

October 10, 2017



# Intellipharmaceuticals Announces Third Quarter 2017 Results

TORONTO, Oct. 10, 2017 (GLOBE NEWSWIRE) -- **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 three and nine months ended August 31, 2017. All dollar amounts referenced herein are in United States dollars unless otherwise noted.

## Third Quarter Highlights

- Revenues increase to \$1.2 million from \$0.6 million in third quarter 2016
- Mallinckrodt LLC (“Mallinckrodt”) launched all strengths of 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 oxycodone hydrochloride extended-release tablets (formerly known as Rexista™) (“Oxycodone ER”) program

“We are pleased with our progress this quarter, showing positive momentum across our various commercial and development initiatives, in particular with the launch of our second commercial product, which we believe will contribute to near-term revenue growth,” said Dr. Isa Odidi, CEO of Intellipharmaceuticals. “While we have not received approval of the NDA in relation to our Oxycodone ER application, the FDA’s CRL has provided a path to resubmission.

“Looking forward, we have a number of products in our pipeline at various stages of the approval process, and hope to commercialize one or more of these in 2018. While our financial results do not yet reflect the commercial potential of our assets, we are making progress in our strategy that has provided Intellipharmaceuticals with a broad portfolio of high-potential assets. Finally, we have unique proprietary technologies with the potential to address an as yet underserved need amid the ongoing opioid crisis in North America, and we are focused on developing these technologies into strong market contenders with significant commercial potential. We look forward to providing regular updates as we make progress on all of our initiatives.”

## Corporate Developments

- In September 2017 the Company received a CRL for its 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 Intellipharmaceuticals 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 Intellipharmaceutics submit an alternate proposed proprietary name for Oxycodone ER. Intellipharmaceutics has been given one year to respond to the CRL, and can request additional time if necessary.

- In June 2017, we announced that Mallinckrodt, in its capacity as the Company's marketing and distribution partner, launched all strengths of the Company's generic Seroquel XR® in the U.S. This launch follows the recent final approval 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. The approved product is a generic equivalent of the corresponding strengths of the branded product Seroquel XR® sold in the U.S. by Astra Zeneca Pharmaceuticals LP. Under its license and commercial supply agreement with Mallinckrodt, the Company manufactures and supplies generic Seroquel XR® for Mallinckrodt to market, sell and distribute in the U.S.

## Results of Operations

The Company recorded net loss for the three months ended August 31, 2017 of \$2.6 million, or \$0.08 per common share, compared with a net loss of \$2.1 million, or \$0.07 per common share, for the three months ended August 31, 2016. In the three months ended August 31, 2017, the higher net loss is primarily attributed to an increase in third-party R&D expenditures, partially offset by a higher licensing revenue from commercial sales of generic Focalin XR® (dexmethylphenidate hydrochloride extended-release) capsules and generic Seroquel XR® in the third quarter of 2017. During the three months ended August 31, 2016, the loss was due to ongoing R&D and selling, general and administrative expenses, including an increase in options expense, partially offset by licensing revenues from commercial sales of generic Focalin XR® capsules.

Revenues for the three month period ended August 31, 2017 were \$1.2 million, compared to \$0.6 million for the three months ended August 31, 2016. A significant portion of our revenue is from commercial sales of generic Focalin XR® under our license and commercialization agreement with Par Pharmaceutical Inc. ("Par"). The increase in revenues from the prior period quarter is primarily due to Par's launch of additional strengths of generic Focalin XR® capsules in the U.S. in 2017. The Company's revenues on the 25 and 35 mg strengths of generic Focalin XR® experienced some decline in July 2017 as the six month exclusivity period expired, however, revenue from all strengths of the product are higher in the current quarter than in the comparative three month period. Revenue for the third quarter of fiscal 2017 also includes sales of the Company's generic Seroquel XR® launched by Mallinckrodt in June 2017. As several generic competitors entered the market in May 2017, Seroquel XR® sales volumes did not reach the levels anticipated for the first three months. Sales on a month over month basis have shown improvement as generic Seroquel XR® begins to see good traction with key accounts and large wholesalers, and the Company expects revenue from this product to increase going forward. Revenues under the Par and Mallinckrodt agreements represent the commercial sales of the generic products and may not be representative of future sales.

Expenditures for research and development for the three months ended August 31, 2017 increased by \$0.7 million compared to the three months ended August 31, 2016. The

increase is primarily due to higher third party consulting fees associated with our preparation for the Anesthetic and Analgesic Drug Products Advisory Committee and Drug Safety and Risk Management Advisory Committee of the FDA meeting in relation to our Oxycodone ER NDA filing. After adjusting for the stock-based compensation expenses discussed above, expenditures for R&D for the three months ended August 31, 2017 were higher by \$0.8 million compared to the three months ended August 31, 2016. This is primarily due to an increase in third party R&D expenditures.

Selling, general and administrative expenses were \$0.8 million for the three months ended August 31, 2017 in comparison to \$0.9 million for the three months ended August 31, 2016. The decrease is primarily due to the lower expenses related to a decrease in wages, and marketing cost, partially offset by an increase in occupancy cost.

## **About Intellipharma**

Intellipharma 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. Intellipharma 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 our Oxycodone ER product, an abuse deterrent oxycodone 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).

There can be no assurance that we will not be required to conduct further studies for Rexista™, that the FDA will ultimately approve the NDA for the sale of Rexista™ in the U.S. market, or that it will ever be successfully commercialized. There can be no assurance that generic Seroquel XR® or generic Focalin XR® or any other Company product, or any particular strength, will be successfully commercialized.

## **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, 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 "may", "will", "should", "expects", "plans", "plans to", "anticipates", "believes", "estimates", "predicts", "confident", "prospects", "potential", "continue", "intends", "look forward", "could", 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, 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, 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 ER 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), failure to demonstrate that a product candidate is safe and effective for its proposed use, 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](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 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 three and nine months ended August 31, 2017 will be accessible on Intellipharmaceutics' website at [www.intellipharmaceutics.com](http://www.intellipharmaceutics.com) and will be available on SEDAR and EDGAR.

**Summary financial tables are provided below.**

**Intellipharmaceutics International Inc.**

Condensed unaudited interim consolidated balance sheets

As at  
(Stated in U.S. dollars)

	August 31, 2017	November 30, 2016
	\$	\$
<b>Assets</b>		
Current		
Cash	735,156	4,144,424
Accounts receivable, net	845,363	472,474
Investment tax credits	663,597	681,136
Prepaid expenses, sundry and other assets	174,448	400,642
Inventory	187,416	-
	2,605,980	5,698,676
Deferred offering costs	680,245	386,375
Property and equipment, net	3,372,149	1,889,638
	6,658,374	7,974,689
<b>Liabilities</b>		
Current		
Accounts payable	2,533,883	807,295
Accrued liabilities	512,025	384,886
Employee costs payable	201,221	1,044,151
Capital lease obligations	-	14,829
Convertible debenture	1,316,516	1,494,764
Deferred revenue	450,000	450,000
	5,013,645	4,195,925
Deferred revenue	2,437,500	2,662,500
	7,451,145	6,858,425
<b>Shareholders' (deficiency) equity</b>		
Capital stock		
Authorized		
Unlimited common shares without par value		
Unlimited preference shares		
Issued and outstanding		
31,023,152 common shares	32,460,925	29,830,791
(November 30, 2016 - 29,789,992)		
Additional paid-in capital	35,824,406	34,017,071
Accumulated other comprehensive income	284,421	284,421
Accumulated deficit	(69,362,523 )	(63,016,019 )
	(792,771 )	1,116,264
Contingencies	6,658,374	7,974,689

**Intellipharma International Inc.**

Condensed unaudited interim consolidated statements of operations and comprehensive loss

(Stated in U.S. dollars)

Three months ended

Nine months ended

	August 31, 2017	August 31, 2016	August 31, 2017	August 31, 2016
	\$	\$	\$	\$
<b>Revenue</b>				
Licensing	1,189,739	554,925	4,426,617	1,677,906
	1,189,739	554,925	4,426,617	1,677,906
<b>Cost of goods sold</b>				
Cost of goods sold	376,054	-	587,426	-
<b>Gross Margin</b>	813,685	554,925	3,839,191	1,677,906
<b>Expenses</b>				
Research and development	2,298,804	1,633,150	7,007,503	4,904,405
Selling, general and administrative	756,635	855,597	2,468,436	2,521,427
Depreciation	126,316	97,254	331,102	283,380
	3,181,755	2,586,001	9,807,041	7,709,212
Loss from operations	(2,368,070 )	(2,031,076 )	(5,967,850 )	(6,031,306 )
Net foreign exchange loss	(90,875 )	(26,163 )	(73,569 )	(31,715 )
Interest income	5	-	15,030	204
Interest expense	(91,374 )	(52,917 )	(320,115 )	(167,456 )
Net loss and comprehensive loss	(2,550,314 )	(2,110,156 )	(6,346,504 )	(6,230,273 )
Loss per common share, basic and diluted	(0.08 )	(0.07 )	(0.21 )	(0.24 )
<b>Weighted average number of common shares outstanding, basic and diluted</b>				
	30,713,781	28,437,368	30,359,066	25,878,966

### Intellipharmaceuticals International Inc.

Condensed unaudited interim consolidated statements of cash flows

(Stated in U.S. dollars)

	Three months ended		Nine months ended	
	August 31, 2017	August 31, 2016	August 31, 2017	August 31, 2016
	\$	\$	\$	\$
<b>Net loss</b>	(2,550,314 )	(2,110,156 )	(6,346,504 )	(6,230,273 )
Items not affecting cash				
Depreciation	138,401	97,254	343,187	283,380
Stock-based compensation	32,105	332,358	1,676,974	1,033,216
Deferred share units	7,222	8,200	22,577	24,195
Accreted interest on convertible debenture	48,675	4,919	192,320	22,633
Unrealized foreign exchange loss	95,834	34,860	76,339	29,823
Change in non-cash operating assets & liabilities				
Accounts receivable	137,446	33,389	(372,889 )	121,989
Investment tax credits	(72,627 )	(56,474 )	17,539	(210,535 )
Inventory	305,201	-	(187,416 )	-
Prepaid expenses, sundry and other assets	296,071	23,038	226,194	(4,997 )
Accounts payable, accrued liabilities and employee costs payable	282,273	(2,230,625 )	549,240	(2,057,880 )

Deferred revenue	(75,000 )	-	(225,000 )	-
Cash flows used in operating activities	(1,354,713 )	(3,863,237 )	(4,027,439 )	(6,988,449 )
<b>Financing activities</b>				
Repayment of principal on convertible debenture	-	-	(150,000 )	-
Repayment of capital lease obligations	(3,787 )	(6,047 )	(14,829 )	(15,518 )
Proceeds from issuance of common shares on at-the-market financing	1,047,143	414,034	2,495,615	1,962,049
Proceeds from issuance of units	-	5,939,967	-	5,939,967
Proceeds from issuance of common shares on exercise of warrants	28,950	-	324,258	122,092
Proceeds from issuance of common shares on option exercise	-	-	12,465	-
Offering costs	(151,972 )	(617,743 )	(223,640 )	(663,252 )
Cash flows provided from financing activities	920,334	5,730,211	2,443,869	7,345,338
<b>Investing activity</b>				
Purchase of property and equipment	(306,083 )	(56,941 )	(1,825,698 )	(128,724 )
Cash flows used in investing activities	(306,083 )	(56,941 )	(1,825,698 )	(128,724 )
(Decrease) increase in cash	(740,462 )	1,810,033	(3,409,268 )	228,165
Cash, beginning of period	1,475,618	173,328	4,144,424	1,755,196
<b>Cash, end of period</b>	<b>735,156</b>	<b>1,983,361</b>	<b>735,156</b>	<b>1,983,361</b>
<b>Supplemental cash flow information</b>				
Interest paid	-	75,400	82,398	120,246
Taxes paid	-	-	-	-

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Source: Intellipharma International Inc.