



# Intellipharma Announces First Quarter 2017 Results

TORONTO, April 11, 2017 (GLOBE NEWSWIRE) -- **Intellipharma International Inc.** (NASDAQ:IPCI) (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, 2017. All dollar amounts referenced herein are in United States dollars unless otherwise noted.

## First Quarter Key Highlights

- Revenues double to \$1.2 million from \$0.6 million (launch of 2 new generic Focalin XR® strengths)
- FDA accepts filing of Rexista™ NDA, grants PDUFA date of September 25, 2017
- Patents covering aspects of overdose prevention technology, PODRAS™, issued by U.S. and Canadian patent offices
- Continued progress made towards May 2017 anticipated launch of generic Seroquel XR®

*"We are pleased with the revenue improvement resulting from the launch of the additional generic Focalin XR® strengths, given they reflect only 7 weeks of sales. We look forward to Par launching the remaining four strengths in the first half of 2017. While 2017 is off to a great start, we expect revenues will continue to strengthen as we make progress towards the anticipated launch of our generic Seroquel XR® tablets by Mallinckrodt in May 2017,"* stated Dr. Isa Odidi, Chairman and CEO. *"More importantly, our priorities over the next few months will be increasingly focused on working with the FDA towards advancing our Rexista™ NDA candidate."*

## Corporate Developments

- In February 2017, we received final approval from the U.S. Food and Drug Administration ("FDA") for our Abbreviated New Drug Application ("ANDA") for metformin hydrochloride extended release tablets in the 500 and 750 mg strengths. Our newly-approved product is a generic equivalent for the corresponding strengths of the branded product Glucophage® XR sold in the U.S. by Bristol-Myers Squibb. We are actively evaluating options to realize commercial returns from this new approval.
- In February 2017, the FDA accepted for filing our New Drug Application ("NDA") filed in November 2016, seeking authorization to market our Rexista™ product candidate (abuse-deterrent oxycodone hydrochloride extended release tablets) in the 10, 15, 20, 30, 40, 60 and 80 mg strengths. The FDA determined that our application is sufficiently complete to permit a substantive review, and has set a target action date

under the Prescription Drug User Fee Act (“PDUFA”) of September 25, 2017. The submission is supported by pivotal pharmacokinetic studies that demonstrated that Rexista™ is bioequivalent to OxyContin® (oxycodone hydrochloride extended release). The submission also includes abuse-deterrent studies conducted to support abuse-deterrent label claims related to abuse of the drug by various pathways, including oral, intra-nasal and intravenous.

- In January 2017, our U.S. marketing partner, Par Pharmaceutical Inc. (“Par”), launched the 25 and 35 mg strengths of its generic Focalin XR® (dexamethylphenidate hydrochloride extended-release) capsules in the U.S., complementing the 15 and 30 mg strengths of our generic Focalin XR® currently marketed by Par. The FDA had recently granted final approval to Par’s ANDA for its generic Focalin XR® capsules in the 5, 10, 15, 20, 25, 30, 35 and 40 mg strengths. We expect sales of the 25 and 35 mg strengths to significantly improve our revenues in 2017. As the first filer of an ANDA for generic Focalin XR® in the 25 and 35 mg strengths, Par has 180 days of U.S. generic marketing exclusivity for these strengths. We believe Par is preparing to launch all the remaining strengths in the first half of 2017.
- In December 2016, U.S. Patent No. 9,522,119 and Canadian Patent No. 2,910,865 were issued by the U.S. Patent and Trademark Office and the Canadian Intellectual Property Office in respect of “Compositions and Methods for Reducing Overdose”. The issued patents cover aspects of our Paradoxical OverDose Resistance Activating System (“PODRAS™”) delivery technology, which is designed to prevent overdose when more pills than prescribed are swallowed intact. Preclinical studies of prototypes of oxycodone with PODRAS™ technology suggest that, unlike other third-party abuse-deterrent oxycodone products in the marketplace, if more tablets than prescribed are deliberately or inadvertently swallowed, the amount of drug active released over 24 hours may be substantially less than expected. However, if the prescribed number of pills is swallowed, the drug release should be as expected. The issuance of these patents provides us with the opportunity to accelerate our PODRAS™ development plan in 2017 by pursuing proof of concept studies in humans. We intend to incorporate this technology in an alternate Rexista™ product candidate.

We cannot provide any assurance that any target launch date will be met for the remaining strengths of Par’s generic Focalin XR® or for our generic Seroquel XR®. Also, 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, that our approved generic versions of Keppra XR® or Glucophage XR® will be successfully commercialized, 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, or that they will ever be successfully commercialized and produce significant revenue for us.

### **Recently Commenced Litigation**

In connection with our NDA filed in November 2016 for our Rexista™ product candidate

(abuse-deterrent oxycodone hydrochloride extended release tablets), we relied on the 505(b)(2) regulatory pathway and referenced data from Purdue Pharma L.P.'s file for its OxyContin® extended release oxycodone hydrochloride. Our Rexista™ application was accepted by the FDA for further review in February 2017. We certified to the FDA that we believed that our Rexista™ product candidate would not infringe any of sixteen (16) patents associated with the branded product Oxycontin® (the “Oxycontin® patents”) listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book (the “Orange Book”), or that such patents are invalid, and so notified Purdue Pharma L.P. and the other owners of the subject patents listed in the Orange Book of such certification. On April 7, 2017, we received notice that Purdue Pharma L.P., Purdue Pharmaceuticals L.P., The P.F. Laboratories, Inc., Rhodes Technologies, and Grünenthal GmbH (collectively, “Purdue litigation plaintiffs”) 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 Rexista™, alleging that Rexista™ infringes six (6) out of the sixteen (16) patents. The complaint seeks injunctive relief as well as attorneys’ fees and costs and such other and further relief as the Court may deem just and proper.

As a result of the commencement of these legal proceedings, the FDA is stayed for 30 months from granting final approval to our Rexista™ product candidate. That time period commenced on February 24, 2017, when the Purdue litigation plaintiffs were notified of our certification concerning the patents, and will expire on August 24, 2019, unless the stay is earlier terminated by a final declaration of the courts that the patents are invalid, or are not infringed, or the matter is otherwise settled among the parties. We are confident that we do not infringe the subject patents, and will vigorously defend against these claims.

## **2017 First Quarter Financial Results**

The Company recorded revenues of \$1.2 million for the three months ended February 28, 2017 versus \$0.6 million for the three months ended February 29, 2016. For the three months ended February 28, 2017, we recognized licensing revenue of \$1.2 million from commercial sales of 15, 25, 30 and 35 mg strengths of generic Focalin XR® capsules under the Par agreement. The increase in revenues is due to Par’s January 2017 launch of the 25 and 35 mg strengths of generic Focalin XR® capsules in the U.S. Based on the most recent information available to us, our overall market share on the combined 15 and 30 mg strengths of generic Focalin XR® capsules is approximately 34%. It is too soon for us to estimate our market share for the recently launched 25 and 35 mg strengths. Revenue under the Par agreement represents the commercial sales of the generic product in those strengths and may not be representative of future sales. In addition, in the fourth quarter of 2016, the Company received a non-refundable up-front payment of \$3,000,000 from Mallinckrodt LLC (“Mallinckrodt”) pursuant to the Mallinckrodt agreement, of which \$75,000 was recognized as revenue during the three months ended February 28, 2017. Such up-front fees are recognized over the expected 10 year term of the contract. There were no up-front fees recognized in the three months ended February 29, 2016.

The Company recorded net loss for the three months ended February 28, 2017 of \$2.0 million, or \$0.07 per common share, compared with a net loss of \$2.1 million, or \$0.09 per common share, for the three months ended February 29, 2016. The lower net loss is primarily attributed to higher licensing revenues from commercial sales of generic Focalin

XR<sup>®</sup>, as discussed above, in the first quarter of 2017 partially offset by an increase in performance-based options expense and legal and other professional fees. For the three months ended February 29, 2016, the net loss was attributed to lower licensing revenues and an increase in performance-based options expense compared to the prior period. Stock option expense is a non-cash item.

Research and development (“R&D”) expenditures for the three months ended February 28, 2017 were \$2.0 million in comparison to \$1.8 million in the three months ended February 29, 2016. The increase is primarily due to higher stock option compensation expense as a result of certain performance-based stock options vesting upon FDA approval of our generic Glucophage XR<sup>®</sup> tablets. After adjusting for the stock-based compensation expenses, expenditures for R&D for the three months ended February 28, 2017 were higher by \$53,245 compared to the three months ended February 29, 2016. This is primarily due to higher compensation expense.

Selling, general and administrative expenses were \$1.0 million for the three months ended February 28, 2017 in comparison to \$0.8 million for the three months ended February 29, 2016, an increase of \$0.2 million. The increase is due to higher corporate legal activities and other professional fees, as well as higher compensation expenses.

The Company had cash of \$2.4 million as at February 28, 2017 compared to \$4.1 million as at November 30, 2016. The decrease in cash during the three months ended February 28, 2017 was mainly a result of our ongoing expenditures in R&D and selling, general, and administrative expenses, and an increase in purchases of production equipment to support our anticipated generic Seroquel XR<sup>®</sup> launch, which were only partially offset by cash receipts from commercialized sales of our generic Focalin XR<sup>®</sup> and cash receipts provided from financing activities derived from common share sales under the Company’s at-the-market offering program.

As of April 11, 2017, our cash balance was \$1.7 million. We currently expect to satisfy our operating cash requirements until July 2017 from cash on hand and higher quarterly profit share payments from Par. Should the Company secure final FDA approval on its generic Seroquel XR<sup>®</sup> ANDA and, in collaboration with its marketing and distribution partner Mallinckrodt, successfully launch all or some of the strengths in May 2017, then the Company may be cash flow positive in the third quarter of 2017. Failing this, 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. There can be no assurance as to when or if Par will launch the additional strengths of its generic Focalin XR<sup>®</sup> and, if launched, whether they will be successfully commercialized, or if generic Seroquel XR<sup>®</sup> will be approved or successfully commercialized. If necessary, we expect to utilize our at-the-market offering program to bridge any funding shortfall in the second quarter of 2017.

## **About Intellipharma**

Intellipharma 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<sup>™</sup> 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, Intellipharma 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 Abbreviated New Drug Submission filed with Health Canada) in therapeutic areas that include neurology, cardiovascular, gastrointestinal tract, diabetes and pain.

Intellipharma also has NDA 505(b)(2) specialty drug product candidates in its development pipeline. These include Rexista™, 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). 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," "confident," "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 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 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 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® (dexamethylphenidate hydrochloride extended-release) capsules which may produce substantial fluctuations in revenues, 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 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, 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, 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 Rexista™ in particular, as a patent infringement suit has been filed against us, 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](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,” “Intellipharma,” and the “Company” refer to Intellipharma 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 months ended February 28, 2017 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)

	February 28, 2017	November 30, 2016
	\$	\$
<b>Assets</b>		
Current		
Cash	2,384,624	4,144,424
Accounts receivable, net	1,069,551	472,474
Investment tax credits	743,605	681,136
Prepaid expenses, sundry and other assets	443,549	400,642
Inventory	402,974	-
	5,044,303	5,698,676
Deferred offering costs	394,741	386,375
Property and equipment, net	2,520,572	1,889,638
	7,959,616	7,974,689

### Liabilities

Current

Accounts payable	1,018,352	807,295
Accrued liabilities	624,825	384,886
Employee costs payable	1,077,091	1,044,151
Capital lease obligations	9,497	14,829
Convertible debenture	1,321,032	1,494,764
Deferred revenue	450,000	450,000
	<u>4,500,797</u>	<u>4,195,925</u>
Deferred revenue	2,587,500	2,662,500
	<u>7,088,297</u>	<u>6,858,425</u>

#### Shareholders' equity

##### Capital stock

##### Authorized

Unlimited common shares without par value

Unlimited preference shares

##### Issued and outstanding

30,155,837 common shares 30,733,030 29,830,791

(November 30, 2016 - 29,789,992)

Additional paid-in capital 34,860,748 34,017,071

Accumulated other comprehensive income 284,421 284,421

Accumulated deficit (65,006,880 ) (63,016,019 )

871,319 1,116,264

##### Contingencies

7,959,616 7,974,689

#### Intellipharmaceuticals International Inc.

Condensed unaudited interim consolidated statements of operations

and comprehensive loss

for the three months ended February 28, 2017 and February 29, 2016

(Stated in U.S. dollars)

	2017	2016
	\$	\$
<b>Revenue</b>		
Licensing	1,160,366	566,937
Up-front fees	75,000	-
	<u>1,235,366</u>	<u>566,937</u>
<b>Expenses</b>		
Research and development	2,031,192	1,812,608
Selling, general and administrative	961,578	756,428
Depreciation	91,508	92,235
	<u>3,084,278</u>	<u>2,661,271</u>
Loss from operations	(1,848,912 )	(2,094,334 )
	(16,588 )	29,895
Net foreign exchange (loss) gain		
Interest income	5	140
Interest expense	(125,366 )	(55,741 )
Net loss and comprehensive loss	<u>(1,990,861 )</u>	<u>(2,120,040 )</u>

Net loss per common share, basic and diluted

Basic and diluted	(0.07 )	(0.09 )
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Weighted average number of common shares  
outstanding

Basic and diluted	29,966,330	24,431,202
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# **Intellipharmaceuticals International Inc.**

Condensed unaudited interim consolidated statements of cash flows  
for the three months ended February 28, 2017 and February 29, 2016  
(Stated in U.S. dollars)

	2017	2016
	\$	\$
<b>Net loss</b>	(1,990,861 )	(2,120,040 )
Items not affecting cash		
Depreciation	91,508	92,235
Stock-based compensation	822,925	660,109
Deferred share units	7,261	8,051
Accreted interest on convertible debenture	83,230	8,831
Unrealized foreign exchange gain	(37,871 )	(18,046 )
Change in non-cash operating assets & liabilities		
Accounts receivable	(597,077 )	192,329
Investment tax credits	(62,469 )	(82,562 )
Prepaid expenses, sundry and other assets	(42,907 )	(69,576 )
Inventory	(402,974 )	-
Accounts payable, accrued liabilities and employee costs payable	483,936	(455,398 )
Deferred revenue	(75,000 )	-
Cash flows used in operating activities	(1,720,299 )	(1,784,067 )
<b>Financing activities</b>		
Repayment of principal on convertible debenture	(150,000 )	-
Issuance of common shares on exercise of options	12,465	-
Repayment of capital lease obligations	(5,332 )	(5,322 )
Issuance of common shares on at-the-market financing	577,023	397,244
Financing cost for shares issued	(16,565 )	(11,142 )
Proceeds from issuance of common shares on exercise of warrants	265,350	122,092
Cash flows provided from financing activities	682,941	502,872
<b>Investing activity</b>		
Purchase of property and equipment	(722,442 )	(49,317 )
Cash flows used in investing activities	(722,442 )	(49,317 )
Decrease in cash	(1,759,800 )	(1,330,512 )
Cash, beginning of period	4,144,424	1,755,196
<b>Cash, end of period</b>	<b>2,384,624</b>	<b>424,684</b>
<b>Supplemental cash flow information</b>		
Interest paid	30,062	15,277
Taxes paid	-	-

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Source: Intellipharmaeutics International Inc.