Intellipharmaceutics International Inc.
Form 424B3
February 26, 2019

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Registration No. 333-227448
and Registration No. 333-227794

PROSPECTUS SUPPLEMENT NO. 16
(To Prospectus dated October 12, 2018)

INTELLIPHARMACEUTICS INTERNATIONAL INC.

Common Shares

This Prospectus Supplement No. 16 (this "Prospectus Supplement") amends and supplements our Prospectus dated October 12, 2018, as previously supplemented (the "Prospectus"), which form a part of our Registration Statement (our "Registration Statement") on Form F-1 (Registration Nos. 333-227448 and 333-227794). This Prospectus Supplement is being filed to update, amend and supplement the information included or incorporated by reference in the Prospectus with the information contained in this Prospectus Supplement. The Prospectus and this Prospectus Supplement relate to the public offering of common shares issuable upon the exercise of warrants, pre-funded warrants and underwriter's warrants issued in the public offering of securities which closed on October 16, 2018.

This Prospectus Supplement includes certain information from our Report on Form 6-K, which was filed with the Securities and Exchange Commission on February 22, 2019.

This Prospectus Supplement should be read in conjunction with the Prospectus, except to the extent that the information in this Prospectus Supplement updates and supersedes the information contained in the Prospectus.

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

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The date of this Prospectus Supplement is February 26, 2019

2018 Year End
Management Discussion and Analysis

MANAGEMENT DISCUSSION AND ANALYSIS
OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS
FOR THE YEAR ENDED NOVEMBER 30, 2018

The following Management Discussion and Analysis ("MD&A") should be read in conjunction with the November 30, 2018 audited consolidated financial statements of Intellipharmaceutics International Inc. The audited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"), as outlined in the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC"). Our accounting policies have the potential to have a significant impact on our audited consolidated financial statements, either due to the significance of the financial statement item to which they relate or because they require judgment and/or estimation due to the uncertainty involved in measuring, at a specific point in time, events which are continuous in nature. The information contained in this document is current in all material respects as of February 22, 2019 unless otherwise noted.

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 document 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 "$" are to the lawful currency of the United States and all references to "C$" are to the lawful currency of Canada. We refer in this document 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 document, all rights to such trademarks are nevertheless reserved. Unless otherwise noted, other trademarks used in this document 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 which became effective on each of The NASDAQ Capital Market ("Nasdaq") and the Toronto Stock Exchange ("TSX") at the open of market on September 14, 2018, (ii) "consolidation" or "share consolidation" are intended to refer to such reverse split, and (iii) "pre-consolidation" and "post-consolidation" are intended to refer to "pre-reverse split" and "post-reverse split", respectively.

FORWARD-LOOKING STATEMENTS

Certain statements in this document constitute "forward-looking statements" within the meaning of the United States Private Securities Litigation Reform Act of 1995 and/or "forward-looking information" under the Securities Act (Ontario). These statements include, without limitation, statements expressed or implied regarding our 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”, “expec “plans”, “plans to”, “anticipates”, “believes”, “estimates”, “predicts”, “confident”, “prospects”, “potential”, “continue”, “intend forward", “could”, “would”, “projected”, “set to”, “goals”, “seeking” or the negative of such terms or other comparable terminology. We made a number of assumptions in the preparation of our forward-looking statements. You should not place undue reliance on our forward-looking statements, which are subject to a multitude of known and unknown risks and uncertainties that could cause actual results, future circumstances or events to differ materially from those stated in or implied by the forward-looking statements.

Risks, uncertainties and other factors that could affect our actual results include, but are not limited to, the effects of general economic conditions, securing and maintaining corporate alliances, our estimates regarding our capital requirements and the effect of capital market conditions and other factors, including the current status of our product development programs, 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 continued listing requirements of the principal markets on which our securities are traded including risks or uncertainties related to our ability to comply with the Nasdaq and 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 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. Other factors that could cause actual results to differ materially include but are not limited to:

the actual or perceived benefits to users of our drug delivery technologies, products and product candidates as compared to others;

our ability to establish and maintain valid and enforceable intellectual property rights in our drug delivery technologies, products and product candidates;

the scope of protection provided by intellectual property 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 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 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 for 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 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. 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.

This discussion should not 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.

CORPORATE DEVELOPMENTS

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 the Toronto Stock Exchange 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.

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 Hearings Panel (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 research and development program of pharmaceutical cannabidiol (“CBD”) based products. As part of this research and development 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 ("DEL") 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:

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.

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 are 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 (the “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 the 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 Pharma L.P., 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.

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 Hearing 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 the Toronto Stock Exchange 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 Securities and Exchange Commission (“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's 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.

BUSINESS OVERVIEW

On October 22, 2009, Intellipharmaceutics Ltd. (“IPC Ltd.”) and Vasogen Inc. (“Vasogen”) completed a court-approved plan of arrangement and merger (the “IPC Arrangement Agreement”), resulting in the formation of the Company, which is incorporated under the laws of Canada and the common shares of which are traded on the Toronto Stock Exchange and Nasdaq.

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 a license and commercialization agreement between Par Pharmaceutical, Inc. (“Par”) and us (as amended on August 12, 2011 and September 24, 2013, the “Par agreement”), 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 LLC ("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 October 2016, we received tentative approval from the FDA for our ANDA for quetiapine fumarate extended-release 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”). 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 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 and launched

Desvenlafaxine extended-release tablets (generic Pristiq®) – Tentative approval received from the FDA

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.

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 research and development (“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 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 active pharmaceutical ingredients ("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

HypermatrixTM

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

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

nPODDDSTM

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.

PODRASTM

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.

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)	Philippines and Vietnamese rights subject to licensing and distribution agreements Intellipharmaceutics and Mallinckrodt (US)
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	Philippines, Malaysian and Vietnamese rights subject to licensing and distribution agreements

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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 the “Business Overview” and the “Other Potential Products and Markets” sections. 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 Pharmaceuticals USA, Inc. 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.

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 (“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.

Metformin hydrochloride – 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 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.

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

In October 2016, we received tentative approval from the FDA for our ANDA for quetiapine fumarate extended-release 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. 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 LLC ("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.

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 Pharma L.P. (“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 (“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 Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book (the "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 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 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 (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 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 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.

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 ("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.

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.

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 research and development program of pharmaceutical cannabidiol, or CBD, based products. As part of this research and development 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.

SELECTED FINANCIAL INFORMATION

	For the years ended		
	November 30, 2018	November 30, 2017	November 30, 2016
	$	$	$
Revenue	1,712,731	5,504,452	2,247,002
Cost of goods sold	124,870	704,006	-
Expenses	14,914,127	13,066,228	12,098,078
Loss from operations	(13,326,266)	(8,265,782)	(9,851,076)
Net loss per common share, basic and diluted	(2.89)	(2.86)	(3.80)
Cash	6,641,877	1,897,061	4,144,424
Total assets	11,474,227	7,396,781	7,974,689
Convertible debentures	1,790,358	1,290,465	1,494,764
Total liabilities	7,371,920	7,010,398	6,858,425
Shareholders' equity	4,102,307	386,383	1,116,264
Total liabilities and shareholders equity	11,474,227	7,396,781	7,974,689

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

We have identified the following accounting policies that we believe require application of management's most significant judgments, often requiring the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods.

Disclosure regarding our ability to continue as a going concern is included in Note 1 to our audited consolidated financial statements for the year ended November 30, 2018.

Use of Estimates

The preparation of the audited consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the year. Actual results could differ from those estimates.

Areas where significant judgment is involved in making estimates are: the determination of the functional currency; the fair values of financial assets and liabilities; the determination of units of accounting for revenue recognition; the accrual of licensing and milestone revenue; and forecasting future cash flows for assessing the going concern assumption.

Revenue recognition

The Company accounts for revenue in accordance with the provisions of ASC topic 605 Revenue Recognition. The Company earns revenue from non-refundable upfront fees, milestone payments upon achievement of specified research or development, exclusivity milestone payments and licensing payments on sales of resulting products. Revenue is realized or realizable and earned when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price to the customer is fixed or determinable, and collectability is reasonably assured. From time to time, the Company enters into transactions that represent multiple-element arrangements. Management evaluates arrangements with multiple deliverables to determine whether the deliverables represent one or more units of accounting for the purpose of revenue recognition.

A delivered item is considered a separate unit of accounting if the delivered item has stand-alone value to the customer, the fair value of any undelivered items can be reliably determined, and the delivery of undelivered items is probable and substantially in the Company's control.

The relevant revenue recognition accounting policy is applied to each separate unit of accounting.

Licensing

The Company recognizes revenue from the licensing of the Company's drug delivery technologies, products and product candidates. Licensing revenue is recognized as earned in accordance with the contract terms when the amounts can be reasonably estimated and collectability is reasonably assured.

The Company has a license and commercialization agreement with Par. Under the exclusive territorial license rights granted to Par, the agreement requires that Par manufacture, promote, market, sell and distribute the product. Licensing revenue amounts receivable by the Company under this agreement are calculated and reported to the Company by Par, with such amounts generally based upon net product sales and net profit which include estimates for chargebacks, rebates, product returns, and other adjustments. Licensing revenue payments received by the Company

from Par under this agreement are not subject to further deductions for chargebacks, rebates, product returns, and other pricing adjustments. Based on this arrangement and the guidance per ASC topic 605, the Company records licensing revenue as earned in the audited consolidated statements of operations and comprehensive loss.

The Company also has a license and commercial supply agreement with Mallinckrodt which provides Mallinckrodt an exclusive license to market sell and distribute in the U.S. three drug product candidates for which the Company has ANDAs filed with the FDA, one of which (the Company's generic Seroquel XR®) received final approval from the FDA in 2017. Under the terms of this agreement, the Company is responsible for the manufacture of approved products for subsequent sale by Mallinckrodt in the U.S. market. Following receipt of final FDA approval for its generic Seroquel XR®, the Company began shipment of manufactured product to Mallinckrodt. Licensing revenue in respect of manufactured product is reported as revenue in accordance with ASC topic 605. Once product is sold by Mallinckrodt, the Company receives downstream licensing revenue amounts calculated and reported by Mallinckrodt, with such amounts generally based upon net product sales and net profit which includes estimates for chargebacks, rebates, product returns, and other adjustments. Such downstream licensing revenue payments received by the Company under this agreement are not subject to further deductions for chargebacks, rebates, product returns, and other pricing adjustments. Based on this agreement and the guidance per ASC topic 605, the Company records licensing revenue as earned in the audited consolidated statements of operations and comprehensive loss.

Milestones

The milestone method recognizes revenue on substantive milestone payments in the period the milestone is achieved. Milestones are considered substantive if all of the following conditions are met: (i) the milestone is commensurate with either the vendor's performance to achieve the milestone or the enhancement of the value of the delivered item or items as a result of a specific outcome resulting from the vendor's performance to achieve the milestone; (ii) the milestone relates solely to past performance; and (iii) the milestone is reasonable relative to all of the deliverables and payment terms within the arrangement. Non-substantive milestone payments that might be paid to the Company based on the passage of time or as a result of a partner's performance are allocated to the units of accounting within the arrangement; they are recognized as revenue in a manner similar to those units of accounting.

Research and development

Under arrangements where the license fees and R&D activities can be accounted for as a separate unit of accounting, non-refundable upfront license fees are deferred and recognized as revenue on a straight-line basis over the expected term of the Company's continued involvement in the R&D process.

Deferred revenue

Deferred revenue represents the funds received from clients, for which the revenues have not yet been earned, as the milestones have not been achieved, or in the case of upfront fees for drug development, where the work remains to be completed. During the year ended November 30, 2016, the Company received an up-front payment of $3,000,000 from Mallinckrodt pursuant to the Mallinckrodt license and commercial supply agreement, and initially recorded it as deferred revenue, as it did not meet the criteria for recognition. For the year ended November 30, 2018, the Company recognized $300,000 (2017 - $300,000) of revenue based on a straight-line basis over the expected term of the Mallinckrodt agreement of 10 years. In 2015, the Company received an up-front payment of $150,000 from Teva Pharmaceuticals USA, Inc. which the Company recognized as revenue during the year ended November 30, 2017. As of November 30, 2018, the Company has recorded a deferred revenue balance of $2,362,500 (November 30, 2017 - $2,662,500) relating to the underlying contracts, of which $300,000 (November 30, 2017 - $300,000) is considered a current portion of deferred revenue.

Research and development costs

Research and development costs related to continued R&D programs are expensed as incurred in accordance with ASC topic 730. However, materials and equipment are capitalized and amortized over their useful lives if they have alternative future uses.

Inventory

Inventories comprise raw materials, work in process, and finished goods, which are valued at the lower of cost or market, on a first-in, first-out basis. Cost for work in process and finished goods inventories includes materials, direct labor, and an allocation of manufacturing overhead. Market for raw materials is replacement cost, and for work in process and finished goods is net realizable value. The Company evaluates the carrying value of inventories on a regular basis, taking into account such factors as historical and anticipated future sales compared with quantities on hand, the price the Company expects to obtain for products in their respective markets compared with historical cost and the remaining shelf life of goods on hand. As of November 30, 2018, the Company had raw materials inventories of $144,659 (2017 - $115,667), work in process of $73,927 (2017 - $Nil) and finished goods inventory of $33,065 (2017 - $Nil) relating to the Company's generic Seroquel XR® product. The recoverability of the cost of any pre-launch inventories with a limited shelf life is evaluated based on the specific facts and circumstances surrounding

the timing of the anticipated product launch.

Translation of foreign currencies

Transactions denominated in currencies other than the Company and its wholly owned operating subsidiaries' functional currencies, the monetary assets and liabilities are translated at the period end rates. Revenue and expenses are translated at rates of exchange prevailing on the transaction dates. All of the exchange gains or losses resulting from these other transactions are recognized in the audited consolidated statements of operations and comprehensive loss.

The Company's functional and reporting currency is the U.S. dollar.

Convertible debentures

In fiscal 2013, the Company issued an unsecured convertible debenture in the principal amount of $1.5 million (the "2013 Debenture"). At issuance, the conversion option was bifurcated from its host contract and the fair value of the conversion option was characterized as an embedded derivative upon issuance as it met the criteria of ASC topic 815 Derivatives and Hedging. Subsequent changes in the fair value of the embedded derivative were recorded in the consolidated statements of operations and comprehensive loss. The proceeds received from the 2013 Debenture less the initial amount allocated to the embedded derivative were allocated to the liability and were accreted over the life of the 2013 Debenture using the imputed rate of interest. The Company changed its functional currency effective December 1, 2013 such that the conversion option no longer met the criteria for bifurcation and was prospectively reclassified to shareholders' equity under ASC Topic 815 at the U.S. dollar translated amount at December 1, 2013.

On September 10, 2018, the Company completed a private placement financing of an unsecured convertible debenture in the principal amount of $0.5 million (the "2018 Debenture"). At issuance, the conversion price was lower than the market share price, and the value of the beneficial conversion feature related to the 2018 Debenture was allocated to shareholders' equity.

Investment tax credits

The investment tax credits (“ITC") receivable are amounts considered recoverable from the Canadian federal and provincial governments under the Scientific Research & Experimental Development (“SR&ED”) incentive program. The amounts claimed under the program represent the amounts based on management estimates of eligible research and development costs incurred during the year. Realization is subject to government approval. Any adjustment to the amounts claimed will be recognized in the year in which the adjustment occurs. Refundable ITCs claimed relating to capital expenditures are credited to property and equipment. Refundable ITCs claimed relating to current expenditures are netted against research and development expenditures.

Recently adopted accounting pronouncements

In August 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update (“ASU”) No. 2016-15, Statement of Cash Flows (Topic 230) Classification of Certain Cash Receipts and Cash Payments, which makes eight targeted changes to how cash receipts and cash payments are presented and classified in the Statement of Cash Flows. ASU 2016-15 became effective on May 1, 2018. The Company adopted ASU 2016-15 and the amendments did not have any material impact on the Company’s financial position, results of operations, cash flows or disclosures.

Future accounting pronouncements

In May 2014, the FASB issued ASU No. 2014-09 (“Topic 606”), Revenue from Contracts with Customers, requiring an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The updated standard will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. In March 2016, the FASB issued ASU No. 2016-08 to clarify the implementation guidance on considerations of whether an entity is a principal or an agent, impacting whether an entity reports revenue on a gross or net basis. In April 2016, the FASB issued ASU No. 2016-10 to clarify guidance on identifying performance obligations and the implementation guidance on licensing. In May 2016, the FASB issued amendments ASU No. 2016-11 and 2016-12 to amend certain aspects of the new revenue guidance (including transition, collectability, noncash consideration and the presentation of sales and other similar taxes) and provided certain practical expedients. The guidance is effective for annual reporting periods beginning after December 15, 2017 (including interim reporting periods). Early adoption is permitted but not before the annual reporting period (and interim reporting period) beginning January 1, 2017. Entities have the option of using either a full retrospective or a modified approach to adopt the guidance. The Company anticipates that the adoption of Topic 606 will not have a material impact on the Company’s financial position, results of operations, and cash flows.

In January 2016, the FASB issued ASU No. 2016-01, which makes limited amendments to the guidance in U.S. GAAP on the classification and measurement of financial instruments. The new standard significantly revises an entity’s accounting related to (1) the classification and measurement of investments in equity securities and (2) the presentation of certain fair value changes for financial liabilities measured at fair value. It also amends certain disclosure requirements associated with the fair value of financial instruments. ASU No. 2016-01 is effective for fiscal years beginning after December 15, 2017, and interim periods within those annual periods. The Company anticipates that the adoption of this standard will not have a material impact on the Company’s financial position, results of operations, and cash flows.

In February 2016, the FASB issued new guidance, ASU No. 2016-02, Leases (Topic 842). The main difference between current U.S. GAAP and the new guidance is the recognition of lease liabilities based on the present value of remaining lease payments and corresponding lease assets for operating leases under current U.S. GAAP with limited exception. Additional qualitative and quantitative disclosures are also required by the new guidance. Topic 842 is

effective for annual reporting periods (including interim reporting periods) beginning after December 15, 2018. Early adoption is permitted. The Company is in the process of evaluating the amendments to determine if they have a material impact on the Company's financial position, results of operations, cash flows or disclosures.

In August 2016, the FASB issued ASU 2017-01 that changes the definition of a business to assist entities with evaluating when a set of transferred assets and activities is a business. The guidance requires an entity to evaluate if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets; if so, the set of transferred assets and activities is not a business. ASU 2017-01 also requires a business to include at least one substantive process and narrows the definition of outputs by more closely aligning it with how outputs are described in ASC 606.1. ASU 2017-01 is effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those years. Early adoption is permitted. The Company does not expect the adoption of the amendments to have a material impact on the Company's financial position, results of operations, cash flows or disclosures.

In May 2017, the FASB issued ASU 2017-09 in relation to Compensation —Stock Compensation (Topic 718), Modification Accounting. The amendments provide guidance on changes to the terms or conditions of a share-based payment award, which require an entity to apply modification accounting in Topic 718. The amendments are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period, for (1) public business entities for reporting periods for which financial statements have not yet been issued and (2) all other entities for reporting periods for which financial statements have not yet been made available for issuance. The amendments should be applied prospectively to an award modified on or after the adoption date. The Company does not expect the adoption of the amendments to have a material impact on the Company's financial position, results of operations, cash flows or disclosures.

RESULTS OF OPERATIONS

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.

	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:							