



Intellipharma Provides Operational Update

TORONTO, Jan. 24, 2018 (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- and targeted-release oral solid dosage drugs, today provided an operational update on its plans and projected timelines for the 2018 year.

"2017 marked a series of important accomplishments that we believe will set the stage for growth in 2018 and beyond," commented Dr. Isa Odidi, Chief Executive Officer and co-founder of Intellipharma. "We continue to be optimistic about our abuse-deterrent oxycodone hydrochloride extended release tablets (Oxycodone ER) product candidate. The complete response letter (CRL) from the FDA in our view was favorable as it clarified concerns expressed by the FDA Advisory Committees and the path for resubmission of the application. We remain confident in the potential commercial opportunity for Oxycodone ER, and our other drug development and commercialization initiatives also remain on track. We believe that our product portfolio positions us well for growth and look forward to further executing on our plans into 2018."

2017 key operational highlights include:

- Intellipharma commenced in-house manufacture of its first commercial product (all strengths of generic Seroquel XR® (quetiapine fumarate extended-release) tablets) for export to the United States.
- Intellipharma's marketing and distribution partner, Mallinckrodt LLC ("Mallinckrodt") launched all strengths of generic Seroquel XR® in the United States, providing us with the full line of generic Seroquel XR® strengths available in the U.S. market.
- Our marketing partner, Par Pharmaceutical, Inc. ("Par") completed the launch of all strengths of generic Focalin XR® (dexamethylphenidate hydrochloride extended-release) capsules in the United States, providing us with the full line of generic Focalin XR® strengths available in the U.S. market.
- The United States Food and Drug Administration ("FDA") accepted for filing our new drug application ("NDA") seeking authorization to market our Oxycodone ER product candidate in the 10, 15, 20, 30, 40, 60 and 80 mg strengths.
- We received a complete response letter (the "CRL") from the FDA providing certain recommendations and requests for information regarding our Oxycodone ER (formerly known as Rexista™) NDA.

- We received final approval from the FDA for our abbreviated new drug application (“ANDA”) for metformin hydrochloride extended release tablets in the 500 and 750 mg strengths (a generic equivalent for the corresponding strengths of the branded product Glucophage® XR sold in the United States by Bristol-Myers Squibb).
- The Company announced the grant of additional U.S. Patents in respect of “Compositions and Methods for Reducing Overdose”, covering aspects of the Company's Paradoxical OverDose Resistance Activating System (“PODRAS™”) delivery technology, which is designed to prevent overdose when more pills than prescribed are swallowed intact.

Drug Portfolio Update

Oxycodone ER Abuse-Deterrent Program

The Company's NDA for an abuse-deterrent version of Oxycodone ER was accepted for filing by the FDA less than twelve months ago. The submission was supported by Category 1 abuse-deterrent studies (to support intravenous abuse deterrent label claim) and pivotal pharmacokinetic studies that demonstrated that the product is bioequivalent to OxyContin® (oxycodone hydrochloride extended release) and can be administered with or without a meal (i.e., no food effect).

The joint meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and Drug Safety and Risk Management Advisory Committee of the FDA held in July 2017 expressed a desire to review additional data for Oxycodone ER that may be obtained from human abuse potential studies for the oral and intranasal routes of administration. The CRL from the FDA received in September 2017 clarified concerns expressed by the advisory committees and the path for resubmission of the application. Subsequent to receiving the CRL, the Company immediately began preparing its response, including finalizing protocols and plans to complete the Category 2 and 3 studies to support the application.

The planned studies to support both the oral and intranasal route of abuse-deterrent label claims are scheduled to commence within the next few weeks and expected to be take approximately six months from commencement. We anticipate that the NDA will be resubmitted to the FDA in late summer 2018. As previously announced, as a result of the patent infringement proceedings against us in the United States launched by Purdue Pharma L.P. *et al* (collectively, “Purdue”), the FDA is stayed from granting approval of our Oxycodone ER product until August 24, 2019 unless the court declares Purdue's patents to be invalid, or not infringed; or the matter is otherwise settled among the parties. The Company believes that it does not infringe the subject patents and that it has a well-prepared strategy to vigorously defend against the claims. A trial date for Purdue against the Company regarding the product has been set for October 22, 2018. With a resubmission of the NDA ahead of this date, the Company anticipates that it will remain on its original schedule with respect to commercialization at the earliest possible opportunity.

Intellectual Property Portfolio

PODRAS™ Technology

Intellipharma continues to make progress regarding its PODRAS™ delivery

technology, recently obtaining three additional patents from the U.S. Patent and Trademark Office (U.S. Patent Nos. 9700515 and 9700516 in July 2017 and No. 9,801,939 in October 2017) also entitled "Compositions and Methods for Reducing Overdose" and covering aspects of the Company's PODRAS™ delivery technology. The Company is optimistic about the prospects of this technology, which deliberately regulates the bioavailability of active ingredients in both generic and non-generic medications in a way that reduces the opportunity for overdose and/or abuse. The Company is finalizing plans to initiate proof of concept trials in humans. The Company believes that the preclinical work on the technology to date has shown encouraging results, but human trials are required to show that the technology works as expected. The human studies for PODRAS™ are expected to take place in the first half of 2018. Based on the results of these studies, the Company will evaluate commercial opportunities for the technology including potential out-licensing as well as incorporation into products within our pipeline.

Drug Development and Commercialization Progress

Generic Seroquel XR® and Generic Focalin XR®

Intellipharma's marketing and distribution partner, Mallinckrodt launched all strengths of generic Seroquel XR® (quetiapine fumarate extended-release tablets) in the U.S. in June 2017. With the launch of two additional strengths of generic Focalin XR® (dexamethylphenidate hydrochloride extended-release capsules) in November 2017, the Company's marketing and distribution partner, Par has now launched all strengths of generic Focalin XR in the U.S. Intellipharma continues to work with Mallinckrodt and Par to gain traction in the competitive U.S. market, and is actively pursuing opportunities it has identified outside of the U.S. to expand global market reach.

Regabatin™ XR

The Company has had in development a once-a-day non-generic controlled release version of pregabalin (marketed in the U.S. by Pfizer under the Lyrica® brand) under the NDA 505(b)(2) regulatory pathway, with a view to possible commercialization in the U.S. at some time following the December 30, 2018 expiry of the patent covering the pregabalin molecule. Regabatin™ XR is based on our controlled release drug delivery technology platform which utilizes the symptomatology and chronobiology of fibromyalgia in a formulation intended to provide a higher exposure of pregabalin during the first 12 hours of dosing. The FDA has recently approved Lyrica® CR, a branded controlled release formulation of pregabalin. The Company believes its product has significant additional benefits to anything currently on the market and is very excited to continue development of its formulation. We are currently evaluating partners for required Phase III studies and expect to begin these studies in the second half of 2018.

Other Products and Markets

Intellipharma continues to pursue partnering opportunities of its other ANDA, Abbreviated New Drug Submission ("ANDS") and NDA products and product candidates, both in the U.S. and internationally. The Company has a strong pipeline of ANDAs. Two ANDAs have recently been approved and others are in various stages of the FDA review process. While commercialization opportunities for our product have been challenging in the U.S. due to the extremely competitive cost environment, the Company has been working

with its supply partners to reduce input costs and achieve efficiencies which we expect to lead to new opportunities in the U.S.

In addition, the Company continues efforts to identify opportunities overseas, including in China, that could if effectuated provide product distribution alternatives through partnerships and therefore do not require an investment or asset acquisition by the Company. The Company recently visited China where discussions toward establishing a partnership to facilitate future development activities are ongoing. The Company has not entered into any such arrangements at this time. These opportunities could involve out-licensing of our products, third-party manufacturing supply and more efficient access to pharmaceutical ingredients and therefore assist with the development of our growing product pipeline.

As the Company builds its product portfolio, we are also seeking to add additional product development candidates to our pipeline. We have received considerable interest and are investigating several opportunities to develop products in collaboration with international partners.

Year-end Financial Results

The Company is currently working to finalize its 2017 annual financial report and expects to set a release date shortly. In addition to the release of the financial report, management will also hold a conference call to discuss the results and answer any questions. Details on the date and time, as well as conference call information will be announced in the coming days.

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

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 Oxycodone ER abuse deterrent oxycodone formulation based on its proprietary nPODDDS™ novel Point Of Divergence Drug Delivery System (for which an NDA has been filed with the FDA), and Regabatin™ XR (pregabalin extended-release capsules).

Cautionary Statement Regarding Forward-Looking Information

Certain statements in this document constitute "forward-looking statements" within the meaning of the United States Private Securities Litigation Reform Act of 1995 and/or "forward-looking information" under the Securities Act (Ontario). These statements include, without limitation, statements expressed or implied regarding our plans, goals, timelines 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 "expects", "plans", "anticipates", "believes", "confident", "prospects", "potential", "intends", "look forward", "would", "projected", "set to", "seeking" or the negative of such terms or other comparable terminology. We made a number of assumptions in the preparation of our forward-looking statements. You should not place undue reliance on our forward-looking statements, which are subject to a multitude of known and unknown risks and uncertainties that could cause actual results, future circumstances or events to differ materially from those stated in or implied by the forward-looking statements. Risks, uncertainties and other factors that could affect our actual results include, but are not limited to, 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 or our securities, 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, 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, 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, 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 availability and pricing of third-party sourced products and materials, 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 Oxycodone ER 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, and 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). Additional risks and uncertainties relating to us and our business can be found in the "Risk Factors" section of our latest annual information form, our latest Form 20-F, and our latest Form F-3 (including any documents forming a part thereof or incorporated by reference therein), as well as in our reports, public disclosure documents and other filings with the securities commissions and other regulatory bodies in Canada and the U.S. which are available on

www.sedar.com and www.sec.gov. The forward-looking statements reflect our current views with respect to future events, and are based on what we believe are reasonable assumptions as of the date of this document, and we disclaim any intention and have no obligation or responsibility, except as required by law, to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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

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