

October 13, 2016



# Intellipharmaceuticals Announces Third Quarter 2016 Results

TORONTO, Oct. 13, 2016 (GLOBE NEWSWIRE) -- Intellipharmaceuticals International Inc. (NASDAQ:IPCI) (TSX:I) ("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, 2016. All dollar amounts referenced herein are in United States dollars unless otherwise noted.

## Recent Highlights

- Announced Tentative Approval by the U.S. Food and Drug Administration ("FDA") of the Company's generic Seroquel XR®
- Signed an Exclusive License and Commercial Supply Agreement with Mallinckrodt for the Company's generic Seroquel®, generic Pristiq® and generic Lamictal® XR™
- October 2016 cash on hand of \$4.5 million

## Corporate Developments

- In October 2016, the Company entered into a license and commercial supply agreement with Mallinckrodt LLC ("Mallinckrodt"), granting Mallinckrodt an exclusive license to market, sell and distribute in the U.S. the following extended release drug product candidates (the "licensed products") for which the Company has Abbreviated New Drug Applications ("ANDAs") filed with the FDA:
  - Quetiapine fumarate extended-release tablets (generic Seroquel XR®) – ANDA Tentatively Approved by FDA
  - Desvenlafaxine extended-release tablets (generic Pristiq®) – ANDA Under FDA Review
  - Lamotrigine extended-release tablets (generic Lamictal® XR™) – ANDA Under FDA Review

Under the terms of the 10-year agreement, the Company received a non-refundable upfront payment of \$3 million in October 2016. In addition, the agreement also provides for a long-term profit sharing arrangement with respect to the licensed products. The Company has agreed to manufacture and supply the licensed products exclusively for Mallinckrodt, and Mallinckrodt has agreed that the Company will be its sole supplier of the licensed products marketed in the U.S. The agreement contains customary terms and conditions for an agreement of this kind, and is subject to early termination in the event the Company does not obtain FDA approvals of the licensed products by specified dates, or pursuant to any one of several termination rights of each party.

- In October 2016, the Company received tentative approval from the FDA for its ANDA

for generic Seroquel® (quetiapine fumarate extended-release tablets) in the 50, 150, 200, 300 and 400 mg strengths. Pursuant to a settlement agreement between the Company and AstraZeneca Pharmaceuticals LP (“AstraZeneca”) dated July 30, 2012, the Company is permitted to launch its generic versions of the 50, 150, 200, 300 and 400 mg strengths of generic Seroquel XR®, on November 1, 2016, subject to FDA final approval of the Company's ANDA for those strengths. Such FDA final approval is subject to a 180 day exclusivity period relating to a prior filer or filers of a generic equivalent of the branded product. To our knowledge, two companies have first-to-file status and may be in a position to launch on November 1, 2016, although we cannot be certain of that date. Our intent is to launch these strengths after FDA final approval following expiry of the other companies’ exclusivity period(s). There are currently no generics of Seroquel XR® available in the U.S. market as the product is still under AstraZeneca’s patent protection until November 1, 2017.

- In July 2016, the FDA completed its review of our previously requested waiver of the New Drug Applications (“NDAs”) user fee related to our Rexista® (abuse deterrent oxycodone hydrochloride extended release tablets) NDA product candidate. The FDA, under the small business waiver provision section 736(d)(1)(D) of the Federal Food, Drug, and Cosmetics Act, granted the Company a waiver of the \$1,187,100 application fee for Rexista®.
- In July 2016, the Company announced the results of a food effect study conducted on its behalf for Rexista®. The study design was a randomized, one-treatment two periods, two sequences, crossover, open label, laboratory-blind bioavailability study for Rexista® following a single 80 mg oral dose to healthy adults under fasting and fed conditions. The study showed that Rexista® can be administered with or without a meal (i.e., no food effect). Rexista® met the bioequivalence criteria (90% confidence interval of 80% to 125%) for all matrices, involving maximum plasma concentration and area under the curve (i.e., Cmax ratio of Rexista® taken under fasted conditions to fed conditions, and AUC metrics taken under fasted conditions to fed conditions). The Company believes that Rexista® is well differentiated from currently marketed oral oxycodone extended release products. The Company plans to file the NDA for Rexista® in the fourth quarter of 2016.
- In June 2016, the Company completed an underwritten public offering of 3,229,814 units of common shares and warrants, at a price of \$1.61 per unit. The warrants are currently exercisable, have a term of five years and an exercise price of \$1.93 per common share. The Company issued at the initial closing of the offering an aggregate of 3,229,814 common shares and warrants to purchase an additional 1,614,907 common shares. The underwriter also purchased at such closing additional warrants to acquire 242,236 common shares pursuant to the over-allotment option exercised in part by the underwriter. The Company subsequently sold an aggregate of 459,456 additional common shares at the public offering price of \$1.61 per share in connection with subsequent partial exercises of the underwriter’s over-allotment option. The closings of these partial exercises brought the total net proceeds from the offering to approximately \$5.1 million, after deducting the underwriter’s discount and offering expenses.

There can be no assurance as to when or if any of the licensed products will receive final FDA approval or that, if so approved, the licensed products will be successfully commercialized and produce significant revenues for us. Also, there can be no assurance

that we will not be required to conduct further studies for Rexista®, that we will continue to satisfy the criteria for the waiver of the application fee, that we will file an NDA for Rexista® in the fourth quarter of 2016, 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, that we will be successful in submitting any additional ANDAs, Abbreviated New Drug Submissions (“ANDSs”) or NDAs with the FDA or similar applications 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 and produce significant revenue for us.

## **2016 Third Quarter Financial Results**

Revenue related to the Company’s license and commercialization agreement with Par Pharmaceutical, Inc. in the three months ended August 31, 2016 was \$0.6 million versus \$0.8 million for the three months ended August 31, 2015. These revenues are principally from sales of its generic Focalin XR® (dexmethylphenidate hydrochloride extended-release capsules) for the 15 and 30 mg strengths. The decrease in revenues is primarily due to increased competition and a softening of pricing conditions for our generic Focalin XR® capsules. A fifth generic competitor entered the market in the second half of 2015, resulting in increased price competition and lower market share. Our market share for the combined strengths has stabilized over the last several months at approximately 32% for the combined strengths of our generic Focalin XR® capsules.

The Company recorded net loss for the three months ended August 31, 2016 of \$2.1 million or \$0.07 per common share, compared with a net loss of \$1.9 or \$0.08 per common share for the three months ended August 31, 2015. The net loss for the three months ended August 31, 2016, is higher than the comparable prior period primarily due to the lower licensing revenues from commercial sales of generic Focalin XR®. The loss for the 2016 period was due to ongoing research and development (“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®.

Expenditures for R&D for the three months ended August 31, 2016 were \$1.6 million, compared to \$1.7 million for the three month period ended August 31, 2015. In the three months ended August 31, 2016, we incurred lower expenses on the development of several generic product candidates, and an increase in options expense, compared to the three months ended August 31, 2015.

Selling, general and administrative expenses were \$0.9 million for the three months ended August 31, 2016 in comparison to \$0.8 million for the three months ended August 31, 2015, an increase of \$39,330. The slight increase in selling, general and administrative expense is due to the increase in wages and benefits related to stock options issuance and marketing costs, partially offset by a decrease in administrative costs.

For the three months ended August 31, 2016, net cash flows provided from financing activities of \$5.7 million principally related to the June 2016 closing of the Company’s underwritten public offering of 3,229,814 units of 3,229,814 common shares and warrants to purchase an additional 1,614,907 common shares, at a price of \$1.61 per unit. The total net proceeds to the Company from the offering (after the closing of partial exercises of the underwriter’s over-allotment option) were approximately \$5.1 million, after deducting the

underwriter's discount and offering expenses. In addition, during the three months ended August 31, 2016, an aggregate of 217,707 of common shares were sold on NASDAQ under the Company's at-the-market offering program for gross proceeds of \$414,034, net proceeds of \$402,009.

The Company had cash of \$2.0 million as at August 31, 2016 compared to \$0.2 million as at May 31, 2016. The increase in cash during the three months ended August 31, 2016 was mainly a result of an increase in cash flows provided from financing activities which were mainly from the closing of an underwritten public offering and common share sales under the Company's at-the-market offering program, partially offset by lower cash receipts relating to commercial sales of our generic Focalin XR®. As of October 13, 2016, after the recent receipt of the \$3 million payment from Mallinckrodt, we had a cash balance of \$4.5 million.

## **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 the efficient development of a wide range of existing and new pharmaceuticals. Based on this technology platform, Intellipharmaceutics has developed several drug delivery systems and a pipeline of products (some of which have received FDA approval) and product candidates in various stages of development, including ANDAs filed with the FDA (and one ANDS filed with Health Canada) in therapeutic areas that include neurology, cardiovascular, gastrointestinal tract, diabetes and pain.

Intellipharmaceutics also has NDA 505(b)(2) specialty drug product candidates in its development pipeline. These include Rexista® (abuse deterrent oxycodone hydrochloride extended release tablets) based on its proprietary nPODDDS™ novel Point Of Divergence Drug Delivery System and PODRAS™ Paradoxical OverDose Resistance Activating System, and Regabatin™ XR (pregabalin extended-release capsules). Our current development effort is increasingly directed towards improved difficult-to-develop controlled-release drugs which follow an NDA 505(b)(2) regulatory pathway. The Company has increased its research and development emphasis towards new product development, facilitated by the 505(b)(2) regulatory pathway, by advancing the product development program for both Rexista® and Regabatin™. The 505(b)(2) pathway (which relies in part upon the approving agency's findings for a previously approved drug) both accelerates development timelines and reduces costs in comparison to NDAs for new chemical entities. An advantage of our strategy for development of NDA 505(b)(2) drugs is that our product candidates can, if approved for sale by the FDA, potentially enjoy an exclusivity period which may provide for greater commercial opportunity relative to the generic ANDA route.

## **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,” “potential,” “continue,” “intends,” “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 potential dilutive effects of any future financing and the expected use of any proceeds from any offering of our securities, 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, 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 collaborators with the ability to fund patent litigation and with acceptable 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 collaborators, 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 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 inability to forecast wholesaler demand and/or wholesaler buying patterns, the seasonal fluctuation in the numbers of prescriptions written for our Focalin XR® (dexmethylphenidate hydrochloride extended-release) capsules which may produce substantial fluctuations in revenues, the timing and amount of insurance reimbursement for our products, changes in laws and regulations affecting the conditions required by the FDA for approval and labelling of drugs including abuse or overdose deterrent properties, and changes affecting how opioids are regulated and prescribed by physicians, changes in the laws and regulations, including Medicare and Medicaid, affecting among other things, pricing and reimbursement of pharmaceutical products, 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 product candidates, the manufacturing capacity of third-party manufacturers that we may use for our products, the successful compliance with FDA, Health Canada and other governmental regulations applicable to the Company and its third party manufacturers' facilities, products and/or businesses, difficulties, delays or changes in the FDA approval process or test criteria for ANDAs and NDAs, risks associated with cyber-security and the potential for vulnerability of the digital information of the Company or a current and/or future drug development or commercialization partner of the Company 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 the Company 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.

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

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 and nine months ended August 31, 2016 will be accessible on Intellipharma's website at [www.intellipharma.com](http://www.intellipharma.com) and will be available on SEDAR and EDGAR.

## Summary financial tables are provided below.

### Intellipharma International Inc.

Condensed unaudited interim consolidated balance sheets

As at

(Stated in U.S. dollars)

	August 31, 2016	November 30, 2015
	\$	\$
<b>Assets</b>		
Current		
Cash	1,983,361	1,755,196
Accounts receivable, net	356,685	478,674
Investment tax credits	668,556	458,021
Prepaid expenses, sundry and other assets	234,222	229,225

	3,242,824	2,921,116
Deferred offering costs	468,961	543,745
Property and equipment, net	1,655,720	1,759,438
	5,367,505	5,224,299
<b>Liabilities</b>		
Current		
Accounts payable	1,534,499	3,027,974
Accrued liabilities	238,794	454,290
Employee costs payable	176,562	175,172
Current portion of capital lease obligations	20,602	20,460
Convertible debenture	1,493,759	1,518,429
	3,464,216	5,196,325
Capital lease obligations	-	15,660
Deferred revenue	150,000	150,000
	3,614,216	5,361,985
<b>Shareholders' equity (deficiency)</b>		
Capital stock		
Authorized		
Unlimited common shares without par value		
Unlimited preference shares		
Issued and outstanding		
28,964,770 common shares	27,621,693	21,481,242
(2015 - 24,244,050)		
Additional paid-in capital	32,949,890	30,969,093
Accumulated other comprehensive income	284,421	284,421
Accumulated deficit	(59,102,715 )	(52,872,442 )
	1,753,289	(137,686 )
	5,367,505	5,224,299

**Intellipharmaceuticals 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, 2016	August 31, 2015	August 31, 2016	August 31, 2015
	\$	\$	\$	\$
<b>Revenue</b>				
Licensing	554,925	840,748	1,677,906	3,248,678
	554,925	840,748	1,677,906	3,248,678
<b>Expenses</b>				
Research and development	1,633,150	1,676,549	4,904,405	4,288,624

Selling, general and administrative	855,597	816,267	2,521,427	2,664,369
Depreciation	97,254	97,796	283,380	270,829
	2,586,001	2,590,612	7,709,212	7,223,822
Loss from operations	(2,031,076 )	(1,749,864 )	(6,031,306 )	(3,975,144 )
Net foreign exchange (loss) gain	(26,163 )	10,626	(31,715 )	33,723
Interest income	-	1,481	204	1,498
Interest expense	(52,917 )	(29,890 )	(167,456 )	(249,654 )
Loss on extinguishment of debt	-	(114,023 )	-	(114,023 )
Net loss and comprehensive loss	(2,110,156 )	(1,881,670 )	(6,230,273 )	(4,303,600 )
Loss per common share, basic and diluted	(0.07 )	(0.08 )	(0.24 )	(0.18 )
<b>Weighted average number of common shares outstanding, basic and diluted</b>	28,437,368	23,951,160	25,878,966	23,552,824

#### Intellipharmaceuticals International Inc.

Condensed unaudited interim consolidated statements of cash flows

(Stated in U.S. dollars)

	Three months ended		Nine months ended	
	August 31, 2016	August 31, 2015	August 31, 2016	August 31, 2015
	\$	\$	\$	\$
<b>Net loss</b>	(2,110,156 )	(1,881,670 )	(6,230,273 )	(4,303,600 )
Items not affecting cash				
Depreciation	97,254	97,796	283,380	270,829
Stock-based compensation	332,358	24,384	1,033,216	75,553
Deferred shared units	8,200	8,171	24,195	25,417
Accreted interest on convertible debt	4,919	(20,764 )	22,633	83,759
Loss on extinguishment of debt	-	114,023	-	114,023
Unrealized foreign exchange loss/(gain)	34,860	44,306	29,823	2,895
Change in non-cash operating assets & liabilities				
Accounts receivable	33,389	207,891	121,989	498,528
Investment tax credits	(56,474 )	(16,170 )	(210,535 )	(63,207 )
Prepaid expenses, sundry assets and other assets	23,038	52,660	(4,997 )	127,820
Accounts payable and accrued liabilities	(2,230,625 )	166,728	(2,057,880 )	537,429
Deferred revenue	-	-	-	150,000
Cash flows used in operating activities	(3,863,237 )	(1,202,645 )	(6,988,449 )	(2,480,554 )
<b>Financing activities</b>				
Repayment of capital lease obligations	(6,047 )	(7,400 )	(15,518 )	(22,099 )
Issuance of common shares on at-the-market financing	414,034	718,151	1,962,049	970,363
Proceeds from issuance of shares on exercise of warrants	-	562,500	122,092	562,500

Issuance of common shares on option exercise	-	8,695	-	167,962
Proceeds from issuance of shares and warrants	5,939,967	-	5,939,967	-
Offering costs	(617,743 )	(115,278 )	(663,252 )	(253,016 )
<b>Cash flows from financing activities</b>	<b>5,730,211</b>	<b>1,166,668</b>	<b>7,345,338</b>	<b>1,425,710</b>
<b>Investing activity</b>				
Purchase of property and equipment	(56,941 )	(174,643 )	(128,724 )	(360,030 )
<b>Cash flows used in investing activities</b>	<b>(56,941 )</b>	<b>(174,643 )</b>	<b>(128,724 )</b>	<b>(360,030 )</b>
Increase (Decrease) in cash	1,810,033	(210,620 )	228,165	(1,414,874 )
Cash, beginning of period	173,328	3,029,721	1,755,196	4,233,975
<b>Cash, end of period</b>	<b>1,983,361</b>	<b>2,819,101</b>	<b>1,983,361</b>	<b>2,819,101</b>
<b>Supplemental cash flow information</b>				
Interest paid	75,400	45,339	120,246	135,031
Taxes paid	-	-	-	-

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