

Intellipharma Announces First Quarter 2019 Results

TORONTO, ON / ACCESSWIRE / April 15, 2019 / Intellipharma International Inc. (OTCQB: IPCIF and TSX: IPCI) ("Intellipharma" 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 three months ended February 28, 2019. All dollar amounts referenced herein are in United States dollars unless otherwise noted.

Corporate Developments

- 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 has been released from certain obligations under the license and commercial supply agreement as of April 12, 2019. The Company is in discussions with other parties who are interested in marketing and distributing our products which have been licensed under the agreement.
- In March 2019, we announced that the United States Food and Drug Administration ("FDA") acknowledged receipt of our resubmission of the abuse-deterrent oxycodone hydrochloride extended release formulation ("Oxycodone ER") New Drug Application ("NDA") filed on February 28, 2019. The FDA informed us 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 Prescription Drug User Fee Act ("PDUFA") goal date of August 28, 2019.
- In March 2019, the Nasdaq Hearings Panel determined to delist our 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 OTCQB Venture Market ("OTCQB"), which is operated by the OTC Markets Group Inc., 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.
- On February 21, 2019, we and our CEO, Dr. Isa Odidi ("Defendants"), were served with a Statement of Claim filed in the Superior Court of Justice of Ontario ("Court") for a proposed class action under the Ontario Class Proceedings Act ("Action"). The Action was brought by Victor Romita, the proposed representative plaintiff ("Plaintiff"), on behalf of a class of Canadian persons ("Class") who traded shares of the Company during the period from February 29, 2016 to July 26, 2017 ("Period"). The Statement of Claim, under the caption *Victor Romita v. Intellipharma International Inc. and Isa Odidi*, asserts that the Defendants knowingly or negligently made certain public statements during the Period that contained or omitted material facts concerning Oxycodone ER abuse-deterrent oxycodone hydrochloride extended release tablets. The Plaintiff alleges that he and the Class suffered loss and damages as a result of their trading in the Company's shares during the 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 the Company's shares on the Toronto Stock Exchange ("TSX") during the Period. No date has been set for the hearing of the Notice of Motion. 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.
- In February 2019, we received tentative approval from the FDA for our Abbreviated New Drug Application ("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.
- In January 2019, we announced that we had commenced a research and development ("R&D") program of pharmaceutical cannabidiol ("CBD") based products. As part of this R&D program, we filed provisional patent applications with the United States Patent and Trademark Office pertaining to the delivery and application of cannabinoid-based therapeutics, began talks with potential commercialization partners in the cannabidiol

industry, and identified a potential supplier of CBD. We hold a Health Canada Drug Establishment License, or DEL, and a dealer's license under the Narcotics Control Regulations ("NCR"). Under the NCR license, we are currently authorized to possess, produce, sell and deliver drug products containing various controlled substances, including CBD, in Canada.

- On April 4, 2019, a tentative approval from TSX was received for a proposed refinancing of the debenture originally issued to us in 2013 (the "2013 Debenture") subject to certain conditions being met. As a result of the proposed refinancing, the principal amount owing under the 2013 Debenture will be financed by a new debenture (the "New Debenture"). If issued, the New Debenture will have a principal amount of \$1,050,000 and will mature on November 1, 2019, bear interest at a rate 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, will be the holders of the New Debenture.

Results of Operations

The Company recorded net loss for the three months ended February 28, 2019 of \$3.2 million or \$0.16 per common share, compared with a net loss of \$3.1 million or \$0.91 per common share for the three months ended February 28, 2018. In the three months ended February 28, 2019, the net loss is attributed to the lower licensing revenues from commercial sales of generic Focalin XR[®] and, to a lesser extent, sales of generic Seroquel XR[®] shipped to Mallinckrodt, combined with increased administrative expense related to professional and legal fees. In the three months ended February 28, 2018, the net loss was attributed to lower licensing revenues from commercial sales of generic Focalin XR[®] and, to a lesser extent, sales of generic Seroquel XR[®] shipped to Mallinckrodt, combined with increased R&D expenses.

The Company recorded revenues of \$0.3 million for the three months ended February 28, 2019 versus \$0.3 million for the three months ended February 28, 2018. Such revenues consisted primarily of licensing revenues from commercial sales of the 15, 25, 30 and 35 mg strengths of our generic Focalin XR[®] under its license and commercialization agreement with Par Pharmaceutical, Inc. The increase in revenues in the three months ended February 28, 2019 compared to the three months ended February 28, 2018 is primarily due to slightly higher profit share payments from sales of generic Focalin XR[®] capsules in the U.S. Beginning in early 2018, we began to see a significant impact from aggressive pricing by competitors, resulting in a marked increase in gross-to-net deductions such as wholesaler rebates, chargebacks and pricing adjustments. While the gross-to-net deductions fluctuate on a quarter over quarter basis, profit share payments for the last quarter has been consistent over the same period in 2018. Revenues from generic Seroquel XR[®] are still well below levels expected at the launch of the product in 2017, primarily due to the Company's commercial partner entering the market later than planned. Management is continuing to evaluate strategic options to improve returns from this product.

Expenditures for R&D for the three months ended February 28, 2019 were lower by \$0.1 million compared to the three months ended February 28, 2018. The decrease is primarily due to significantly lower patent litigation expenses partially offset by higher third party consulting fees.

Selling, general and administrative expenses were \$1.2 million for the three months ended February 28, 2019 in comparison to \$1.0 million for the three months ended February 28, 2018, resulting in an increase of \$0.2 million. The increase is due to higher expenses related to administrative costs, partially offset by a decrease in wages and marketing cost.

The Company had cash of \$2.8 million as at February 28, 2019 compared to \$0.3 million as at February 28, 2018. The increase in cash was mainly due to the cash receipts provided from financing activities derived from the Company's two registered direct offerings in March 2018, the a convertible debenture financing in September 2018 and an underwritten public offering in October 2018, offset by ongoing expenditures in R&D and selling, general and administrative expenses.

As of February 28, 2019, our cash balance was \$2.8 million. We currently expect to satisfy our operating cash requirements into the third quarter of 2019 from cash on hand and quarterly profit share payments. The Company will need to obtain additional funding as we further the development of our product candidates. Potential sources of capital may include payments from licensing agreements, cost savings associated with managing operating expense levels, equity and/or debt financings and/or new strategic partnership agreements which fund some or all costs of product development. We intend to utilize the capital 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 we will enter into new license and commercial supply agreement for the marketing and distribution of products which have been licensed under the Mallinckrodt agreement, that our products will be successfully commercialized or produce significant revenues for us. Also, there can be no assurance that we will not be required to conduct further studies for our Oxycodone ER product candidate, that the FDA will approve any of our requested abuse-deterrent label claims or that the FDA will meet its deadline for review and ultimately approve the NDA for the sale of our Oxycodone ER product candidate in the U.S. market, that we will be successful in submitting any additional ANDAs or NDAs with the FDA or Abbreviated New Drug Submissions ("ANDSs") with Health Canada, that the FDA or Health Canada will approve any of our current or future product candidates for sale in the U.S. market and Canadian market, that any of our products or product candidates will receive regulatory approval for sale in other jurisdictions, that our desvenlafaxine extended-release product candidate will receive final FDA approval, or that any of our products will ever be successfully commercialized and produce significant revenue for us. Moreover, there can be no assurance that any of our provisional patent applications will successfully mature into patents, or that any cannabidiol-based product candidates we develop will ever be successfully commercialized or produce significant revenue for us.

About Intellipharmaceutics

Intellipharmaceutics International Inc. is a pharmaceutical company specializing in the research, development and manufacture of novel and generic controlled-release 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 Company's Oxycodone ER 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 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 and risks or uncertainties arising from the delisting of our shares from Nasdaq and our ability to comply with OTCQB and TSX requirements. 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 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 and 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 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 ANDAs and NDAs, challenges in securing final FDA approval for our product candidates, including our oxycodone hydrochloride extended release tablets 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 our latest annual information form, our latest Form 20-F, and our latest Form F-1 and F-3 registration statements (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.

Trademarks used herein are the property of their respective holders.

Unless the context otherwise requires, all references (i) to "we," "us," "our," "Intellipharma," and the "Company" refer to Intellipharma International Inc. and its subsidiaries and (ii) in this document to share

amounts, per share data, share prices, exercise prices and conversion rates have been adjusted to reflect the effect of the 1-for-10 reverse split which became effective on each of Nasdaq and TSX at the open of market on September 14, 2018. The common shares of the Company are currently traded on the OTCQB and the TSX.

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 condensed unaudited interim consolidated financial statements, accompanying notes to the condensed unaudited interim consolidated financial statements, and Management Discussion and Analysis for the three months ended February 28, 2019 will be accessible on Intellipharmaceuticals' website at www.intellipharmaceuticals.com and will be available on SEDAR and EDGAR.

Summary financial tables are provided below.

Intellipharmaceuticals International Inc.

Condensed unaudited interim consolidated balance sheets
(Stated in U.S. dollars)

	February 28, 2019	November 30, 2018
	\$	\$
Assets		
Current		
Cash	2,821,669	6,641,877
Accounts receivable, net	214,979	239,063
Investment tax credits	1,043,849	998,849
Prepaid expenses, sundry and other assets	618,477	586,794
Inventory	219,928	251,651
	<u>4,918,902</u>	<u>8,718,234</u>
Property and equipment, net	2,633,618	2,755,993
	<u>7,552,520</u>	<u>11,474,227</u>
Liabilities		
Current		
Accounts payable	1,769,675	2,643,437
Accrued liabilities	875,590	353,147
Employee costs payable	214,874	222,478
Convertible debentures	1,498,295	1,790,358
Deferred revenue	300,000	300,000
	<u>4,658,434</u>	<u>5,309,420</u>
Deferred revenue	1,987,500	2,062,500
	<u>6,645,934</u>	<u>7,371,920</u>
Shareholders' equity		
Capital stock		
Authorized		
Unlimited common shares without par value		
Unlimited preference shares		
Issued and outstanding		
21,925,577 common shares	45,281,501	44,327,952
(November 30, 2018 - 18,252,243)		
Additional paid-in capital	44,186,052	45,110,873
Accumulated other comprehensive income	284,421	284,421
Accumulated deficit	<u>(88,845,388)</u>	<u>(85,620,939)</u>
	906,586	4,102,307
Contingencies		
	<u>7,552,520</u>	<u>11,474,227</u>

Intellipharmaceuticals International Inc.

Condensed unaudited interim consolidated statements of operations
and comprehensive loss
for the three months ended February 28, 2019 and 2018
(Stated in U.S. dollars)

	<u>2019</u>	<u>2018</u>
	\$	\$
Revenues		
Licensing	264,551	252,272
Up-front fees	<u>78,985</u>	<u>82,246</u>
	<u>343,536</u>	<u>334,518</u>
Cost of goods sold	<u>33,068</u>	-
Gross Margin	<u>310,468</u>	<u>334,518</u>
Expenses		
Research and development	2,132,261	2,264,128
Selling, general and administrative	1,207,243	1,013,470
Depreciation	<u>125,284</u>	<u>148,182</u>
	<u>3,464,788</u>	<u>3,425,780</u>
Loss from operations	<u>(3,154,320)</u>	<u>(3,091,262)</u>
Net foreign exchange (loss) gain	(11,332)	25
Interest income	11	-
Interest expense	<u>(58,808)</u>	<u>(58,351)</u>
Net loss and comprehensive loss	<u>(3,224,449)</u>	<u>(3,149,588)</u>
Loss per common share, basic and diluted	<u>(0.16)</u>	<u>(0.91)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>20,058,207</u>	<u>3,470,451</u>

Intellipharmaceutics International Inc.

Condensed unaudited interim consolidated statements of cash flows
for the three months ended February 28, 2019 and 2018
(Stated in U.S. dollars)

	<u>2019</u>	<u>2018</u>
	\$	\$
Net loss	<u>(3,224,449)</u>	<u>(3,149,588)</u>
Items not affecting cash		
Depreciation	126,165	148,182
Stock-based compensation	2,274	31,688
Deferred share units	-	7,565
Accreted interest	7,937	15,971
Unrealized foreign exchange loss	-	13,118
Change in non-cash operating assets & liabilities		
Accounts receivable	24,084	570,213
Investment tax credits	(45,000)	(45,002)
Prepaid expenses, sundry and other assets	(31,683)	(174,740)
Inventory	31,723	(95,181)
Accounts payable, accrued liabilities and employee costs payable	(358,923)	1,164,764
Deferred revenue	<u>(75,000)</u>	<u>(75,000)</u>
Cash flows used in operating activities	<u>(3,542,872)</u>	<u>(1,588,010)</u>
Financing activities		
Proceeds from issuance of shares on exercise of 2018 Pre-Funded Warrants	26,454	-
Cash flows used in financing activities	<u>(273,546)</u>	-
Investing activity		
Purchase of property and equipment	<u>(3,790)</u>	<u>(38,825)</u>
Cash flows used in investing activities	<u>(3,790)</u>	<u>(38,825)</u>
Decrease in cash	<u>(3,820,208)</u>	<u>(1,626,835)</u>

Cash, beginning of period	<u>6,641,877</u>	<u>1,897,061</u>
Cash, end of period	<u>2,821,669</u>	<u>270,226</u>
Supplemental cash flow information		
Interest paid	63,836	67,860
Taxes paid	<u>-</u>	<u>-</u>

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