Intellipharmaceutics International Inc. Form 20-F/A March 04, 2019
UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549 FORM 20-F/A (Amendment No. 1) [_]
REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934
OR
[X]
ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended November 30, 2018
OR
TRANSITION REPORT PURSUANT TO SECTION 13 OR $15(d)$ OF THE SECURITIES EXCHANGE ACT OF 1934
OR
SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
Date of event requiring this shell company report
For the transition period from to
Commission File No. 0-53805
INTELLIPHARMACEUTICS INTERNATIONAL INC.
(Exact name of registrant as specified in its charter)
Canada
(Jurisdiction of incorporation or organization)

30 Worcester Road Toronto, Ontario M9W 5X2 (Address of principal executive offices)

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

Securities registered or to be registered pursuant to Section 12(b) of the Act:  Title of each class  Name of each exchange on which registered
Common shares, no par value NASDAQ TSX
Securities registered or to be registered pursuant to Section 12(g) of the Act: None
Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None
As of November 30, 2018, the registrant had 18,252,243 common shares outstanding.
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes [_] No [X]
If this report is an annual report or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.
Yes [_] No [X]
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes [X] No [_]
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).
Yes [X] No [_]
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or an emerging growth company. See definition of "large accelerated filer", "accelerated filer" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):
Large accelerated filer [_] Accelerated filer [_] Non-accelerated filer [X] Emerging growth company [_]
If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act. [_]

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting

Standards Board to its Accounting Standards Codification after April 5, 2012.

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

in this filing:		
U.S. GAAP	International Financial Reporting Standards as issued by the International Accounting	Other
[X]	Standards Board [_]	[_]

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow:
Item 17 [_] Item 18 [_]
If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes [_] No [X]

### **EXPLANATORY NOTE**

This Amendment No. 1 on Form 20-F/A (this "Amendment") amends the annual report on Form 20-F of Intellipharmaceutics International Inc. (the "Company") for the fiscal year ended November 30, 2018, as filed with the Securities and Exchange Commission on February 28, 2019 (the "Original Filing"). This Amendment is being filed solely to (i) include information regarding the Company's resubmission of its New Drug Application to the U.S. Food and Drug Administration for the Company's Oxycodone ER product candidate on February 28, 2019; (ii) include hyperlinks to each listed exhibit as required by Form 20-F; and (iii) make revisions to (a) "Item 3.D. Risk Factors", "Item 4.B. Business Overview", "Item 6.A. Directors and Senior Management", "Item 6.B. Compensation", "Item 6.E. Share Ownership", "Item 7.A. Major Shareholders", "Item 8.A. Consolidated Statements and Other Financial Information", and "Item 10.C. Major Contracts" of Part I of the Original Filing, and (b) "Item 19. Exhibits" of Part III of the Original Filing.

In accordance with Rule 12b-15 of the Securities Exchange Act of 1934, as amended, this Amendment includes new certifications required by Sections 302 and 906 of the Sarbanes-Oxley Act of 2002, as amended, dated as of the filing date of this Amendment. In addition, although no changes have been made to the financial statements included in Item 18 of Part III, the Consent of Independent Registered Chartered Accountants is included with this Amendment, filed as Exhibit 15.1 to this Amendment, and is dated as of the filing date of this Amendment.

This Amendment speaks as of the filing date of the Original Filing on February 28, 2019. For ease of reference, the entire Form 20-F, including all exhibits filed therewith, is included in this Amendment. Other than as set forth above, this Amendment does not, and does not purport to, amend, update, modify or restate any other information or disclosure included in the Original Filing or reflect any events occurring after the filing of the Original Filing. Accordingly, statements relating to the currency of information without reference to a date and references to information being current as of "as of the date of this annual report", "the date of this document" or "the date hereof" are current as of the February 28, 2019, filing date of the Original Filing.

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### DISCLOSURE REGARDING FORWARD-LOOKING INFORMATION

Certain statements in this annual report constitute "forward-looking statements" within the meaning of the United States Private Securities Litigation Reform Act of 1995 and/or "forward-looking information" under the Securities Act (Ontario). These statements include, without limitation, statements expressed or implied regarding our expectations, plans, goals and milestones, status of developments or expenditures relating to our business, plans to fund our current activities, and statements concerning our partnering activities, health regulatory submissions, strategy, future operations, future financial position, future sales, revenues and profitability, projected costs and market penetration. In some cases, you can identify forward-looking statements by terminology such as "appear", "unlikely", "target", "may", "will", "should", "expects", "plans", "plans to", "anticipates", "believes", "estimates", "predicts", "confident", "prospects", "potential "intends", "look forward", "could", "would", "projected", "goals", "set to", "seeking" or the negative of such terms or other co terminology. We made a number of assumptions in the preparation of our forward-looking statements. You should not place undue reliance on our forward-looking statements, which are subject to a multitude of known and unknown risks and uncertainties that could cause actual results, future circumstances or events to differ materially from those stated in or implied by the forward-looking statements. Risks, uncertainties and other factors that could affect our actual results include, but are not limited to, the effects of general economic conditions, securing and maintaining corporate alliances, our estimates regarding our capital requirements, and the effect of capital market conditions and other factors, including the current status of our product development programs, capital availability, the estimated proceeds (and the expected use of any proceeds) we may receive from any offering of our securities, the potential dilutive effects of any future financing, potential liability from and costs of defending pending or future litigation, our ability to comply with the Nasdaq Stock Market LLC ("Nasdaq") and the Toronto Stock Exchange ("TSX") continued listing standards and our ability to develop and implement a plan of compliance with the Nasdaq continued listing standards acceptable to a Nasdaq Hearings Panel (the "Nasdaq Panel"), our programs regarding research, development and commercialization of our product candidates, the timing of such programs, the timing, costs and uncertainties regarding obtaining regulatory approvals to market our product candidates and the difficulty in predicting the timing and results of any product launches, the timing and amount of profit-share payments from our commercial partners, and the timing and amount of any available investment tax credits, the actual or perceived benefits to users of our drug delivery technologies, products and product candidates as compared to others, our ability to establish and maintain valid and enforceable intellectual property rights in our drug delivery technologies, products and product candidates, the scope of protection provided by intellectual property rights for our drug delivery technologies, products and product candidates, recent and future legal developments in the United States and elsewhere that could make it more difficult and costly for us to obtain regulatory approvals for our product candidates and negatively affect the prices we may charge, increased public awareness and government scrutiny of the problems associated with the potential for abuse of opioid based medications, pursuing growth through international operations could strain our resources, our limited manufacturing, sales, marketing or distribution capability and our reliance on third parties for such, the actual size of the potential markets for any of our products and product candidates compared to our market estimates, our selection and licensing of products and product candidates, our ability to attract distributors and/or commercial partners with the ability to fund patent litigation and with acceptable product development, regulatory and commercialization expertise and the benefits to be derived from such collaborative efforts, sources of revenues and anticipated revenues, including contributions from distributors and commercial partners, product sales, license agreements and other collaborative efforts for the development and commercialization of product candidates, our ability to create an effective direct sales and marketing infrastructure for products we elect to market and sell directly, the rate and degree of market acceptance of our products, delays in product approvals that may be caused by changing regulatory requirements, the difficulty in predicting the timing of regulatory approval and launch of competitive products, the difficulty in predicting the impact of competitive products on sales volume, pricing, rebates and other allowances, the number of competitive product entries, and the nature and extent of any aggressive pricing and rebate activities that may follow, the inability to forecast wholesaler demand and/or wholesaler buying patterns, seasonal fluctuations in the number of prescriptions written for our generic Focalin XR® capsules, which may produce

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

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

Additional risks and uncertainties relating to us and our business can be found in the "Risk Factors" section in Item 3.D below, the "Risk Factors" sections of our latest annual information form and our latest registration statements on Form F-1 and F-3 (including any documents forming a part thereof or incorporated by reference therein), as amended, as well as in our reports, public disclosure documents and other filings with the securities commissions and other regulatory bodies in Canada and the U.S., which are available on www.sedar.com and www.sec.gov. The forward-looking statements reflect our current views with respect to future events, and are based on what we believe are reasonable assumptions as of the date of this document and we disclaim any intention and have no obligation or responsibility, except as required by law, to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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

In this annual report, unless the context otherwise requires, the terms "we", "us", "our", "Intellipharmaceutics," and the "Company" refer to Intellipharmaceutics International Inc. and its subsidiaries. Any reference in this annual report to our "products" includes a reference to our product candidates and future products we may develop. Whenever we refer to any of our current product candidates (including additional product strengths of products we are currently marketing) and future products we may develop, no assurances can be given that we, or any of our strategic partners, will successfully commercialize or complete the development of any of such product candidates or future products under development or proposed for development, that regulatory approvals will be granted for any such product candidate or future product, or that any approved product will be produced in commercial quantities or sold profitably.

Unless stated otherwise, all references to "\$", "U.S.\$", or "U.S. Dollars" are to the lawful currency of the United States and all references to "C\$" are to the lawful currency of Canada. In this annual report, we refer to information regarding

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

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

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

### PART I.

Item 1. Identity of Directors, Senior Management and Advisers

A. Directors and Senior Management

Not applicable.

B. Advisers

Not applicable

C. Auditors

Not applicable

Item 2. Offer Statistics and Expected Timetable

A. Offer statistics

Not applicable

B. Method and expected timetable

Not applicable

Item 3. Key Information

### A. Selected Financial Data

The following selected financial data of the Company has been derived from the audited consolidated financial statements of the Company as at and for the years ended November 30, 2018, 2017, 2016, 2015, and 2014. The comparative number of shares issued and outstanding, basic and diluted loss per share have been amended to give effect to this arrangement transaction. These statements were prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). All dollar amounts in this annual report are expressed in U.S. dollars, unless otherwise indicated.

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

	As at and for the year ended November 30, 2018	•	As at and for the year ended November 30, 2016	•	As at and for the year ended November 30, 2014
Revenue	\$	\$	\$	\$	\$