

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of February 2020.

Commission File Number: 000-53805

**Intellipharmaeueuties International Inc.**  
(Translation of registrant's name into English)

**30 WORCESTER ROAD TORONTO, ONTARIO M9W 5X2**  
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F. Form 20-F [ x ] Form 40-F [ ]

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): \_\_\_\_

**Note:** Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): \_\_\_\_

Note: Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's "home country"), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

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**EXHIBIT LIST**

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Exhibit	Description
99.1	Annual Information Form
99.2	Form 52-109F1 - Chief Executive Officer
99.3	Form 52-109F1 - Chief Financial Officer

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**Intellipharmaceutics International Inc.**

(Registrant)

**/s/ Greg Powell**

Greg Powell

*Chief Financial Officer*

Date: February 28, 2020

**ANNUAL INFORMATION FORM**

**INTELLIPHARMACEUTICS INTERNATIONAL INC.  
30 Worcester Road  
Toronto, Ontario  
M9W 5X2  
CANADA**

**Tel: (416) 798-3001  
Fax: (416) 798-3007**

**February 28, 2020**

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INTELLIPHARMACEUTICS INTERNATIONAL INC.

ANNUAL INFORMATION FORM  
For the Fiscal Year Ended November 30, 2019

REFERENCE INFORMATION

In this annual information form, unless the context otherwise requires, the terms “we”, “us”, “our”, “Intellipharmaceutics” and the “Company” refer to Intellipharmaceutics International Inc. and its subsidiaries.

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.

Any reference in this annual information form 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.

In this annual information form, we refer to information regarding potential markets for our products, product candidates and other industry data. We believe that all such information has been obtained from reliable sources that are customarily relied upon by companies in our industry. However, we have not independently verified any such information.

We initially named our oxycodone hydrochloride extended-release tablets (“Oxycodone ER”) “Rexista™,” but later changed the name of our product candidate to “Aximris™” as the FDA did not approve the proposed name “Rexista”. References in this prospectus, any prospectus supplement, and/or the documents incorporated by reference herein or therein to Oxycodone ER, Rexista™ or Aximris™ are intended to refer to our oxycodone hydrochloride extended release tablets product candidate.

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

FORWARD-LOOKING INFORMATION

Certain statements in this annual information form constitute “forward-looking statements” within the meaning of the United States Private Securities Litigation Reform Act of 1995 and/or “forward-looking information” under the Securities Act (Ontario). These statements include, without limitation, statements expressed or implied regarding our expectations, plans, goals and milestones, status of developments or expenditures relating to our business, plans to fund our current activities, and statements concerning our partnering activities, health regulatory submissions, strategy, future operations, future financial position, future sales, revenues and profitability, projected costs and market penetration. In some cases, you can identify forward-looking statements by terminology such as “appear”, “unlikely”, “target”, “may”, “will”, “should”, “expects”, “plans”, “plans to”, “anticipates”, “believes”, “estimates”, “predicts”, “confident”, “prospects”, “potential”, “continue”, “intends”, “look forward”, “could”, “would”, “projected”, “goals”, “set to”, “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 OTCQB tier of the OTC Markets Group (“OTCQB”) and the Toronto Stock Exchange (“TSX”) continued listing standards, our programs regarding research, development and commercialization of our product candidates, the timing of such programs,

the timing, costs and uncertainties regarding obtaining regulatory approvals to market our product candidates and the difficulty in predicting the timing and results of any product launches, the timing and amount of profit-share payments from our commercial partners, and the timing and amount of any available investment tax credits, the actual or perceived benefits to users of our drug delivery technologies, products and product candidates as compared to others, our ability to establish and maintain valid and enforceable intellectual property rights in our drug delivery technologies, products and product candidates, the scope of protection provided by intellectual property rights for our drug delivery technologies, products and product candidates, recent and future legal developments in the United States and elsewhere that could make it more difficult and costly for us to obtain regulatory approvals for our product candidates and negatively affect the prices we may charge, increased public awareness and government scrutiny of the problems associated with the potential for abuse of opioid based medications, pursuing growth through international operations could strain our resources, our limited manufacturing, sales, marketing or distribution capability and our reliance on third parties for such, the actual size of the potential markets for any of our products and product candidates compared to our market estimates, our selection and licensing of products and product candidates, our ability to attract distributors and/or commercial partners with the ability to fund patent litigation and with acceptable product development, regulatory and commercialization expertise and the benefits to be derived from such collaborative efforts, sources of revenues and anticipated revenues, including contributions from distributors and commercial partners, product sales, license agreements and other collaborative efforts for the development and commercialization of product candidates, our ability to create an effective direct sales and marketing infrastructure for products we elect to market and sell directly, the rate and degree of market acceptance of our products, delays in product approvals that may be caused by changing regulatory requirements, the difficulty in predicting the timing of regulatory approval and launch of competitive products, the difficulty in predicting the impact of competitive products on sales volume, pricing, rebates and other allowances, the number of competitive product entries, and the nature and extent of any aggressive pricing and rebate activities that may follow, the inability to forecast wholesaler demand and/or wholesaler buying patterns, seasonal fluctuations in the number of prescriptions written for our generic Focalin XR® capsules, which may produce substantial fluctuations in revenue, the timing and amount of insurance reimbursement regarding our products, changes in laws and regulations affecting the conditions required by the United States Food and Drug Administration (“**FDA**”) for approval, testing and labeling of drugs including abuse or overdose deterrent properties, and changes affecting how opioids are regulated and prescribed by physicians, changes in laws and regulations, including Medicare and Medicaid, affecting among other things, pricing and reimbursement of pharmaceutical products, the effect of recent changes in U.S. federal income tax laws, including but not limited to, limitations on the deductibility of business interest, limitations on the use of net operating losses and application of the base erosion minimum tax, on our U.S. corporate income tax burden, the success and pricing of other competing therapies that may become available, our ability to retain and hire qualified employees, the availability and pricing of third-party sourced products and materials, challenges related to the development, commercialization, technology transfer, scale-up, and/or process validation of manufacturing processes for our products or product candidates, the manufacturing capacity of third-party manufacturers that we may use for our products, potential product liability risks, the recoverability of the cost of any pre-launch inventory, should a planned product launch encounter a denial or delay of approval by regulatory bodies, a delay in commercialization, or other potential issues, the successful compliance with FDA, Health Canada and other governmental regulations applicable to us and our third party manufacturers’ facilities, products and/or businesses, our reliance on commercial partners, and any future commercial partners, to market and commercialize our products and, if approved, our product candidates, difficulties, delays, or changes in the FDA approval process or test criteria for Abbreviated New Drug Applications (“**ANDAs**”) and New Drug Applications (“**NDAs**”), challenges in securing final FDA approval for our product candidates, including our oxycodone hydrochloride extended release tablets (“**Oxycodone ER**”) product candidate, in particular, if a patent infringement suit is filed against us with respect to any particular product candidates (such as in the case of Oxycodone ER), which could delay the FDA’s final approval of such product candidates, healthcare reform measures that could hinder or prevent the commercial success of our products and product candidates, the risk that the FDA may not approve requested product labeling for our product candidate(s) having abuse-deterrent properties and targeting common forms of abuse (oral, intra-nasal and intravenous), risks associated with cyber-security and the potential 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 the “Risk Factors” section of this annual information form as well as in our reports, public disclosure documents and other filings with the securities commissions and other regulatory bodies in Canada and the U.S., which are available on [www.sedar.com](http://www.sedar.com) and [www.sec.gov](http://www.sec.gov). The forward-looking statements reflect our current views with respect to future events, and are based on what we believe are reasonable assumptions as of the date of this annual information form and we disclaim any intention and have no obligation or responsibility, except as required by law, to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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

#### TRADEMARKS

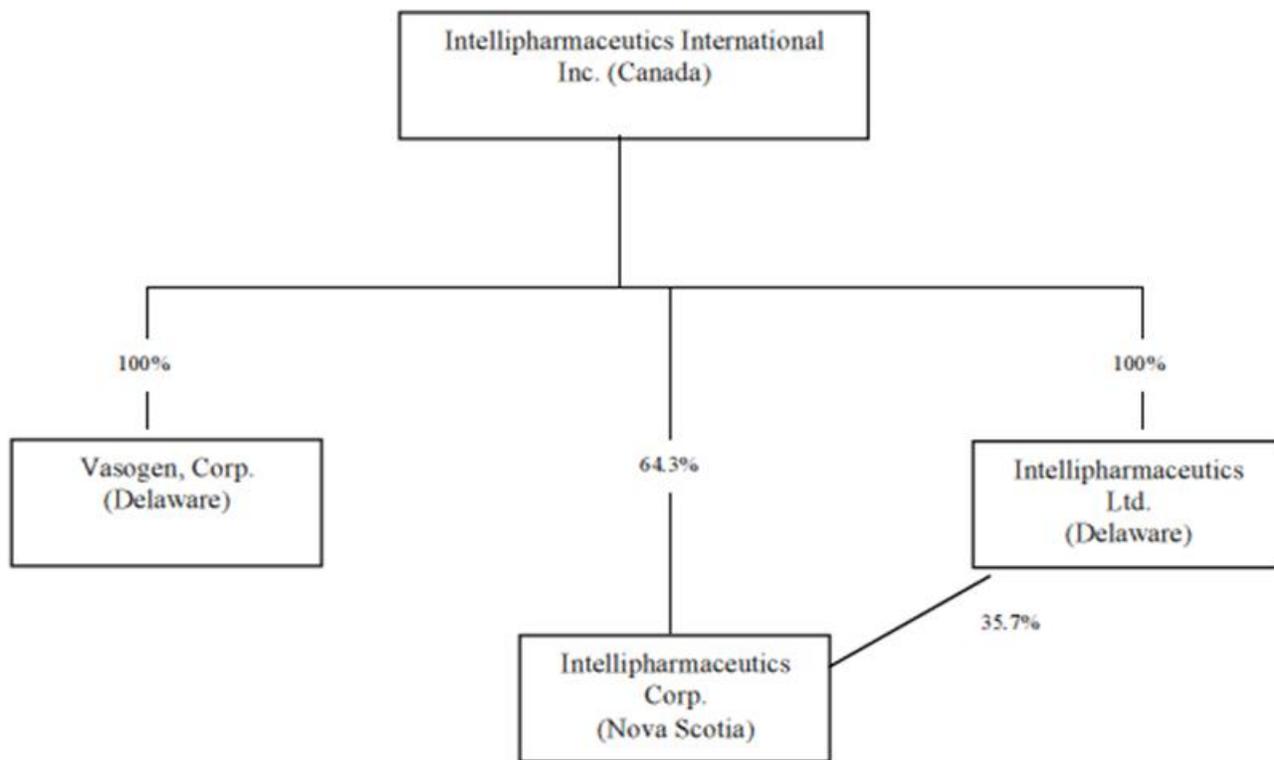
Intellipharmaceutics™, Hypermatrix™, Drug Delivery Engine™, IntelliFoam™, IntelliGITransporter™, IntelliMatrix™, IntelliOsmotics™, IntelliPaste™, IntelliPellets™, IntelliShuttle™, nPODDDS™, PODRAS™, Regabatin™ and Aximris XR™ are our trademarks. These trademarks are important to our business. Although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

We initially named our oxycodone hydrochloride extended-release tablets (“Oxycodone ER”) “Rexista™,” but later changed the name of our product candidate to “Aximris XR™” as the FDA did not approve the proposed name “Rexista”. References in this Annual information Form, and/or the documents incorporated by reference herein or therein to Oxycodone ER, Rexista™ or Aximris XR™ are intended to refer to our oxycodone hydrochloride extended release tablets product candidate.

#### CORPORATE STRUCTURE

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

The following chart shows the corporate relationship structure of Intellipharmaceutics and its three wholly-owned subsidiaries, including jurisdictions of incorporation, as at November 30, 2019.



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

We are currently a “reporting issuer” in all of the provinces and territories of Canada.

Our website is [www.intellipharma.com](http://www.intellipharma.com). Any information contained on our website is not, and will be deemed not to be, incorporated herein by reference.

#### GENERAL DEVELOPMENT OF THE BUSINESS

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.

## Overview of Recent Corporate Developments

On February 5, 2020, we announced the resignation of Greg Powell, our Chief Financial Officer, for personal and family reasons. Mr. Powell has agreed to continue to offer his services to us through March 4, 2020 and is willing to continue thereafter on a consulting basis on mutually agreeable terms. Pending the hiring of a replacement for Mr. Powell, the functions of Chief Financial Officer for us will be carried out by our President and former Chief Financial Officer, Dr. Amina Odidi. Fazayill Shaideen, who has been our Controller for the past 8 years, will continue to handle accounting activities.

On January 15, 2020, at a joint meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and Drug Safety and Risk Management Advisory Committee ("Advisory Committees") of the U.S. Food and Drug Administration ("FDA") to discuss our New Drug Application ("NDA") for Aximris XR™, abuse-deterrent oxycodone hydrochloride extended-release tablets, the Advisory Committees voted 24 to 2 against the approval of our NDA for Aximris XR™ for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The FDA will take action on our application after completion of their review of the NDA.

On November 25, 2019, we announced that we had entered into a license and commercial supply agreement with Tris Pharma, Inc. ("Tris"), by which we granted Tris an exclusive license to market, sell and distribute in the United States, Venlafaxine ER in the 37.5, 75, and 150 mg strengths (the "licensed products") approved for sale in the US market by the FDA. Several other generic versions of the licensed products are currently available in the market.

On November 15, 2019, we issued to Drs. Isa and Amina Odidi, by way of a private placement, an unsecured convertible debenture of the Company in consideration for, and in the aggregate principal amount of, USD\$250,000 (the "November 2019 Debenture"). The principal amount owing under the November 2019 Debenture is convertible at any time and from time to time into Common Shares at a conversion price equal to U.S. \$0.12 per Common Share. Up to an aggregate of 2,083,333 Common Shares may be issued upon conversion of the principal amount owing under the November 2019 Debenture, representing approximately 9.43% of the issued and outstanding Common Shares. The November 2019 Debenture bears interest at a rate of 12% per annum (calculated monthly) and, subject to our right to prepay the November 2019 Debenture in whole or in part at any time without penalty, and matures on December 31, 2019. Effective January 31, 2020, the December 31, 2019 maturity date was extended to March 31, 2020. We used the proceeds from the November 2019 Debenture for working capital and general corporate purposes. Dr. Isa Odidi is our Chairman, Chief Executive Officer and Co-Chief Scientific Officer, and Dr. Amina Odidi is our President, Chief Operating Officer and Co-Chief Scientific Officer.

On November 7, 2019, we announced that the parties in *Shanawaz v. Intellipharmaceutics International, Inc. et al.* case No. 1:17-cv-05761-JPO., an action pending in the Southern District of New York asserting claims under the U.S. federal securities laws on behalf of an alleged class of investors in Intellipharmaceutics Common Shares against us, our chief executive officer, Dr. Isa Odidi, who is also a member of our board of directors, and our former chief financial officer, Domenic Della Penna, had entered into a stipulation of settlement to resolve all claims asserted in the action. The settlement is subject to the approval of the court following notice to class members. The stipulation of settlement provides for a settlement payment of US\$1.6 million, which we anticipate will be funded by available insurance. As part of the settlement, we also agreed to contribute to the settlement fund specific anticipated Canadian tax refunds of up to US\$400,000 to the extent received within 18 months after the entry of final judgment. The stipulation acknowledges that we and the other defendants continue to deny that they committed any violation of the U.S. securities laws or engaged in any other wrongdoing and that they are entering into the settlement at this time based on the burden, expense, and inherent uncertainty of continuing the litigation. If the stipulation of settlement is not approved or otherwise fails to become effective, then the parties will be returned to their respective positions in the litigation as of August 9, 2019.

On October 4, 2019 we announced that following the filing of a bankruptcy stay by Purdue Pharma L.P., our ongoing litigation cases, number 1:17-cv-00392-RGA and 1:18-cv-00404-RGA-SRF between Purdue Pharma L.P. et al and Intellipharmaceutics, originally scheduled to begin on November 12, 2019, had been stayed and the trial dates in both cases had been vacated by orders issued in each case by the judge in the District of Delaware on October 3, 2019. No new dates were given for reinstatement; however, the parties are required to provide a further status report to the judge in each case no later than March 13, 2020. The previous 30-month stay date of March 2, 2020, remains unchanged at this time, absent a further order of the judge.

On September 30, 2019, pursuant to an Abbreviated New Drug Application ("ANDA") Sale Agreement (the "Levetiracetam ANDA Agreement") we sold all of the assets relating to our ANDA for Levetiracetam extended-release tablets 500mg and 750 mg (the "Levetiracetam ANDA") to the ANDA Repository, LLC (the "Levetiracetam ANDA Purchaser") in exchange for a purchase price of \$1.00. Additionally, pursuant to the Levetiracetam ANDA Agreement, we agreed to pay the Levetiracetam ANDA Purchaser an annual fee for each fiscal year, equal to 50% of the difference between the FDA Program Fee tier for 6 to 19 approved ANDAs and the FDA Program Fee tier for 1 to 5 approved ANDAs. Under the Levetiracetam ANDA Agreement, we have the option to repurchase at any time the Transferred Levetiracetam ANDA for a purchase price of \$1.

On September 5, 2019, we announced we had entered into a license and commercial supply agreement with Tris Pharma Inc. (Tris), by which we granted Tris an exclusive license to market, sell and distribute in the United States, Desvenlafaxine Succinate ER in the 50 and 100 mg strengths approved for sale in the U.S. market by the FDA.

On August 15, 2019, we announced we had entered into a license and commercial supply agreement with Tris, by which we granted Tris an exclusive license to market, sell and distribute in the United States, Quetiapine ER in the 50, 150, 200, 300 and 400 mg strengths approved for sale in the U.S. market by the FDA.

On July 24, 2019, we announced that the Company has been advised by the FDA that the FDA "is postponing product-specific advisory committee meetings for opioid analgesics," including the one previously scheduled to discuss the Company's NDA, "while it continues to consider a number of scientific and policy issues relating to this class of drugs." According to the FDA, the reason for the postponement is not unique to our Product and the Anesthetic and Analgesic Drug products Advisory Committee ("AADPAC") meeting earlier planned by the FDA, to discuss our NDA will be rescheduled at a future date. The FDA informed the Company that it would continue to review the Company's NDA according to the existing Prescription Drug User Fee Act ("PDUFA") timeline, but noted that, due to the postponement of the AADPAC meeting, it is possible that the FDA may be unable to meet the PDUFA goal date of August 28, 2019. The FDA did not meet the goal date of August 28, 2019, and the Company is awaiting to hear back from the FDA for an Advisory Committee meeting date and a new PDUFA goal date.

On July 8, 2019, we announced that the Company has obtained an equity financing commitment of up to \$10,000,000 from Silverback Capital Corporation, a private investment firm. The Company has not used this commitment and is exploring terminating it.

On May 30, 2019, we announced that our pre-existing license to conduct activities with cannabidiol ("CBD") has been migrated by Health Canada to a Cannabis Drug License ("CDL") under the Cannabis Regulations. Intellipharma's new CDL allows the Company to continue to possess cannabis, produce a drug containing cannabis and sell a drug containing cannabis. The CDL is unique from other forms of cannabis licenses in Canada as, according to Health Canada, it is a requirement for any company that intends to produce and sell a prescription drug containing cannabis or cannabinoids.

On May 10, 2019, we announced that we had received approval from the FDA for our ANDA for desvenlafaxine extended-release tablets in the 50 and 100 mg strengths. The approved product is a generic equivalent of the branded product Pristiq®. Desvenlafaxine extended-release tablets are a serotonin and norepinephrine reuptake inhibitor ("SNRI") indicated for the treatment of major depressive disorder ("MDD").

On April 12, 2019, we and Mallinckrodt LLC ("Mallinckrodt") mutually agreed to terminate our license and commercial supply agreement with Mallinckrodt. Effective August 12, 2019 the Mallinckrodt agreement was terminated.

On April 4, 2019, a tentative approval from TSX was received for a proposed refinancing of the 2013 Debenture subject to certain conditions being met. As a result of the proposed refinancing, the principal amount owing under the 2013 Debenture was refinanced by a new debenture (the “2019 Debenture”). On May 1, 2019, the 2019 Debenture was issued with a principal amount of \$1,050,000, that will mature on November 1, 2019, bear interest at a rate of 12% per annum and be convertible into 1,779,661 common shares of the Company at a conversion price of \$0.59 per common share. Dr. Isa Odidi and Dr. Amina Odidi, who are shareholders, directors, and executive officers of the Company, are the holders of the 2019 Debenture.

On August 26, 2019, the Company issued an unsecured convertible debenture in the principal amount of \$140,800 (the “August 2019 Debenture”). At issuance, the conversion price was lower than the market share price, and the value of the beneficial conversion feature related to the August 2019 Debenture was allocated to Additional paid-in capital in the consolidated statements of shareholders’ equity (deficiency). In November 2019, the debt was paid in full.

As more fully described below (under the heading “Nasdaq Delisting and OTCQB Quotation”), in March 2019, a Nasdaq Hearings Panel (the “Nasdaq Panel”) determined to delist our Common Shares from Nasdaq based upon our non-compliance with the \$1.00 minimum bid price requirement, as set forth in Nasdaq Listing Rule 5550(a)(2). The suspension of trading on Nasdaq took effect at the open of business on March 21, 2019. Our shares began trading on the OTCQB, which is operated by OTC Markets Group Inc., commencing on March 21, 2019. Our Common Shares are also listed on the Toronto Stock Exchange and our non-compliance with Nasdaq’s bid price requirement did not impact our listing or trading status on that exchange.

On February 21, 2019, we and our CEO, Dr. Isa Odidi, were served with a Statement of Claim filed in the Superior Court of Justice of Ontario for a proposed class action under the Ontario Class Proceedings Act. The action was brought by Victor Romita, the proposed representative plaintiff, on behalf of a class of Canadian persons who traded Common Shares during the period from February 29, 2016 to July 26, 2017. The Statement of Claim, under the caption Victor Romita v. Intellipharmaceuticals International Inc. and Isa Odidi, asserted that the defendants knowingly or negligently made certain public statements during the relevant period that contained or omitted material facts concerning Oxycodone ER abuse-deterrent oxycodone hydrochloride extended release tablets. The plaintiff alleged that he and the class suffered loss and damages as a result of their trading in our shares during the relevant period. The plaintiff seeks, among other remedies, unspecified damages, legal fees and court and other costs as the Court may permit. On February 26, 2019, the plaintiff delivered a Notice of Motion seeking the required approval from the Court, in accordance with procedure under the Ontario Securities Act, to allow the statutory claims under the Ontario Securities Act to proceed with respect to the claims based upon the acquisition or disposition of our shares on the TSX during the relevant period. On June 28, 2019, the Court endorsed a timetable for the exchange of material leading to the hearing of the Motion scheduled for January 27-28, 2020. On October 28, 2019, plaintiff’s counsel advised the court that the Plaintiff intended to amend his claim and could not proceed with the Leave Motion scheduled for January 27-28, 2020. As such the court released those dates. On January 28, 2020 the Plaintiff served a Motion to amend the Statement of Claim (“Amendment Motion”). The proposed Fresh as Amended Statement of Claim purports, among other things, to include common law claims for misrepresentation and add an additional representative plaintiff. The plaintiff’s Amendment Motion has been scheduled for April 21, 2020. The hearing of the Leave Motion has not yet been rescheduled and no date has been set for the hearing of the certification application. The defendants intend to vigorously defend the action and have filed a Notice of Intent to Defend.

On October 7, 2019, a complaint was filed in the U.S. District Court for the Southern District of New York by Alpha Capital Anstalt (“Alpha”) against the Company, two of its existing officers and directors and its former Chief Financial Officer. In the complaint, Alpha alleges that the Company and the executive officers/directors named in the complaint violated Sections 11, 12(a)(2) and 15 of the U.S. Securities Act by allegedly making false and misleading statements in the Company’s Registration Statement on Form F-1 filed with the U.S. Securities and Exchange Commission on September 20, 2018, as amended by failing to disclose certain information regarding the resignation of the Company’s then Chief Financial Officer, which was announced several weeks after such registration statement was declared effective. In the complaint Alpha seeks unspecified damages, rescission of its purchase of the Company’s securities in the relevant offering, attorneys’ fees and other costs and further relief as the court may find just and proper. On December 12, 2019, the Company and the other defendants in the action filed a motion to dismiss for failure to state a claim. The Plaintiff filed an opposition to that motion on February 4, 2020 and briefing is scheduled to be complete on March 6, 2020 if they are served in the action. The Company and other defendants intend to vigorously defend against the allegations set forth in the complaint. However, there can be no assurance that the case can be resolved in the Company’s favor.

## History

On October 19, 2009, the shareholders of Intellipharmaceutics Ltd. (“**IPC Ltd.**”) and Vasogen Inc. (“**Vasogen**”) approved a court-approved plan of arrangement and merger (the “**IPC Arrangement Agreement**”) that resulted in the October 22, 2009 combination of IPC Ltd. and Intellipharmaceutics Corp. with 7231971 Canada Inc., a new Vasogen company that acquired substantially all of the assets and certain liabilities of Vasogen, including the proceeds from its non-dilutive financing transaction with Cervus LP (the “**IPC Arrangement Transaction**”). The completion of the IPC Arrangement Transaction on October 22, 2009 resulted in the formation of the Company, which is incorporated under the laws of Canada. The common shares of the Company are traded on the TSX and Nasdaq up to March 21, 2019 when the Company was delisted from the Nasdaq, the shares are currently trading on the TSX and OTCQB.

## Nasdaq Delisting and OTCQB Quotation

In March 2019, we received formal notice that the Nasdaq Panel had determined to delist our shares from Nasdaq based upon our non-compliance with the \$1.00 bid price requirement, as set forth in Nasdaq Listing Rule 5550(a)(2). The suspension of trading on Nasdaq took effect at the open of business on March 21, 2019. Our shares began trading on the OTCQB under the symbol “IPCIF”, commencing on March 21, 2019. Our shares also are listed on the TSX under the symbol “IPCI” and our non-compliance with Nasdaq’s requirements did not impact our listing or trading status on that exchange.

## Our Strategy

Our Hypermatrix™ technologies are central to the development and manufacture of novel and generic controlled-release and targeted-release oral solid dosage drugs. The Hypermatrix™ technologies are a multidimensional controlled-release drug delivery platform that we believe can be applied to the efficient development of a wide range of existing and new pharmaceuticals. We believe that the flexibility of these technologies allows us to develop complex drug delivery solutions within an industry-competitive timeframe. Based on this technology platform, we have developed several drug delivery systems and a pipeline of products (some of which have received FDA approval) and product candidates in various stages of development, including ANDAs filed with the FDA (and one ANDS filed with Health Canada) and one NDA filing, in therapeutic areas that include neurology, cardiovascular, GIT, diabetes and pain. We expect that certain, but not all, of the products in our pipeline may be developed from time to time for third parties pursuant to drug development agreements with those third parties, under which our commercialization partner may pay certain of the expenses of development, make certain milestone payments to us and receive a share of revenues or profits if the drug is developed successfully to completion, the control of which would generally be in the discretion of our drug development partner.

The principal focus of our development activities previously targeted difficult-to-develop controlled-release generic drugs which follow an ANDA regulatory path. Our current development effort is increasingly directed towards improved difficult-to-develop controlled-release drugs which follow an NDA 505(b)(2) regulatory pathway. We have increased our R&D emphasis towards specialty new product development, facilitated by the 505(b)(2) regulatory pathway, by advancing the product development program for both Oxycodone ER and Regabatin™. In January 2019, we announced that we had commenced an R&D program of CBD-based products. As part of this R&D program, we filed provisional patent applications with the United States Patent and Trademark Office pertaining to the delivery and application of cannabinoid-based therapeutics, began talks with potential commercialization partners in the cannabidiol industry, and identified a potential supplier of CBD. We hold a Health Canada DEL and a dealer’s license under the 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. 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 PODRAS™ delivery technology platform was designed to prevent an overdose when more pills than prescribed are swallowed intact. Preclinical studies of prototypes of oxycodone with PODRAS™ technology suggest that, unlike other third-party abuse-deterrent oxycodone products in the marketplace, if more tablets than prescribed are deliberately or inadvertently swallowed, the amount of drug active ingredient (“drug active”) released over 24 hours may be substantially less than expected. However, if the prescribed number of pills is swallowed, the drug release should be as expected. Certain aspects of our PODRAS™ technology are covered by U.S. Patent Nos. 9,522,119, 9,700,515, 9,700,516 and 9,801,939 and Canadian Patent No. 2,910,865 issued by the U.S. Patent and Trademark Office and the Canadian Intellectual Property Office in respect of “Compositions and Methods for Reducing Overdose” in December 2016, July 2017 and October 2017, respectively. The issuance of these patents provides us with the opportunity to accelerate our PODRAS™ development plan by pursuing proof of concept studies in humans. We intend to incorporate this technology in future product candidates, including Oxycodone ER and other similar pain products, as well as pursuing out-licensing opportunities. The Company started 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**

### ***Hypermatrix™***

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

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

### ***nPODDDS™***

In addition to continuing efforts with Hypermatrix™ as a core technology, our scientists continue to pursue novel research activities that address unmet needs. Oxycodone ER (abuse deterrent oxycodone hydrochloride extended release tablets) is an NDA candidate, with a unique long acting oral formulation of oxycodone intended to treat moderate-to-severe pain. The formulation is intended to present a significant barrier to tampering when subjected to various forms of physical and chemical manipulation commonly used by abusers. It is also designed to prevent dose dumping when inadvertently co-administered with alcohol. The technology that supports our abuse deterrent formulation of oxycodone is the nPODDDS™ Point of Divergence Drug Delivery System. The use of nPODDDS™ does not interfere with the bioavailability of oxycodone. We intend to apply the nPODDDS™ technology platforms to other extended release opioid drug candidates (e.g., oxymorphone, hydrocodone, hydromorphone and morphine) utilizing the 505(b)(2) regulatory pathway.

### ***PODRAS™***

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

In December 2016, July 2017 and October 2017, U.S. Patent Nos. 9,522,119, 9,700,515, 9,700,516 and 9,801,939 and Canadian Patent No. 2,910,865 were issued by the U.S. Patent and Trademark Office and the Canadian Intellectual Property Office in respect of “Compositions and Methods for Reducing Overdose”. The issued patents cover aspects of the PODRAS™ delivery technology. The issuance of these patents represents a significant advance in our abuse deterrence technology platform. The PODRAS™ platform has the potential to positively differentiate our technology from others of which we are aware, and may represent an important step toward addressing the FDA’s concern over the ingestion of a number of intact pills or tablets. In addition to its use with opioids, the PODRAS™ 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., oxycodone, hydrocodone, hydromorphone and morphine) utilizing the 505(b)(2) regulatory pathway.

### **The Hypermatrix™ Family of Technologies**

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

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

#### ***IntelliFoam™***

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

#### ***IntelliGITransporter™***

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

#### ***IntelliMatrix™***

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

### ***IntelliOsmotics™***

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

### ***IntelliPaste™***

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

### ***IntelliPellets™***

The IntelliPellets™ technology consists of one or more type (population) of granule, bead, pellet, or tablet in a holding chamber or reservoir, such as a hard gelatin capsule. Each type (population) may be uniquely different from the other in the manner or rate it releases the drug. Our IntelliPellets™ technology is designed to control, prolong, delay or modify the release of drugs. It is particularly useful for the delivery of multiple drugs, for delayed, timed, pulsed or for chronotherapeutic drug delivery, designed to mimic our internal clocks for therapeutic optimization (the drug is delivered in the right amount for the patient at the right time). This technology is most useful for the delivery of multiple-drug cocktails, or in situations where the timing of a single dose or the sequencing of multiple doses of the same drug is important.

### ***IntelliShuttle™***

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

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

### **Our Products and Product Candidates**

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

Generic name	Brand	Indication	Stage of Development <sup>(1)</sup>	Regulatory Pathway	Market Size (in millions) <sup>(2)</sup>	Rights <sup>(3)</sup>
<b>Dexamethylphenidate hydrochloride extended-release capsules</b>	Focalin XR®	Attention deficit hyperactivity disorder	Received final approval for 5, 10, 15, 20, 25, 30, 35 and 40 mg strengths from FDA <sup>(4)</sup>	ANDA	\$877	Intellipharmaceutics and Par (US)  Philippines rights subject to licensing and distribution agreement
<b>Levetiracetam extended-release tablets</b>	Keppra XR®	Partial onset seizures for epilepsy	Received final approval for the 500 and 750 mg strengths from FDA	ANDA	\$141	ANDA Repository <sup>(5)</sup>
<b>Venlafaxine hydrochloride extended-release capsules</b>	Effexor XR®	Depression	Received final approval for 37.5, 75 and 150 mg strengths from FDA	ANDA	\$838	Intellipharmaceutics
<b>Pantoprazole sodium delayed-release tablets</b>	Protonix®	Conditions associated with gastroesophageal reflux disease	ANDA application for commercialization approval for 2 strengths under review by FDA	ANDA	\$385	Intellipharmaceutics and Tris Pharma
<b>Metformin hydrochloride extended-release tablets</b>	Glucophage® XR	Management of type 2 diabetes	Received final approval for 500 and 750 mg strengths from FDA	ANDA	\$208 (500 and 750 mg only)	Intellipharmaceutics  Philippines and Vietnamese rights subject to licensing and distribution agreements
<b>Quetiapine fumarate extended-release tablets</b>	Seroquel XR®	Schizophrenia, bipolar disorder & major depressive disorder	Received final FDA approval for all 5 strengths. ANDS under review by Health Canada	ANDA ANDS	\$112	Intellipharmaceutics (US)Tris Pharma  Philippines, Malaysian and Vietnamese rights subject to licensing and distribution agreements  Vietnamese distribution rights to unannounced pharmaceutical distributor
<b>Lamotrigine extended-release tablets</b>	Lamictal® XR™	Anti-convulsant for epilepsy	ANDA application for commercialization approval for 6 strengths under review by FDA	ANDA	\$523	Intellipharmaceutics
<b>Desvenlafaxine extended-release tablets</b>	Pristiq®	Depression	Received tentative approval for the 50 and 100 mg strengths from FDA	ANDA	\$275	Intellipharmaceutics and Tris Pharma
<b>Trazodone hydrochloride extended-release tablets</b>	Oleptro™	Depression	ANDA application for commercialization approval for 2 strengths under review by FDA	ANDA	\$240	Intellipharmaceutics
<b>Carvedilol phosphate extended-release capsules</b>	Coreg CR®	Heart failure, hypertension	Late-stage development	ANDA	\$49	Intellipharmaceutics
<b>Oxycodone hydrochloride controlled-release capsules</b>	OxyContin®	Pain	NDA application accepted February 2017 and under review by FDA	NDA 505(b)(2)	\$1,200	Intellipharmaceutics
<b>Pregabalin extended-release capsules</b>	Lyrica®	Neuropathic pain	IND application submitted in August 2015	NDA 505(b)(2)	\$3,594	Intellipharmaceutics
<b>Ranolazine extended-release tablets</b>	Ranexa®	Chronic angina	ANDA application for commercialization approval for 2 strengths under review by FDA	ANDA	\$566	Intellipharmaceutics
<b>Oxycodone hydrochloride immediate release tablets (IPC1006)</b>	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 2020 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 (as hereinafter defined), the Mallinckrodt agreement (as hereinafter defined) and the licensing and distribution agreements with pharmaceutical distributors in Malaysia, Vietnam and the Philippines, see "General Development of the Business", "Other Potential Products and Markets". There can be no assurance as to when, or if at all, any of our products or product candidates, as the case may be, will receive regulatory approval for sale in the Philippines, Malaysia or Vietnam. For unpartnered products, we are exploring licensing agreement opportunities or other forms of distribution. While we believe that licensing agreements are possible, there can be no assurance that any can be secured.
- (4) Includes a Company ANDA (as hereinafter defined under "Material Contracts") final approval for our 15 and 30 mg strengths, and a Par ANDA (as hereinafter defined under "Material Contracts") 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) As at September 30, 2019, pursuant to an ANDA Sale Agreement (the "ANDA Agreement") we sold Levetiracetam extended-release tablets 500mg and 750 mg to the ANDA Repository, LLC (the "Purchaser") in exchange for a purchase price of \$1.00 for the "Transferred ANDA". "Transferred ANDA" is defined as all of the assets relating to the ANDA for Levetiracetam extended-release tablets 500mg and 750 mg. Under the ANDA Agreement, we have the option to repurchase the Levetiracetam ANDA for a purchase price of \$1 at any time according to the terms of the agreement.

***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. (“**Teva**”) to 180 days of generic exclusivity from the date of first launch of such products. In January 2017, Par launched the 25 and 35 mg strengths of its generic Focalin XR® capsules in the U.S., and in May 2017, Par launched the 10 and 20 mg strengths, complementing the 15 and 30 mg strengths of our generic Focalin XR® marketed by Par. In November 2017, Par launched the remaining 5 and 40 mg strengths providing us with the full line of generic Focalin XR® strengths available in the U.S. market.

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

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

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

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

On September 30, 2019, pursuant to an ANDA Sale Agreement (the “**ANDA Agreement**”) we sold Levetiracetam extended-release tablets 500mg and 750 mg to the ANDA Repository, LLC (the “**Purchaser**”) in exchange for a purchase price of \$1.00 for the “**Transferred ANDA**”. “**Transferred ANDA**” is defined as all of the assets relating to the ANDA for Levetiracetam extended-release tablets 500mg and 750 mg. Additionally, pursuant to the ANDA Agreement, we agreed to pay the Purchaser an annual fee for each fiscal year equal to 50% of the difference between the FDA Program Fee tier for 6 to 19 approved ANDAs and the FDA Program Fee based on 1 to 5 approved ANDAs. Further, under the ANDA Agreement, we have the option to repurchase the Levetiracetam ANDA for a purchase price of \$1 at any time according to the terms of the agreement.

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

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

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

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

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

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

We received final approval from the FDA in November 2018 for our ANDA for venlafaxine hydrochloride extended-release capsules in the 37.5, 75 and 150 mg strengths. The approved product is a generic equivalent of the branded product Effexor® XR sold in the U.S. by Wyeth Pharmaceuticals, LLC. Effexor® XR, and the drug active venlafaxine hydrochloride, are indicated for the treatment of major depressive disorder or MDD. We are actively exploring the best approach to maximize our commercial returns from this approval. On November 25, 2019, we announced that we had entered into a license and commercial supply agreement with Tris Pharma, Inc. ("Tris"), by which we granted Tris an exclusive license to market, sell and distribute in the United States, Venlafaxine extended-release capsules in the 37.5, 75, and 150 mg strengths. Several other generic versions of the licensed products are currently available in the market and that this limits the overall market opportunity. There can be no assurance that the Company's venlafaxine hydrochloride extended-release capsules for the 37.5 mg, 75 mg, and 150 mg will be successfully commercialized and produce significant revenue for us.

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

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

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

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

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

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

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

Our NDA was filed under Paragraph IV of the Hatch-Waxman Act, as amended. We certified to the FDA that we believed that our Oxycodone ER product candidate would not infringe any of the OxyContin® patents listed in the FDA's 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 on July 9, 2018. The existence and publication of additional patents in the Orange Book, and litigation arising therefrom, is an ordinary and to be expected occurrence in the course of such litigation.

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

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

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

In June 2017, we announced that a joint meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and Drug Safety and Risk Management Advisory Committee of the FDA (together, the “**Advisory Committees**”) meeting was scheduled for July 26, 2017 to review our NDA for Oxycodone ER. The submission requested that our Oxycodone ER product candidate include product label claims to support the inclusion of language regarding abuse-deterrent properties for the intravenous route of administration.

In July 2017, the Company announced that the FDA Advisory Committees voted 22 to 1 in finding that the Company’s NDA for Oxycodone ER should not be approved at this time. The Advisory Committees also voted 19 to 4 that the Company had not demonstrated that Oxycodone ER has properties that can be expected to deter abuse by the intravenous route of administration, and 23 to 0 that there was not sufficient data for Oxycodone ER to support inclusion of language regarding abuse-deterrent properties in the product label for the intravenous route of administration. The Advisory Committees expressed a desire to review the additional safety and efficacy data for Oxycodone ER that may be obtained from human abuse potential studies for the oral and intranasal routes of administration.

In September 2017, the Company received a Complete Response Letter (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.

In March 2019, the FDA acknowledged receipt of our resubmission of the Oxycodone ER NDA filed on February 28, 2019. The FDA had informed the Company that it considers the resubmission a complete response to the September 22, 2017 action letter it issued in respect of the NDA. The FDA also assigned a PDUFA goal date of August 28, 2019.

On July 24, 2019, we announced that the Company has been advised by the FDA that the FDA “is postponing product-specific advisory committee meetings for opioid analgesics,” including the one previously scheduled to discuss our NDA, “while it continues to consider a number of scientific and policy issues relating to this class of drugs.” According to the FDA, the reason for the postponement is not unique to our product and the Anesthetic and Analgesic Drug Products Advisory Committee (“AADPAC”) meeting earlier planned by the FDA, to discuss our NDA will be rescheduled at a future date. The FDA informed the Company that it would continue to review the Company’s NDA according to the existing PDUFA timeline, but noted that, due to the postponement of the AADPAC meeting, it is possible that the FDA may be unable to meet the PDUFA goal date of August 28, 2019. The FDA did not meet the goal date of August 28, 2019, and the Company is awaiting to hear back from the FDA a new PDUFA goal date.

In December 2019, 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 has been scheduled for January 15, 2020 to review the NDA for Aximris XR™ abuse-deterrent oxycodone hydrochloride extended-release tablets.

On January 15, 2020, at a joint meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and Drug Safety and Risk Management Advisory Committee (“Advisory Committees”) of the FDA to review our NDA for Aximris XR™, abuse-deterrent oxycodone hydrochloride extended-release tablets, the Advisory Committees voted 24 to 2 against the approval of our NDA for Aximris XR™ for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The FDA will take action on our application after completion of their review.

There can be no assurance that the FDA will approve any of the Company’s requested abuse-deterrence label claims or that the FDA will ultimately approve our NDA for the sale of Oxycodone ER in the U.S. market, or that it will ever be successfully commercialized and produce significant revenue for us.

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

***Oxycodone Hydrochloride IR Tablets (“IPC1006”) (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 IPC1006 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. IPC1006 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 IPC1006 tablets.

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

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

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

In May 2017, we received final approval from the FDA for our ANDA for quetiapine fumarate extended-release tablets in the 50, 150, 200, 300 and 400 mg strengths. Our approved product is a generic equivalent for the corresponding strengths of the branded product Seroquel XR® sold in the U.S. by AstraZeneca. Pursuant to a settlement agreement between us and AstraZeneca dated July 30, 2012, we were permitted to launch our generic versions of the 50, 150, 200, 300 and 400 mg strengths of generic Seroquel XR®, on November 1, 2016, subject to FDA final approval of our ANDA for those strengths. The Company manufactured and shipped commercial quantities of all strengths of generic Seroquel XR® to our then marketing and distribution partner Mallinckrodt, and Mallinckrodt launched all strengths in June 2017. On April 12, 2019, we and Mallinckrodt mutually agreed to terminate the Mallinckrodt agreement, and effective August 12, 2019 the Mallinckrodt agreement was terminated. On August 15, 2019 we announced a license and commercial supply agreement with Tris Pharma, granting Tris an exclusive license to market, sell and distribute all strengths of the product in the United States.

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 May 2019, we received 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. Pristiq®, and the drug active desvenlafaxine succinate, are indicated for use in the management of depression. We previously announced that we had entered into the Mallinckrodt agreement, 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 profit-sharing arrangement with respect to the licensed product. On April 12, 2019, we and Mallinckrodt mutually agreed to terminate the Mallinckrodt agreement effective no later than August 31, 2019. Effective August 12, 2019, the Mallinckrodt agreement was terminated. On September 5, 2019, we announced a license and commercial supply agreement with Tris Pharma, granting Tris an exclusive license to market, sell and distribute the two strengths of the product in the United States. There can be no assurance that our desvenlafaxine extended-release tablets in the 50 and 100 mg strengths will be successfully commercialized and produce significant revenue 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 or Pre-IND meeting request for our once-a-day Regabatin™ XR non-generic controlled release version of pregabalin under the NDA 505(b)(2) regulatory pathway, with a view to possible commercialization in the U.S. at some time following the December 30, 2018 expiry of the patent covering the pregabalin molecule. Regabatin™ XR is based on our controlled release drug delivery technology platform which utilizes the symptomatology and chronobiology of fibromyalgia in a formulation intended to provide a higher exposure of pregabalin during the first 12 hours of dosing. Based on positive feedback and guidance from the FDA, we submitted an IND application for Regabatin™ XR in August 2015. The FDA completed its review of the IND application and provided constructive input that we will use towards further development of the program. We believe our product candidate has significant additional benefits to existing treatments and are currently evaluating strategic options to advance this opportunity.

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

#### **Other Potential Products and Markets**

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

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

In November 2018, we announced that we had entered into an exclusive licensing and distribution agreement for our abuse resistant Oxycodone ER product candidate and four generic drug products with a pharmaceutical distributor in the Philippines. Under the terms of the agreement the distributor was granted the exclusive right, subject to regulatory approval, to import and market our first novel drug formulation, abuse-deterrent Oxycodone ER, in the Philippines. Additionally, this distributor was granted, subject to regulatory approval, the exclusive right to import and market our generic Seroquel XR®, Focalin XR®, Glucophage® XR, and Keppra XR® in the Philippines. Under the terms of the agreement, the distributor will be required to purchase a minimum yearly quantity of all products included in the agreement and we will be the exclusive supplier of said products. The multi-year agreement with the Philippines distributor is subject to early termination. Financial terms of the agreement have not been disclosed. There can be no assurance as to when or if any of our products or product candidates will receive regulatory approval for sale in the Philippines or that, if so approved, any such products will be successfully commercialized there and produce significant revenues for us. Moreover, there can be no assurance that we will not be required to conduct further studies for Oxycodone ER, that the FDA will approve any of our requested abuse-deterrent label claims or that the FDA will ultimately approve the NDA for the sale of Oxycodone ER in the U.S. market, or that it will ever be successfully commercialized.

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

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

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

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

Additionally, in January 2018, we announced we had commenced a 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.

### **Intellectual Property**

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

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

Country	Issue Date	Issue No.	Title
U.S.A.	31-Oct-17	9,801,939	Compositions and Methods For Reducing Overdose
U.S.A.	11-Jul-17	9,700,516	Compositions and Methods For Reducing Overdose
U.S.A.	11-Jul-17	9,700,515	Compositions and Methods For Reducing Overdose
U.S.A.	20-Dec-16	9,522,119	Compositions and Methods For Reducing Overdose
U.S.A.	14-Jul-15	9,078,827	Pharmaceutical Composition Having Reduced Abuse Potential
U.S.A.	12-Aug-14	8,802,139	Proton Pump-Inhibitor-Containing Capsules Which Comprise Subunits Differently Structured For A Delayed Release Of The Active Ingredient
U.S.A.	10-Dec-13	8,603,520	Oral Multi-functional Pharmaceutical Capsule Preparations of Proton Pump Inhibitors
U.S.A.	12-Mar-13	8,394,409	Controlled Extended Drug Release Technology
U.S.A.	15-Mar-11	7,906,143	Controlled Release Pharmaceutical Delivery Device and Process for Preparation Thereof
U.S.A.	28-Dec-10	7,858,119	Extended Release Pharmaceuticals
U.S.A.	15-Aug-06	7,090,867	Controlled Release Delivery Device for Pharmaceutical Agents Incorporating Microbial Polysaccharide Gum
U.S.A.	5-Oct-04	6,800,668	Syntactic Deformable Foam Compositions and Methods for Making
U.S.A.	25-Nov-03	6,652,882	Controlled Release Formulation Containing Bupropion
U.S.A.	19-Aug-03	6,607,751	Novel Controlled Release Delivery Device for Pharmaceutical Agents Incorporating Microbial Polysaccharide Gum
U.S.A.	12-Nov-02	6,479,075	Pharmaceutical Formulations for Acid Labile Substances
U.S.A.	2-Oct-01	6,296,876	Pharmaceutical Formulations for Acid Labile Substances
U.S.A.	5-May-17	9,636,306	Proton Pimp-Inhibitor Containing Capsules which Comprise Subunits Differently Structured for a Delayed Release of the Active Ingredient
U.S.A.	6-Nov-19	10,314,787	Controlled Release Delivery Device Comprising an Organosol Coat
U.S.A.	9-Apr-18	10,064,828	Pulsed Extended-Pulsed and Extended-Pulsed Drug Delivery Systems
U.S.A.	25-Dec-18	10,159,649	Controlled Release Delivery Device Comprising an Organosol Coat
U.S.A.	2-Jul-17	9,561,188	Controlled Release Delivery Device Comprising an Organosol Coat
U.S.A.	21-May-19	10,293,046	Compositions and Methods for Reducing Overdose
Japan	28-Aug-15	5,798,293	Pharmaceutical Composition Having Reduced Abuse Potential
Japan	17-Jan-14	5,457,830	Controlled Release Delivery Device Comprising An Organosol Coat
Japan	8-Aug-14	5,592,547	Drug Delivery Composition
Japan	30-Aug-13	5,349,290	Drug Delivery Composition
Japan	29-Jul-16	5,978,276	Pharmaceutical Composition having Reduced Abuse Potential
Japan	28-Jun-19	6,544,749	Compositions and Methods for Reducing Overdose
India	10-Feb-15	265,141	Pharmaceutical Composition Having Reduced Abuse Potential
India	3-Jul-17	281,085	Drug Delivery Composition
India	19-Jan-17	279,389	Controlled Release Delivery Device Comprising an Organosol Coat
Europe	25-Jul-18	2,112,920	Proton Pump-Inhibitor Containing Capsules which Comprise Subunits Differently Structured for a Delayed Release of the Active Ingredient
Europe	26-Nov-14	2,007,360	Controlled Release Delivery Device Comprising an Organosol Coat
Canada	29-Nov-16	2,910,865	Compositions and Methods for Reducing Overdose
Canada	28-May-19	2,648,278	Drug Delivery Composition
Canada	26-May-15	2,579,382	Controlled Release Composition Using Transition Coating, And Method Of Preparing Same/ Controlled Release Delivery Device
Canada	28-Jan-14	2,571,897	Controlled Extended Drug Release Technology
Canada	8-Apr-14	2,576,556	Drug Delivery Device
Canada	11-Mar-14	2,648,280	Controlled Release Delivery Device Comprising an Organosol Coat
Canada	19-Jun-12	2,626,558	Pharmaceutical Composition having Reduced Abuse Potential
Canada	25-Sep-12	2,529,984	Oral Multi-Functional Pharmaceutical Capsule Preparations of Proton Pump Inhibitors
Canada	22-Feb-11	2,459,857	Combinatorial Type Controlled Release Drug Delivery Device
Canada	15-Mar-05	2,435,276	Syntactic Deformable Foam Compositions and Methods for Making
China	5-Nov-16	ZL 200780019665.5	Drug Delivery Composition
China	25-Nov-15	ZL200780025611.X	Pharmaceutical Composition having Reduced Abuse Potential

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

## **Government Regulation**

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

## **United States Regulation**

### ***New Drug Application***

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

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

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

A new formulation for an existing drug compound requires a 505(b)(2) application. This application contains full reports of investigations of safety and effectiveness but at least some information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. A 505(b)(2) application is submitted when some specific information necessary for approval is obtained from: (1) published literature and/or (2) the FDA findings of safety and effectiveness for an approved drug. The FDA has implemented this approach to encourage innovation in drug development without requiring duplicative studies while protecting the patent and exclusivity rights for the approved drug. A 505(b)(2) application can be submitted for a new chemical entity, a new molecular entity or any changes to previously approved drugs such as dosage form, strength, route of administration, formulation, indication, or bioequivalence where the application may rely on the FDA's finding on safety and effectiveness of the previously approved drug. In addition, the applicant may also submit a 505(b)(2) application for a change in drug product that is eligible for consideration pursuant to a suitability petition. For example, a 505(b)(2) application would be appropriate for a controlled-release product that is bioequivalent to a reference listed drug where the proposed product is at least as bioavailable and the pattern of release is at least as favorable as the approved pharmaceutically equivalent product. A 505(b)(2) application may be granted three years of exclusivity if one or more clinical investigations, other than bioavailability/bioequivalence studies, was essential to the approval and conducted or sponsored by the applicant; five years of exclusivity is granted if it is for a new chemical entity. A 505(b)(2) application may also be eligible for orphan drug and pediatric exclusivity.

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

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

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

#### *Abbreviated New Drug Application*

In certain cases, where the objective is to develop a generic version of an approved product already on the market in controlled-release dosages, an ANDA may be filed in lieu of filing an NDA. Under the ANDA procedure, the FDA waives the requirement to submit complete reports of preclinical and clinical studies of safety and efficacy and instead requires the submission of bioequivalency data, that is, demonstration that the generic drug produces the same effect in the body as its brand-name counterpart and has the same pharmacokinetic profile, or change in blood concentration over time. The ANDA procedure is available to us for a generic version of a drug product approved by the FDA. In certain cases, an ANDA applicant may submit a suitability petition to the FDA requesting permission to submit an ANDA for a drug product that differs from a previously approved reference drug product (the "**Listed Drug**") when the change is one authorized by statute. Permitted variations from the Listed Drug include changes in: (1) route of administration, (2) dosage form, (3) strength and (4) one of the active ingredients of the Listed Drug when the Listed Drug is a combination product. The FDA must approve the petition before the ANDA may be submitted. An applicant is not permitted to petition for any other kinds of changes from Listed Drugs. The information in a suitability petition must demonstrate that the change from the Listed Drug requested for the proposed drug product may be adequately evaluated for approval without data from investigations to show the proposed drug product's safety or effectiveness. The advantages of an ANDA over an NDA include reduced research and development costs associated with bringing a product to market, and generally a shorter review and approval time at the FDA.

The Generic Drug User Fee Amendments of 2012 (“**GDUFA**”) implemented substantial fees for new ANDAs, Drug Master Files, product and establishment fees. In return, the program is intended to provide faster and more predictable ANDA reviews by the FDA and more timely inspections of drug facilities. For the FDA’s fiscal year 2020, the user fee rate is \$176,237. For the FDA’s fiscal year 2020, the FDA charged an annual facility user fee of \$210,662 plus a general program fee of \$166,168. Under GDUFA, generic product companies face significant penalties for failure to pay the new user fees, including rendering an ANDA not “substantially complete” until the fee is paid. It is currently uncertain the effect the new fees will have on our ANDA process and business. However, any failure by us or our suppliers to pay the fees or to comply with the other provisions of GDUFA may adversely impact or delay our ability to file ANDAs, obtain approvals for new generic products, generate revenues and thus may have a material adverse effect on our business, results of operations and financial condition.

#### ***Patent Certification and Exclusivity Issues***

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

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

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

The FDC Act contains other market exclusivity provisions that offer additional protection to pioneer drug products which are independent of any patent coverage that might also apply. Exclusivity refers to the fact that the effective date of approval of a potential competitor’s ANDA for a generic of the pioneer drug may be delayed or, in certain cases, an ANDA may not be submitted until the exclusivity period expires. Five years of exclusivity are granted to the first approval of a “new chemical entity”. Three years of exclusivity may apply to products which are not new chemical entities, but for which new clinical investigations are essential to the approval. For example, a new indication for use, or a new dosage strength of a previously approved product, may be entitled to exclusivity, but only with respect to that indication or dosage strength. Exclusivity only offers protection against a competitor entering the market via the ANDA route, and does not operate against a competitor that generates all of its own data and submits a full NDA.

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

### **Canadian Regulation**

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

#### ***Investigational New Drug Application***

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

#### ***New Drug Submission***

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

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

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

Proposals have recently been made that, if implemented, would significantly change Canada’s drug approval system. In general, the recommendations emphasize the need for efficiency in Canadian drug review. Proposals include establishment of a separate agency for drug regulation and modeling the approval system on those found in European Union countries. There is no assurance, however, that such changes will be implemented or, if implemented, will expedite the approval of new drugs.

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

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

#### **Additional Regulatory Considerations**

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

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

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

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

#### **Competitive Environment**

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

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

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

## Employees

As of November 30, 2019, we had 33 full-time employees, which is a decrease from the 59 employees we had on November 30, 2018. Our employees are not governed by a collective agreement. We have not experienced a work stoppage and believe our employee relations are satisfactory.

The nature of our business requires the recruitment and retention of a highly educated and skilled workforce, including highly qualified management, scientific and manufacturing personnel for innovation, research and development. Typically, a high proportion of our employees have a Bachelor's degree or higher. For each of the last three fiscal years, all employees of the Company were employed at the Company's offices in Toronto.

## Facilities

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

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

## Manufacturing

We have internal manufacturing capabilities consisting of cGLP research laboratories and a current Good Manufacturing Process ("**cGMP**") manufacturing plant for solid oral dosage forms at our facility located at 30 Worcester Road Facility. Raw materials used in manufacturing our products are available from a number of commercial sources and the prices for such raw materials are generally not particularly volatile. In October 2014, the FDA provided us with written notification that 30 Worcester Road Facility had received an "acceptable" classification. Such inspections are carried out on a regular basis by the FDA and an "acceptable" classification is necessary to permit us to be in a position to receive final approvals for ANDAs and NDAs and to permit manufacturing of drug products intended for commercial sales in the United States after any such approvals. The most recent inspections by FDA were conducted July 2017 and June 2019; both closed satisfactorily. Similarly, Health Canada completed an inspection of 30 Worcester Road Facility in September 2015 which resulted in a "compliant" rating. The most recent Health Canada inspection was conducted in June 2019 and a compliance rating was issued August 15, 2019.

## CODE OF CONDUCT

Our Code of Business Conduct and Ethics (“Code of Conduct”) has been implemented and it applies to all directors, officers and employees of the Company and its subsidiaries. It may be viewed on our website at [www.intellipharmaceutics.com](http://www.intellipharmaceutics.com) or under our company profile at [www.sedar.com](http://www.sedar.com). During the year ended November 30, 2019, no waivers or requests for exemptions from the Code of Conduct were either requested or granted.

## RISK FACTORS

*Prospects for companies in the pharmaceutical industry generally may be regarded as uncertain given the research and development nature of the industry and uncertainty regarding the prospects of successfully commercializing product candidates and, accordingly, investments in companies such as ours should be regarded as very speculative. An investor should carefully consider the risks and uncertainties described below, as well as other information contained in this annual information form. The list of risks and uncertainties described below is not an exhaustive list. Additional risks and uncertainties not presently known to us or that we believe to be immaterial may also adversely affect our business. If any one or more of the following risks occur, our business, financial condition and results of operations could be seriously harmed. Further, if we fail to meet the expectations of the public market in any given period, the market price of our common shares could decline. If any of the following risks actually occurs, our business, operating results, or financial condition could be materially adversely affected.*

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

### Risks related to our Company

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

Our business requires substantial capital investment in order to conduct the R&D, clinical and regulatory activities and to defend against patent litigation claims in order to bring our products to market and to establish commercial manufacturing, marketing and sales capabilities. As of November 30, 2018, we had a cash balance of \$6.6 million. As of November 30, 2019, our cash balance was \$67K. While we expect to satisfy certain short-term capital needs from upfront payments for development agreements, sale of one or more approved ANDAs, possible strategic investments in the near term, and other ongoing business development activities, we need to obtain additional funding as we further the development of our products. The Company has funded its business activities principally through the issuance of securities, loans from related parties and funds from development agreements. There is no certainty that such funding will be available going forward. Potential sources of capital may include payments from licensing agreements, cost savings associated with managing operating expense levels, other equity and/or debt financings, and/or new strategic partnership agreements which fund some or all costs of product development. We intend to utilize the equity markets to bridge any funding shortfall and to provide capital to continue to advance our most promising product candidates. Our future operations are highly dependent upon our ability to source additional capital to support advancing our product pipeline through continued R&D activities and to fund any significant expansion of our operations. Our ultimate success will depend on whether our product candidates receive approval by the FDA or Health Canada and the regulatory authorities of other countries in which our products are proposed to be sold and whether we are able to successfully market our approved products. We cannot be certain that we will receive FDA or Health Canada or such other regulatory approval for any of our current or future product candidates, that we will reach the level of sales and revenues necessary to achieve and sustain profitability or that we can secure other capital sources on terms or in amounts sufficient to meet our needs, or at all. Our cash requirements for R&D during any period depend on the number and extent of the R&D activities we focus on. At present, we are working principally on our Oxycodone ER 505(b)(2), PODRAS™ technology (described below), additional 505(b)(2) product candidates for development in various areas and selected generic product candidate development projects. Our development of Oxycodone ER will require significant expenditures, including costs to defend against the Purdue litigation (as described in the “Legal Proceedings” section). For our Regabatin™ XR 505(b)(2) product candidate, Phase III clinical trials can be capital intensive, and will only be undertaken consistent with the availability of funds and a prudent cash management strategy. We anticipate some investment in fixed assets and equipment over the next several months, the extent of which will depend on cash availability.

In January 2013, the Company completed the private placement financing of the unsecured 2013 Debenture in the original principal amount of \$1.5 million. The 2013 Debenture bears interest at a rate of 12% per annum, payable monthly, is pre-payable at any time at the option of the Company and is convertible at any time into common shares at a conversion price of \$30.00 per common share at the option of the holder. Drs. Isa and Amina Odidi, who are directors, executive officers and shareholders of our Company, provided us with the original \$1.5 million of the proceeds for the 2013 Debenture. In December 2016, a principal repayment of \$150,000 was made on the 2013 Debenture and the maturity date was extended until April 1, 2017. Effective March 28, 2017, the maturity date of the 2013 Debenture was extended to October 1, 2017. Effective September 28, 2017, the maturity date of the 2013 Debenture was further extended to October 1, 2018. Effective October 1, 2018, the maturity date for the 2013 Debenture was further extended to April 1, 2019. Effective April 1, 2019, the maturity date for the 2013 Debenture was further extended to May 1, 2019. In December 2018, a principal repayment of \$300,000 was made on the 2013 Debenture. On April 4, 2019, a tentative approval from TSX was received for a proposed refinancing of the 2013 Debenture, subject to certain conditions being met. As a result of the proposed refinancing, the principal amount owing under the 2013 Debenture was refinanced by the 2019 Debenture. On May 1, 2019, the 2019 Debenture was issued with a principal amount of \$1,050,000, that will mature on November 1, 2019, bear interest at a rate of 12% per annum and be convertible into 1,779,661 common shares of the Company at a conversion price of \$0.59 per common share. Dr. Isa Odidi and Dr. Amina Odidi, who are shareholders, directors, and executive officers of the Company, are the holders of the 2019 Debenture. Effective November 1, 2019, the maturity date for the 2019 Debenture was extended to December 31, 2019. Effective December 31, 2019, the maturity date for the 2019 Debenture was extended to February 1, 2020. Effective January 31, 2020, the maturity date for the 2019 Debenture was further extended to March 31, 2020.

On September 10, 2018, the Company issued the 2018 Debenture. The 2018 Debenture bears interest at a rate of 10% per annum, payable monthly, may be prepaid at any time at our option, and is convertible into Common Shares at any time prior to the maturity date at a conversion price of \$3.00 per Common Share at the option of the holder. Drs. Isa and Amina Odidi, who are directors, executive officers and shareholders of our Company, provided us with the original \$500,000 of proceeds for the 2018 Debenture. The maturity date for the 2018 Debenture is September 1, 2020.

On November 15, 2019, we issued to Drs. Isa and Amina Odidi, by way of a private placement, an unsecured convertible debenture of the Company in consideration for, and in the aggregate principal amount of, USD\$250,000 (the "November 2019 Debenture"). The principal amount owing under the November 2019 Debenture is convertible at any time and from time to time into Common Shares at a conversion price equal to U.S. \$0.12 per Common Share. Up to an aggregate of 2,083,333 Common Shares may be issued upon conversion of the principal amount owing under the November 2019 Debenture. The November 2019 Debenture bears interest at a rate of 12% per annum (calculated monthly) and, subject to our right to prepay the November 2019 Debenture in whole or in part at any time without penalty, and matures on December 31, 2019. Effective January 31, 2020, the December 31, 2019 maturity date was extended to March 31, 2020. Dr. Isa Odidi is our Chairman, Chief Executive Officer and Co-Chief Scientific Officer, and Dr. Amina Odidi is our President, Chief Operating Officer and Co-Chief Scientific Officer.

The availability of equity or debt financing will be affected by, among other things, the results of our R&D, our ability to obtain regulatory approvals, our success in commercializing approved products with our commercial partners and the market acceptance of our products, the state of the capital markets generally, strategic alliance agreements and other relevant commercial considerations. In addition, if we raise additional funds by issuing equity securities, our then-existing security holders will likely experience dilution, and the incurring of indebtedness would result in increased debt service obligations and could require us to agree to operating and financial covenants that would restrict our operations. In the event that we do not obtain sufficient additional capital, it will raise substantial doubt about our ability to continue as a going concern, realize our assets, and pay our liabilities as they become due. Our cash outflows are expected to consist primarily of internal and external R&D, legal and consulting expenditures to advance our product pipeline and selling, general and administrative expenses to support our commercialization efforts. Depending upon the results of our R&D programs, the impact of the Purdue litigation and other litigation to which the Company is a party and the availability of financial resources, we could decide to accelerate, terminate, or reduce certain projects, or commence new ones. Any failure on our part to successfully commercialize approved products or raise additional funds on terms favorable to us, or at all, may require us to significantly change or curtail our current or planned operations in order to conserve cash until such time, if ever, that sufficient proceeds from operations are generated, and could result in us not taking advantage of business opportunities, in the termination or delay of clinical trials or us not taking any necessary actions required by the FDA or Health Canada for one or more of our product candidates, in curtailment of our product development programs designed to identify new product candidates, in the sale or assignment of rights to our technologies, products or product candidates, and/or our inability to file ANDAs, ANDSs or NDAs, at all or in time to competitively market our products or product candidates.

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

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

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

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

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

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

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

***We have a history of operating losses, which may continue for the foreseeable future and there is a substantial doubt about our ability to continue as a going concern.***

To date, we have not been profitable and have incurred significant losses and cash flow deficits. For fiscal year ended November 30, 2019, we reported net losses of \$8,084,646, and negative cash flow from operating activities of \$6,663,677. As of November 30, 2019, we had an aggregate accumulated deficit of \$93,705,585. We anticipate that we will continue to report losses and negative operating cash flow. As a result of these net losses and other factors our independent auditors issued an audit opinion with respect to our financial statements for the three years ended November 30, 2019 that indicated that there is a substantial doubt about our ability to continue as a going concern.

There can be no assurance that we will ever be able to achieve or sustain profitability or positive cash flows. In addition to the other factors described in this Annual Information Form, our ultimate success will depend on how many of our product candidates receive approval by the FDA or Health Canada and whether we are able to successfully market approved products. We cannot be certain that we will be able to receive FDA or Health Canada approval for any of our current or future product candidates, or that we will reach the level of sales and revenues necessary to achieve and sustain profitability. If we are unsuccessful in commercializing our products and/or securing sufficient financing, we may need to cease or curtail our operations.

Our financial statements do not include any adjustments that might result from the outcome of this uncertainty. These adjustments would likely include substantial impairment of the carrying amount of our assets and potential contingent liabilities that may arise if we are unable to fulfill various operational commitments. In addition, the value of our securities would be greatly impaired. Our ability to continue as a going concern is dependent upon generating sufficient cash flows from operations and obtaining additional capital and financing. If our ability to generate cash flows from operations is delayed or reduced and we are unable to raise additional funding from other sources, we may be unable to continue in business. For further discussion about our ability to continue as a going concern and our plan for future liquidity, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Ability to Continue as a Going Concern” incorporated herein by reference.

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

We are dependent upon the scientific expertise of Dr. Isa Odidi, our Chairman, Chief Executive Officer and Co-Chief Scientific Officer, and Dr. Amina Odidi, our President, Chief Operating Officer and Co-Chief Scientific Officer. Although we employ other qualified scientists, Drs. Isa and Amina Odidi are our only employees with the knowledge and experience necessary for us to continue the development of controlled-release products. We do not maintain key-person life insurance on any of our officers or employees. Although we have employment agreements with key members of our management team, each of our employees may terminate his or her employment at any time. The success of our business depends, in large part, on our continued ability to attract and retain highly qualified management, scientific, manufacturing and sales and marketing personnel, on our ability to successfully integrate new employees, and on our ability to develop and maintain important relationships with leading research and medical institutions and key distributors. If we lose the services of our executive officers or other qualified personnel or are unable to attract and retain qualified individuals to fill these roles or develop key relationships, our business, financial condition and results of operations could be materially adversely affected.

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

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

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

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

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

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

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

In the United States and elsewhere, recent and proposed legal and regulatory changes to healthcare systems could prevent or delay our receipt of regulatory approval for our product candidates, restrict or regulate our post-approval marketing activities, and adversely affect our ability to profitably sell our products. We do not know whether additional legislative changes will be enacted, or whether the FDA's regulations, guidance or interpretations will be changed, or what impact any such changes will have, if any, on our ability to obtain regulatory approvals for our product candidates. Further, the U.S. Centers for Medicare and Medicaid Services, or CMS, frequently changes product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Also, increased scrutiny by the U.S. Congress of the FDA's approval process could significantly delay or prevent our receipt of regulatory approval for our product candidates and subject us to more stringent product labeling and post-marketing testing and other requirements.

**We operate in a highly litigious environment.**

From time to time, we may be exposed to claims and legal actions in the normal course of business. There has been substantial litigation in the pharmaceutical industry concerning the manufacture, use and sale of new products that are the subject of conflicting patent rights. When we file an ANDA or 505(b)(2) NDA for a bioequivalent version of a drug, we may, in some circumstances, be required to certify to the FDA that any patent which has been listed with the FDA as covering the branded product has expired, the date any such patent will expire, or that any such patent is invalid or will not be infringed by the manufacture, sale or use of the new drug for which the application is submitted. Approval of an ANDA is not effective until each listed patent expires, unless the applicant certifies that the patents at issue are not infringed or are invalid and so notifies the patent holder and the holder of the branded product. A patent holder may challenge a notice of non-infringement or invalidity by suing for patent infringement within 45 days of receiving notice. Such a challenge prevents FDA approval for a period which ends 30 months after the receipt of notice, or sooner if an appropriate court rules that the patent is invalid or not infringed. From time to time, in the ordinary course of business, we face and have faced such challenges and may continue to do so in the future.

As of the date of this Annual information Form, we are not aware of any pending or threatened material litigation claims against us, other than as described in this Annual Information Form under the caption "Legal Proceedings". Litigation to which we are, or may be, subject could relate to, among other things, our patent and other intellectual property rights or such rights of others, business or licensing arrangements with other persons, product liability or financing activities. Such litigation could include an injunction against the manufacture or sale of one or more of our products or potential products or a significant monetary judgment, including a possible punitive damages award, or a judgment that certain of our patent or other intellectual property rights are invalid or unenforceable or infringe the intellectual property rights of others. If such litigation is commenced, our business, results of operations, financial condition and cash flows could be materially adversely affected.

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

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

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

The FDA may institute changes to its ANDA approval requirements, which may make it more difficult or expensive for us to obtain approval for our new generic products. For instance, in July 2012, the Generic Drug User Fee Amendments of 2012, or GDUFA, was enacted into law. The GDUFA legislation implemented substantial fees for new ANDAs, Drug Master Files, product and establishment fees. In return, the program is intended to provide faster and more predictable ANDA reviews by the FDA and more timely inspections of drug facilities. For the FDA's fiscal year 2020, the user fee rate is \$176,237 for new ANDAs. For the FDA's fiscal year 2020, the Company owes an annual facility user fee of \$210,662 plus a general program fee of \$166,168. Under GDUFA, generic product companies face significant penalties for failure to pay the new user fees, including rendering an ANDA not "substantially complete" until the fee is paid. It is currently uncertain the effect the new fees will have on our ANDA process and business. However, any failure by us or our suppliers to pay the fees or to comply with the other provisions of GDUFA may adversely impact or delay our ability to file ANDAs, obtain approvals for new generic products and generate revenues and thus may have a material adverse effect on our business, results of operations and financial condition.

**We cannot ensure the availability of raw materials.**

Certain raw materials necessary for the development and subsequent commercial manufacture of our product candidates may be proprietary products of other companies. While we attempt to manage the risk associated with such proprietary raw materials through contractual provisions in supply contracts, by management of inventory and by continuing to search for alternative authorized suppliers of such materials or their equivalents, if our efforts fail, or if there is a material shortage, contamination, and/or recall of such materials, the resulting scarcity could adversely affect our ability to develop or manufacture our product candidates. In addition, many third party suppliers are subject to governmental regulation and, accordingly, we are dependent on the regulatory compliance of, as well as on the strength, enforceability and terms of our various contracts with, these third party suppliers.

Further, the FDA requires identification of raw material suppliers in applications for approval of drug products. If raw materials are unavailable from a specified supplier, the supplier does not give us access to its technical information for our application or the supplier is not in compliance with FDA or other applicable requirements, FDA approval of the supplier could delay the manufacture of the drug involved. Any inability to obtain raw materials on a timely basis, or any significant price increases which cannot be passed on to our customers, could have a material adverse effect on our business, results of operations, financial condition and cash flows.

**Our product candidates may not be successfully developed or commercialized.**

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

- for ANDA candidates, bioequivalence studies results may not meet regulatory requirements or guidelines for the demonstration of bioequivalence;
- for NDA candidates, a product may not demonstrate acceptable large-scale clinical trial results, even though it demonstrated positive preclinical or initial clinical trial results;
- for NDA candidates, a product may not be effective in treating a specified condition or illness;
- a product may have harmful side effects on humans;
- products may fail to receive the necessary regulatory approvals from the FDA or other regulatory bodies, or there may be delays in receiving such approvals;
- changes in the approval process of the FDA or other regulatory bodies during the development period or changes in regulatory review for each submitted product application may also cause delays in the approval or result in rejection of an application;
- difficulties may be encountered in formulating products, scaling up manufacturing processes or in getting approval for manufacturing;
- difficulties may be encountered in the manufacture and/or packaging of our products;
- once manufactured, our products may not meet prescribed quality assurance and stability tests;
- manufacturing costs, pricing or reimbursement issues, other competitive therapeutics, or other commercial factors may make the product uneconomical; and
- the proprietary rights of others, and their competing products and technologies, may prevent the product from being developed or commercialized.

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

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

Near-term revenue depends significantly on the success of our commercialized products.

## **Our ability to generate significant near-term revenue will depend upon successful commercialization of our ANDA products**

Our ANDA product, a once daily generic Focalin XR® capsules, for which we received final approval from the FDA in November 2013 under the Company ANDA (as defined below) to launch the 15 and 30 mg strengths. Commercial sales of these strengths were launched immediately by our commercialization partner in the U.S., Par Pharmaceutical, Inc. ("Par"). Our 5, 10, 20 and 40 mg strengths were also then tentatively FDA approved, subject to the right of Teva Pharmaceuticals USA, Inc. ("Teva") to 180 days of generic exclusivity from the date of first launch of such products. Teva launched its own 5, 10, 20 and 40 mg strengths of generic Focalin XR® capsules on November 11, 2014, February 2, 2015, June 22, 2015 and November 19, 2013, respectively. In January 2017, Par launched the 25 and 35 mg strengths of its generic Focalin XR® capsules in the U.S., and in May 2017, Par launched the 10 and 20 mg strengths, complementing the 15 and 30 mg strengths of our generic Focalin XR® marketed by Par. The FDA granted final approval under the Par ANDA (as defined in Item 4.B. below) for its generic Focalin XR® capsules in the 5, 10, 15, 20, 25, 30, 35 and 40 mg strengths. As the first filer of an ANDA for generic Focalin XR® in the 25 and 35 mg strengths, Par had 180 days of U.S. generic marketing exclusivity for those strengths. In November 2017, Par launched the remaining 5 and 40 mg strengths of generic Focalin XR®, complementing the 10, 15, 20, 25, 30 and 35 mg strengths previously launched and marketed by Par and providing us with the full line of general Focalin XR® strengths available in the U.S. market. Under the Par agreement, we receive calendar quarterly profit-share payments on Par's U.S. sales of generic Focalin XR®. There can be no assurance whether any strengths will be successfully commercialized. We depend significantly on the actions of our marketing partner Par in the prosecution, regulatory approval and commercialization of our generic Focalin XR® capsules and on their timely payment to us of the contracted calendar quarterly payments as they come due.

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 "**Mallinckrodt agreement**"):

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

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

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

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, however the arrangement did not generate significant revenue. The Mallinckrodt agreement was terminated effective August 12, 2019.

On August 15, 2019, we announced a license and commercial supply agreement with Tris Pharma, Inc. ("Tris"), granting Tris the exclusive license to market, sell and distribute all strengths of generic Seroquel XR® (quetiapine fumarate extended-release tablets in the United States. In May 2019, we received approval from the FDA for our ANDA for desvenlafaxine extended-release tablets in the 50 and 100 mg strengths and on September 5, 2019, we announced an agreement with Tris, granting Tris an exclusive license to market, sell and distribute it in the United States. Our Venlafaxine hydrochloride extended-release capsules received final approval from FDA in the 37.5, 75 and 150 mg strengths in November 2018; and the company announced an exclusive licensing agreement with Tris Pharma to market, sell and distribute the product in the United States on November 2019.

There can be no assurance whether any strengths of these products will be successfully commercialized. We depend significantly on the actions of our marketing partner Tris Pharma in the commercialization of the products and on their timely payment to us of the contracted payments as they come due.

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

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

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

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

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

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

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

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

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

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

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

We set goals regarding the expected timing of meeting certain corporate objectives, such as the commencement and completion of clinical trials, anticipated regulatory approval and product launch dates. From time to time, we may make certain public statements regarding these goals. The actual timing of these events can vary dramatically due to, among other things, insufficient funding, delays or failures in our clinical trials or bioequivalence studies, the uncertainties inherent in the regulatory approval process, such as failure to secure appropriate product labeling approvals, requests for additional information, delays in achieving manufacturing or marketing arrangements necessary to commercialize our product candidates and failure by our collaborators, marketing and distribution partners, suppliers and other third parties to fulfill contractual obligations. In addition, the possibility of a patent infringement suit regarding one or more of our product candidates could delay final FDA approval of such candidates. If we fail to achieve one or more of these planned goals, the price of our common shares could decline.

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

While we have our own manufacturing facility in Toronto, we rely on third-party manufacturers to supply pharmaceutical ingredients, and we will be reliant upon a third-party manufacturer to produce certain of our products and product candidates. Third-party manufacturers may not be able to meet our deadlines or adhere to quality standards and specifications. Our reliance on third parties for the manufacture of pharmaceutical ingredients and finished products creates a dependency that could severely disrupt our research and development, our clinical testing, and ultimately our sales and marketing efforts if such third party manufacturers fail to perform satisfactorily, or do not adequately fulfill their obligations. If our manufacturing operation or any contracted manufacturing operation is unreliable or unavailable, we may not be able to move forward with our intended business operations and our entire business plan could fail. There is no assurance that our manufacturing operation or any third-party manufacturers will be able to meet commercialized scale production requirements in a timely manner or in accordance with applicable standards or current Good Manufacturing Process.

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

If our manufacturing facility fails to comply with regulatory requirements or encounter other manufacturing difficulties, it could adversely affect our ability to supply products. All facilities and manufacturing processes used for the manufacture of pharmaceutical products are subject to inspection by regulatory agencies at any time and must be operated in conformity with the current Good Manufacturing Practices (“cGMP”) regulations. Compliance with FDA and Health Canada cGMP requirements applies to both drug products seeking regulatory approval and to approved drug products. In complying with cGMP requirements, pharmaceutical manufacturing facilities must continually expend significant time, money and effort in production, record-keeping and quality assurance and control so that their products meet applicable specifications and other requirements for product safety, efficacy and quality. Failure to comply with applicable legal requirements subjects our manufacturing facility to possible legal or regulatory action, including shutdown, which may adversely affect our ability to manufacture product. Were we not able to manufacture products at our manufacturing facility because of regulatory, business or any other reasons, the manufacture and marketing of these products would be interrupted. This could have a material adverse impact on our business, results of operations, financial condition, cash flows and competitive position.

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

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

- filing “citizen petitions” with the FDA that may delay competition by causing delays of our product approvals;
- seeking to establish regulatory and legal obstacles that would make it more difficult to demonstrate a product’s bioequivalence or “sameness” to the related innovator product;
- filing suits for patent infringement that automatically delay FDA approval of products seeking approval based on the Section 505(b)(2) pathway;
- obtaining extensions of market exclusivity by conducting clinical trials of innovator drugs in pediatric populations or by other methods;
- persuading the FDA to withdraw the approval of innovator drugs for which the patents are about to expire, thus allowing the innovator company to develop and launch new patented products serving as substitutes for the withdrawn products;
- seeking to obtain new patents on drugs for which patent protection is about to expire;
- and
- initiating legislative and administrative efforts in various states to limit the substitution of innovator products by pharmacies.

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

**Our products and product candidates, if approved for sale, may not gain acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenue.**

Even if we are able to obtain regulatory approvals for our product candidates, the success of any of our products will be dependent upon market acceptance by physicians, healthcare professionals and third-party payers and our profitability and growth will depend on a number of factors, including:

- demonstration of safety and efficacy;
- changes in the practice guidelines and the standard of care for the targeted indication;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- the availability of alternative products from competitors;
- the prices of our products relative to those of our competitors;
- pricing, reimbursement and cost effectiveness, which may be subject to regulatory control;
- the number of competitive product entries, and the nature and extent of any aggressive pricing and rebate activities that may follow;
- the timing of our market entry;
- the ability to market our products effectively at the retail level;
- the acceptance of our products by government and private formularies;
- and

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

If any product candidate that we develop does not provide a treatment regimen that is as beneficial as, or is perceived as being as beneficial as, the current standard of care or otherwise does not provide patient benefit, that product candidate, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance. Our ability to effectively promote and sell any approved products will also depend on pricing and cost-effectiveness, including our ability to produce a product at a competitive price and our ability to obtain sufficient third-party coverage or reimbursement. If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, patients and third-party payers, our ability to generate revenues from that product would be substantially reduced. In addition, our efforts to educate the medical community and third-party payers on the benefits of our product candidates may require significant resources, may be constrained by FDA rules and policies on product promotion, and may never be successful.

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

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

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

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

- the failure of patients to complete clinical trials due to adverse side effects, dissatisfaction with the product candidate, or other reasons;
- governmental or regulatory delays or changes in regulatory requirements, policy and guidelines; and
- varying interpretation of data by the FDA or other applicable foreign regulatory agencies.

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

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

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

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

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

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

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

We rely on collaborative arrangements with third parties that provide manufacturing and/or marketing support for some or all of our products and product candidates. Even if we find a potential partner, we may not be able to negotiate an arrangement on favourable terms or achieve results that we consider satisfactory. In addition, such arrangements can be terminated under certain conditions and do not assure a product's success. We also face intense competition for collaboration arrangements with other pharmaceutical and biotechnology companies.

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

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

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

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

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

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

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

- Difficulties in achieving volume production, quality control and quality assurance, or technology transfer, as well as with shortages of qualified personnel;
- The failure to establish and follow cGMP and to document adherence to such practices;
- The need to revalidate manufacturing processes and procedures in accordance with FDA and other nationally mandated cGMPs and potential prior regulatory approval upon a change in contract manufacturers;

- Failure to perform as agreed or to remain in the contract manufacturing business for the time required to produce, store and distribute our products successfully;
- The potential for an untimely termination or non-renewal of contracts; and
- The potential for us to be in breach of our collaboration and marketing and distribution arrangements with third parties for the failure of our contract manufacturers to perform their obligations to us.

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

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

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

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

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

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

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

**We have limited sales, marketing and distribution experience.**

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

**Our effective tax rate may vary.**

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

The effect of U.S. federal income tax law changes enacted in 2017 on the U.S. corporate income tax burden on our future U.S. operations cannot be predicted. Although such legislation reduced the maximum corporate income tax rate from 35% to 21%, it also introduced several changes that could increase our effective rate of tax on our net operating income. For example, if our operations are highly leveraged, the new limitations on business interest deductions may prevent us from being able to reduce our corporate income tax base by a significant amount of interest incurred on debt necessary to fund operations. In addition, newly enacted limitations on a corporation's ability to reduce its taxable income by net operating loss carryovers may prevent us from using prior year accumulated losses fully to offset taxable income earned in profitable years. Finally, if we make significant payments for interest, royalties, services and otherwise deductible items to our foreign affiliates, the base erosion minimum tax enacted in 2017 may apply to increase our effective rate of U.S. corporate income tax.

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

Drs. Amina and Isa Odidi, our President, Chief Operating Officer and Co-Chief Scientific Officer and our Chairman, Chief Executive Officer and Co-Chief Scientific Officer, respectively, and shareholders of our Company, and Odidi Holdings Inc., a privately-held company controlled by Drs. Amina and Isa Odidi, own in the aggregate approximately 2.44% of our issued and outstanding Common Shares as of February 28, 2020 (and collectively beneficially owned in the aggregate approximately 19.32% of our Common Shares, including Common Shares issuable upon the exercise of outstanding options and the conversion of the 2018 Debenture, 2019 Debenture and November 2019 Debenture (collectively, the "Debentures")). As a result, these shareholders have the ability to exercise significant influence over all matters submitted to our shareholders for approval.

**Stockholder ownership interest in the Company may be diluted as a result of future financings and acquisitions.**

The Company may seek to raise funds from time to time in public or private issuances of equity in the near future or over the longer term. Sales of the Company's securities offered through future equity offerings may result in substantial dilution to the interests of the Company's current shareholders. The sale of a substantial number of securities to investors, or anticipation of such sales, could make it more difficult for the Company to sell equity or equity-related securities in the future at a time and at a price that the Company might otherwise wish to effect sales. In addition, the Company may issue its Common Shares for various acquisitions in the future, which may also result in substantial dilution to the interests of the Company's current shareholders.

**Authorized capital consists of an unlimited number of shares of one class designated as Common Shares.**

The Company's authorized capital consists of an unlimited number of shares of one class designated as Common Shares. The directors may create any class or series of shares by resolution but may not make any modification to the provisions attaching to our Common Shares without the affirmative vote of two-thirds of the votes cast by the holders of the Common Shares. The Company's Common Shares do not have pre-emptive rights to purchase additional shares.

**We may lose our foreign private issuer status in the future, which could result in significant additional costs and expenses.**

We are a “foreign private issuer,” as such term is defined under the U.S. Securities Act, and, therefore, we are not required to comply with all the periodic disclosure and current reporting requirements of the U.S Exchange Act and related rules and regulations. Under the U.S. Securities Act, the determination of foreign private issuer status is made annually on the last business day of an issuer’s most recently completed second fiscal quarter and, accordingly, the next determination will be made with respect to us on May 30, 2020.

In the future, we would lose our foreign private issuer status if a majority of our shareholders, directors or management continue to be U.S. citizens or residents and we fail to meet additional requirements necessary to avoid loss of foreign private issuer status. Although we have elected to comply with certain U.S. regulatory provisions, our loss of foreign private issuer status would make such provisions mandatory. If we are not a foreign private issuer, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive than the forms available to a foreign private issuer. For example, the annual report on Form 10-K requires domestic issuers to disclose executive compensation information on an individual basis with specific disclosure regarding the domestic compensation philosophy, objectives, annual total compensation (base salary, bonus and equity compensation) and potential payments in connection with change in control, retirement, death or disability, while the annual report on Form 20-F permits foreign private issuers to disclose compensation information on an aggregate basis. We will also have to mandatorily comply with U.S. federal proxy requirements, and our executive officers, directors and principal shareholders will become subject to the short-swing profit disclosure and recovery provisions of Section 16 of the U.S. Exchange Act. We may also be required to modify certain of our policies to comply with good governance practices associated with U.S. domestic issuers. In addition, we may lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers. Such transition and modifications will involve additional costs and may divert our management’s attention from other business concerns, which could have a material adverse effect on our business, financial condition and results of operations.

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

We may need to issue substantial amounts of Common Shares in the future. There can be no assurance that we will be able to sell any additional shares. To the extent that the market price of our Common Shares declines, we will need to issue an increasing number of Common Shares per dollar of equity investment. In addition to our Common Shares issuable in connection with the exercise of our outstanding warrants, our employees, and directors will hold rights to acquire substantial amounts of our Common Shares. In order to obtain future financing if required, it is likely that we will issue additional Common Shares or financial instruments that are exchangeable for or convertible into Common Shares. Also, in order to provide incentives to employees and induce prospective employees and consultants to work for us, we may offer and issue options to purchase Common Shares and/or rights exchangeable for or convertible into Common Shares. Future issuances of shares could result in substantial dilution to shareholders. Capital raising activities, if available, and dilution associated with such activities could cause our share price to decline. In addition, the existence of Common Share purchase warrants may encourage short selling by market participants. Also, in order to provide incentives to current employees and directors and induce prospective employees and consultants to work for us, we have historically granted options and deferred share units (“DSUs”), and intend to continue to do so or offer and issue other rights exchangeable for or convertible into Common Shares. Future issuances of shares could result in substantial dilution to all our shareholders. In addition, future public sales by holders of our Common Shares could impair our ability to raise capital through any future equity offerings.

On July 17, 2017, the Shelf Registration Statement was declared effective by the SEC. The Shelf Registration Statement allows for, subject to securities regulatory requirements and limitations, the potential offering of up to an aggregate of \$100 million of the Company’s Common Shares, preference shares, warrants, subscription receipts, subscription rights and units, or any combination thereof, from time to time in one or more offerings, and are intended to give the Company the flexibility to take advantage of financing opportunities when, and if, market conditions are favorable to the Company. The specific terms of such future offerings, if any, would be established, subject to the approval of the Company’s Board, at the time of such offering and will be described in detail in a prospectus supplement filed at the time of any such offering. As of February 28, 2020, the Company has issued 1,246,969 Common Shares using the Shelf Registration Statement, and there can be no assurance that any additional securities will be sold under the Shelf Registration Statement. In March 2018, the Company terminated its continuous offering under the prospectus supplement dated July 18, 2017 and prospectus dated July 17, 2017 in respect of its at-the-market program.

## Risks related to our Industry

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Individual state legislatures in the U.S. have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing. Some of these measures include price or patient reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure and transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

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

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

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

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

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

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

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

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

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

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

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

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

- varying regulatory restrictions on sales of our products to certain markets and unexpected changes in regulatory requirements;
- tariffs, customs, duties, and other trade barriers;
- difficulties in managing foreign operations and foreign distribution partners;
- longer payment cycles and problems in collecting accounts receivable;
- political risks;
- foreign exchange controls that may restrict or prohibit repatriation of funds;
- export and import restrictions or prohibitions, and delays from customs brokers or government agencies;
- seasonal reductions in business activity in certain parts of the world; and
- potentially adverse tax consequences.

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

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

In connection with any geographic expansion we may pursue, international operations would involve substantial additional risks, including, among others: difficulties complying with the U.S. Foreign Corrupt Practices Act and other applicable anti-bribery laws. difficulties maintaining compliance with the various laws and regulations of multiple jurisdictions that may be applicable to our business, many of which may be unfamiliar to us. more complexity in our regulatory and accounting compliance. differing or changing obligations regarding taxes, duties or other fees. limited intellectual property protection in some jurisdictions. risks associated with currency exchange and convertibility, including vulnerability to appreciation and depreciation of foreign currencies. uncertainty related to developing legal and regulatory systems and standards for economic and business activities in some jurisdictions. trade restrictions or barriers, including tariffs or other charges and import-export regulations, changes in applicable laws or policies. the impact of and response to natural disasters. and the potential for war, civil or political unrest and economic and financial instability. The occurrence of any of these risks could limit our ability to pursue international expansion, increase our costs or expose us to fines or other legal sanctions, any of which could negatively impact our business, reputation and financial condition.

**Risks related to our common shares**

**Trading on the OTC Markets is volatile and sporadic, which could depress the market price of the Company's Common Shares and make it difficult for the Company's stockholders to resell their shares.**

The Company's Common Shares are quoted on the OTCQB tier of the OTC Markets. Trading in stock quoted on the OTC Markets is often thin and characterized by wide fluctuations in trading prices, due to many factors, some of which may have little to do with the Company's operations or business prospects. This volatility could depress the market price of the Company's Common Shares for reasons unrelated to operating performance. Moreover, the OTC Markets is not a stock exchange, and trading of securities on the OTC Markets is often more sporadic than the trading of securities listed on a quotation system like Nasdaq or a stock exchange like the New York Stock Exchange. These factors may result in investors having difficulty reselling any shares of the Company's Common Shares.

**We may on occasion be unable to timely file certain periodic reports and other documents with the regulatory bodies in Canada and the United States**

We may not be able to timely file with the regulatory bodies in Canada and the United States our year-end financial statements, management discussion and analysis, Annual Information Form and 20F within the required 120 days of our fiscal year end. If we are not able to file our current and periodic reports and other documents in the future in the times specified by the Securities Exchange Act, we will continue to lose our eligibility to use Form F-1 for future capital raises, and that could impair our ability to conduct more efficient and expeditious public offerings of our stock. Our inability to timely file current and periodic reports in the future could materially and adversely affect our financial condition and results of operations.

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

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

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

- limited daily trading volume; and
- developments regarding our patents or other intellectual property or that of our competitors.

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

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

As of February 28, 2020, we had approximately 23,678,105 Common Shares outstanding. In addition, a substantial portion of our shares are currently freely trading without restriction under the U.S. Securities Act, having been registered for resale or held by their holders for over six months and are eligible for sale under Rule 144.

On July 17, 2017, the Company's most recent Shelf Registration Statement was declared effective by the SEC. The Shelf Registration Statement allows for, subject to securities regulatory requirements and limitations, the potential offering of up to an aggregate of US\$100 million of the Company's Common Shares, preference shares, warrants, subscription receipts, subscription rights and units, or any combination thereof, from time to time in one or more offerings, and are intended to give the Company the flexibility to take advantage of financing opportunities when, and if, market conditions are favorable to the Company. The specific terms of such future offerings, if any, would be established, subject to the approval of the Company's board of directors (the "Board"), at the time of such offering and will be described in detail in a prospectus supplement filed at the time of any such offering. To the extent any securities of the Company are issued by the Company under the Shelf Registration Statement or the shelf prospectus, a shareholder's percentage ownership will be diluted and our stock price could be further adversely affected. As of February 28, 2020, the Company has issued 1,246,969 Common Shares using the Shelf Registration Statement, and there can be no assurance that any additional securities will be sold under the Shelf Registration Statement or the shelf prospectus. Notwithstanding the foregoing, currently the Company does not meet the requirements to utilize its Form F-3 to issue any further securities under the Form F-3.

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

As of February 28, 2020, there are currently Common Shares issuable upon the exercise of outstanding options and warrants and the conversion of the Debentures for an aggregate of approximately 28,204,519 Common Shares. To the extent any of our options and warrants is exercised and the convertible debenture is converted, a shareholder's percentage ownership will be diluted and our stock price could be further adversely affected. Moreover, as the underlying shares are sold, the market price could drop significantly if the holders of these restricted shares sell them or if the market perceives that the holders intend to sell these shares.

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

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

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

There is no guarantee that an active trading market for our common shares will be maintained on Nasdaq or TSX. Investors may not be able to sell their shares quickly or at the latest market price if trading in our common shares is not active.

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

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

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

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

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

We may need to issue substantial amounts of common shares in the future. There can be no assurance that we will be able to sell any additional shares. To the extent that the market price of our common shares declines, we will need to issue an increasing number of common shares per dollar of equity investment. In addition to our common shares issuable in connection with the exercise of our outstanding warrants, our employees, and directors will hold rights to acquire substantial amounts of our common shares. In order to obtain future financing if required, it is likely that we will issue additional common shares or financial instruments that are exchangeable for or convertible into common shares. Also, in order to provide incentives to employees and induce prospective employees and consultants to work for us, we may offer and issue options to purchase common shares and/or rights exchangeable for or convertible into common shares. Future issuances of shares could result in substantial dilution to shareholders. Capital raising activities, if available, and dilution associated with such activities could cause our share price to decline. In addition, the existence of common share purchase warrants may encourage short selling by market participants. Also, in order to provide incentives to current employees and directors and induce prospective employees and consultants to work for us, we have historically granted options and deferred share units (“DSUs”), and intend to continue to do so or offer and issue other rights exchangeable for or convertible into common shares. Future issuances of shares could result in substantial dilution to all our shareholders. In addition, future public sales by holders of our common shares could impair our ability to raise capital through any future equity offerings.

On July 17, 2017, the Shelf Registration Statement was declared effective by the SEC. The Shelf Registration Statement allows for, subject to securities regulatory requirements and limitations, the potential offering of up to an aggregate of \$100 million of the Company’s common shares, preference shares, warrants, subscription receipts, subscription rights and units, or any combination thereof, from time to time in one or more offerings, and are intended to give the Company the flexibility to take advantage of financing opportunities when, and if, market conditions are favorable to the Company. The specific terms of such future offerings, if any, would be established, subject to the approval of the Company’s board of directors, at the time of such offering and will be described in detail in a prospectus supplement filed at the time of any such offering. As of February 28, 2020, the Company has issued 1,246,969 common shares using the Shelf Registration Statement, and there can be no assurance that any additional securities will be sold under the Shelf Registration Statement. In March 2018, the Company terminated its continuous offering under the prospectus supplement dated July 18, 2017 and prospectus dated July 17, 2017 in respect of its at-the-market program.

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

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

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

Failure to maintain the applicable continued listing requirements of the TSX could result in our common shares being delisted from the TSX. The TSX will normally consider the delisting of securities if, in the opinion of the exchange, it appears that the public distribution, price, or trading activity of the securities has been so reduced as to make further dealings in the securities on TSX unwarranted. For example, participating securities may be delisted from the TSX if, among other things, the market value of an issuer's securities that are listed on the TSX is less than C\$3,000,000 over any period of 30 consecutive trading days. In such circumstances, the TSX may notify an issuer that it is under delisting review and the issuer will normally be given up to 120 days from the date of such notification to correct the fall in market value and such other deficiencies noted by the TSX. At any time prior to the end of the delisting review period, the TSX will provide the issuer with an opportunity to be heard where the issuer may present submissions to satisfy the TSX that all deficiencies identified in the TSX's notice have been rectified. If at the conclusion of the hearing the issuer cannot satisfy the TSX that the deficiencies identified have been rectified and that no other delisting criteria are then applicable to the issuer, the TSX will determine whether to delist the issuer's securities.

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

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

Our Common Shares are currently a "penny stock" under SEC rules. It may be more difficult to resell shares of Common Shares classified as "penny stock."

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

- make a special written suitability determination for the purchaser;
- receive the purchaser's written agreement to a transaction prior to sale;

- provide the purchaser with risk disclosure documents which identify risks associated with investing in “penny stocks” and which describe the market for these “penny stocks” as well as a purchaser’s legal remedies; and
- obtain a signed and dated acknowledgment from the purchaser demonstrating that the purchaser has actually received the required risk disclosure document before a transaction in a “penny stock” can be completed.

As a result of these requirements, since our Common Shares are subject to the “penny stock” rules, broker-dealers may find it difficult to effectuate customer transactions and trading activity in these shares in the United States may be significantly limited. Accordingly, the market price of the shares may be depressed, and investors may find it more difficult to sell the shares.

**As long as our stock price remains below \$5.00 per share, our shareholders will face restrictions in using our shares as collateral for margin accounts.**

The closing price of our Common Shares on the OTCQB on February 27, 2020 was \$0.154 per share. If the market price of our Common Shares remains below \$5.00 per share, under Federal Reserve regulations and account maintenance rules of many brokerages, our shareholders will face restrictions in using such shares as collateral for borrowing in margin accounts. These restrictions on the use of our Common Shares as collateral may lead to sales of such shares creating downward pressure on and increased volatility in, the market price of our Common Shares. In addition, many institutional investors will not invest in stocks whose prices are below \$5.00 per share.

**Our shareholders may face significant restrictions on the resale of our Common Shares due to state “Blue Sky” laws.**

Each state has its own securities laws, often called “blue sky” laws, which (i) limit sales of securities to a state’s residents unless the securities are registered in that state or qualify for an exemption from registration, and (ii) govern the reporting requirements for broker-dealers doing business directly or indirectly in the state. Before a security is sold in a state, there must be a registration in place to cover the transaction, or the transaction must be exempt from registration. The applicable broker must be registered in that state.

Absent compliance with such individual state laws, our Common Shares may not be traded in such jurisdictions. Because the securities registered hereunder have not been registered for resale under the Blue Sky laws of any state, the holders of such shares and persons who desire to purchase them in any trading market that might develop in the future, should be aware that there may be significant state Blue Sky law restrictions upon the ability of investors to sell the securities and of purchasers to purchase the securities. Accordingly, investors may not be able to liquidate their investments and should be prepared to hold the shares of our Common Shares for an indefinite period of time. You should therefore consider the resale market for our Common Shares to be limited, as you may be unable to resell your shares without the significant expense of state registration or qualification.

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

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

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

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

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

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

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

The possible classification of our Company as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes could have significant and adverse tax consequences for U.S. Holders (as defined below) with respect to the sale or other disposition of our Common Shares acquired through the exercise of certain warrants. It may be possible for U.S. Holders of Common Shares to mitigate certain of these consequences by making an election (a so-called “QEF Election”) to treat us as a “qualified electing fund” or “QEF” under Section 1295 of the Code; or a mark-to-market election under Section 1296 of the Code. A non-U.S. corporation generally will be a PFIC if, for a taxable year (a) 75% or more of the gross income of such corporation for such taxable year consists of specified types of passive income or (b) on average, 50% or more of the assets held by such corporation either produce passive income or are held for the production of passive income, based on the fair market value of such assets (or on the adjusted tax basis of such assets, if such non-U.S. corporation is not publicly traded and either is a “controlled foreign corporation” under Section 957(a) of the Code, or makes an election to determine whether it is a PFIC based on the adjusted basis of the assets).

The determination of whether we are, or will be, a PFIC for a taxable year depends, in part, on the application of complex U.S. federal income tax rules, which are subject to various interpretations. We believe that there is a substantial basis for concluding that we were not a PFIC during our 2019 taxable year and will likely not be a PFIC during our 2020 taxable year, although that conclusion is not free from doubt. Because PFIC status is based on our income, assets and activities for the entire taxable year, and our market capitalization, it is not possible to determine whether we will be characterized as a PFIC for the 2020 taxable year until after the close of the taxable year. The tests for determining PFIC status are subject to a number of uncertainties. These tests are applied annually, and it is difficult to accurately predict future income, assets and activities relevant to this determination. In addition, because the market price of our Common Shares is likely to fluctuate, the market price may affect the determination of whether we will be considered a PFIC. There can be no assurance that we will not be considered a PFIC for any taxable year (including our 2020 taxable year). Absent one of the elections described above, if we are a PFIC for any taxable year during which a U.S. Holder holds our Common Shares, we generally will continue to be treated as a PFIC regardless of whether we cease to meet the PFIC tests in one or more subsequent years. Accordingly, no assurance can be given that we will not constitute a PFIC in the current (or any future) tax year or that the Internal Revenue Service (the “IRS”) will not challenge any determination made by us concerning our PFIC status.

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

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

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

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

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

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

#### **Other Risks**

**There are other unidentified risks.**

The risks set forth above are not a complete list of the risks facing purchasers of our Common Shares. We acknowledge that there may exist significant risks yet to be recognized or encountered to which we may not be able to effectively respond. There can be no assurance that we will succeed in addressing these risks or future potential risks, and any failure to do so could have a material adverse effect on our business, financial condition and results of operations.

#### **DIVIDENDS**

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

## CAPITAL STRUCTURE

Our authorized share capital consists of an unlimited number of common shares, all without nominal or par value and an unlimited number of preference shares issuable in series. At November 30, 2019, there were 22,085,856 common shares and no preference shares issued and outstanding. As of the date of this annual information form there were 23,678,105 common shares and no preference shares issued and outstanding.

### Common Shares

Each of our common shares entitles the holder thereof to one vote at any meeting of shareholders of the Company, except meetings at which only holders of a specified class of shares are entitled to vote. Subject to the prior rights of the holders of any preference shares, the holders of common shares of the Company are entitled to receive, as and when declared by the board of directors, dividends in such amounts as shall be determined by the board of directors of the Company. The holders of common shares of the Company have the right to receive the remaining property of the Company in the event of liquidation, dissolution, or winding-up of the Company, whether voluntary or involuntary.

### Preference Shares

The preference shares may at any time and from time to time be issued in one or more series. The board of directors will, by resolution, from time to time, before the issue thereof, fix the rights, privileges, restrictions and conditions attaching to the preference shares of each series. Except as required by law, the holders of any series of preference shares will not as such be entitled to receive notice of, attend or vote at any meeting of the shareholders of the Company. Holders of preference shares will be entitled to preference with respect to payment of dividends and the distribution of assets in the event of liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, or any other distribution of the assets of the Company among its shareholders for the purpose of winding up its affairs, on such shares over the common shares and over any other shares ranking junior to the preference shares.

### Warrants

At November 30, 2019, an aggregate of 23,601,551 common shares were issuable upon the exercise of outstanding common share purchase warrants, with a weighted average exercise price of \$1.03 per common share. As of the date of this annual information form, an aggregate of 21,984,884 common shares were issuable upon the exercise of outstanding common share purchase warrants, with a weighted average exercise price of \$1.10 per common share.

### Options

At November 30, 2019, an aggregate of 2,353,829 common shares were issuable upon the exercise of outstanding options, with a weighted average exercise price of \$8.35 per common share and up to 131,150 additional common shares were reserved for issuance under our stock option plan.

From November 30, 2019 to the date of this annual information form, no options to purchase our common shares were granted, no options to purchase our common shares were exercised, no options to purchase our common shares expired, and no options to purchase our common shares were cancelled. At the date of this annual information form, up to 418,230 additional common shares were reserved for issuance under our stock option plan.

### Convertible Debenture

In January 2013, the Company completed the private placement financing of an unsecured debenture in the original principal amount of \$1.5 million (the "2013 Debenture"). The 2013 Debenture bore interest at a rate of 12% per annum, payable monthly, was pre-payable at any time at the option of the Company and was convertible at any time into Common Shares at a conversion price of \$30.00 per Common Share at the option of the holder. Drs. Isa and Amina Odidi, who are directors, executive officers and shareholders of our Company, provided us with the original \$1.5 million of the proceeds for the 2013 Debenture. In December 2016, a principal repayment of \$150,000 was made on the 2013 Debenture and the maturity date was extended until April 1, 2017. Effective March 28, 2017, the maturity date of the 2013 Debenture was extended to October 1, 2017. Effective September 28, 2017, the maturity date of the 2013 Debenture was further extended to October 1, 2018. Effective October 1, 2018, the maturity date for the 2013 Debenture was further extended to April 1, 2019. Effective April 1, 2019, the maturity date for the 2013 Debenture was further extended to May 1, 2019. In December 2018, a principal repayment of \$300,000 was made on the 2013 Debenture. On April 4, 2019, a tentative approval from TSX was received for a proposed refinancing of the 2013 Debenture, subject to certain conditions being met. As a result of the proposed refinancing, the principal amount owing under the 2013 Debenture was refinanced by the 2019 Debenture. On May 1, 2019, the 2019 Debenture was issued with a principal amount of \$1,050,000, that will mature on November 1, 2019, bear interest at a rate of 12% per annum and be convertible into 1,779,661 common shares of the Company at a conversion price of \$0.59 per common share. Dr. Isa Odidi and Dr. Amina Odidi, who are shareholders, directors, and executive officers of the Company, are the holders of the 2019 Debenture. Effective November 1, 2019, the maturity date for the 2019 Debenture was extended to December 31, 2019. Effective December 31, 2019, the maturity date for the 2019 Debenture was extended to February 1, 2020. Effective January 31, 2020, the maturity date for the 2019 Debenture was further extended to March 31, 2020.

In September 2018, the Company completed a private placement financing of an unsecured convertible debenture in the principal amount of \$500,000 (the "2018 Debenture"). The 2018 Debenture bears interest at a rate of 10% per annum, is payable monthly, may be prepaid at any time at our option, and is convertible into Common Shares at any time prior to the maturity date at a conversion price of \$3.00 per Common Share at the option of the holder. Drs. Isa and Amina Odidi, who are directors, executive officers and shareholders of our Company, provided us with the original \$500,000 of proceeds for the 2018 Debenture. The maturity date for the 2018 Debenture is September 1, 2020. The net proceeds of the 2018 Debenture were used for working capital and general corporate purposes.

On November 15, 2019, we issued to Drs. Isa and Amina Odidi, by way of a private placement, an unsecured convertible debenture of the Company in consideration for, and in the aggregate principal amount of, USD\$250,000 (the "November 2019 Debenture"). The principal amount owing under the November 2019 Debenture is convertible at any time and from time to time into Common Shares at a conversion price equal to U.S. \$0.12 per Common Share. Up to an aggregate of 2,083,333 Common Shares may be issued upon conversion of the principal amount owing under the November 2019 Debenture. The November 2019 Debenture bears interest at a rate of 12% per annum (calculated monthly) and, subject to our right to prepay the November 2019 Debenture in whole or in part at any time without penalty, and matures on December 31, 2019. Effective January 31, 2020, the December 31, 2019 maturity date was extended to March 31, 2020. Dr. Isa Odidi is our Chairman, Chief Executive Officer and Co-Chief Scientific Officer, and Dr. Amina Odidi is our President, Chief Operating Officer and Co-Chief Scientific Officer.

#### **Deferred Share Units**

At November 30, 2019, there were no deferred share units ("DSUs") issued and outstanding. At February 28, 2020, 11,000 additional DSUs are reserved for issuance under our DSU plan. A description of the principal aspects of our DSU plan is contained in our May 2019 management information circular available under our company profile on SEDAR at [www.sedar.com](http://www.sedar.com).

#### **Restricted Share Units**

At November 30, 2019, there were no restricted share units ("RSUs") issued and outstanding. From November 30, 2019 to the date of this annual information form, no RSUs have been issued. At the date of this annual information form, 33,000 RSUs are reserved for issuance under our RSU Plan. A description of the principal aspects of our RSU plan is contained in our latest management information circular available under our company profile on SEDAR at [www.sedar.com](http://www.sedar.com).

### **MARKET FOR SECURITIES**

#### **Trading Price and Volume**

Our common shares are currently listed on the TSX and quoted for trading on Nasdaq, in each case under the symbols "IPCI", respectively. Our shares began trading on October 22, 2009, when the transaction with Vasogen was completed.

In March 2019, we received formal notice that the Nasdaq Panel had determined to delist our shares from Nasdaq based upon our non-compliance with the \$1.00 bid price requirement, as set forth in Nasdaq Listing Rule 5550(a)(2). The suspension of trading on Nasdaq took effect at the open of business on March 21, 2019. Our shares began trading on the OTCQB under the symbol "IPCF", commencing on March 21, 2019. Our shares also are listed on the TSX under the symbol "IPCF" and our non-compliance with Nasdaq's requirements did not impact our listing or trading status on that exchange.

The following table sets forth the monthly trading history for the fiscal year ended November 30, 2019, the reported high, low and closing prices (in Canadian dollars) and total volume traded of our common shares on the TSX and reported high, low and closing prices (in United States dollars) and total volume of our common shares traded on Nasdaq/OTCQB.

Date	TSX				Nasdaq			
	High	Low	Close	Volume	High	Low	Close	Volume
18-Dec	0.46	0.27	0.32	475,300	0.35	0.20	0.25	14,026,100
19-Jan	0.36	0.24	0.33	15,248,800	0.49	0.31	0.43	349,200
19-Feb	0.43	0.29	0.31	37,065,300	0.56	0.39	0.41	1,017,200
19-Mar	0.34	0.14	0.23	12,925,700	0.46	0.20	0.31	1,968,800
19-Apr	0.36	0.19	0.20	2,560,900	0.47	0.26	0.26	2,665,000
19-May	0.33	0.17	0.25	788,300	0.45	0.24	0.34	4,768,800
19-Jun	0.26	0.20	0.23	4,181,100	0.35	0.28	0.30	509,000
19-Jul	0.32	0.20	0.21	2,297,900	0.43	0.26	0.28	2,382,500
19-Aug	0.25	0.19	0.21	1,812,900	0.34	0.26	0.27	841,200
19-Sep	0.22	0.17	0.17	2,144,100	0.28	0.23	0.24	430,200
19-Oct	0.19	0.09	0.13	1,424,500	0.25	0.12	0.17	827,700
19-Nov	0.16	0.11	0.15	9,563,300	0.22	0.15	0.20	782,100

#### Prior Sales

During the 12-month period prior to the date of this Annual Information Form, we have issued Common Shares, or securities convertible into Common Shares, as follows:

In January 2013, the Company completed the private placement financing of the unsecured convertible 2013 Debenture in the original principal amount of \$1.5 million. The 2013 Debenture bears interest at a rate of 12% per annum, payable monthly, is pre-payable at any time at the option of the Company and is convertible at any time into Common Shares at a conversion price of \$30.00 per Common Share at the option of the holder. Drs. Isa and Amina Odidi, who are directors, executive officers and shareholders of our Company, provided us with the original \$1.5 million of the proceeds for the 2013 Debenture. In December 2016, a principal repayment of \$150,000 was made on the 2013 Debenture and the maturity date was extended until April 1, 2017. Effective March 28, 2017, the maturity date of the 2013 Debenture was extended to October 1, 2017. Effective September 28, 2017, the maturity date of the 2013 Debenture was further extended to October 1, 2018. Effective October 1, 2018, the maturity date for the 2013 Debenture was further extended to April 1, 2019. Effective April 1, 2019, the maturity date for the 2013 Debenture was further extended to May 1, 2019. In December 2018, a principal repayment of \$300,000 was made on the 2013 Debenture.

On April 4, 2019, a tentative approval from TSX was received for a proposed refinancing of the 2013 Debenture, subject to certain conditions being met. As a result of the proposed refinancing, the principal amount owing under the 2013 Debenture was refinanced by the 2019 Debenture. On May 1, 2019, the 2019 Debenture was issued with a principal amount of \$1,050,000, that will mature on November 1, 2019, bear interest at a rate of 12% per annum and be convertible into 1,779,661 common shares of the Company at a conversion price of \$0.59 per common share. Dr. Isa Odidi and Dr. Amina Odidi, who are shareholders, directors, and executive officers of the Company, are the holders of the 2019 Debenture. Effective November 1, 2019, the maturity date for the 2019 Debenture was extended to December 31, 2019. Effective December 31, 2019, the maturity date for the 2019 Debenture was extended to February 1, 2020. Effective January 31, 2020, the maturity date for the 2019 Debenture was further extended to March 31, 2020.

On September 10, 2018, the Company issued the 2018 Debenture. The 2018 Debenture bears interest at a rate of 10% per annum, payable monthly, may be prepaid at any time at our option, and is convertible into Common Shares at any time prior to the maturity date at a conversion price of \$3.00 per Common Share at the option of the holder. Drs. Isa and Amina Odidi, who are directors, executive officers and shareholders of our Company, provided us with the original \$500,000 of proceeds for the 2018 Debenture. The maturity date for the 2018 Debenture is September 1, 2020.

On November 15, 2019, we issued to Drs. Isa and Amina Odidi, by way of a private placement, an unsecured convertible debenture of the Company in consideration for, and in the aggregate principal amount of, USD\$250,000 (the "November 2019 Debenture"). The principal amount owing under the November 2019 Debenture is convertible at any time and from time to time into Common Shares at a conversion price equal to U.S. \$0.12 per Common Share. Up to an aggregate of 2,083,333 Common Shares may be issued upon conversion of the principal amount owing under the November 2019 Debenture. The November 2019 Debenture bears interest at a rate of 12% per annum (calculated monthly) and, subject to our right to prepay the November 2019 Debenture in whole or in part at any time without penalty, and matures on December 31, 2019. Effective January 31, 2020, the December 31, 2019 maturity date was extended to March 31, 2020. Dr. Isa Odidi is our Chairman, Chief Executive Officer and Co-Chief Scientific Officer, and Dr. Amina Odidi is our President, Chief Operating Officer and Co-Chief Scientific Officer.

During the 12-month period ended November 30, 2019, warrants (including Pre-Funded Warrants) to purchase an aggregate of 2,793,334 common shares were exercised.

During the 12-month period ended November 30, 2019, 1,887,000 options were granted, and no options were exercised.

During the 12-month period ended November 30, 2019, no DSUs were granted, 10,279 DSUs were exercised.

#### **DIRECTORS AND OFFICERS**

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

Name and Province of Residence	Position held with the Company	Principal Occupations During the Last 5 Years	Other Public Company Boards	Director Since
<b>Dr. Isa Odidi</b> Ontario, Canada	Chairman of the Board and Chief Executive Officer	Officer of the Company	None	September 2004
<b>Dr. Amina Odidi</b> Ontario, Canada	President, Chief Operating Officer and Director	Officer of the Company	None	September 2004
<b>Norman Betts</b> <sup>(1)</sup> New Brunswick, Canada	Director <sup>(4)</sup>	Associate Professor and Professor, University of New Brunswick, Faculty of Business Administration	Tanzanian Royalty Exploration Inc.; Adex Mining Inc.; 49 North Resources Inc.; Biotricity Inc.; Canada House Wellness Group Inc.	January 2019
<b>Shawn Graham</b> <sup>(2)(3)</sup> New Brunswick, Canada	Director	Associate Professor and Professor, University of New Brunswick, Faculty of Business Administration	None	May 2018
<b>Kenneth Keirstead</b> <sup>(1)(2)(3)</sup> New Brunswick, Canada	Director	Executive Manager of Lyceum Group, a consulting business	None	January 2006
<b>Bahadur Madhani</b> <sup>(1)(3)</sup> Ontario, Canada	Director	Chief Executive Officer of Equiprop Management Limited, a consulting business	None	March 2006
<b>Greg Powell</b> <sup>(5)</sup> Ontario, Canada	Chief Financial Officer	Officer of the Company since February 2019; Director of Finance of Wave Financial Inc. from August 2018 - January 2019; Director of Finance of ViXS Systems Inc. August 2013 - August 2018	None	N/A
<b>Dr. Patrick Yat</b> Ontario, Canada	Vice-President, Chemistry and Analytical Services	Officer of the Company	None	N/A

Notes:

- (1) Member of the Audit Committee.
- (2) Member of the Compensation Committee.
- (3) Member of the Corporate Governance Committee.
- (4) Dr. Betts was appointed a director of the Company on January 22, 2019 to fill the vacancy created by the resignation of Dr. Eldon Smith.
- (5) Mr. Powell resigned as Chief Financial Officer of the Company on February 4, 2020. Mr. Powell has agreed to continue to offer his services to the Company through March 4, 2020.

As of February 28, 2020, the directors and executive officers of the Company as a group owned, directly and indirectly, or exercise control or direction over 583,029 common shares, representing approximately 2.46% of the issued and outstanding common shares of the Company (and beneficially owned approximately 5,896,757 common shares representing 20.3% of our common shares including common shares issuable upon the exercise of outstanding options and the conversion of the outstanding Debentures that are exercisable or convertible within 60 days of the date hereof). Drs. Amina and Isa Odidi, our President and Chief Operating Officer and our Chairman and Chief Executive Officer, respectively, and Odidi Holdings Inc., a privately-held company controlled by Drs. Amina and Isa Odidi, owned in the aggregate directly and indirectly 578,131 common shares, representing approximately 2.44% of our issued and outstanding common shares of the Company (and collectively beneficially owned in the aggregate approximately 5,671,853 common shares representing 19.32% of our common shares including common shares issuable upon the exercise of outstanding options and the conversion of the outstanding Debentures that are exercisable or convertible within 60 days of the date hereof).

Drs. Isa Odidi and Amina Odidi are spouses to each other.

**Cease Trade Order**

Except as noted below, no director or executive officer of the Company is, as at the date of this annual information form, or has been within 10 years before the date of this annual information form, a director, chief executive officer or chief financial officer of any company that was the subject of a cease trade or similar order, or an order that denied the other issuer access to any statutory exemptions, for a period of more than thirty consecutive days (i) while that person was acting as a director, chief executive officer or chief financial officer; or (ii) after that person ceased acting as a director, chief executive officer or chief financial officer which resulted from an event that occurred while that person was acting in that capacity.

From March 2006 until June 2013, Dr. Norman Betts served as a director of Starfield Resources Inc. (TSX: SRU) (“**Starfield**”). On August 22, 2013, Starfield was the subject of a cease trade order issued by the Ontario Securities Commission as a result of Starfield’s failure to file, *inter alia*, its audited annual financial statements, related management’s discussion and analysis and officer certifications for the year ended February 28, 2013. The order is still in effect. On April 18, 2013, Starfield’s shares were delisted from the TSX.

From August 2012 to November 2012, Mr. Powell was the chief financial officer of Shear Diamonds Ltd. (“**Shear**”), a reporting issuer in Alberta and British Columbia that was listed on the TSX Venture Exchange. On October 30, 2012, Shear, as a result of a lack of financial resources, was unable to prepare and file its third quarter interim financial statements and management discussion & analysis for the period ended August 31, 2012. As a result, a cease trade order was issued by the Alberta Securities Commission on November 1, 2012 and by the British Columbia Securities Commission on November 6, 2012, which cease trade orders have not been revoked as of the date hereof. As a result, Shear was demoted from the TSX Venture Exchange to the NEX board of TSX Venture Exchange on May 15, 2013 and delisted from NEX on May 10, 2017. Mr. Powell resigned as an officer of Shear in November 2012.

### **Bankruptcies**

Except as noted below, no director or executive officer or a shareholder holding a sufficient number of securities of the Company to affect materially the control of the Company (i) is, as at the date of this annual information form, or has been, within 10 years before the date of this annual information form, a director or executive officer of any company that, while that person was acting in that capacity, or within a year of that person ceasing to act in that capacity, became bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or was subject to or instituted any proceedings, arrangement or compromise with creditors or had a receiver, receiver manager or trustee appointed to hold its assets, or (ii) has, within 10 years before the date of this annual information form, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency or (iii) was subject to or instituted any proceedings, arrangement or compromise with creditors or had a receiver, receiver manager or trustee appointed to hold its assets.

From March 2006 until June 2013, Dr. Norman Betts served as a director of Starfield. On July 2, 2013, Starfield announced that it was deemed to have made an assignment in bankruptcy, effective at the close of business on June 28, 2013 for failure to file a proposal before the time for doing so had past pursuant to the provisions of the *Bankruptcy and Insolvency Act* (Canada) (the “**BIA**”). Starfield had previously filed a Notice of Intention to Make a Proposal (“**Notice of Intention**”) pursuant to the provisions of Part III of the BIA. Pursuant to the Notice of Intention, PriceWaterhouseCoopers Inc. (“**PwC**”) was appointed as the trustee (“**Proposal Trustee**”) in Starfield’s proposal proceedings. Pursuant to a Order of the Ontario Superior Court of Justice (Commercial List), the time for Starfield to file a proposal expired at the end of the day on June 28, 2013. Starfield completed a sale of substantially all of its assets related to its Ferguson Lake Project in early June 2013. However, in consultation with the Proposal Trustee, Starfield determined that it would not be able to put forward a viable proposal and would not be filing a proposal by the deadline. As a result, Starfield was deemed to have made an assignment in bankruptcy at the end of the day on June 28, 2013. PwC acted as the trustee in bankruptcy for Starfield.

### **Conflicts of Interest**

Certain of the directors and officers of the Company and its subsidiaries are also directors, officers and shareholders of other companies and conflicts may arise between their duties as directors or officers of the Company and its subsidiaries and as directors, officers or shareholders of other companies. All such possible conflicts are required to be disclosed in accordance with the requirements of the *Canada Business Corporations Act* and the Company’s Code of Business Conduct and Ethics and those concerned are required to govern themselves in accordance with the obligations imposed upon them by law and such code.

## AUDIT COMMITTEE

The Audit Committee of the Board monitors our financial activities, policies, and internal control procedures. The Audit Committee assists the Board in fulfilling its oversight responsibility to shareholders, potential shareholders, the investment community, and others with respect to the Company's financial statements, financial reporting process, systems of internal accounting and disclosure controls, performance of the external auditors, and risk assessment and management. The Audit Committee has the power to conduct or authorize investigations into any matters within its scope of responsibilities, with full access to all books, records, facilities and personnel of the Company, its auditors and its legal advisors. In connection with such investigations or otherwise in the course of fulfilling its responsibilities under the Audit Committee Charter, the Audit Committee has the authority to independently retain special legal, accounting, or other consultants to advise it.

### Audit Committee Charter

The text of the Audit Committee Charter is set out in Schedule A hereto.

### Composition of the Audit Committee

Our Audit Committee is comprised of Norman Betts, Kenneth Keirstead and Bahadur Madhani, each of whom is considered independent and financially literate (as such terms are defined under National Instrument 52-110 – *Audit Committee*). The members of the Audit Committee have selected a Chair from amongst themselves, being Mr. Madhani.

Under the SEC rules implementing the Sarbanes-Oxley Act of 2002, Canadian issuers filing reports in the United States must disclose whether their audit committees have at least one "audit committee financial expert". Additionally, under Nasdaq Listing Rule 5605(c)(2)(A), Nasdaq requires that one member of the audit committee be financially sophisticated, meaning that they must have "past employment experience in finance or accounting, requisite professional certification in accounting, or any other comparable experience or background which results in the individual's financial sophistication, including being or having been a chief executive officer, chief financial officer, or other senior officer with financial oversight responsibilities." The Board has determined that Mr. Madhani qualifies as an Audit Committee financial expert under the SEC rules and as financially sophisticated under the applicable Nasdaq rules.

### Relevant Education and Experience

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

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

Bahadur Madhani is a chartered accountant who has been a director of the Company since March 31, 2006. He was a member of the advisory board of Quebecor Ontario and former Chairman of United Way of Toronto, former Chair of YMCA of Greater Toronto, former Chair of Nelson Mandela Children's Fund Canada, former Chair of YMCA Canada and former Chair, Toronto Grants Review Team of the Ontario Trillium Foundation. He was awarded membership in the Order of Canada in 2001. Since 1983, Mr. Madhani's principal occupation has been as President and CEO of Equiprop Management Limited, a Canadian property management company of which Mr. Madhani is the principal shareholder.

## Pre-Approval Policies and Procedures

The Audit Committee reviewed with the independent auditor (who is responsible for expressing an opinion on the conformity of the Company's audited financial statements with accounting principles generally accepted in the United States of America) their judgments as to the quality, not just the acceptability, of the Company's accounting principles and such other matters as are required to be discussed with the Audit Committee under Canadian and United States generally accepted auditing standards. In addition, the Audit Committee has discussed with the independent auditor the auditor's independence from management and the Company including the matters in the written disclosures provided to the Audit Committee by the independent auditor, and considered the compatibility of non-audit services with the auditor's independence.

The Company's independent auditor is accountable to the Board and to the Audit Committee. The Board, through the Audit Committee, has the ultimate responsibility to evaluate the performance of the independent auditor, and through the shareholders, to appoint, replace and compensate the independent auditor. Under the Sarbanes-Oxley Act of 2002, the independent auditor of a public company is prohibited from performing certain non-audit services. The Audit Committee has adopted procedures and policies for the pre-approval of non-audit services, as described in the Audit Committee Charter. Under the terms of such policies and procedures, the Audit Committee has adopted a list of pre-approved services, including audit and audit-related services and tax services, and a list of prohibited non-audit services deemed inconsistent with an auditor's independence.

The list of pre-approved services includes:

1. Audit Services
  - Audits of the Company's consolidated financial statements;  
and
  - Statutory audits of the financial statements of the Company's subsidiaries.
2. Audit-Related Services
  - Reviews of the quarterly consolidated financial statements of the Company;
  - Services associated with registration statements, prospectuses, periodic reports and other documents filed with securities regulatory bodies (such as the SEC and the Ontario Securities Commission) or other documents issued in connection with securities offerings (e.g., comfort letters and consent letters) and assistance in responding to comment letters from securities regulatory bodies;
  - Special attest services as required by regulatory and statutory requirements;
  - Regulatory attestation of management reports on internal controls as required by the regulators;
  - Consultations with the Company's management as to the accounting or disclosure treatment of transactions or events and/or the actual or potential impact of final or proposed rules, standards or interpretations by the securities regulatory authorities, accounting standard setting bodies (such as the Financial Accounting Standards Board or Chartered Professional Accountants of Canada), or other regulatory or standard setting bodies;

- Presentations or training on accounting or regulatory pronouncements; and
- Due diligence services related to accounting and tax matters in connection with potential acquisitions / dispositions.

3. Tax Services

*a. Compliance Services*

- Assistance with the preparation of corporate income tax returns and related schedules for the Company and its subsidiaries;
- Assistance with the preparation of Scientific Research & Experimental Development investment tax credit claims and amended tax returns of the Company; and
- Assistance in responding to Canada Revenue Agency or Internal Revenue Service on proposed reassessments and other matters.

*b. Canadian & International Planning Services*

- Advice with respect to cross-border/transfer pricing tax issues;
- Advice related to the ownership of corporate intellectual property in jurisdictions outside of Canada;
- Assistance in interpreting and understanding existing and proposed domestic and international legislation, and the administrative policies followed by various jurisdictions in administering the law, including assisting in applying for and requesting advance tax rulings or technical interpretations;
- Assistance in interpreting and understanding the potential impact of domestic and foreign judicial tax decisions;
- Assistance and advising on routine planning matters; and
- Assistance in advising on the implications of the routine financing of domestic and foreign operations, including the tax implications of using debt or equity in structuring such financing, the potential impact of non-resident withholding tax and the taxation of the repatriation of funds as a return of capital, a payment of a dividend, or a payment of interest.

*c. Commodity Tax Services*

- Assistance regarding Harmonized Sales Tax/Goods and Services Sales Tax/Provincial Sales Tax/Customs/Property Tax filings and assessments;
- Commodity tax advice and compliance assistance with business reorganizations;
- Advice and assistance with respect to government audits/assessments;
- Advice with respect to other provincial tax filings and assessments; and
- Assistance with interpretations or rulings.

4. All Other Services

- Advice and documentation assistance with respect to internal controls over financial reporting and disclosure controls and procedures of the Company.

The list of prohibited services includes:

- Bookkeeping or other services related to the preparation of accounting records or financial statements;
- Financial information systems design and implementation;
- Appraisal or valuation services for financial reporting purposes;
- Actuarial services for items recorded in the financial statements;
- Internal audit outsourcing services;
- Management functions;
- Human resources;
- Certain corporate finance and other services;
- Legal services; and
- Certain expert services unrelated to the audit.

The Audit Committee also discusses with the Company's independent auditor the overall scope and plans for their audit. The Audit Committee meets with the independent auditor, with and without management present, to discuss the results of their examination, their evaluations of the Company's internal controls, and the overall quality of the Company's financial reporting. The Audit Committee held 4 meetings during the period from December 1, 2018 to November 30, 2019.

In reliance on the reviews and discussions referred to above, the Audit Committee recommended to the Board (and the Board approved) that the audited consolidated financial statements be included in the Annual Report for the year ended November 30, 2019 for filing with the Canadian provincial securities commissions and the SEC.

### EXTERNAL AUDITOR SERVICE FEES

The following table summarizes the total fees paid or accrued by the Company for audit and other services provided by MNP LLP, the Company's external auditor since July 27, 2016, in relation to the fiscal year ended November 30, 2019 and 2018:

	<u>2019 MNP LLP</u>	<u>2018 MNP LLP</u>
Audit Fees <sup>(1)</sup>	\$ C171,200	\$ C139,100
Audit-Related Fees <sup>(2)</sup>	\$ C143,741	\$ C160,603
Tax Fees <sup>(3)</sup>	\$ C35,331	\$ C29,305
All Other Fees <sup>(4)</sup>	-	-
Total Fees	<u>\$ C350,272</u>	<u>\$ C329,008</u>

Notes:

- (1) Audit fees consist of fees related to the audit of the Company's consolidated financial statements.
- (2) Audit-related fees consist of consultation on accounting and disclosure matters and reviews of quarterly interim financial statements, prospectus and base shelf activities and Form 20-F reviews.
- (3) Tax fees consist of fees for tax consultation, tax advice and tax compliance services for the Company and its subsidiaries.
- (4) All other fees related to internal control reviews.

## INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS

To our knowledge, except as set forth below, no director or officer of the Company or any other insider of the Company, or any associate or affiliate thereof, has or had any material interest, direct or indirect, in any transaction within the three most recently completed fiscal years or during the current fiscal year that has materially affected or is reasonably expected to materially affect the Company.

In January 2013, the Company completed the private placement financing of an unsecured debenture in the original principal amount of \$1.5 million (the "2013 Debenture"). The 2013 Debenture bore interest at a rate of 12% per annum, payable monthly, was pre-payable at any time at the option of the Company and was convertible at any time into Common Shares at a conversion price of \$30.00 per Common Share at the option of the holder. Drs. Isa and Amina Odidi, who are directors, executive officers and shareholders of our Company, provided us with the original \$1.5 million of the proceeds for the 2013 Debenture. In December 2016, a principal repayment of \$150,000 was made on the 2013 Debenture and the maturity date was extended until April 1, 2017. Effective March 28, 2017, the maturity date of the 2013 Debenture was extended to October 1, 2017. Effective September 28, 2017, the maturity date of the 2013 Debenture was further extended to October 1, 2018. Effective October 1, 2018, the maturity date for the 2013 Debenture was further extended to April 1, 2019. Effective April 1, 2019, the maturity date for the 2013 Debenture was further extended to May 1, 2019. In December 2018, a principal repayment of \$300,000 was made on the 2013 Debenture. On April 4, 2019, a tentative approval from TSX was received for a proposed refinancing of the 2013 Debenture, subject to certain conditions being met. As a result of the proposed refinancing, the principal amount owing under the 2013 Debenture was refinanced by the 2019 Debenture. On May 1, 2019, the 2019 Debenture was issued with a principal amount of \$1,050,000, that will mature on November 1, 2019, bear interest at a rate of 12% per annum and be convertible into 1,779,661 common shares of the Company at a conversion price of \$0.59 per common share. Dr. Isa Odidi and Dr. Amina Odidi, who are shareholders, directors, and executive officers of the Company, are the holders of the 2019 Debenture. Effective November 1, 2019, the maturity date for the 2019 Debenture was extended to December 31, 2019. Effective December 31, 2019, the maturity date for the 2019 Debenture was extended to February 1, 2020. Effective January 31, 2020, the maturity date for the 2019 Debenture was further extended to March 31, 2020.

In September 2018, the Company completed a private placement financing of an unsecured convertible debenture in the principal amount of \$500,000 (the "2018 Debenture"). The 2018 Debenture bears interest at a rate of 10% per annum, is payable monthly, may be prepaid at any time at our option, and is convertible into Common Shares at any time prior to the maturity date at a conversion price of \$3.00 per Common Share at the option of the holder. Drs. Isa and Amina Odidi, who are directors, executive officers and shareholders of our Company, provided us with the original \$500,000 of proceeds for the 2018 Debenture. The maturity date for the 2018 Debenture is September 1, 2020. The net proceeds of the 2018 Debenture were used for working capital and general corporate purposes.

In September 2019, the Company issued two unsecured, non-interest bearing promissory notes, with no fixed repayment terms, in the amounts of US\$6,500 and CDN\$203,886, to Dr. Isa Odidi and Dr. Amina Odidi, our principal stockholders, directors and executive officers of the Company. The proceeds from such notes were used for working capital and general corporate purposes.

On November 15, 2019, we issued to Drs. Isa and Amina Odidi, by way of a private placement, an unsecured convertible debenture of the Company in consideration for, and in the aggregate principal amount of, US\$250,000 (the "November 2019 Debenture"). The principal amount owing under the November 2019 Debenture is convertible at any time and from time to time into Common Shares at a conversion price equal to U.S. \$0.12 per Common Share. Up to an aggregate of 2,083,333 Common Shares may be issued upon conversion of the principal amount owing under the November 2019 Debenture. The November 2019 Debenture bears interest at a rate of 12% per annum (calculated monthly) and, subject to our right to prepay the November 2019 Debenture in whole or in part at any time without penalty, and matures on December 31, 2019. Effective January 31, 2020, the December 31, 2019 maturity date was extended to March 31, 2020. Dr. Isa Odidi is our Chairman, Chief Executive Officer and Co-Chief Scientific Officer, and Dr. Amina Odidi is our President, Chief Operating Officer and Co-Chief Scientific Officer.

Since the beginning of the Company's preceding three financial years to the date hereof, other than discussed above in this section, there have been no transactions or proposed transactions which are material to the Company or to any associate, holder of 10% of the Company's outstanding shares, director or officer or any transactions that are unusual in their nature or conditions to which the Company or any of its subsidiaries was a party.

The Company's Corporate Governance Committee, made up of independent directors, oversees any potential transaction and negotiation that could give rise to a related party transaction or create a conflict of interest, and conducts an appropriate review.

#### **LEGAL PROCEEDINGS AND REGULATORY ACTIONS**

From time to time, we may be exposed to claims and legal actions in the normal course of business. As at November 30, 2019, and continuing as at February 28, 2020, we are not aware of any pending or threatened material litigation claims against us, other than the following as described below.

In November 2016, we filed an NDA for our Oxycodone ER product candidate, relying on the 505(b)(2) regulatory pathway, which allowed us to reference data from Purdue's file for its OxyContin® extended release oxycodone hydrochloride. Our Oxycodone ER application was accepted by the FDA for further review in February 2017. We certified to the FDA that we believed that our Oxycodone ER product candidate would not infringe any of the OxyContin® patents listed in the Orange Book, or that such patents are invalid, and so notified Purdue and the other owners of the subject patents listed in the Orange Book of such certification.

On April 7, 2017, we received notice that the Purdue litigation plaintiffs had commenced patent infringement proceedings 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. The Company then similarly certified to the FDA concerning such further patents. On March 16, 2018, we received notice that the Purdue litigation plaintiffs had commenced further such patent infringement proceedings against us adding the 4 further patents. This lawsuit is also in the District of Delaware federal court under docket number 18-404.

As a result of the commencement of the first of these legal proceedings, the FDA is stayed for 30 months from granting final approval to our Oxycodone ER product candidate. That time period commenced on February 24, 2017, when the Purdue litigation plaintiffs received notice of our certification concerning the patents, and will expire on August 24, 2019, unless the stay is earlier terminated by a final declaration of the courts that the patents are invalid, or are not infringed, or the matter is otherwise settled among the parties.

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

On July 6, 2018 the court issued a claims construction on the first case which we believe does not weaken the case.

On July 24, 2018, the parties to the case mutually agreed to dismiss 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. Infringement claims related to this patent have been dismissed without prejudice.

On October 4, 2018, the parties to the 17-392 docket case 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. That filing was timely filed at the end of February 2019. The trial in the 17-392 case was scheduled for November 12, 2019. On January 17, 2019, the court issued a scheduling order in 18-404 that schedules the remaining major portions. The trial in the 18-404 case was scheduled for June 2020.

The U.S. Federal Circuit Court of Appeal affirmed on April 4, 2019 the invalidity of one Purdue OxyContin® patent. The patent is: 9,060,976. The patent was nominally in our 17-392 and 18-404 cases. The invalidity ruling reduces yet another patent from the overall picture. However, it does not, by itself, eliminate the 30 month litigation stay in either docketed case. On October 3, 2019 following the filing of a bankruptcy stay by Purdue Pharma, the ongoing litigation case numbers 1:17-cv-00392-RGA and 1:18-cv-00404-RGA-SRF between Purdue Pharma L.P. et al and Intellipharmaceutics International have been stayed and the existing dates in both cases vacated by an order issued by the courts in the District of Delaware. No new dates were given for reinstatement; however, the parties are required to provide a further status report no later than March 13, 2020. The current 30-month regulatory stay date for FDA of March 2, 2020 remains unchanged at this time, absent a further order of the judge.

We are confident that we do not infringe any of the subject patents in either of the two cases and will vigorously defend against these claims.

In July 2017, three complaints were filed in the U.S. District Court for the Southern District of New York that were later consolidated under the caption *Shanawaz v. Intellipharmaceutics Int'l Inc., et al.*, No. 1:17-cv-05761 (S.D.N.Y.). The lead plaintiffs filed a consolidated amended complaint on January 29, 2018. In the amended complaint, the lead plaintiffs assert claims on behalf of a putative class consisting of purchasers of our securities between May 21, 2015 and July 26, 2017. The amended complaint alleges that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder by making allegedly false and misleading statements or failing to disclose certain information regarding our NDA for Oxycodone ER abuse-deterrent oxycodone hydrochloride extended release tablets. The complaint seeks, among other remedies, unspecified damages, attorneys' fees and other costs, equitable and/or injunctive relief, and such other relief as the court may find just and proper.

On March 30, 2018, the Company and the other defendants filed a motion to dismiss the amended complaint for failure to state a valid claim. The defendants' motion to dismiss was granted in part, and denied in part, in an Order dated December 17, 2018. In its Order, the court dismissed certain of the plaintiffs' securities claims to the extent that the claims were based upon statements describing the Oxycodone ER product's abuse-deterrent features and its bioequivalence to OxyContin®. However, the court allowed the claims to proceed to the extent plaintiffs challenged certain public statements describing the contents of the Company's Oxycodone ER NDA. Defendants filed an answer to the amended complaint on January 7, 2019. On February 5, 2019, the court held an initial pretrial conference and entered a scheduling order governing discovery and class certification. In an order entered at the parties request on May 9, 2019, the Court stayed proceedings in the action to permit the parties time to conduct a mediation. As a result of subsequent extensions, the stay was extended through October 10, 2019. The parties participated in a mediation on August 1, 2019, during which the parties tentatively agreed to the terms of a settlement of the action subject to the satisfaction of certain financial conditions by the Company. On October 10, 2019, the Company provided notice that it was not able to satisfy those conditions. As a result, it is possible that the parties will resume active litigation in the action in the near future. If a settlement does not go forward, the Company and the other defendants intend to vigorously defend themselves against the remainder of the claims asserted in the consolidated action.

On November 7, 2019 the Company announced that the parties in *Shanawaz v. Intellipharma International, Inc.*, an action pending in New York reached a settlement that is subject to the approval of the court following notice to class members. The stipulation of settlement provides for a settlement payment of US\$1.6 million, which Intellipharma anticipates will be funded by available insurance. As part of the settlement, the Company also agreed to contribute to the settlement fund specific anticipated Canadian tax refunds of up to US\$400,000 to the extent received within 18 months after the entry of final judgment. The stipulation acknowledges that the Company and the other defendants continue to deny that they committed any violation of the U.S. securities laws or engaged in any other wrongdoing and that they are entering into the settlement at this time based on the burden, expense, and inherent uncertainty of continuing the litigation.

Although the Company believes that the settlement represents a fair and reasonable compromise of the matters in dispute in the litigation, there can be no assurance that the court will approve the stipulation of settlement as proposed, or at all. If the stipulation of settlement is not approved or otherwise fails to become effective, then the parties will be returned to their respective positions in the litigation as of August 9, 2019.

On February 21, 2019, we and our CEO, Dr. Isa Odidi, were served with a Statement of Claim filed in the Superior Court of Justice of Ontario for a proposed class action under the Ontario Class Proceedings Act. The action was brought by Victor Romita, the proposed representative plaintiff, on behalf of a class of Canadian persons who traded Common Shares during the period from February 29, 2016 to July 26, 2017. The Statement of Claim, under the caption *Victor Romita v. Intellipharma International Inc. and Isa Odidi*, asserted that the defendants knowingly or negligently made certain public statements during the relevant period that contained or omitted material facts concerning Oxycodone ER abuse-deterrent oxycodone hydrochloride extended release tablets. The plaintiff alleged that he and the class suffered loss and damages as a result of their trading in our shares during the relevant period. The plaintiff seeks, among other remedies, unspecified damages, legal fees and court and other costs as the Court may permit. On February 26, 2019, the plaintiff delivered a Notice of Motion seeking the required approval from the Court, in accordance with procedure under the Ontario Securities Act, to allow the statutory claims under the Ontario Securities Act to proceed with respect to the claims based upon the acquisition or disposition of our shares on the TSX during the relevant period. On June 28, 2019, the Court endorsed a timetable for the exchange of material leading to the hearing of the Motion scheduled for January 27-28, 2020. On October 28, 2019, plaintiff's counsel advised the court that the Plaintiff intended to amend his claim and could not proceed with the Leave Motion scheduled for January 27-28, 2020. As such the court released those dates. On January 28, 2020 the Plaintiff served a Motion to amend the Statement of Claim ("Amendment Motion"). The proposed Fresh as Amended Statement of Claim purports, among other things, to include common law claims for misrepresentation and add an additional representative plaintiff. The plaintiff's Amendment Motion has been scheduled for April 21, 2020. The hearing of the Leave Motion has not yet been rescheduled and no date has been set for the hearing of the certification application. The defendants intend to vigorously defend the action and have filed a Notice of Intent to Defend.

On October 7, 2019, a complaint was filed in the U.S. District Court for the Southern District of New York by Alpha Capital Anstalt ("Alpha") against the Company, two of its existing officers and directors and its former Chief Financial Officer. In the complaint, Alpha alleges that the Company and the executive officers/directors named in the complaint violated Sections 11, 12(a)(2) and 15 of the U.S. Securities Act by allegedly making false and misleading statements in the Company's Registration Statement on Form F-1 filed with the U.S. Securities and Exchange Commission on September 20, 2018, as amended by failing to disclose certain information regarding the resignation of the Company's then Chief Financial Officer, which was announced several weeks after such registration statement was declared effective. In the complaint Alpha seeks unspecified damages, rescission of its purchase of the Company's securities in the relevant offering, attorneys' fees and other costs and further relief as the court may find just and proper. On December 12, 2019, the Company and the other defendants in the action filed a motion to dismiss for failure to state a claim. The Plaintiff's opposition to that motion was filed on February 4, 2020 and briefing is scheduled to be complete on March 6, 2020 if they are served in the action. The Company and other defendants intend to vigorously defend against the allegations set forth in the complaint. However, there can be no assurance that the case can be resolved in the Company's favor.

## TRANSFER AGENTS AND REGISTRARS

Our Canadian transfer agent and registrar is AST Trust Company, 1 Toronto Street, Suite 1200, Toronto, Ontario, M5C 2V6. Our United States co-transfer agent and registrar is American Stock Transfer & Trust Co., LLC, 59 Maiden Lane, Plaza Level, New York, NY 10038.

## MATERIAL CONTRACTS

Except for contracts entered into in the ordinary course of business and not required to be filed under Canadian securities laws, the only contracts which are regarded as material and which were entered into by the Company in the period subsequent to the recently completed fiscal year, within the most recently completed fiscal year or before the most recently completed fiscal year, but are still in effect, are the following:

- On November 21, 2005, the Company entered into the Par agreement (as amended on August 12, 2011 and September 24, 2013), pursuant to which the Company granted Par an exclusive, royalty-free license to make and distribute in the United States 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. The Company is responsible under the Par agreement for the development of the product and most related costs which, with the applications to and recent approvals by the FDA, the Company now considers to be completed.
- The acknowledgement and agreement of the Company dated October 22, 2009 to be bound by the performance based stock option agreement dated September 10, 2004 pursuant to which Drs. Isa and Amina Odidi are entitled to purchase up to 276,394 of the Company’s shares upon payment of \$36.20 per share, subject to satisfaction of the performance vesting conditions being the acceptance by the FDA of the filing of an application for approval of a drug product or the approval of such an application. In January 2013, the Company completed the private placement financing of an unsecured debenture in the original principal amount of \$1.5 million (the “2013 Debenture”). The 2013 Debenture bore interest at a rate of 12% per annum, payable monthly, was pre-payable at any time at the option of the Company and was convertible at any time into Common Shares at a conversion price of \$30.00 per Common Share at the option of the holder. Drs. Isa and Amina Odidi, who are directors, executive officers and shareholders of our Company, provided us with the original \$1.5 million of the proceeds for the 2013 Debenture. In December 2016, a principal repayment of \$150,000 was made on the 2013 Debenture and the maturity date was extended until April 1, 2017. Effective March 28, 2017, the maturity date of the 2013 Debenture was extended to October 1, 2017. Effective September 28, 2017, the maturity date of the 2013 Debenture was further extended to October 1, 2018. Effective October 1, 2018, the maturity date for the 2013 Debenture was further extended to April 1, 2019. Effective April 1, 2019, the maturity date for the 2013 Debenture was further extended to May 1, 2019. In December 2018, a principal repayment of \$300,000 was made on the 2013 Debenture. As a result of a refinancing transaction, the principal amount owing under the 2013 Debenture was refinanced by the 2019 Debenture. On May 1, 2019, the 2019 Debenture was issued with a principal amount of \$1,050,000. On April 4, 2019, a tentative approval from TSX was received for a proposed refinancing of the 2013 Debenture, subject to certain conditions being met. As a result of the proposed refinancing, the principal amount owing under the 2013 Debenture was refinanced by the 2019 Debenture. On May 1, 2019, the 2019 Debenture was issued with a principal amount of \$1,050,000, that will mature on November 1, 2019, bear interest at a rate of 12% per annum and be convertible into 1,779,661 common shares of the Company at a conversion price of \$0.59 per common share. Dr. Isa Odidi and Dr. Amina Odidi, who are shareholders, directors, and executive officers of the Company, are the holders of the 2019 Debenture. Effective November 1, 2019, the maturity date for the 2019 Debenture was extended to December 31, 2019. Effective December 31, 2019, the maturity date for the 2019 Debenture was extended to February 1, 2020. Effective January 31, 2020, the maturity date for the 2019 Debenture was further extended to March 31, 2020.

- In September 2018, the Company completed a private placement financing of an unsecured convertible debenture in the principal amount of \$500,000 (the "2018 Debenture"). The 2018 Debenture bears interest at a rate of 10% per annum, is payable monthly, may be prepaid at any time at our option, and is convertible into Common Shares at any time prior to the maturity date at a conversion price of \$3.00 per Common Share at the option of the holder. Drs. Isa and Amina Odidi, who are directors, executive officers and shareholders of our Company, provided us with the original \$500,000 of proceeds for the 2018 Debenture. The maturity date for the 2018 Debenture is September 1, 2020. The net proceeds of the 2018 Debenture were used for working capital and general corporate purposes.
- On November 25, 2019, entered into a license and commercial supply agreement with Tris Pharma, Inc. ("Tris Pharma"), by which we granted Tris Pharma an exclusive license to market, sell and distribute in the United States, Venlafaxine ER in the 37.5, 75, and 150 mg strengths approved for sale in the US market by the FDA. Several other generic versions of these licensed products are currently available in the market.
- On November 15, 2019, we issued to Drs. Isa and Amina Odidi, by way of a private placement, an unsecured convertible debenture of the Company in consideration for, and in the aggregate principal amount of, USD\$250,000 (the "November 2019 Debenture"). The principal amount owing under the November 2019 Debenture is convertible at any time and from time to time into Common Shares at a conversion price equal to U.S. \$0.12 per Common Share. Up to an aggregate of 2,083,333 Common Shares may be issued upon conversion of the principal amount owing under the November 2019 Debenture, representing approximately 9.43% of the issued and outstanding Common Shares. The November 2019 Debenture bears interest at a rate of 12% per annum (calculated monthly) and, subject to our right to prepay the November 2019 Debenture in whole or in part at any time without penalty, and matures on December 31, 2019. Effective January 31, 2020, the December 31, 2019 maturity date was extended to March 31, 2020. We used the proceeds from the November 2019 Debenture for working capital and general corporate purposes. Dr. Isa Odidi is our Chairman, Chief Executive Officer and Co-Chief Scientific Officer, and Dr. Amina Odidi is our President, Chief Operating Officer and Co-Chief Scientific Officer.
- In September 2019, the Company issued two Promissory note payable, unsecured, non-interest bearing with no fixed repayment terms, in the amounts of US\$6,500 and CDN\$203,886, to Dr. Isa Odidi and Dr. Amina Odidi, our principal stockholders, directors and executive officers of the Company.
- On September 5, 2019, we announced we had entered into a license and commercial supply agreement with Tris Pharma, by which we granted Tris Pharma an exclusive license to market, sell and distribute in the United States, Desvenlafaxine Succinate ER in the 50 and 100 mg strengths approved for sale in the U.S. market by the FDA. Several other generic versions of these licensed products are currently available in the market.
- On August 15, 2019, we announced we had entered into a license and commercial supply agreement with Tris Pharma, by which we granted Tris Pharma an exclusive license to market, sell and distribute in the United States, Quetiapine ER in the 50, 150, 200, 300 and 400 mg strengths approved for sale in the U.S. market by the FDA. Several other generic versions of these licensed products are currently available in the market. On April 12, 2019, we and Mallinckrodt LLC ("Mallinckrodt") mutually agreed to terminate our license and commercial supply agreement, effective no later than August 31, 2019. Under the terms of our mutual agreement, Mallinckrodt was released from certain obligations under the license and commercial supply agreement as of April 12, 2019. Effective August 12, 2019 the Mallinckrodt agreement was terminated.
- Pursuant to the 2017 Wainwright Agreement, in October 2017, we completed a registered direct offering consisting of 363,636 common shares at a price of \$11.00 per share and warrants to purchase an aggregate of 181,818 common shares, for gross proceeds of \$4.0 million. The warrants became exercisable six months from issuance, will expire 30 months after they become exercisable and have an exercise price of \$12.50 per common share. The common shares (but not the warrants or the common shares underlying the warrants) were offered by us through a prospectus supplement pursuant to our shelf registration statement on Form F-3 as previously filed and declared effective by the SEC and the base prospectus contained therein (Registration Statement No. 333-218297). The warrants described above were offered in a private placement under Section 4(a)(2) of the U.S. Securities Act, and Regulation D promulgated thereunder and, along with the common shares underlying the warrants, have not been registered under the U.S. Securities Act, or applicable state securities laws. The Company also issued to the placement agents warrants to purchase 18,181 common shares at an exercise price of \$13.75 per share. The total net proceeds from the offering were \$3.5 million, after deducting the underwriter's discount and the offering expenses.

- Pursuant to the March 2018 Wainwright Agreements, the Company completed, in March 2018, 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.
- The Company entered into an engagement letter (the “**August 2018 Engagement Letter**”) with Wainwright on August 15, 2018, pursuant to which Wainwright agreed to serve as (i) exclusive placement agent or underwriter for any offering in the United States of the securities of the Company to take place within the following 5 months, and (ii) exclusive agent or advisor in connection with the solicitation in respect of the Company’s outstanding warrants. The Company agreed to pay Wainwright a cash fee, or as to an underwritten offering an underwriter discount, equal to a maximum of 8% of the aggregate gross proceeds raised by the Company from the sale of securities in each offering during the term of the engagement. The Company also agreed to grant to Wainwright, or its designees, warrants to purchase up to a maximum of 6% of the aggregate number of shares sold in the offering and issued on each closing. The August 2018 Engagement Letter provides that such warrants should have substantially the same terms as the other warrants sold in the offering, except that their exercise price should equal 125% of the offering price per share. The August 2018 Engagement Letter has indemnity and other customary provisions for transactions of this nature. The Company agreed to pay Wainwright a management fee equal to 1% of the gross proceeds raised in the offering, a reimbursement for non-accountable expenses of \$35,000 and for up to \$100,000 for fees and expenses of legal counsel and other out-of-pocket expenses, as well as a reimbursement for up to \$10,000 for the out-of-pocket costs of clearing agent settlement and financing. In addition, the Company granted Wainwright, for a period of 10 months from the closing of an offering, a right of first refusal to act as sole book-running manager or sole placement agent for every future public or private equity or debt offering using a manager or agent by the Company, or any of its successors or subsidiaries. The Company also agreed to a tail fee equal to the cash and warrant compensation provided in connection an offering if any investor to which Wainwright introduced the Company, or that Wainwright contacted, with respect to an offering during the term of the engagement provides the Company with capital in a public or private offering, or financing or capital raising transaction during the 12 month period following termination of the Company’s engagement of Wainwright.
- In October 2018, we completed an underwritten public offering in the United States, resulting in the sale to the public of 827,970 units at \$0.75 per unit, which were comprised of one common share and one 2018 Unit Warrant exercisable at \$0.75 per share. We concurrently sold an additional 1,947,261 common shares and 2018 Option Warrants to purchase 2,608,695 common shares exercisable at \$0.75 per share pursuant to the over-allotment option exercised in part by the underwriter. The price for the common shares issued in connection with exercise of the overallotment option was \$0.74 per share and the price for the warrants issued in connection with the exercise of the overallotment option was \$0.01 per warrant, less in each case the underwriting discount. In addition, we issued 16,563,335 2018 Pre-Funded Units, each 2018 Pre-Funded Unit consisting of one 2018 Pre-Funded Warrant to purchase one common share and one 2018 Warrant to purchase one common share. The 2018 Pre-Funded Units were offered to the public at \$0.74 each, and a 2018 Pre-Funded Warrant is exercisable at \$0.01 per share. Each 2018 Firm Warrant is exercisable immediately and has a term of five years and each 2018 Pre-Funded Warrant is exercisable immediately and until all 2018 Pre-Funded Warrants are exercised. We also issued October 2018 Placement Agent Warrants to the placement agents to purchase 1,160,314 common shares at an exercise price of \$0.9375 per share, which were exercisable immediately upon issuance. In aggregate, the Company issued 2,775,231 common shares, 16,563,335 2018 Pre-Funded Warrants and 20,000,000 2018 Firm Warrants in addition to 1,160,314 October 2018 Placement Agent Warrants. During the year ended November 30, 2018, 12,153,334 2018 Pre-Funded Warrants were exercised for proceeds of \$121,553.

Copies of the above agreements have been filed on SEDAR at [www.sedar.com](http://www.sedar.com)

#### **INTERESTS OF EXPERTS**

Our auditor is MNP LLP (“MNP”), Chartered Professional Accountants, 111 Richmond Street West, Suite 300, Toronto, ON M5H 2G4. MNP is independent with respect to the Company within the meaning of the Rules of Professional Conduct of the Chartered Professional Accountants of Ontario.

#### **ADDITIONAL INFORMATION**

Additional information relating to the Company may be found under the Company’s profile on SEDAR at [www.sedar.com](http://www.sedar.com). Additional information relating to directors’ and officers’ remuneration and indebtedness, principal holders of securities, and securities authorized for issuance under equity compensation plans, is contained in the latest management information circular of the Company filed on SEDAR at [www.sedar.com](http://www.sedar.com).

Additional financial information is provided in the consolidated financial statements and the accompanying Management Discussion and Analysis for our fiscal year ended November 30, 2019. Copies of such documents are filed on SEDAR at [www.sedar.com](http://www.sedar.com) and may be obtained upon request from our Chief Financial Officer or President at 30 Worcester Road, Toronto, Ontario, Canada M9W 5X2.

**SCHEDULE A**

**INTELLIPHARMACEUTICS INTERNATIONAL INC.**

**AUDIT COMMITTEE CHARTER**

**I. Mandate and Purpose of the Committee**

The Audit Committee (the “**Committee**”) of the board of directors (the “**Board**”) of Intellipharmaceutics International Inc. (the “**Company**”) is a standing committee of the Board whose primary function is to assist the Board in fulfilling its oversight responsibilities relating to:

- (a) the integrity of the Company’s financial statements;
- (b) the Company’s compliance with legal and regulatory requirements, as they relate to the Company’s financial statements;
- (c) the qualifications, independence and performance of the Company’s auditor;
- (d) internal controls and disclosure controls;
- (e) the performance of the Company’s internal audit function; and
- (f) performing the additional duties set out in this Charter or otherwise delegated to the Committee by the Board.

**II. Authority**

The Committee has the authority to:

- (a) engage and compensate independent counsel and other advisors as it determines necessary or advisable to carry out its duties; and
- (b) communicate directly with the Company’s auditor.

The Committee has the authority to delegate to individual members or subcommittees of the Committee.

**III. Composition and Expertise**

The Committee shall be composed of a minimum of three members, each whom is a director of the Company. Each Committee member must be “independent” and “financially literate” as such terms are defined in applicable securities legislation.

Committee members shall be appointed annually by the Board at the first meeting of the Board following each annual meeting of shareholders. Committee members hold office until the next annual meeting of shareholders or until they are removed by the Board or cease to be directors of the Company.

The Committee shall appoint one of its members to act as Chair of the Committee. If the Chair of the Committee is absent from any meeting, the Committee shall select one of the other members of the Committee to preside at that meeting.

#### **IV. Meetings**

Any member of the Committee or the auditor may call a meeting of the Committee. The Committee shall meet at least four times per year and as many additional times as the Committee deems necessary to carry out its duties. The Chair shall develop and set the Committee's agenda, in consultation with other members of the Committee, the Board and senior management.

Notice of the time and place of every meeting shall be given in writing to each member of the Committee, at least 72 hours (excluding holidays) prior to the time fixed for such meeting. The Company's auditor shall be given notice of every meeting of the Committee and, at the expense of the Company, shall be entitled to attend and be heard thereat. If requested by a member of the Committee, the Company's auditor shall attend every meeting of the Committee held during the term of office of the Company's auditor.

A majority of the Committee shall constitute a quorum. No business may be transacted by the Committee except at a meeting of its members at which a quorum of the Committee is present in person or by means of such telephonic, electronic or other communications facility that permits all persons participating in the meeting to communicate adequately with each other during the meeting.

The Committee may invite such directors, officers and employees of the Company and advisors as it sees fit from time to time to attend meetings of the Committee.

The Committee shall meet without management present whenever the Committee deems it appropriate.

The Committee shall appoint a Secretary who need not be a director or officer of the Company. Minutes of the meetings of the Committee shall be recorded and maintained by the Secretary and shall be subsequently presented to the Committee for review and approval.

#### **V. Committee and Charter Review**

The Committee shall conduct an annual review and assessment of its performance, effectiveness and contribution, including a review of its compliance with this Charter. The Committee shall conduct such review and assessment in such manner as it deems appropriate and report the results thereof to the Board.

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The Committee shall also review and assess the adequacy of this Charter on an annual basis, taking into account all legislative and regulatory requirements applicable to the Committee, as well as any guidelines recommended by securities regulators, the Toronto Stock Exchange or any other stock exchange or market on which the Corporation's shares are listed or posted for trading, and shall recommend changes to the Board thereon.

**VI. Reporting to the Board**

The Committee shall report to the Board in a timely manner with respect to each of its meetings held. This report may take the form of circulating copies of the minutes of each meeting held.

**VII. Duties and Responsibilities**

**(a) Financial Reporting**

The Committee is responsible for reviewing and recommending approval to the Board of the Company's annual and interim financial statements, MD&A and related news releases, before they are released.

The Committee is also responsible for:

- (i) being satisfied that adequate procedures are in place for the review of the Company's public disclosure of financial information extracted or derived from the Company's financial statements, other than the public disclosure referred to in the preceding paragraph, and for periodically assessing the adequacy of those procedures;
- (ii) engaging the Company's auditor to perform a review of the interim financial statements and receiving from the Company's auditor a formal report on the auditor's review of such interim financial statements;
- (iii) discussing with management and the Company's auditor the quality of generally accepted accounting principles ("GAAP"), not just acceptability of GAAP;
- (iv) discussing with management any significant variances between comparative reporting periods;  
and
- (v) in the course of discussion with management and the Company's auditor, identifying problems or areas of concern and ensuring such matters are satisfactorily resolved.

**(b) Auditor**

The Committee is responsible for recommending to the Board:

- (i) the auditor to be nominated for the purpose of preparing or issuing an auditor's report or performing other audit, review or attest services for the Company; and
  - (ii) the compensation of the Company's auditor.
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The Company's auditor reports directly to the Committee. The Committee is directly responsible for overseeing the work of the Company's auditor engaged for the purpose of preparing or issuing an auditor's report or performing other audit, review or attest services for the Company, including the resolution of disagreements between management and the Company's auditor regarding financial reporting.

**(c) Relationship with the Auditor**

The Committee is responsible for reviewing the proposed audit plan and proposed audit fees. The Committee is also responsible for:

- (i) establishing effective communication processes with management and the Company's auditor so that it can objectively monitor the quality and effectiveness of the auditor's relationship with management and the Committee;
- (ii) receiving and reviewing regular feedback from the auditor on the progress against the approved audit plan, important findings, recommendations for improvements and the auditor's final report;
- (iii) reviewing, at least annually, a report from the auditor on all relationships and engagements for non-audit services that may be reasonably thought to bear on the independence of the auditor; and
- (iv) meeting in camera with the auditor whenever the Committee deems it appropriate.

**(d) Accounting Policies**

The Committee is responsible for:

- (i) reviewing the Company's accounting policy note to ensure completeness and acceptability with GAAP as part of the approval of the financial statements;
- (ii) discussing and reviewing the impact of proposed changes in accounting standards or securities policies or regulations;
- (iii) reviewing with management and the auditor any proposed changes in major accounting policies and key estimates and judgments that may be material to financial reporting;
- (iv) discussing with management and the auditor the acceptability, degree of aggressiveness/conservatism and quality of underlying accounting policies and key estimates and judgments; and
- (v) discussing with management and the auditor the clarity and completeness of the Company's financial disclosures.

**(e) Risk and Uncertainty**

The Committee is responsible for reviewing, as part of its approval of the financial statements:

- (i) uncertainty notes and disclosures;  
and
- (ii) MD&A disclosures.

The Committee, in consultation with management, will identify the principal business risks and decide on the Company's "appetite" for risk. The Committee is responsible for reviewing related risk management policies and recommending such policies for approval by the Board. The Committee is then responsible for communicating and assigning to the applicable Board committee such policies for implementation and ongoing monitoring.

The Committee is responsible for requesting the auditor's opinion of management's assessment of significant risks facing the Company and how effectively they are managed or controlled.

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**(f) Controls and Control Deviations**

The Committee is responsible for reviewing:

- (i) the plan and scope of the annual audit with respect to planned reliance and testing of controls; and
- (ii) major points contained in the auditor's management letter resulting from control evaluation and testing.

The Committee is also responsible for receiving reports from management when significant control deviations occur.

**(g) Compliance with Laws and Regulations**

The Committee is responsible for reviewing regular reports from management and others (e.g. auditors) concerning the Company's compliance with financial related laws and regulations, such as:

- (i) tax and financial reporting laws and regulations;
- (ii) legal withholdings requirements;
- (iii) environmental protection laws; and
- (iv) other matters for which directors face liability exposure.

**VIII. Non-Audit Services**

All non-audit services to be provided to the Company or its subsidiary entities by the Company's auditor must be pre-approved by the Committee.

**IX. Submission Systems and Treatment of Complaints**

The Committee is responsible for establishing procedures for:

- (a) the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls, or auditing matters; and
- (b) the confidential, anonymous submission by employees of the Company of concerns regarding questionable accounting or auditing matters.

**X. Hiring Policies**

The Committee is responsible for reviewing and approving the Company's hiring policies regarding partners, employees and former partners and employees of the present and former auditor of the Company.

## CERTIFICATION OF ANNUAL FILINGS

## FULL CERTIFICATE

I, Dr. Isa Odidi, Chief Executive Officer, of Intellipharmaceutics International Inc., certify the following:

1. **Review:** I have reviewed the AIF, if any, annual financial statements and annual MD&A, including, for greater certainty, all documents and information that are incorporated by reference in the AIF (together, the “annual filings”) of Intellipharmaceutics International Inc. (the “issuer”) for the financial year ended November 30, 2019.

2. **No misrepresentations:** Based on my knowledge, having exercised reasonable diligence, the annual filings do not contain any untrue statement of a material fact or omit to state a material fact required to be stated or that is necessary to make a statement not misleading in light of the circumstances under which it was made, for the period covered by the annual filings.

3. **Fair presentation:** Based on my knowledge, having exercised reasonable diligence, the annual financial statements together with the other financial information included in the annual filings fairly present in all material respects the financial condition, results of operations and cash flows of the issuer, as of the date of and for the periods presented in the annual filings.

4. **Responsibility:** The issuer’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (DC&P) and internal control over financial reporting (ICFR), as those terms are defined in National Instrument 52-109 *Certification of Disclosure in Issuers’ Annual and Interim Filings*, for the issuer.

5. **Design:** Subject to the limitations, if any, described in paragraphs 5.2 and 5.3, the issuer’s other certifying officer(s) and I have, as at the financial year end

- A. designed DC&P, or caused it to be designed under our supervision, to provide reasonable assurance that
  - I. material information relating to the issuer is made known to us by others, particularly during the period in which the annual filings are being prepared; and
  - II. information required to be disclosed by the issuer in its annual filings, interim filings or other reports filed or submitted by it under securities legislation is recorded, processed, summarized and reported within the time periods specified in securities legislation; and
- B. designed ICFR, or caused it to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with the issuer’s GAAP.

5.1 **Control framework:** The control framework the issuer’s other certifying officer and I used to design the issuer’s ICFR is the Committee of Sponsoring Organizations Internal Control Framework.

5.2 **ICFR – material weakness relating to design:** The issuer has disclosed in its annual MD&A for each material weakness relating to design existing at the financial year end

- A. a description of the material weakness;
- B. the impact of the material weakness on the issuer’s financial reporting and its ICFR; and
- C. the issuer’s current plans, if any, or any actions already undertaken, for remediating the material weakness.

5.3 *N/A*

6. **Evaluation:** The issuer’s other certifying officer and I have

- A. evaluated, or caused to be evaluated under our supervision, the effectiveness of the issuer’s DC&P at the financial year end and the issuer has disclosed in its annual MD&A our conclusions about the effectiveness of DC&P at the financial year end based on that evaluation; and
  - B. evaluated, or caused to be evaluated under our supervision, the effectiveness of the issuer’s ICFR at the financial year end and the issuer has disclosed in its annual MD&A
    - I. our conclusions about the effectiveness of ICFR at the financial year end based on that evaluation; and
    - II. *N/A*
-

**7. Reporting changes in ICFR:** The issuer has disclosed in its annual MD&A any change in the issuer's ICFR that occurred during the period beginning on September 1, 2019 and ended on November 30, 2019 that has materially affected, or is reasonably likely to materially affect, the issuer's ICFR.

**8. Reporting to the issuer's auditors and board of directors or audit committee:** The issuer's other certifying officer and I have disclosed, based on our most recent evaluation of ICFR, to the issuer's auditors, and the board of directors or the audit committee of the board of directors any fraud that involves management or other employees who have a significant role in the issuer's ICFR.

Date: February 28, 2020

/s/ Dr. Isa Odidi

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Dr. Isa Odidi  
Chief Executive Officer

## FORM 52-109F1

## CERTIFICATION OF ANNUAL FILINGS

## FULL CERTIFICATE

I, Greg Powell, Chief Financial Officer, of Intellipharmaceutics International Inc., certify the following:

1. **Review:** I have reviewed the AIF, if any, annual financial statements and annual MD&A, including, for greater certainty, all documents and information that are incorporated by reference in the AIF (together, the “annual filings”) of Intellipharmaceutics International Inc. (the “issuer”) for the financial year ended November 30, 2019.

2. **No misrepresentations:** Based on my knowledge, having exercised reasonable diligence, the annual filings do not contain any untrue statement of a material fact or omit to state a material fact required to be stated or that is necessary to make a statement not misleading in light of the circumstances under which it was made, for the period covered by the annual filings.

3. **Fair presentation:** Based on my knowledge, having exercised reasonable diligence, the annual financial statements together with the other financial information included in the annual filings fairly present in all material respects the financial condition, results of operations and cash flows of the issuer, as of the date of and for the periods presented in the annual filings.

4. **Responsibility:** The issuer’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (DC&P) and internal control over financial reporting (ICFR), as those terms are defined in National Instrument 52-109 *Certification of Disclosure in Issuers’ Annual and Interim Filings*, for the issuer.

5. **Design:** Subject to the limitations, if any, described in paragraphs 5.2 and 5.3, the issuer’s other certifying officer(s) and I have, as at the financial year end

A. designed DC&P, or caused it to be designed under our supervision, to provide reasonable assurance that

I. material information relating to the issuer is made known to us by others, particularly during the period in which the annual filings are being prepared; and

II. information required to be disclosed by the issuer in its annual filings, interim filings or other reports filed or submitted by it under securities legislation is recorded, processed, summarized and reported within the time periods specified in securities legislation; and

B. designed ICFR, or caused it to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with the issuer’s GAAP.

5.1 **Control framework:** The control framework the issuer’s other certifying officer and I used to design the issuer’s ICFR is the Committee of Sponsoring Organizations Internal Control Framework.

5.2 **ICFR – material weakness relating to design:** The issuer has disclosed in its annual MD&A for each material weakness relating to design existing at the financial year end

A. a description of the material weakness;

B. the impact of the material weakness on the issuer’s financial reporting and its ICFR; and

C. the issuer’s current plans, if any, or any actions already undertaken, for remediating the material weakness.

5.3 *N/A*

6. **Evaluation:** The issuer’s other certifying officer and I have

A. evaluated, or caused to be evaluated under our supervision, the effectiveness of the issuer’s DC&P at the financial year end and the issuer has disclosed in its annual MD&A our conclusions about the effectiveness of DC&P at the financial year end based on that evaluation; and

B. evaluated, or caused to be evaluated under our supervision, the effectiveness of the issuer’s ICFR at the financial year end and the issuer has disclosed in its annual MD&A

I. our conclusions about the effectiveness of ICFR at the financial year end based on that evaluation; and

II. *N/A*

**7. Reporting changes in ICFR:** The issuer has disclosed in its annual MD&A any change in the issuer's ICFR that occurred during the period beginning on September 1, 2019 and ended on November 30, 2019 that has materially affected, or is reasonably likely to materially affect, the issuer's ICFR.

**8. Reporting to the issuer's auditors and board of directors or audit committee:** The issuer's other certifying officer and I have disclosed, based on our most recent evaluation of ICFR, to the issuer's auditors, and the board of directors or the audit committee of the board of directors any fraud that involves management or other employees who have a significant role in the issuer's ICFR.

Date: February 28, 2020

/s/ Greg Powell

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Greg Powell  
Chief Financial Officer