic Seroquel XR® are still well below levels expected at the launch of the product in 2017, primarily due to the Company's commercial partner entering the market later than planned. Several initiatives to gain market share have shown some improved returns. However, it will take some time to determine if the product can achieve meaningful market penetration. Management is continuing to evaluate strategic options to improve returns from this product.

Cost of goods sold

The Company recorded cost of goods sold of $124,870 for the year ended November 30, 2018 versus $704,006 for the year ended November 30, 2017. Cost of sales reflects the Company's manufacturing shipments of generic Seroquel XR® to Mallinckrodt.

Research and Development

Expenditures for R&D for the year ended November 30, 2018 were higher by $1,555,940 compared to the year ended November 30, 2017. The increase is primarily due to higher third party consulting fees and higher patent litigation expenses.

In the year ended November 30, 2018, we recorded $883,064 of expenses for stock-based compensation for R&D employees compared to $1,654,051 for the year ended November 30, 2017, of which $793,795 was for expenses related to performance-based stock options which vested on FDA approval for venlafaxine hydrochloride extended-release capsules in November 2018, and for the year ended November 30, 2017, $1,577,772 of the expenses for stock-based compensation was for expenses related to performance-based stock options which vested on FDA approval for metformin hydrochloride extended release tablets in February 2017 and FDA approval of our quetiapine fumarate extended release tablets in May 2017.

After adjusting for the stock-based compensation expenses discussed above, expenditures for R&D for the year ended November 30, 2018 were higher by $2,326,927 compared to the year ended November 30, 2017. The increase was primarily due to an increase in third party R&D expenditures as a result of clinical trials for Oxycodone ER and higher patent litigation expenses.

Selling, General and Administrative

Selling, general and administrative expenses were $3,476,450 for the year ended November 30, 2018 in comparison to $3,287,914 for the year ended November 30, 2017, an increase of $188,536. The increase is due to higher expenses

related to administrative costs, partially offset by a decrease in wages and marketing cost.

Administrative costs for the year ended November 30, 2018 were $1,793,724 in comparison to $1,402,253 in the year ended November 30, 2017. The increase for the year ended November 30, 2018 was due to the increase in professional fees and legal fees.

Expenditures for wages and benefits for the year ended November 30, 2018 were $1,124,568 in comparison to $1,240,361 in the year ended November 30, 2017. For the year ended November 30, 2018, we recorded $44,622 as expense for stock-based compensation compared to an expense of $95,948 for the year ended November 30, 2017. After adjusting for the stock-based compensation expenses, expenditures for wages for the year ended November 30, 2018 were lower by $64,467 compared to the year ended November 30, 2017.

Marketing costs for the year ended November 30, 2018 were $421,401 in comparison to $502,688 in the year ended November 30, 2017. This decrease is primarily the result of a decrease in travel expenditures related to business development and investor relations activities.

Occupancy costs for the year ended November 30, 2018 were $136,757 in comparison to $142,612 for the year ended November 30, 2017. The slight decrease is due to lower facility operating expenses.

Depreciation

Depreciation expenses for the year ended November 30, 2018 were $610,384 in comparison to $506,961 in the year ended November 30, 2017. The increase is primarily due to the additional investment in production, laboratory and computer equipment during the year ended November 30, 2018.

Foreign Exchange Gain

Foreign exchange gain was $8,592 for the year ended November 30, 2018 in comparison to a loss of $80,093 in the year ended November 30, 2017. The foreign exchange gain for the year ended November 30, 2018 was due to the strengthening of the U.S. dollar against the Canadian dollar during the year ended November 30, 2018 as the exchange rates changed to $1.00 for C$1.3301 as at November 30, 2018 from $1.00 for C$1.2888 as at November 30, 2017. The foreign exchange loss for the year ended November 30, 2017 was due to the weakening of the U.S. dollar against the Canadian dollar during the year ended November 30, 2017 as the exchange rates changed to $1.00 for C$1.2888 as at November 30, 2017 from $1.00 for C$1.3429 as at November 30, 2016.

Interest Income

Interest income for the year ended November 30, 2018 was lower by $14,810 in comparison to the prior period. For the year ended November 30, 2018 interest was lower largely due to interest received on input tax credit refunds under the SR&ED incentive program in the third quarter of 2017.

Interest Expense

Interest expense for the year ended November 30, 2018 was lower by $134,008 compared with the prior year. This is primarily due to interest expense paid on the 2013 Debenture, which accrues interest payable at 12% annually, as well as the 2018 Debenture, which accrues interest payable at 10% annually, and the related conversion option embedded derivative accreted at an annual effective interest of approximately 4.9% during the 2018 fiscal year in comparison to the fiscal year 2017 when the 2013 Debenture effective interest was approximately 15.2%.

Net Loss

The Company recorded net loss for the year ended November 30, 2018 of $13,747,480 or $2.89 per common share, compared with a net loss of $8,857,440 or $2.86 per common share for the year ended November 30, 2017. In the year ended November 30, 2018, the higher net loss is attributed to the lower licensing revenues from commercial sales of generic Focalin XR® and lower licensing revenues from Quetiapine ER our generic Seroquel XR® (quetiapine fumarate extended-release) combined with increased third party R&D expenses primarily related to clinical trials for the Company’s Oxycodone ER product, legal and other administrative expenses. In the year ended November 30, 2017, the net loss was attributed to the ongoing R&D and selling, general and administrative expenses, partially offset by licensing revenues from commercial sales of generic Focalin XR® and, to a lesser extent, sales of generic Seroquel XR® shipped to Mallinckrodt.

Year Ended November 30, 2017 Compared to the Year Ended November 30, 2016

Revenue

The Company recorded revenues of $5,504,452 for the year ended November 30, 2017 versus $2,247,002 for the year ended November 30, 2016. Revenues consisted primarily of licensing revenues from commercial sales of the 10, 15, 20, 25, 30 and 35 mg of generic Focalin XR® under the Par agreement. The increase in revenues for the year ended November 30, 2017 was primarily due to the launch in January 2017 of the 25 and 35 mg strengths of generic Focalin XR® capsules in the U.S and also reflects revenue from the Company's generic Seroquel XR® launched by Mallinckrodt in June 2017. The Company's revenues on the 25 and 35 mg strengths of generic Focalin XR® showed some decline commencing July 2017 when their 6 month exclusivity expired, but have since levelled off. The 15 and 30mg strengths continue to perform well, with the 10 and 20 mg strengths contributing less due to their launch date being late August 2017. The 5 and 40 mg strengths did not contribute at all to top line revenue in fiscal 2017 as the products were not in the market until after year end. Revenues from generic Seroquel XR® were considerably lower than originally anticipated, primarily due to timing of the product launch, which was several weeks after other generics entered the market. Revenues under the Par agreement and Mallinckrodt agreement represent the commercial sales of the generic products in those strengths and may not be representative of future sales.

Cost of goods sold

The Company recorded cost of goods sold of $704,006 for the year ended November 30, 2017 versus $Nil for the year ended November 30, 2016. Cost of sales for the year ended November 30, 2017, reflects the Company's shipments of generic Seroquel XR® to Mallinckrodt which are manufactured by the Company and supplied to Mallinckrodt on a cost-plus basis. This product was not marketed or sold prior to fiscal 2017. The R&D expenses for the year ended November 30, 2016 were revised higher by $1,177,782 as a result of our shareholders approving an extension of the expiry date of certain performance based stock options.

Research and Development

Expenditures for R&D for the year ended November 30, 2017 were higher by $1,104,617 compared to the year ended November 30, 2016. The increase was primarily due to higher stock option compensation expense as a result of certain performance based stock options vesting upon FDA approval of quetiapine fumarate extended release tablets in the 50, 150, 200, 300 and 400 mg strengths, as detailed below. R&D expenses were also higher due to higher third party consulting fees associated with our preparation for the FDA Advisory Committees meeting in relation to our Oxycodone ER NDA filing. The R&D expenses for the year ended November 30, 2016 were revised higher by $1,177,782 as a result of our shareholders approving an extension of the expiry date of certain performance based stock options.

In the year ended November 30, 2017, we recorded $1,654,051 of expenses for stock-based compensation for R&D employees, of which $1,577,772 was for expenses related to performance based stock options which vested on FDA approval for metformin hydrochloride extended release tablets in February 2017 and FDA approval of our quetiapine fumarate extended release tablets in May 2017. In the year ended November 30, 2016, we recorded $1,995,805 as expense for stock based compensation for R&D employees, of which $620,632 was for expenses related to performance based stock options which vested on FDA approval of our generic Keppra XR® in February 2016.

After adjusting for the stock-based compensation expenses discussed above, expenditures for R&D for the year ended November 30, 2017 were higher by $1,446,371 compared to the year ended November 30, 2016. The increase was primarily due to costs related to preparing for the FDA Advisory Committees meeting, an increase in third party R&D expenditures and higher compensation expense.

Selling, General and Administrative

Selling, general and administrative expenses were $3,287,914 for the year ended November 30, 2017 in comparison to $3,546,132 for the year ended November 30, 2016, a decrease of $258,218. The decrease is due to lower wages and benefits and administrative costs partially offset by higher expenses related to marketing cost and occupancy cost discussed in greater detail below.

Expenditures for wages and benefits for the year ended November 30, 2017 were $1,240,361 in comparison to $1,454,501 in the year ended November 30, 2016. For the year ended November 30, 2017, we recorded $95,948 as expense for stock-based compensation compared to an expense of $265,639 for the year ended November 30, 2016. After adjusting for the stock-based compensation expenses, expenditures for wages for the year ended November 30, 2017 were lower by $44,449 compared to the year ended November 30, 2016. The decrease was attributable to the accrual of bonuses to certain management employees in the year ended November 30, 2016, there were no bonuses paid in the year ended November 30, 2017.

Administrative costs for the year ended November 30, 2017 were $1,402,253 in comparison to $1,558,633 in the year ended November 30, 2016. The decrease relates primarily to lower professional fees.

Marketing costs for the year ended November 30, 2017 were $502,688 in comparison to $413,646 in the year ended November 30, 2016. The increase was primarily the result of an increase in travel expenditures related to business development and investor relations activities.

Occupancy costs for the year ended November 30, 2017 were $142,612 in comparison to $119,352 for the year ended November 30, 2016. The increase was due to the incremental cost of leasing an adjoining facility in order to meet the Company's anticipated growth requirements.

Depreciation

Depreciation expenses for the year ended November 30, 2017 were $506,961 in comparison to $385,210 in the year ended November 30, 2016. The increase is primarily due to the additional investment in production, laboratory and computer equipment during the year ended November 30, 2017.

Foreign Exchange Loss

Foreign exchange loss was $80,093 for the year ended November 30, 2017 in comparison to a loss of $22,470 in the year ended November 30, 2016. The foreign exchange loss for the year ended November 30, 2017 was due to the weakening of the Canadian dollar against the U.S. dollar during the year ended November 30, 2017 as the exchange rates changed to $1.00 for C$1.2888 as at November 30, 2017 from $1.00 for C$1.3429 as at November 30, 2016. The foreign exchange loss for the year ended November 30, 2016 was due to the weakening of the Canadian dollar against the U.S. dollar during the year ended November 30, 2016 as the exchange rates changed to $1.00 for C$1.3429 as at November 30, 2016 from $1.00 for C$1.3353 as at November 30, 2015.

Interest Income

Interest income for the year ended November 30, 2017 was higher by $14,830 in comparison to the prior period. For the year ended November 30, 2017, interest income was higher largely due to interest received on input tax credit refunds under the SR&ED program.

Interest Expense

Interest expense for the year ended November 30, 2017 was higher by $119,001 compared with the prior period. This is due to interest expense paid in 2017 on the 2013 Debenture which accrues interest payable at 12% annually and the related conversion option embedded derivative accreted at an annual effective interest of approximately 15.2%, in comparison to the fiscal year 2016 when the 2013 Debenture effective interest was approximately 4.2%.

Net Loss

The Company recorded net loss for the year ended November 30, 2017 of $8,857,440 or $2.86 per common share, compared with a net loss of $10,143,577 or $3.80 per common share for the year ended November 30, 2016. In the year ended November 30, 2017, the net loss was attributed to the ongoing R&D and selling, general and administrative expenses, partially offset by licensing revenues from commercial sales of generic Focalin XR® and to a lesser extent, sales of generic Seroquel XR® shipped to Mallinckrodt. The net loss in 2017 is lower compared to 2016 due to higher licensing revenues which were partially offset by an increase in performance based stock option expense and higher third party R&D expenditures. Revenue from commercial sales of generic Focalin XR® and

generic Seroquel XR® in the year ended November 30, 2017, was $4,269,691 versus $2,209,502 in fiscal 2016. This is primarily due to the launch of additional strengths of generic Focalin XR® in 2017 as well as the launch of generic Seroquel XR®, In the year ended November 30, 2016, the higher net loss was primarily attributed to lower licensing revenues from commercial sales of generic Focalin XR® for 2016. To a lesser extent, the higher loss for the 2016 period was due to the accrual of management bonuses and additional compensation costs related to vested performance options as a result of the FDA approval of generic Keppra XR® and the Company’s shareholders approving an extension of the expiry date of the performance based stock options.

B. Liquidity and Capital Resources

	For the years ended						
	November 30, 2018	November 30, 2017	November 30, 2016	Change (2017 vs 2016)			
	$	$	$	$	%	$	%
Cash flows used in operating activities	(12,508,960)	(6,105,785)	(6,254,985)	(6,403,175)	105%	149,200	-2%
Cash flows provided from financing activities	17,354,954	5,682,168	9,159,623	11,672,786	205%	(3,477,455)	-38%
Cash flows used in investing activities	(101,178)	(1,823,746)	(515,410)	1,722,568	-94%	(1,308,336)	254%
Increase (decrease) in cash	4,744,816	(2,247,363)	2,389,228	6,992,179	-311%	(4,636,591)	-194%
Cash, beginning of year	1,897,061	4,144,424	1,755,196	(2,247,363)	-54%	2,389,228	136%
Cash, end of year	6,641,877	1,897,061	4,144,424	4,744,816	250%	(2,247,363)	-54%

The Company had cash of $6,641,877 as at November 30, 2018 compared to $1,897,061 as at November 30, 2017. The increase in cash was mainly due to the cash receipts provided from financing activities derived from the Company's two registered direct offerings in March 2018, the 2018 Debenture Financing in September 2018 and an underwritten public offering in October 2018, offset by ongoing expenditures in R&D and selling, general and administrative expenses. The decrease in cash during the year ended November 30, 2017 was mainly a result of our ongoing expenditures in R&D and selling, general, and administrative expenses, which included increased consulting fees incurred to prepare for the July 26, 2017 FDA Advisory Committees meeting and an increase in purchases of plant and production equipment to support our generic Seroquel XR® launch, which were only partially offset by higher cash receipts from commercialized sales of our generic Focalin XR® and cash receipts provided from financing activities derived from common share sales under the Company's at-the-market offering program and the Company's underwritten public offering in October 2017. The increase in cash during the year ended November 30, 2016 was mainly a result of an increase in cash flows provided from financing activities which were mainly from the Company's underwritten public offering in June 2016 and common share sales under the Company's at-the-market offering program, the receipt of a non-refundable upfront payment of $3,000,000 under the Mallinckrodt agreement, partially offset by lower cash receipts relating to commercialized sales of our generic Focalin XR® and a reduction in accounts payable and accrued liabilities. In November 2013, the Company entered into an equity distribution agreement with Roth Capital Partners, LLC ("Roth"), pursuant to which the Company originally could from time to time sell up to 530,548 of the Company's common shares for up to an aggregate of $16.8 million (or such lesser amount as may then be permitted under applicable exchange rules and securities laws and regulations) through at-the-market issuances on Nasdaq or otherwise. Under the equity distribution agreement, the Company was able at its discretion, from time to time, offer and sell common shares through Roth or directly to Roth for resale to the extent permitted under Rule 415 under the U.S. Securities Act at such time and at such price as were acceptable to the Company by means of ordinary brokers' transactions on Nasdaq or otherwise at market prices prevailing at the time of sale or as determined by the Company. The Company has paid Roth a commission, or allowed a discount, of 2.75% of the gross proceeds that the Company received from any sales of common shares under the equity distribution agreement. The Company also agreed to reimburse Roth for certain expenses relating to the at-the-market offering program. During the year ended November 30, 2018, an aggregate of Nil (adjusted to reflect the reverse split: 2017 - 110,815; 2016 –

147,126) common shares were sold on Nasdaq for gross proceeds of $Nil (2017- $2,541,640; 2016 - $3,469,449), with net proceeds to the Company of $Nil (2017 - $2,468,474; 2016 - $3,368,674), respectively, under the at-the-market offering program. In March 2018, the Company terminated its continuous offering under the prospectus supplement dated July 18, 2017 and prospectus dated July 17, 2017 in respect of its at-the-market program. The underwriting agreement relating to the October 2018 offering restricts the Company's ability to use this equity distribution agreement. It contains a prohibition on the Company: (i) for a period of two years following the date of the underwriting agreement, from directly or indirectly in any at-the-market or continuous equity transaction, offer to sell, or otherwise dispose of shares of capital stock of the Company or any securities convertible into or exercisable or exchangeable for its shares of capital stock or (ii) for a period of five years following the closing, effecting or entering into an agreement to effect any issuance by the Company of common shares or common share equivalents involving a certain variable rate transactions under an at-the-market offering agreement, whereby the Company may issue securities at a future determined price, except that, on or after the date that is two years after the closing, the Company may enter into an at-the-market offering agreement.

For the year ended November 30, 2018, net cash flows used in operating activities increased to $12,508,960 as compared to net cash flows used in operating activities for the year ended November 30, 2017 of $6,105,785. The increase was primarily a result of the higher loss from operations, an increase in prepaid expenses, and accounts payable, partially offset by a decrease in accounts receivable. For the year ended November 30, 2017, net cash flows used in operating activities decreased to $6,105,785 as compared to net cash flows used in operating activities for the year ended November 30, 2016 of $6,254,985. The decrease was primarily due to a significant reduction in accounts payable and accrued liabilities in fiscal 2016 as well as a reduction of inventory and accounts receivable levels in fiscal 2017. The November 30, 2016 decrease was due to lower cash receipts relating to commercial sales of our generic Focalin XR® capsules by Par for the 15 and 30 mg strengths and a reduction in accounts payable and accrued liabilities, partially offset by the receipt of a non-refundable upfront payment of $3,000,000 under the Mallinckrodt agreement.

R&D costs, which are a significant portion of the cash flows used in operating activities, related to continued internal R&D programs are expensed as incurred. However, equipment and supplies are capitalized and amortized over their useful lives if they have alternative future uses. For the year ended November 30, 2018 and the year ended November 30, 2017, R&D expense was $10,827,293, and $9,271,353, respectively. The increase was primarily due to an increase in third party R&D expenditures as a result of clinical trials for Oxycodone ER and higher patent litigation expenses. For the year ended November 30, 2017 and the year ended November 30, 2016, R&D expense was $9,271,353, and $8,166,736, respectively. The increase for the year ended November 30, 2017 was mainly due to consulting fees associated with our preparation for the FDA Advisory Committees meeting in relation to our Oxycodone ER NDA filing and the increase in stock based compensation expenses of $1,577,772 related to vested performance options during the year ended November 30, 2017.

For the year ended November 30, 2018, net cash flows provided from financing activities of $17,354,954 principally relate to two registered direct offerings of an aggregate of 883,333 common shares at a price of $6.00 per share (post reverse split) for gross proceeds of $5,300,000 in March 2018, and the 2018 Debenture Financing in the aggregate principal amount of $0.5 million in September 2018, and an underwritten public offering in October 2018 (described below) which raised $14,344,906 in gross proceeds. In October 2018, we completed an underwritten public offering in the United States, resulting in the sale to the public of 827,970 units at $0.75 per unit, which were comprised of one common share and one 2018 Unit Warrant exercisable at $0.75 per share. We concurrently sold an additional 1,947,261 common shares and 2018 Option Warrants to purchase 2,608,695 common shares exercisable at $0.75 per share pursuant to the over-allotment option exercised in part by the underwriter. The price for the common shares issued in connection with exercise of the overallotment option was $0.74 per share and the price for the warrants issued in connection with the exercise of the overallotment option was $0.01 per warrant, less in each case the underwriting discount. In addition, we issued 16,563,335 2018 Pre-Funded Units, each 2018 Pre-Funded Unit consisting of one 2018 Pre-Funded Warrant to purchase one common share and one 2018 Warrant to purchase one common share. The 2018 Pre-Funded Units were offered to the public at $0.74 each, and a 2018 Pre-Funded Warrant is exercisable at $0.01 per share. Each 2018 Firm Warrant is exercisable immediately and has a term of five years and each 2018 Pre-Funded Warrant is exercisable immediately and until all 2018 Pre-Funded Warrants are exercised. We also issued October 2018 Placement Agent Warrants to the placement agents to purchase 1,160,314 common shares at an exercise price of $0.9375 per share, which were exercisable immediately upon issuance. In aggregate, the Company issued 2,775,231 common shares, 16,563,335 2018 Pre-Funded Warrants and 20,000,000 2018 Firm Warrants in addition to 1,160,314 October 2018 Placement Agent Warrants. During the year ended November 30, 2018, 12,153,334 2018 Pre-Funded Warrants were exercised for proceeds of $121,553.

For the year ended November 30, 2017, net cash flows provided from financing activities of $5,682,168 principally related to the Company completing an underwritten public offering in October 2017 of 363,636 common shares, at a price of $11.00 per share and warrants to purchase an aggregate of 181,818 common shares, for gross proceeds of $4,000,000. The warrants became exercisable six months from issuance, will expire 30 months after they become

exercisable and have an exercise price of $12.50 per common share. The Company also issued to the placement agents warrants to purchase 18,181 shares of common stock at an exercise price of $13.75 per share. The total net proceeds from the offering were $3,499,508, after deducting offering expenses at-the-market issuances of common shares, and the exercise of warrants, offset by payments on the 2013 Debenture.

For the year ended November 30, 2018, net cash flows used in investing activities of $101,178 related mainly to the purchase of production, laboratory and computer equipment.

For the year ended November 30, 2017, net cash flows used in investing activities of $1,823,746 related primarily to purchase of plant and production equipment required to support our generic Seroquel XR® launch. For the year ended November 30, 2016, net cash flows used in investing activities of $515,410 related mainly to purchase of production, laboratory and computer equipment.

All non-cash items have been added back or deducted from the consolidated audited statements of cash flows.

With the exception of the quarter ended February 28, 2014, the Company has incurred losses from operations since inception. To date, the Company has funded its R&D activities principally through the issuance of securities, loans from related parties, funds from the IPC Arrangement Agreement and funds received under commercial license agreements. Since November 2013, research has also been funded from revenues from sales of our generic Focalin XR® capsules for the 15 and 30 mg strengths. With the launch of the 25 and 35 mg strengths by Par in January 2017, the launch of the 10 and 20 mg strengths in May 2017 along with the launch of the 5 and 40 mg strengths in November 2017, we expect sales of generic Focalin XR®, due to continued competitive pressures, to be negatively impacted for the next several quarters. As of November 30, 2018, the Company had a cash balance of $6.6 million. As of February 28, 2019, our cash balance was $3.0 million. We currently expect to satisfy our operating cash requirements until May 2019 from cash on hand and quarterly profit share payments from Par and Mallinckrodt. The Company will need to obtain additional funding as we further the development of our product candidates. Potential sources of capital may include payments from licensing agreements, cost savings associated with managing operating expense levels, equity and/or debt financings and/or new strategic partnership agreements which fund some or all costs of product development. We intend to utilize the equity markets to bridge any funding shortfall and to provide capital to continue to advance our most promising product candidates. Our future operations are highly dependent upon our ability to source additional capital to support advancing our product pipeline through continued R&D activities and to fund any significant expansion of our operations. Our ultimate success will depend on whether our product candidates receive the approval of the FDA or Health Canada and whether we are able to successfully market approved products. We cannot be certain that we will be able to receive FDA or Health Canada approval for any of our current or future product candidates, that we will reach the level of sales and revenues necessary to achieve and sustain profitability, or that we can secure other capital sources on terms or in amounts sufficient to meet our needs or at all. Our cash requirements for R&D during any period depend on the number and extent of the R&D activities we focus on. At present, we are working principally on our Oxycodone ER 505(b)(2), PODRASTM technology (as defined in Item 4.B. above), additional 505(b)(2) product candidates for development in various indication areas and selected generic, product candidate development projects. Our development of Oxycodone ER will require significant expenditures, including costs to defend against the Purdue litigation. For our Regabatin™ XR 505(b)(2) product candidate, Phase III clinical trials can be capital intensive, and will only be undertaken consistent with the availability of funds and a prudent cash management strategy. We anticipate some investment in fixed assets and equipment over the next several months, the extent of which will depend on cash availability. In October 2018, we raised $14,344,906 in gross proceeds as part of an underwritten public offering from the sale of 827,970 Units at $0.75 per one common share and one warrant exercisable at $0.75 per share. We concurrently sold an additional 1,947,261 common shares at $0.74 per share and 2,608,695 2018 Option Warrants exercisable at $0.75 per share pursuant to the over-allotment option exercised in part by the underwriter. In addition, we issued 16,563,335 2018 Pre-Funded Units, each 2018 Pre-Funded Unit consisted of one 2018 Pre-Funded Warrant to purchase one common share and one 2018 Warrant to purchase one common share. The 2018 Pre-Funded Units were offered at $0.74 each, and the 2018 Pre-Funded Warrant is exercisable at $0.01 per share. During the year ended November 30, 2018, 12,153,334 2018 Pre-Funded Warrants were exercised for proceeds of $121,553.

On September 10, 2018, the Company completed a private placement financing of the 2018 Debenture in the principal amount of $0.5 million. The 2018 Debenture is due to mature on September 1, 2020. The 2018 Debenture bears interest at a rate of 10% per annum, payable monthly, is pre-payable at any time at the option of the Company and is convertible at any time into common shares at a conversion price of $3.00 per common share at the option of the holder. Drs. Isa and Amina Odidi, who are directors, executive officers and shareholders of our Company, provided us with the original $500,000 of the proceeds for the 2018 Debenture.

Effective October 1, 2018, the maturity date for the 2013 Debenture was extended to April 1, 2019. In December 2018, a principal repayment of $300,000 was made on the 2013 Debenture in respect of the $1,500,000 loan. The Company currently expects to repay the current outstanding principal amount of $1,050,000 on or about April 1, 2019, if the Company then has cash available.

The availability of equity or debt financing will be affected by, among other things, the results of our R&D, our ability to obtain regulatory approvals, our success in commercializing approved products with our commercial partners and 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 sufficient additional capital, it will raise substantial doubt about our ability to continue as a going concern, realize our assets and pay our liabilities as they become due. Our cash outflows are expected to consist primarily of internal and external R&D, legal and consulting expenditures to advance our product pipeline and selling, general and administrative expenses to support our commercialization efforts. Depending upon the results of our R&D programs, the impact of the litigation against us and the availability of financial resources, we could decide to accelerate, terminate, or reduce certain projects, or commence new ones. Any failure on our part to successfully commercialize approved products or 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 us not taking advantage of business opportunities, in the termination or delay of clinical trials or in not taking any necessary actions required by the FDA or Health Canada 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 in our inability to file ANDAs, ANDSs or NDAs at all or in time to competitively market our products or product candidates.

C. Research and development, patents, and licenses, etc.

We expense R&D costs. For the years ended November 30, 2018, 2017 and 2016, R&D expense was $10,827,293, $9,271,353 and $8,166,736, respectively.

D. Trend Information

It is important to note that historical patterns of revenue and expenditures cannot be taken as an indication of future revenue and expenditures. Net loss has been somewhat variable over the last eight quarters and is reflective of varying levels of commercial sales of generic Focalin XR® capsules, the level of our R&D spending, and the vesting or modification of performance based stock options. The lower net loss in the fourth quarter of 2018 is primarily attributed to lower R&D spending and selling, general and administrative expenses, offset by licensing revenues. The higher net loss in the third quarter of 2018 is primarily attributed to higher third party R&D expenses as a result of clinical trials for Oxycodone ER, as well as increased patent litigation expenses. The lower net loss in the second quarter of 2018 is primarily attributed to slightly higher licensing revenues and lower R&D spending. The net loss in the first quarter of 2018 is primarily attributed to lower licensing revenues from commercial sales of generic Focalin XR®, along with higher R&D expenses. The lower net loss in the fourth quarter of 2017 is primarily attributed to higher licensing revenues and lower R&D spending and selling, general and administrative expenses. The net loss in the third quarter of 2017 was primarily due to higher licensing revenue, partially offset by higher expenses related to the FDA Advisory Committees meeting in July 2017. The lower net loss in the second quarter of 2017 was primarily attributed to higher than normal licensing revenues from commercial sales of generic Focalin XR® in the 25 and 35 mg strengths complementing the 15 and 30 mg strengths of our generic Focalin XR® marketed by Par, partially offset by an increase in performance based options expense and higher third party consulting fees. The lower net loss in the first quarter of 2017 is primarily attributed to higher licensing revenues from commercial sales of generic Focalin XR® due to Par’s launch of the 25 and 35 mg strengths of its generic Focalin XR® capsules in that quarter, partially offset by an increase in performance based stock options expense and legal and other professional fees. The higher net loss in the fourth quarter of 2016 was attributable to the accrual of management bonuses and additional compensation costs related to vested performance based stock options as a result of the Company’s shareholders approving an

extension of the expiry date of the performance based stock options.

The table below outlines financial data for the eight most recent quarters. The quarterly results are unaudited and have been prepared in accordance with U.S. GAAP, for interim financial information:

Quarter Ended	Revenue	Net loss	Loss per share	
			Basici	Dilutedi
	$	$	$	$
November 30, 2018	387,691	(3,784,512)	(0.67)	(0.67)
August 31, 2018	413,555	(3,954,104)	(0.91)	(0.91)
May 31, 2018	576,967	(2,859,276)	(0.68)	(0.68)
February 28, 2018	334,518	(3,149,588)	(0.91)	(0.91)
November 30, 2017	1,077,835	(2,510,936)	(0.76)	(0.76)
August 31, 2017	1,189,739	(2,550,314)	(0.83)	(0.83)
May 31, 2017	2,001,512	(1,805,329)	(0.59)	(0.59)
February 28, 2017	1,235,366	(1,990,861)	(0.66)	(0.66)

(1)
Quarterly per share amounts may not sum due to rounding.

E. Off-balance sheet arrangements

The Company, as part of its ongoing business, does not participate in transactions that generate relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities (“SPE”), which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As of November 30, 2018, the Company was not involved in any material unconsolidated SPE transactions.

F. Tabular disclosure of contractual obligations

In the table below, we set forth our enforceable and legally binding obligations and future commitments and obligations related to all contracts. Some of the figures we include in this table are based on management’s estimate and assumptions about these obligations, including their duration, the possibility of renewal, anticipated actions by third parties, and other factors. Operating lease obligations relate to the lease of premises for the Combined Properties (as defined in Item 4.B. above), comprising the Company’s premises that it operates from in the 30 Worcester Road Facility (as defined in Item 4.B. above) as well as the adjoining 22 Worcester Road Facility (as defined in Item 4.B. above), which is indirectly owned by the same landlord, which will expire in November 2020, subject to a 5 year renewal option. The Company also has an option to purchase the Combined Properties up to November 30, 2020 based on a fair value purchase formula, but does not currently expect to exercise this option in 2019.

	Payments Due by Period				
Contractual Obligations	Total	Less than 1 Year	1 - 3 Years	3 - 5 Years	More than 5 Years
	$	$	$	$	$
Third parties					

Accounts payable	2,643,437	2,643,437	-	-	-
Accrued liabilities	353,147	353,147	-	-	-
Related parties			-		
Employee costs payable	222,478	222,478	-	-	-
Convertible debentures	1,991,956	1,454,148	537,808	-	-
Total contractual obligations	5,211,018	4,673,210	537,808	-	-

G. Safe Harbor

See “Disclosure Regarding Forward-Looking Information” in the introduction to this annual report.

Item 6. Directors, Senior Management and Employees

A. Directors and Senior Management

DIRECTORS AND OFFICERS
The name and province of residence of each of our directors and officers as at the date hereof, the office presently held, principal occupation, and the year each director first became a director of the Company or its predecessor, IPC Ltd., are set out below. Each director is elected to serve until the next annual meeting of our shareholders or until his or her successor is elected or appointed. Officers are appointed annually and serve at the discretion of the Board .

Name and Province of Residence	Position held with the Company	Officer/Director Since
Dr. Isa Odidi Ontario, Canada	Chairman of the Board and Chief Executive Officer	September 2004
Dr. Amina Odidi Ontario, Canada	President, Chief Operating and Director	September 2004
Norman Betts(1), New Brunswick, Canada	Director(4)	January 2019
Shawn Graham(2) (3), New Brunswick, Canada	Director	May 2018
Kenneth Keirstead(1)(2)(3) New Brunswick, Canada	Director	January 2006
Bahadur Madhani(1) Ontario, Canada	Director	March 2006
Greg Powell(5)Ontario, Canada	Chief Financial Officer	February 2019
Dr. Patrick Yat Ontario, Canada	Vice-President, Chemistry and Analytical Services	N/A

Notes:

(1)
Member of the Audit Committee.

(2)
Member of the Compensation Committee.

(3)
Member of the Compensation Committee and Corporate Governance Committee.

(4)
Dr. Betts was appointed a director of the Company on January 22, 2019 to fill the vacancy created by the resignation of Dr. Eldon Smith.

(5)
Mr. Powell was appointed the Company’s Chief Financial Officer effective February 11, 2019 after the resignation of the Company’s former Chief Financial Officer, Andrew Patient. Between the time of Mr. Patient’s resignation and Mr. Powell’s appointment, Dr. Amina Odidi assumed the responsibilities of the Company’s Chief Financial Officer.

Eldon Smith served as a Director to the Company from October 2009 until his resignation effective January 8, 2019) to pursue other opportunities. During the 2018 fiscal year, he served on the Audit Committee, the Compensation Committee and the Corporate Governance Committee. In the last 5 years, he has been the President and CEO of Eldon

R. Smith and Associates Ltd., a consulting business, and since January 19, 2017, he has been Chief Medical Officer of Cardiol Therapeutics Inc. He is a director of the following public companies: Zenith Capital Corp. and Resverlogix Corp.

John Allport served as the Company's Vice President, Legal Affairs and Licensing and as a director from September 2004 until his resignation (effective May 17, 2017) for personal reasons. Mr. Allport entered into a consulting agreement with the Company effective May 17, 2017 to provide ongoing services to the Company on an as-needed basis.

Michael Campbell served as General Counsel and Corporate Secretary of the Company from July 10, 2017 until his resignation (effective February 22, 2018) for personal reasons.

Isa Odidi, Ph.D., MBA – Chairman, CEO, Co-Chief Scientific Officer and Executive Director

Dr. Isa Odidi has served as Chairman of the Board of the Company and Chief Executive Officer and Co-Chief Scientific Officer of the Company since September 2004. In 1998, Dr. Odidi co-founded Intellipharmaceutics Inc., the predecessor of publicly-traded Intellipharmaceutics International Inc. From 1995 to 1998, Dr. Odidi held positions, first as Director, then as Vice President of Research of Drug Development and New Technologies, at Biovail Corporation International, (now Valeant Pharmaceutical International, Inc.), a drug delivery company. Dr. Odidi currently holds a Chair as Professor of Pharmaceutical Technology at the Toronto Institute of Pharmaceutical Technology in Canada and is an Adjunct Professor at the Institute for Molecular Medicine in California. Dr. Isa Odidi is also the Chairman of Smart Pharmaceutical (Shanghai) Ltd, China. Dr. Odidi holds a bachelor of science degree in pharmacy from Ahmadu Bello University, Nigeria, a master of science in pharmaceutical technology, Ph.D. pharmaceutics from the University of London, and his MBA from Joseph L. Rotman School of Management, University of Toronto. He is also a graduate of the Western Executive Program, Ivey School of Business at the University of Western Ontario. Dr. Odidi was recently awarded an Honorary Doctor of Science degree (Honoris causa) from the University of Benin, Nigeria.

Amina Odidi, Ph.D. – President, COO, Co-Chief Scientific Officer and Executive Director

Dr. Amina Odidi has served as President, Chief Operating Officer and Co-Chief Scientific Officer of the Company since September 2004. In 1998, Dr. Odidi co-founded Intellipharmaceutics Inc., the predecessor of publicly-traded Intellipharmaceutics International Inc. She has extensive experience developing and applying proprietary technologies to the development of controlled-release drug products for third-party pharmaceutical companies. She has invented or co-invented various proprietary controlled delivery devices for the delivery of pharmaceutical, nutraceutical, biological, agricultural and chemical agents. In the past she has worked for the pharmaceutical and health care industry. Dr. Odidi has co-authored eight articles, papers and textbooks. Dr. Odidi holds a bachelor of science in pharmacy, a master of science in biopharmaceutics, and a Ph.D. in pharmaceutics from the University of London.

Greg Powell, CPA-CGA – Chief Financial Officer

Greg Powell has served as the Chief Financial Officer of the Company since February 2019. Mr. Powell has over 15 years of extensive experience as a senior financial professional, in large as well as small scale operations in industries ranging from international mining, exploration and construction to technology sector operations in multiple jurisdictions. In 2013, Mr. Powell became the Director of Finance for ViXS System Inc. (now Pixelworks Canada), a multimedia solutions innovator, where he was instrumental in streamlining the financial reporting process to meet public company standards. In August 2018, he became Director of Finance at Wave Financial, Inc., a private company that provides financial services for small businesses. Mr. Powell is a Chartered Professional Accountant – Certified General Accountant, and in 2012 was awarded Fellowship in the Association of Chartered Certified Accountants.

Bahadur Madhani, CM – Non-Executive Director

Bahadur Madhani, an accountant by training, has been a director since March 2006. Since 1983, Mr. Madhani's principal occupation has been President and CEO of Equiprop Management Limited, a Canadian property management company of which he is the principal shareholder. At present, he is also on the Board of the YMCA of Toronto and YMCA Canada. He was previously a member of the advisory board of Quebecor Ontario. He has also served as Chairman of United Way of Toronto, Chairman of the YMCA of greater Toronto, and Chairman of the Nelson Mandela Children's Fund of Canada. Mr. Madhani was awarded membership in the Order of Canada in 2001.

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Kenneth Keirstead – Non-Executive Director

Kenneth Keirstead has served as a director of the Company since January 2006. Mr. Keirstead is educated in clinical biochemistry and business administration. He has worked in the health care delivery and pharmaceutical industries for over 45 years. Since 1998, Mr. Keirstead's principal occupation has been Executive Manager of the Lyceum Group, a Canadian consulting services company primarily active in the health care field, of which he is the founder. In addition, he was President and CEO of Sanofi Winthrop Canada Inc., General Manager of Squibb Medical Systems International, President of Chemfet International and President of Quinton Instruments, among other positions. He has published studies and reports on health care and related services.

Shawn Graham – Non-Executive Director

Shawn Graham has been a director of the Company since May 2018. Mr. Graham is the President and CEO of G&R Holdings Inc., which assists companies with developing and implementing global projects and business alliance strategies with a special focus on globalizing with China. From October 2006 until October 2010, Mr. Graham served as 31st Premier of Province of New Brunswick. He is a former Chair of the Council of The Federation, Co-chair of Northeastern Governors and Eastern Canadian Premiers, and Co-chair of a Pan-Canadian trade mission to China. He is currently a member of the advisory board of the faculty of business, University of New Brunswick, Saint John as well as a national board member to Ducks Unlimited Canada. Mr. Graham has been awarded an Honorary Doctor of Laws Degree from the University of New Brunswick.

Norman Betts – Non-Executive Director

Norman Betts is a Professor, Faculty of Business Administration, University of New Brunswick, a Chartered Professional Accountant Fellow (FCPA) and a member of the Institute of Corporate Directors (ICD). Dr. Betts currently serves as a director and member of the audit committees of Tanzanian Royalty Exploration Corporation, 49 North Resources, Biotricity Inc and Adex Mning Inc. He has extensive public company and Crown Corporation experience including having served on boards including Tembec Inc, New Brunswick Power Corporation, and the Bank of Canada. He is also co-chair of the board of trustees of the University of New Brunswick Pension Plan for Academic Employees. Dr. Betts is a former Finance Minister and Minister of Business New Brunswick with the Province of New Brunswick. He was awarded a Ph.D. in Management from the School of Business at Queens University in 1992.

From March 2006 until June 2013, Dr. Norman Betts served as a director of Starfield Resources Inc. (TSX: SRU) ("Starfield"). On August 22, 2013, Starfield was the subject of a cease trade order issued by the Ontario Securities Commission as a result of Starfield's failure to file, inter alia, its audited annual financial statements, related management's discussion and analysis and officer certifications for the year ended February 28, 2013. The order is still in effect. On April 18, 2013, Starfield's shares were delisted from the TSX. On July 2, 2013, Starfield announced that it was deemed to have made an assignment in bankruptcy, effective at the close of business on June 28, 2013 for failure to file a proposal before the time for doing so had past pursuant to the provisions of the Bankruptcy and Insolvency Act (Canada). Starfield had previously filed a Notice of Intention to Make a Proposal ("Notice of Intention") pursuant to the provisions of Part III of the Bankruptcy and Insolvency Act (Canada). Pursuant to the Notice of Intention, PriceWaterhouseCoopers Inc. ("PwC") was appointed as the trustee ("Proposal Trustee") in Starfield's proposal proceedings. Pursuant to a Order of the Ontario Superior Court of Justice (Commercial List), the time for Starfield to file a proposal expired at the end of the day on June 28, 2013. Starfield completed a sale of substantially all of its assets related to its Ferguson Lake Project in early June 2013. However, in consultation with the Proposal Trustee, Starfield determined that it would not be able to put forward a viable proposal and would not be filing a proposal by the deadline. As a result, Starfield was deemed to have made an assignment in bankruptcy at the end of the day on June 28, 2013. PwC acted as the trustee in bankruptcy for Starfield.

As of February 28, 2019, the directors and executive officers of the Company as a group owned, directly and indirectly, or exercise control or direction over 594,828 common shares, representing approximately 2.7% of the issued and outstanding common shares of the Company (and beneficially owned approximately 1,325,501 common shares representing 5.9% of our common shares including common shares issuable upon the exercise of outstanding options and the conversion of the outstanding Debentures that are exercisable or convertible within 60 days of the date hereof). 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 directly and indirectly 578,131 common shares, representing approximately 2.6% of our issued and outstanding common shares of the Company (and collectively beneficially owned in the aggregate approximately 1,182,525 common shares representing 5.2% of our common shares including common shares issuable upon the exercise of outstanding options and the conversion of the outstanding Debentures that are exercisable or convertible within 60 days of the date hereof). (Reference is made to the section entitled “E. Share Ownership” under this “Item 6. Directors, Senior Management and Employees” for additional information regarding the options to purchase common shares held by directors and officers of the Company and the Debentures held by Drs. Amina and Isa Odidi.).

Family Relationships

Except Drs. Isa Odidi and Amina Odidi who are spouses to each other, there are no other family relationships among any of our officers and directors.

B. Compensation

Compensation Discussion and Analysis

Background – 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 (some of which have received FDA approval) and product candidates in various stages of development, including ANDAs filed with the FDA (and one ANDS filed with Health Canada) and one NDA filing, in therapeutic areas that include neurology, cardiovascular, GIT, diabetes and pain. As of November 30, 2018, the Company had 59 full-time employees engaged in administration and research and development.

Compensation Governance – The Company's Compensation Committee is comprised of three directors, Messrs. Graham, Madhani and Keirstead, each of whom is considered "independent" within the meaning of section 2.4 of Form 51-102F6 – Statement of Executive Compensation. Each member of the Compensation Committee has sufficient experience in order to make decisions on the suitability of the Company's compensation policies and practices.

The Compensation Committee recommends compensation policies concerning officers and senior management to the Board. The Corporate Governance Committee recommends compensation policies concerning independent directors to the Board. The Board makes the final determinations regarding the adequacy and form of the compensation for non-executive directors to ensure that such compensation realistically reflects the responsibilities and risks involved, without compromising a director's independence. Further details relating to the role and function of the Compensation Committee and the Corporate Governance Committee is provided in Item 6.C.

Risk Management – The Board is responsible for identifying the principal risks of the Company's business and ensuring the implementation of appropriate systems to manage these risks. Through the Compensation Committee, the Board is involved in the design of compensation policies to meet the specific compensation objectives discussed below and considers the risks relating to such policies, if any. The Compensation Committee is ultimately responsible for ensuring compliance of the compensation policies and practices of the Company. To date, the Board and the Compensation Committee have not identified any risks arising from the Company's compensation policies and practices that would be reasonably likely to have a material adverse effect on the Company.

Objectives – The overall objectives of the Company's compensation program include: (a) attracting and retaining talented executive officers; (b) aligning the interests of those executive officers with those of the Company; and (c) linking individual executive officer compensation to the performance of the Company. The Company's compensation program is currently designed to compensate executive officers for performance of their duties and to reward certain executive officers for performance relative to certain milestones applicable to their services.

Elements of Compensation – The elements of compensation awarded to, earned by, paid to, or payable to the Named Executive Officers (as hereinafter defined) for the most recently completed financial year are: (a) base salary and discretionary bonuses; (b) long-term incentives in the form of stock options; (c) restricted share unit awards; and (d) perquisites and personal benefits. Prior to the most recently completed financial year, the Named Executive Officers have also received option-based awards which were assumed by the Company pursuant to the plan of arrangement

completed on October 22, 2009.

Base Salary and Discretionary Bonus – Base salary is a fixed element of compensation payable to each Named Executive Officer for performing his or her position's specific duties. The amount of base salary for a Named Executive Officer has been determined through negotiation of an employment agreement with each Named Executive Officer (see "Employment Agreements" below). While base salary is intended to fit into the Company's overall compensation objectives in order to attract and retain talented executive officers, the size of the Company and the nature and stage of its business also impact the level of base salary. To date, the level of base salary has not impacted the Company's decisions about any other element of compensation and the Board may consider discretionary bonuses for individual employees based on exceptional performance by such individuals in a particular fiscal year.

Option-Based Awards – Option-based awards are a variable element of compensation that rewards each Named Executive Officer for individual and corporate performance overall determined by the Board. Option-based awards are intended to fit into the Company's overall compensation objectives by aligning the interests of all Named Executive Officers with those of the Company, and linking individual Named Executive Officers' compensation to the performance of the Company. The Board, which includes two of the Named Executive Officers, is responsible for setting and amending any equity incentive plan under which an option-based award is granted.

The Company has in place a stock option plan (the "Option Plan") for the benefit of certain officers, directors, employees and consultants of the Company, including the Named Executive Officers (as described in greater detail in Item 6.E below). Named Executive Officers have been issued options under such plan.

The Company has also granted performance-based options to Dr. Isa Odidi and Dr. Amina Odidi pursuant to a separate option agreement which was negotiated at the same time as their employment agreements. These options vest upon the Company attaining certain milestones relating to FDA filings and approvals for Company drugs, such that 27,639 options vest in connection with each of the FDA filings for the first five Company drugs and 27,639 options vest in connection with each of the FDA approvals for the first five Company drugs.

The Company's Option Plan was adopted effective October 22, 2009 as part of the IPC Arrangement Agreement approved by the shareholders of IPC Ltd., the predecessor company of the Company, at the meeting of shareholders held on October 19, 2009. Subject to the requirements of the Option Plan, the Board, with the assistance of the Compensation Committee, has the authority to select those directors, officers, employees and consultants to whom options will be granted, the number of options to be granted to each person and the price at which common shares of the Company may be purchased. Grants are determined based on individual and aggregate performance, as determined by the Board.

RSUs – The Company established a restricted share unit plan (the "RSU Plan") to form part of its incentive compensation arrangements available for officers and employees of the Company and its designated affiliates (as described in greater detail in Item 6.E) as of May 28, 2010, when the RSU Plan received shareholder approval.

Perquisites and personal benefits – The Company also provides perquisites and personal benefits to its Named Executive Officers, including basic employee benefit plans, which are available to all employees, and a car allowance to cover the cost of an automobile for business purposes. These perquisites and personal benefits were determined through negotiation of an employment agreement with each Named Executive Officer (see "Employment Agreements" below). While perquisites and personal benefits are intended to fit into the Company's overall compensation objectives by serving to attract and retain talented executive officers, the size of the Company and the nature and stage of its business also impact the level of perquisites and benefits. To date, the level of perquisites and benefits has not impacted the Company's decisions about any other element of compensation.

Other Compensation-Related Matters – The Company's share trading policy prohibits all directors and officers of the Company from, among other things, engaging in any short sales designed to hedge or offset a decrease in market

value of the securities of the Company.

Executive Compensation

The following table sets forth all direct and indirect compensation for, or in connection with, services provided to the Company for the fiscal years ended November 30, 2018, November 30, 2017 and November 30, 2016 in respect of the Chief Executive Officer, the Chief Operating Officer, and the Chief Financial Officers (current and former) ("Named Executive Officers"). No other officers of the Company earned greater than C$150,000 in total compensation in the fiscal year ended November 30, 2018.

SUMMARY COMPENSATION TABLE

Name and principal position(a)	Year(b)	Salary (U.S.$)(1)(c)	Share-based awards (U.S.$)(d)	Option-based awards (U.S.$)(2)(e)	Non-equity incentive plan compensation (U.S.$)(f) Annual incentive plans(3)	Long-term incentive plans	Pension value (U.S.$)(g)	All other compensation (U.S.$)(4)(h)	Total compensation (U.S.$)(i)
Dr. Isa Odidi, Chairman, Chief Executive Officer and Co-Chief Scientific Officer	2018	$350,306	N/A	$811,208	N/A	N/A	N/A	$13,950	$1,175,465
	2017	$343,430	N/A	$1,609,573	N/A	N/A	N/A	$13,676	$1,966,680
	2016	$340,464	N/A	$703,016	$340,464	N/A	N/A	$13,558	$1,397,502
Dr. Amina Odidi, President, Chief Operating Officer and Co-Chief Scientific Officer	2018	$350,306	N/A	$811,208	N/A	N/A	N/A	$13,950	$1,175,465
	2017	$343,430	N/A	$1,609,573	N/A	N/A	N/A	$13,676	$1,966,680
	2016	$340,464	N/A	$703,016	$340,464	N/A	N/A	$13,558	$1,397,502
Andrew Patient, Former Chief Financial Officer(5)	2018	$232,504	N/A	$11,619	N/A	N/A	N/A	$13,950	$258,073
	2017	$54,395	N/A	$19,800	N/A	N/A	N/A	$3,419	$77,614
Greg Powell, Chief Financial Officer (6)	2018	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Notes:

(1)
Salaries paid by the Company to each Named Executive Officer are paid in Canadian dollars. All amounts are expressed in U.S. dollars converted at the exchange rate of U.S.$0.7750 to C$1.00 (2017 - U.S.$ 0.7598; 2016 – U.S. $0.7932) being the average closing exchange rate quoted by the Bank of Canada for the respective periods. Salary includes all amounts paid or payable to the Named Executive Officer. Actual amount paid to each Named Executive Officer in fiscal 2018, 2017 and 2016 are as disclosed in the table.

(2)
The Company entered into a separate acknowledgement and agreement with Drs. Isa Odidi and Amina Odidi dated October 22, 2009 to be bound by the performance-based stock option agreement dated September 10, 2004 pursuant to which Drs. Isa Odidi and Amina Odidi are entitled to purchase up to 276,394 of the Company’s common shares upon payment of $36.20 per share, subject to satisfaction of the performance vesting conditions. The value of the option-based awards is determined using the Black-Scholes pricing model calculated as at the award date.

(3)
Amount awarded at the discretion of the Board. These bonuses were paid in the second quarter of 2017; no bonuses were paid during the fiscal year 2018

(4)
“All other compensation” includes car allowances and other miscellaneous benefits.

(5)
Mr. Patient served as the Company's Chief Financial Officer from September 6, 2017 until his resignation effective on November 30, 2018.

(6)
Mr. Powell was appointed as Chief Financial Officer of the Company effective February 11, 2019.

During the fiscal year ended November 30, 2018, Mr. Campbell, General Counsel and Corporate Secretary from July 10, 2017 until his resignation (effective February 22, 2018) did not receive option-based awards and received salary, all other compensation and total compensation of $89,279, $4,511 and $93,790, respectively.

Significant factors necessary to understand the information disclosed in the Summary Compensation Table above include the terms of each Named Executive Officer’s employment agreement and the terms of the separate agreement relating to performance-based options applicable to Drs. Isa and Amina Odidi described below.

Employment Agreements

The employment agreement with Dr. Isa Odidi, the Chief Executive Officer and Co-Chief Scientific Officer of the Company, effective September 1, 2004, entitles Dr. Isa Odidi to receive a base salary of $200,000 per year, which is paid in Canadian dollars, and is increased annually each year during the term of the agreement by 20% of the prior year’s base salary. In addition, he is entitled to: (a) participate in the Option Plan; (b) participate in all employee benefit plans and programs, except for the Company’s deferred share unit plan (the “DSU Plan”); and (c) a car allowance of up to $1,000 per month. The initial term of the employment agreement was until September 30, 2007, at which time, pursuant to the terms of the agreement, the agreement was deemed to be extended automatically for an additional three-year period on the same terms and conditions (i.e. until September 30, 2010). The agreement will continue to be extended automatically for successive additional three-year periods on the same terms unless the

Company gives Dr. Isa Odidi written notice at least two years prior to the date on which the agreement would otherwise be extended. See “Termination and Change of Control Benefits” below. Dr. Isa Odidi’s employment agreement was amended on August 1, 2007 and June 8, 2009 to include intellectual property, non-competition and non-solicitation provisions. In April 2010, Dr. Isa Odidi’s employment agreement was amended effective as of December 1, 2009, to eliminate the right to annual increases in his base salary of 20% each year and to roll back his base salary effective December 1, 2009 to the level payable under the employment agreement for the period from September 2008 to August 2009 or C$452,000 per year. Pursuant to such amendment, Dr. Isa Odidi’s base salary is subject to increase on an annual basis at the discretion of the Board, and Dr. Isa Odidi is eligible to receive a bonus, based on his performance, and that of the Company, as determined by the Board. In February 2012, Dr. Isa Odidi received a grant of 30,000 options of which 20,000 vested immediately on issuance and the remaining 10,000 vested on February 17, 2013 at an exercise price of C$32.70 per share. In April 2013, Dr. Isa Odidi received a grant of 7,500 options of which 3,750 vested immediately on issuance and the remaining 3,750 vested on November 30, 2013 at an exercise price of C$18.10 per share. In March 2014, Dr. Isa Odidi received a grant of 5,000 options of which 2,500 vested immediately on issuance and the remaining 2,500 vested on November 30, 2014 at an exercise price of C$42.90 per share. In November 2015, Dr. Isa Odidi received a grant of 7,000 options of which 4,900 vested immediately on issuance, with the remaining 2,100 options vested on November 30, 2016 at an exercise price of C$25.20 per share. In August 2016, Dr. Isa Odidi received a grant of 9,000 options of which 6,000 vested immediately on issuance, with the remaining 3,000 vested on November 30, 2017 at an exercise price of C$24.20 per share. In November 2017, Dr. Isa Odidi received a grant of 7,000 options of which 2,333 vested immediately on issuance, 2,333 vested on November 30, 2018 and 2,334 will vest on November 30, 2019 at an exercise price of C$11.50 per share.

The employment agreement with Dr. Amina Odidi, the President, Chief Operating Officer and Co-Chief Scientific Officer of the Company, effective September 1, 2004, entitles Dr. Amina Odidi to receive a base salary of $200,000 per year, which is paid in Canadian dollars, and is increased annually by 20% of the prior year's base salary. In addition, she is entitled to: (a) participate in the Option Plan; (b) participate in all employee benefit plans and programs, except for the DSU Plan; and (c) a car allowance of up to $1,000 per month. The initial term of the employment agreement was until September 30, 2007, at which time, pursuant to the terms of the agreement, the agreement was deemed to be extended automatically for an additional three-year period on the same terms and conditions (i.e. until September 30, 2010). The agreement will continue to be extended automatically for successive additional three-year periods on the same terms unless the Company gives Dr. Amina Odidi written notice at least two years prior to the date on which the agreement would otherwise be extended. See "Termination and Change of Control Benefits" below. Dr. Amina Odidi's employment agreement was amended on August 1, 2007 and June 8, 2009 to include intellectual property, non-competition and non-solicitation provisions. In April 2010, Dr. Amina Odidi's employment agreement was amended effective as of December 1, 2009, to eliminate the right to annual increases in her base salary of 20% each year and to roll back her base salary effective December 1, 2009 to the level payable under the employment agreement for the period from September 2008 to August 2009, being C$452,000 per year. Pursuant to such amendment, Dr. Amina Odidi's base salary is subject to increase on an annual basis at the discretion of the Board, and Dr. Amina Odidi is eligible to receive a bonus, based on her performance and the Company, as determined by the Board. In February 2012, Dr. Amina Odidi received a grant of 30,000 options of which 20,000 vested immediately on issuance and the remaining 10,000 vested on February 17, 2013 at an exercise price of C$32.70 per share. In April 2013, Dr. Amina Odidi received a grant of 7,500 options of which 3,750 vested immediately on issuance and the remaining 3,750 vested on November 30, 2013 at an exercise price of C$18.10 per share. In March 2014, Dr. Amina Odidi received a grant of 5,000 options of which 2,500 vested immediately on issuance and the remaining 2,500 vested on November 30, 2014 at an exercise price of C$42.90 per share. In November 2015, Dr. Amina Odidi received a grant of 7,000 options of which 4,900 vested immediately on issuance, with the remaining 2,100 options vested on November 30, 2016 at an exercise price of C$25.20 per share. In August 2016, Dr. Amina Odidi received a grant of 9,000 options of which 6,000 vested immediately on issuance, with the remaining 3,000 vested on November 30, 2017 at an exercise price of C$24.20 per share. In November 2017, Dr. Amina Odidi received a grant of 7,000 options of which 2,333 vested immediately on issuance, 2,333 vested on November 30, 2018 and 2,334 will vest on November 30, 2019 at an exercise price of C$11.50 per share.

In addition, the Company entered into a separate acknowledgement and agreement with Drs. Isa Odidi and Amina Odidi dated October 22, 2009 to be bound by the performance-based stock option agreement dated September 10, 2004 pursuant to which Drs. Isa Odidi and Amina Odidi are entitled to purchase up to 276,394 of the Company's common shares. These options were not granted under the Option Plan. These options vest upon the Company attaining certain milestones related to the FDA filings and approvals for Company products and product candidates. The options are exercisable at a price of $36.20 per share and were to expire in September 2014. Effective March 27, 2014, the Company's shareholders approved a two year extension of the performance-based stock option expiry date to September 2016. Effective April 19, 2016, the Company's shareholders approved a further two year extension of the performance-based stock option expiry date to September 2018. Effective May 15, 2018, the Company's shareholders approved a further two year extension of the performance-based stock option expiry date to September 2020. As of the date hereof, 276,394 of these options have vested and are exercisable.

Andrew Patient had served as the Company's Chief Financial Officer from September 6, 2017 until his resignation effective on November 30, 2018. The employment agreement with Andrew Patient, dated August 30, 2017, effective September 6, 2017, entitled Mr. Patient to receive a base salary of C$300,000, which was paid in Canadian dollars, per year. In addition, he was entitled to: (a) participate in the Option Plan; (b) participate in all employee benefit plans and programs; and (c) a car allowance of C$1,500 per month. The agreement provided for automatic renewal on December 31 each year from year to year in absence of notice of termination from the Company at least 90 days prior to the end of the then applicable term. If the agreement was terminated without cause, it required payment to Mr.

Patient of 3 months' base salary, plus 6 weeks' base salary for every full year of service, up to a combined maximum of 12 months. If such termination occurred within six months of a change of control of the Company, it required payment to Mr. Patient of thirteen months' base salary, plus 6 weeks' base salary for every full year of service, up to a combined maximum of 18 months. Mr. Patient's employment agreement contains intellectual property, non-competition and non-solicitation provisions in favor of the Company. Mr. Patient was granted 6,000 options, of which 2,000 vested immediately on issuance, 2,000 vested on October 20, 2018 and the remaining 2,000 were to vest on October 20, 2019 at an exercise price of C$12.70 per share. In November 2017, Mr. Patient received a grant of 1,500 options of which 500 vested immediately on issuance, 500 to vest on November 30, 2018 and the remaining 500 to vest on November 30, 2019 at an exercise price of C$11.50 per share. Mr. Patient's options will cease to be exercisable 120 days after the date on which he ceased to be employed by the Company, i.e. will cease to be exercisable on March 30, 2019.

The employment agreement with Greg Powell, the Chief Financial Officer of the Company, effective February 11, 2019 entitles Mr. Powell to receive a base salary of C$180,000 per year, which is paid in Canadian dollars. In addition, he is entitled to: (a) participate in the Option Plan; (b) participate in all employee benefit plans and programs; and (c) a car allowance of C$1,000 per month. The employment agreement is for an indefinite term. The Company can terminate this agreement without cause upon 3 to 12 months' notice, depending on the length of employment. If the agreement is terminated without cause, payment instead of notice can be provided/it will require payment to Mr. Powell of 3 months' base salary, plus 6 weeks' base salary for every full year of service, up to a combined maximum of 12 months. If such termination occurs within 6 months of a change of control of the Company, it requires payment to Mr. Powell of 12 months' base salary, plus 6 weeks' base salary for every full year of service, up to a combined maximum of 12 months. Mr. Powell's employment agreement contains intellectual property, non-competition and non-solicitation provisions in favor of the Company.

John Allport had served as the Company's Vice President Legal Affairs and Licensing and as a director from September 2004 until his resignation effective on May 17, 2017. The employment agreement with Mr. Allport, effective September 1, 2004, provided for Mr. Allport to receive a base salary of C$95,000, which was paid in Canadian dollars, per year. In addition, he was entitled to: (a) participate in the Option Plan; (b) participate in all employee benefit plans and programs; and (c) a car allowance of C$1,000 per month. The employment agreement was for an indefinite term subject to termination on six months' notice. In December 2011, Mr. Allport's base salary was increased to C$145,000. In February 2012, Mr. Allport received a grant of 25,000 options of which 17,500 vested immediately on issuance and the remaining 7,500 options vested on February 17, 2013 at an exercise price of C$65.40 per share. Mr. Allport's employment agreement included intellectual property, non-competition and non-solicitation provisions in favor of the Company. In April 2013, Mr. Allport received a grant of 2,500 options of which 1,250 vested immediately on issuance and the remaining 1,250 options vested on November 30, 2013 at an exercise price of C$18.10 per share. In March 2014, Mr. Allport received a grant of 5,000 options of which 2,500 vested immediately on issuance and the remaining 2,500 vested on November 30, 2014 at an exercise price of C$42.90 per share. In November 2015, Mr. Allport received a grant of 4,000 options of which 2,800 vested immediately on issuance, with the remaining 1,200 vested on November 30, 2016 at an exercise price of C$25.20 per share. In August 2016, Mr. Allport received a grant of 5,500 options of which 3,700 vested on issuance, with the remaining 1,800 were to vest on November 30, 2017 at an exercise price of C$24.20 per share. Mr. Allport entered into a consulting agreement with the Company effective May 17, 2017 to provide on-going services to the Company on an as-needed basis. The consulting agreement provides that Mr. Allport is to serve as a consultant to the Company to provide pharmaceutical business consulting services when requested from time to time. The agreement is terminable by either the Company or Mr. Allport on less than one-month notice and provides for such consideration as is mutually agreed from time to time. The consulting agreement includes intellectual property, non-competition and non-solicitation provisions in favor of the Company.

The employment agreement with Michael Campbell, the former General Counsel & Corporate Secretary of the Company, effective June 15, 2017 entitled Mr. Campbell to receive a base salary of C$300,000, which is paid in Canadian dollars, per year. In addition, he was entitled to: (a) participate in the Option Plan; (b) participate in all employee benefit plans and programs; and (c) a car allowance of C$1,500 per month. The agreement provided for automatic renewal on December 31 each year from year to year in absence of notice of termination from the Company at least 90 days prior to the end of the then applicable term. If the agreement was terminated without cause, it required payment to Mr. Campbell of 3 months' base salary, plus 6 weeks' base salary for every full year of service, up to a combined maximum of 12 months. If such termination occurred within six months of a change of control of the Company, it required payment to Mr. Campbell of thirteen months' base salary, plus 6 weeks' base salary for every full year of service, up to a combined maximum of 18 months. Mr. Campbell's employment agreement contains intellectual property, non-competition and non-solicitation provisions in favor of the Company. Mr. Campbell served as the Company's General Counsel & Corporate Secretary until his resignation effective on April 5, 2018. Mr. Campbell was granted 6,000 options, of which 2,000 vested immediately on issuance, 2,000 were to vest on October 20, 2018 and the remaining 2,000 were to vest on October 20, 2019 at an exercise price of C$12.70 per share. In November 2017, Mr. Campbell received a grant of 2,500 options of which 834 vested immediately on issuance, 833 were to vest on November 30, 2018 and the remaining 833 were to vest on November 30, 2019 at an exercise price of C$11.50 per share. Mr. Campbell's options ceased to be exercisable 120 days after the date on which he ceased to be employed by the Company, i.e. ceased to be exercisable on August 3, 2018.

Incentive Plan Awards

Outstanding Option-Based Awards and Share-Based Awards – The following table sets forth for each Named Executive Officer all awards outstanding at the end of the most recently completed financial year, including awards granted before the most recently completed financial year. Each option grant allows the holder to purchase one of the Company's common shares.

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Name(a)	Option-based Awards				Share-based Awards	
	Number of securities underlying unexercised options (#)(b)	Option exercise price (C$)(c)	Option expiration date(d)	Value of unexercised in-the-money options (C$)(e)(3)	Number of shares or units of shares that have not vested (#)(f)	Market or payout value of share-based awards that have not vested (C$)(g)
Drs. Isa Odidi and Amina Odidi(1)	276,394	U.S.$36.20	Sept. 10, 2020	N/A	N/A	N/A
Dr. Isa Odidi	30,000	32.70	Feb. 16, 2022 Apr. 13. 2020	N/A	N/A	N/A
	7,500	18.10	Feb. 28,	N/A	N/A	N/A
	5,000	42.90	2019	N/A	N/A	N/A
	7,000	25.20	Nov. 30,	N/A	N/A	N/A
	9,000	24.20	2020	N/A	N/A	N/A
	7,000	11.50	Aug. 31, 2021 Nov. 30, 2022	N/A	N/A	N/A
Dr. Amina Odidi	30,000	32.70	Feb. 16, 2022 Apr. 13. 2020	N/A	N/A	N/A
	7,500	18.10	Feb. 28,	N/A	N/A	N/A
	5,000	42.90	2019	N/A	N/A	N/A
	7,000	25.20	Nov. 30,	N/A	N/A	N/A
	9,000	24.20	2020	N/A	N/A	N/A
	7,000	11.50	Aug. 31, 2021 Nov. 30, 2022	N/A	N/A	N/A
John Allport(2)	25,000	32.70	Feb. 16. 2022 Apr. 13, 2020	N/A	N/A	N/A
	2,500	18.10		N/A	N/A	N/A
	5,000	42.90	Feb. 28, 2019	N/A	N/A	N/A
	4,000	25.20		N/A	N/A	N/A
	5,500	24.20	Nov. 30, 2020 Aug. 31, 2021	N/A	N/A	N/A
Andrew Patient(5)	6,000	12.70	Oct. 20, 2027(5)	N/A	N/A	N/A
	1,500	11.50	Nov. 30, 2022(5)			
	10,000	N/A	N/A	N/A	N/A	

Greg Powell(6)	