

February 16, 2018



Intellipharmaceuticals Announces Fiscal Year 2017 Results

TORONTO, ON / ACCESSWIRE / February 16, 2018 / Intellipharmaceuticals International Inc. (NASDAQ: IPCI, TSX: IPCI) ("Intellipharmaceuticals" or the "Company"), a pharmaceutical company specializing in the research, development and manufacture of novel and generic controlled-release and targeted-release oral solid dosage drugs, today reported the results of operations for the year ended November 30, 2017. All dollar amounts referenced herein are in United States dollars unless otherwise noted.

Fiscal 2017 highlights

- Revenues increased to \$5.5 million in fiscal 2017 from \$2.2 million in fiscal 2016
- Launched second commercial product - generic Seroquel XR® (quetiapine fumarate extended-release tablets)
- Received a Complete Response Letter ("CRL") from the United States Food and Drug Administration ("FDA") clarifying path forward for our abuse-deterrent oxycodone hydrochloride extended release tablets product candidate ("Oxycodone ER")

"Our fiscal 2017 results are a reflection of the many significant milestones reached in our product development, manufacturing and commercial efforts" said Dr. Isa Odidi, CEO of Intellipharmaceuticals. "We continue to place emphasis on completing the remaining work for the resubmission of our Oxycodone ER NDA and obtaining approval for ANDA's in our current development pipeline, while also considering new product candidates."

Corporate Developments

- In February 2018, the Company and the FDA discussed the previously announced Complete Response Letter for Oxycodone ER, including issues related to the blue dye in the product candidate. Based on the meeting, 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.
- In December 2017, the Company was notified by The NASDAQ Stock Market LLC ("Nasdaq") that the minimum bid price per share for the Company's common shares was below \$1.00 for a period of 30 consecutive business days and that the Company did not meet the minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2). The notice does not impact the Company's listing on the Nasdaq at this time. The Company has a period of 180 calendar

days, or until June 4, 2018, to regain compliance with Nasdaq's minimum bid price requirement.

- In November 2017, our U.S. marketing partner, Par Pharmaceutical Inc. ("Par"), launched the 5 and 40 mg strengths of its generic Focalin XR® (dexmethylphenidate hydrochloride extended-release) capsules in the United States, which follows the launch in May 2017 of the 10 and 20 mg strengths in the United States. The launch of the 5 and 40 mg strengths and the 10 and 20 mg strengths complements the 15, 25, 30 and 35 mg strengths of generic Focalin XR® previously launched and marketed by Par and completes the full line of product strengths.

- In October 2017, we completed a registered direct offering consisting of 3,636,364 common shares at a price of \$1.10 per share for gross proceeds of approximately \$4 million. The Company also issued to the investors warrants to purchase an aggregate of 1,818,182 common shares at an exercise price of \$1.25 per share. The warrants are exercisable six months following the October 13, 2017 closing date and will expire 30 months after the date they become exercisable

- In September 2017, the Company was notified by Nasdaq that it is not in compliance with the minimum market value of listed securities requirement set forth in Nasdaq Rules for continued listing on Nasdaq. The notification does not impact the Company's listing on the Nasdaq at this time. Nasdaq Listing Rule 5550(b)(2) requires listed securities to maintain a minimum market value of US \$35.0 million. The Company has a period of 180 calendar days, or until March 19, 2018, to regain compliance.

- In September 2017, we received the above-referenced CRL for our Oxycodone ER New Drug Application ("NDA"), indicating that the FDA could not approve the application in its present form. In its CRL, the FDA provided certain recommendations and requests for information, including that we complete the relevant 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, and that we submit an alternate proposed proprietary name for Oxycodone ER (previously referred to as Rexista™). The Company has been given one year from September 2017 to respond to the CRL, and can request additional time if necessary.

- In July 2017, three complaints were filed in the U.S. District Court for the Southern District of New York asserting claims under the federal securities laws against the Company and two of its executive officers on behalf of a putative class of purchasers of the Company's securities. In a subsequent order, the Court consolidated the three actions under the caption *Shanawaz v. Intellipharma Int'l Inc., et al.*, No. 1:17-cv-05761 (S.D.N.Y.), appointed lead plaintiffs in the consolidated action, and approved lead plaintiffs' selection of counsel.
- In July 2017, a joint meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and Drug Safety and Risk Management Advisory Committee of the FDA (the "Advisory Committees") was held to review the Company's NDA for Oxycodone ER abuse-deterrent oxycodone hydrochloride extended release tablets. The Advisory Committees voted against approving the Company's NDA for Oxycodone ER at this time and 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 June 2017, Mallinckrodt LLC ("Mallinckrodt"), in its capacity as the Company's marketing and distribution partner, launched all strengths of the Company's generic Seroquel XR® in the United States. This launch follows the final approval in May 2017 from the FDA for the Company's Abbreviated New Drug Application ("ANDA") for quetiapine fumarate extended-release tablets in the 50, 150, 200, 300 and 400 mg strengths.
- In April, 2017, we received notice that Purdue Pharma L.P., Purdue Pharmaceuticals L.P., The P.F. Laboratories, Inc., Rhodes Technologies, and Grünenthal GmbH had commenced patent infringement proceedings against us in the U.S. District Court for the District of Delaware in respect of our NDA filing for our Oxycodone ER product candidate, alleging that it infringes six (6) out of the sixteen (16) patents associated with the branded product Oxycontin® listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. We are confident that we do not infringe the subject patents, and will vigorously defend against these claims.
- In February 2017, the FDA accepted for filing the NDA we filed in November 2016 seeking authorization to market our Oxycodone ER product candidate in the 10, 15, 20, 30, 40, 60 and 80 mg strengths.
- In February 2017, we received final approval from the FDA for our ANDA for metformin

hydrochloride extended release tablets in the 500 and 750 mg strengths.

Results of Operations

The Company recorded net loss for the year ended November 30, 2017 of \$8.9 million or \$0.29 per common share, compared with a net loss of \$10.1 million or \$0.38 per common share for the year ended November 30, 2016. In the year ended November 30, 2017, the net loss was attributed to the ongoing R&D and selling, general and administrative expenses, partially offset by licensing revenues from commercial sales of generic Focalin XR® and to a lesser extent, sales of generic Seroquel XR®. The lower net loss in 2017 compared to 2016 is due to higher licensing revenues which were partially offset by higher R&D expenditures as well as an increase in non-cash performance based stock option expense.

Revenues for the year ended November 30, 2017 were \$5.5 million versus \$2.2 million for the year ended November 30, 2016. Revenues consisted primarily of licensing revenues from commercial sales of the 10, 15, 20, 25, 30 and 35 mg of generic Focalin XR® under the Par agreement. The increase in revenues in the current year period is primarily due to the launch in January 2017 of the 25 and 35 mg strengths of generic Focalin XR® capsules in the U.S and also reflects revenue from the Company's generic Seroquel XR® launched by Mallinckrodt in June 2017. The Company's revenues on the 25 and 35 mg strengths of generic Focalin XR® showed some decline commencing July 2017 when their 6-month exclusivity expired, but have since leveled off. The 15 and 30mg strengths continue to perform well, with the 10 and 20 mg strengths contributing less due to their launch date being late August 2017. The 5 and 40 mg strengths did not contribute at all to top line revenue in fiscal 2017 as the products were not in the market until after year end. Revenues from generic Seroquel XR® were considerably lower than originally anticipated, primarily due to timing of the product launch, which was several weeks after other generics entered the market. As such, it is expected to take some time to gain market share as wholesaler contracts come up for renewal. Revenues under the Par and Mallinckrodt agreements represents the commercial sales of the generic products in those strengths and may not be representative of future sales.

Expenditures for R&D for the year ended November 30, 2017 were higher by \$1.1 million compared to the year ended November 30, 2016. The increase is primarily due to higher R&D expenses due to third party consulting fees and other costs associated with our preparation for the FDA Advisory Committee meeting in relation to our Oxycodone ER NDA filing. Non-cash stock based compensation expense was also higher in fiscal 2017 as a result of certain performance-based stock options vesting upon FDA approval of quetiapine fumarate extended release tablets in the 50, 150, 200, 300 and 400 mg strengths. After adjusting for the stock-based compensation expenses, expenditures for R&D for the year ended November 30, 2017 were higher by \$1.4 million compared to the year ended November 30, 2016.

Selling, general and administrative expenses were \$3.3 million for the year ended November 30, 2017 in comparison to \$3.5 million for the year ended November 30, 2016, a decrease of \$0.3 million. The decrease is due to lower wages and benefits and administrative costs offset by higher expenses related to marketing and occupancy costs.

The Company had cash of \$1.9 million as at November 30, 2017 compared to \$4.1 million

as at November 30, 2016. The decrease in cash during the 2017 fiscal year was mainly a result of our ongoing expenditures in R&D and selling, general, and administrative expenses, which included increased consulting fees incurred to prepare for the July 26, 2017 Advisory Committee meeting and an increase in purchases of plant and production equipment to support our generic Seroquel XR® launch, which were only partially offset by higher cash receipts from commercialized sales of our generic Focalin XR® and to a lesser extent sales of generic Seroquel XR®. Cash inflows were also provided from financing activities derived from common share sales under the Company's at-the-market offering program as well as the \$4.0 million underwritten public offering in October 2017.

As of February 15, 2018, our cash balance was \$0.6 million. We currently expect to satisfy our operating cash requirements until June 2018 from cash on hand and quarterly profit share payments from Par and Mallinckrodt. The Company may need to obtain additional funding prior to that time as we further the development of our product candidates and if we accelerate our product commercialization activities. Other potential sources of capital may include payments from licensing agreements, cost savings associated with managing operating expense levels, and/or new strategic partnership agreements which fund some or all costs of product development. If necessary, and conditions permit, we may utilize the equity markets to bridge any funding shortfall and to provide capital to continue to advance our most promising product candidates. Our future operations are highly dependent upon our ability to source additional capital to support advancing our product pipeline through continued R&D activities and to fund any significant expansion of our operations. Our ultimate success will depend on whether our product candidates receive the approval of the FDA or Health Canada and whether we are able to successfully market approved products. We cannot be certain that we will be able to receive FDA or Health Canada approval for any of our current or future product candidates, that we will reach the level of sales and revenues necessary to achieve and sustain profitability, or that we can secure other capital sources on terms or in amounts sufficient to meet our needs or at all.

There can be no assurance that our products or technologies will be successfully commercialized or produce significant revenues for us. Also, there can be no assurance that we will not be required to conduct further studies for our Oxycodone ER product, that the FDA will approve any of the Company's requested abuse-deterrence label claims or that the FDA will ultimately approve the NDA for the sale of our Oxycodone ER product in the U.S. market, or that it will ever be successfully commercialized, that we will be successful in submitting any additional Abbreviated New Drug Submissions or NDAs with the FDA or Abbreviated New Drug Submissions with Health Canada, that the FDA or Health Canada will approve any of our current or future product candidates for sale in the U.S. market and Canadian market, or that they will ever be successfully commercialized or partnered and produce significant revenue for us.

About Intellipharmaceutics

Intellipharmaceutics International Inc. is a pharmaceutical company specializing in the research, development and manufacture of novel and generic controlled- and targeted-release oral solid dosage drugs. The Company's patented Hypermatrix™ technology is a multidimensional controlled-release drug delivery platform that can be applied to a wide range of existing and new pharmaceuticals. Intellipharmaceutics has developed several drug delivery systems based on this technology platform, with a pipeline of products (some of

which have received FDA approval) in various stages of development. The Company has ANDA and NDA 505(b)(2) drug product candidates in its development pipeline. These include the Oxycodone ER abuse deterrent oxycodone formulation based on its proprietary nPODDDS™ novel Point Of Divergence Drug Delivery System (for which an NDA has been filed with the FDA), and Regabatin™ XR (pregabalin extended-release capsules).

Cautionary Statement Regarding Forward-Looking Information

Certain statements in this document constitute "forward-looking statements" within the meaning of the United States Private Securities Litigation Reform Act of 1995 and/or "forward-looking information" under the Securities Act (Ontario). These statements include, without limitation, statements expressed or implied regarding our plans, goals and milestones, status of developments or expenditures relating to our business, plans to fund our current activities, and statements concerning our partnering activities, health regulatory submissions, strategy, future operations, future financial position, future sales, revenues and profitability, projected costs and market penetration. In some cases, you can identify forward-looking statements by terminology such as "appear", "unlikely", "target", "may", "will", "should", "expects", "plans", "plans to", "anticipates", "believes", "estimates", "predicts", "confident", "prospects", "potential", "continue", "intends", "look forward", "could", "would", "projected", "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, on 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 maintain compliance with the continued listing requirements of the principal markets on which our securities are traded including risks or uncertainties related to our ability to implement and execute a plan to regain compliance with Nasdaq 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 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 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 Focalin XR® product 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 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, changes in U.S. federal income tax laws currently being considered, including, but not limited to, the U.S. changing the method by which foreign income is taxed and resulting changes to the passive foreign investment company laws and regulations which may impact our shareholders, 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 ANDAs and NDAs, challenges in securing final FDA approval for our product candidates, including our oxycodone hydrochloride extended release tablets product in particular, if a patent infringement suit is filed against us, with respect to any particular product candidates (such as in the case of Oxycodone ER), which could delay the FDA's final approval of such product candidates, healthcare reform measures that could hinder or prevent the commercial success of our products and product candidates, the FDA may not approve requested product labeling for our product candidate(s) having abuse-deterrent properties 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 our latest annual information form, our latest Form 20-F, and our latest Form F-3 (including any documents forming a part thereof or incorporated by reference therein), 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.

Trademarks used herein are the property of their respective holders.

Unless the context otherwise requires, all references to "we," "us," "our," "Intellipharmaceutics," and the "Company" refer to Intellipharmaceutics International Inc. and its subsidiaries. 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.

The audited consolidated financial statements, accompanying notes to the audited consolidated financial statements, and Management Discussion and Analysis for the year ended November 30, 2017 will be accessible on Intellipharmaceutics' website at www.intellipharmaceutics.com and will be available on SEDAR and EDGAR.

Summary financial tables are provided below.

Intellipharmaceutics International Inc.
Consolidated balance sheets
As at November 30, 2017 and 2016
(Stated in U.S. dollars)

	2017	2016
	\$	\$
Assets		
Current		
Cash	1,897,061	4,144,424
Accounts receivable, net	689,619	472,474
Investment tax credits	636,489	681,136
Prepaid expenses, sundry and other assets	225,092	400,642
Inventory	115,667	-
	3,563,928	5,698,676
Deferred offering costs	565,302	386,375

Property and equipment, net	3,267,551	1,889,638
	<u>7,396,781</u>	<u>7,974,689</u>
Liabilities		
Current		
Accounts payable	2,060,084	807,295
Accrued liabilities	782,369	384,886
Employee costs payable	214,980	1,044,151
Capital lease obligations	-	14,829
Convertible debenture	1,290,465	1,494,764
Deferred revenue	300,000	450,000
	<u>4,647,898</u>	<u>4,195,925</u>
Deferred revenue	2,362,500	2,662,500
	<u>7,010,398</u>	<u>6,858,425</u>
Shareholders' equity		
Capital stock		
Authorized		
Unlimited common shares without par value		
Unlimited preference shares		
Issued and outstanding		
34,704,515 common shares	35,290,034	29,830,791
(November 30, 2016 - 29,789,992)		
Additional paid-in capital	36,685,387	34,017,071
Accumulated other comprehensive income	284,421	284,421
Accumulated deficit	(71,873,459)	(63,016,019)
	<u>386,383</u>	<u>1,116,264</u>
Contingencies		
	<u>7,396,781</u>	<u>7,974,689</u>

Intellipharmaceuticals International Inc.
Consolidated statements of operations and comprehensive loss
for the years ended November 30, 2017, 2016 and 2015
Stated in U.S. dollars

	2017	2016	2015
	\$	\$	\$
Revenues			
Licensing	5,025,350	2,209,502	4,093,781
Up-front fees	479,102	37,500	-
	<u>5,504,452</u>	<u>2,247,002</u>	<u>4,093,781</u>
Cost of goods sold	704,006	-	-
Gross Margin	<u>4,800,446</u>	<u>2,247,002</u>	<u>4,093,781</u>
Expenses			
Research and development	9,271,353	8,166,736	7,247,473
Selling, general and administrative	3,287,914	3,546,132	3,581,913
Depreciation	506,961	385,210	377,849

	13,066,228	12,098,078	11,207,235
Loss from operations	(8,265,782)	(9,851,076)	(7,113,454)
Net foreign exchange (loss) gain	(80,093)	(22,470)	46,211
Interest income	15,037	207	1,507
Interest expense	(389,239)	(270,238)	(256,629)
Financing cost	(137,363)	-	-
Extinguishment loss	-	-	(114,023)
Net loss and comprehensive loss	(8,857,440)	(10,143,577)	(7,436,388)
Loss per common share, basic and diluted	(0.29)	(0.38)	(0.31)
Weighted average number of common shares outstanding, basic and diluted	31,014,482	26,699,579	23,767,677

Intellipharmaceuticals International Inc.
Consolidated statements of cash flows
for the years ended November 30, 2017, 2016 and 2015
(Stated in U.S. dollars)

	2017	2016	2015
	\$	\$	\$
Net loss	(8,857,440)	(10,143,577)	(7,436,388)
Items not affecting cash			
Depreciation	520,838	385,210	377,849
Stock-based compensation	1,749,999	2,261,444	417,818
Deferred share units	30,355	31,628	29,056
Accreted interest	219,497	79,245	27,103
Loss on extinguishment	-	-	114,023
Financing cost	137,363	-	-
Provision for doubtful debts	66,849	-	-
Unrealized foreign exchange loss (gain)	56,998	22,916	(81,063)
Change in non-cash operating assets & liabilities			
Accounts receivable	(283,994)	6,200	532,459
Investment tax credits	44,647	(223,115)	(133,035)
Prepaid expenses, sundry and other assets	175,550	(171,417)	185,438
Inventory	(115,667)	-	-
Accounts payable, accrued liabilities and employee costs payable	599,220	(1,466,019)	2,034,576
Deferred revenue	(450,000)	2,962,500	150,000
Cash flows used in operating activities	(6,105,785)	(6,254,985)	(3,782,164)
Financing activities			
Repayment of convertible debenture	(150,000)	-	-
Repayment of capital lease obligations	(14,829)	(21,291)	(27,489)
Issuance of shares on exercise of stock options	1,742	52,868	167,962
Issuance of common shares on at-the-market financing, gross	2,541,640	3,469,449	1,290,168
Proceeds from issuance of shares and warrants	4,000,000	5,939,967	-

Proceeds from issuance of shares on exercise of warrants	324,258	700,653	562,500
Offering costs	(1,020,643)	(982,023)	(259,276)
Cash flows provided from financing activities	5,682,168	9,159,623	1,733,865
Investing activity			
Purchase of property and equipment	(1,823,746)	(515,410)	(430,480)
Cash flows used in investing activities	(1,823,746)	(515,410)	(430,480)
(Decrease) Increase in cash	(2,247,363)	2,389,228	(2,478,779)
Cash, beginning of year	4,144,424	1,755,196	4,233,975
Cash, end of year	1,897,061	4,144,424	1,755,196
Supplemental cash flow information			
Interest paid	123,204	165,585	179,878
Taxes paid	-	-	-

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