

July 15, 2020



# Intellipharmaceuticals Announces Second Quarter 2020 Results

**TORONTO, ON / ACCESSWIRE / July 15, 2020 / Intellipharmaceuticals International Inc. (OTCQB:IPCF)(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 six months ended May 31, 2020. All dollar amounts referenced herein are in United States dollars unless otherwise noted.

- On July 2, 2020, we announced that the parties in the cases, numbers 17-cv-392-RGA, 18-cv-404-RGA and 20-cv-515-RGA (the "Litigations") between Purdue Pharma L.P. et al ("Purdue Pharma") and Intellipharmaceuticals, have entered into a stipulated dismissal of the Litigations. The stipulated dismissal, which is subject to approval by the bankruptcy court presiding over Purdue Pharma's pending chapter 11 cases, provides for the termination of patent infringement proceedings commenced by Purdue Pharma against the Company in the United States District Court for the District of Delaware in respect of the Company's New Drug Application ("NDA") filing for Aximris XR™ (oxycodone hydrochloride extended release tablets) with the United States Food and Drug Administration ("FDA"). The stipulated dismissal also provides for a thirty (30) day period following a final approval of the Company's Aximris XR™ NDA during which the parties will attempt to resolve any potential asserted patent infringement claims relating to the NDA. If the parties fail to resolve all such claims during a period of thirty (30) days following such final approval, Purdue Pharma L.P. et al will have fifteen (15) days to pursue an infringement action against the Company.
- On April 9, 2020, we announced an update on timing of the release of our first quarter financial results for the three months ended February 29, 2020. The Canadian Securities Administrators had announced temporary relief from certain regulatory filings required to be made on or before June 1, 2020 by reporting issuers in Canada, in view of the recent COVID-19 developments and the impact on market participants. The blanket relief provided a 45-day extension for periodic filings, including financial statements and management's discussion and analysis. We are relying on this 45-day extension period provided under the blanket relief for the filing of our interim financial statements for the three months ended February 29, 2020 and the related MD&A. The Company filed its first quarter results for the three months ended February 29, 2020 on May 29, 2020, within the period of extension.
- On February 5, 2020, we announced the resignation of Greg Powell, our former Chief Financial Officer, for personal and family reasons. Pending the hiring of a replacement for Mr. Powell, the functions of Chief Financial Officer are being carried out by our President and former Chief Financial Officer, Dr. Amina Odidi. Fazayill Shaideen, who has been our Controller for the past 8 years, will continue to handle accounting activities.
- On January 15, 2020, at a joint meeting of the Anesthetic and Analgesic Drug Products

Advisory Committee and Drug Safety and Risk Management Advisory Committee ("Advisory Committees") of the FDA to discuss our New Drug Application ("NDA") for Aximris XR™, abuse-deterrent oxycodone hydrochloride extended-release tablets, the Advisory Committees voted 24 to 2 against the approval of our NDA for Aximris XR™ for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. We expect the FDA to take action on our application, on completion of their review of the NDA.

## Results of Operations

The Company recorded net loss for the three months ended May 31, 2020 of \$1,048,433 or \$0.04 per common share, compared with a net loss of \$2,072,798 or \$0.10 per common share for the three months ended May 31, 2019. In the three months ended May 31, 2020, the net loss is attributed to the decrease in up-front fees recognized in revenue, offset by decreased administrative expenses related to professional and legal fees and R&D expenses related to the decrease in third party consulting fees, decrease in expenses related to biostudies and the reduction in R&D staff. In the three months ended May 31, 2019, the net loss was attributed to the lower licensing revenues from commercial sales of generic Focalin XR® and to a lesser extent, sales of generic Seroquel XR® shipped to Mallinckrodt, combined with increased administrative expense related to professional and legal fees.

The Company recorded revenues of \$395,740 for the three months ended May 31, 2020 versus \$1,214,520 for the three months ended May 31, 2019. Such revenues consisted primarily of licensing revenues from commercial sales of the 15, 25, 30 and 35 mg strengths of our generic Focalin XR® under the Par agreement for the three months ended May 31, 2020. The higher revenue for the three months ended May 31, 2019 is primarily due to the change in contract term with Mallinckrodt which was terminated August 12, 2019 compared to the original ten year term. This resulted in up-front fees of \$814,824 recognized in the three months ended May 31, 2019 versus \$Nil over the same period in 2020. Beginning in early 2018, we began to see a significant impact from aggressive pricing by competitors, resulting in a marked increase in gross-to-net deductions such as wholesaler rebates, chargebacks and pricing adjustments which continues to date. While the gross-to-net deductions fluctuate on a quarter over quarter basis, profit share payments for the last quarter has been consistent over the same period in 2019.

Expenditures for R&D for the three months ended May 31, 2020 were lower by \$1,019,713 compared to the three months ended May 31, 2019. The decrease is primarily due to significantly reduced third party consulting fees, decrease in expenses related to biostudies and the reduction in R&D staff.

Selling, general and administrative expenses were \$548,232 for the three months ended May 31, 2020 in comparison to \$1,476,013 for the three months ended May 31, 2019, resulting in a decrease of \$927,781. The decrease is namely due to a decrease in administrative costs and a decrease in wages and marketing costs, partially offset by an increase in occupancy cost.

The Company had cash of \$72,098 as at May 31, 2020 compared to \$1,030,179 as at May 31, 2019. The decrease in cash was mainly due to expenditures for R&D and selling,

general, and administrative expenses.

As of May 31, 2020, our cash balance was \$72,098. We currently expect to meet our short-term cash requirements from quarterly profit share payments from Par and by cost savings associated with managing operating expense levels. If we are able to supply products to our marketing and distribution partner, Tris Pharma, and it achieves sales of our generic Seroquel XR®, generic Pristiq and generic Effexor XR at anticipated rates, then we may satisfy our cash needs and cost-saving measures. We will need to obtain additional funding to further product commercialization activities and the development of our product candidates. Potential sources of capital may include payments from licensing agreements, and/or debt financings and/or new strategic partnership agreements which the Company is actively exploring. The Company has funded its business activities principally through the issuance of securities, loans from related parties and funds from development agreements. There is no certainty that such funding will be available going forward. If conditions permit, we intend to utilize the equity markets and/or debt financing to bridge any funding shortfall. Our future operations are highly dependent upon our ability to source additional capital to support advancing our product pipeline through continued R&D activities and to fund any significant expansion of our operations. Our ultimate success will depend on whether our product candidates receive approval by the FDA or Health Canada or the regulatory authorities of other countries in which our products are proposed to be sold and on whether we are able to successfully market our approved products. We cannot be certain that we will receive FDA or Health Canada or such other regulatory approval for any of our current or future product candidates, that we will reach the level of sales and revenues necessary to achieve and sustain profitability, or that we can secure other capital sources on terms or in amounts sufficient to meet our needs or at all.

There can be no assurance that we will not be required to conduct further studies for our Aximris XR product candidate, that the FDA will approve any of our requested abuse-deterrence label claims, that the FDA will meet its deadline for review or that the FDA will ultimately approve the NDA for the sale of product candidate in the U.S. market or that the product will ever be successfully commercialized and produce significant revenue for us.

## **About Intellipharmaceutics**

Intellipharmaceutics International Inc. is a pharmaceutical company specializing in the research, development and manufacture of novel and generic controlled-release and targeted-release oral solid dosage drugs. The Company's patented Hypermatrix™ technology is a multidimensional controlled-release drug delivery platform that can be applied to a wide range of existing and new pharmaceuticals. Intellipharmaceutics has developed several drug delivery systems based on this technology platform, with a pipeline of products (some of which have received FDA approval) in various stages of development. The Company has ANDA and NDA 505(b)(2) drug product candidates in its development pipeline. These include the Company's Oxycodone ER based on its proprietary nPODDDS™ novel Point Of Divergence Drug Delivery System (for which an NDA has been filed with the FDA), and Regabatin™ XR (pregabalin extended-release capsules).

## **Cautionary Statement Regarding Forward-Looking Information**

*Certain statements in this document constitute "forward-looking statements" within the meaning of the United States Private Securities Litigation Reform Act of 1995 and/or*

*"forward-looking information" under the Securities Act (Ontario). These statements include, without limitation, statements expressed or implied regarding our expectations, plans, goals and milestones, status of developments or expenditures relating to our business, plans to fund our current activities, and statements concerning our partnering activities, health regulatory submissions, strategy, future operations, future financial position, future sales, revenues and profitability, projected costs and market penetration and risks or uncertainties arising from the delisting of our shares from Nasdaq and our ability to comply with OTCQB and TSX requirements. In some cases, you can identify forward-looking statements by terminology such as "appear", "unlikely", "target", "may", "will", "should", "expects", "plans", "plans to", "anticipates", "believes", "estimates", "predicts", "confident", "prospects", "potential", "continue", "intends", "look forward", "could", "would", "projected", "goals", "set to", "seeking" or the negative of such terms or other comparable terminology. We made a number of assumptions in the preparation of our forward-looking statements. You should not place undue reliance on our forward-looking statements, which are subject to a multitude of known and unknown risks and uncertainties that could cause actual results, future circumstances or events to differ materially from those stated in or implied by the forward-looking statements. Risks, uncertainties and other factors that could affect our actual results include, but are not limited to, the effects of general economic conditions, securing and maintaining corporate alliances, our estimates regarding our capital requirements, and the effect of capital market conditions and other factors, including the current status of our product development programs, capital availability, the estimated proceeds (and the expected use of any proceeds) we may receive from any offering of our securities, the potential dilutive effects of any future financing, potential liability from and costs of defending pending or future litigation, risks associated with the novel coronavirus (COVID-19) including its impact on our business and operations, our programs regarding research, development and commercialization of our product candidates, the timing of such programs, the timing, costs and uncertainties regarding obtaining regulatory approvals to market our product candidates and the difficulty in predicting the timing and results of any product launches, the timing and amount of profit-share payments from our commercial partners, and the timing and amount of any available investment tax credits, the actual or perceived benefits to users of our drug delivery technologies, products and product candidates as compared to others, our ability to establish and maintain valid and enforceable intellectual property rights in our drug delivery technologies, products and product candidates, the scope of protection provided by intellectual property rights for our drug delivery technologies, products and product candidates, recent and future legal developments in the United States and elsewhere that could make it more difficult and costly for us to obtain regulatory approvals for our product candidates and negatively affect the prices we may charge, increased public awareness and government scrutiny of the problems associated with the potential for abuse of opioid based medications, pursuing growth through international operations could strain our resources, our limited manufacturing, sales, marketing and distribution capability and our reliance on third parties for such, the actual size of the potential markets for any of our products and product candidates compared to our market estimates, our selection and licensing of products and product candidates, our ability to attract distributors and/or commercial partners with the ability to fund patent litigation and with acceptable product development, regulatory and commercialization expertise and the benefits to be derived from such collaborative efforts, sources of revenues and anticipated revenues, including contributions from distributors and commercial partners, product sales, license agreements and other collaborative efforts for the development and commercialization of product candidates, our ability to create an effective direct sales and marketing infrastructure for*

products we elect to market and sell directly, the rate and degree of market acceptance of our products, delays in product approvals that may be caused by changing regulatory requirements, the difficulty in predicting the timing of regulatory approval and launch of competitive products, the difficulty in predicting the impact of competitive products on sales volume, pricing, rebates and other allowances, the number of competitive product entries, and the nature and extent of any aggressive pricing and rebate activities that may follow, the inability to forecast wholesaler demand and/or wholesaler buying patterns, seasonal fluctuations in the number of prescriptions written for our generic Focalin XR® capsules which may produce substantial fluctuations in revenue, the timing and amount of insurance reimbursement regarding our products, changes in laws and regulations affecting the conditions required by the FDA for approval, testing and labeling of drugs including abuse or overdose deterrent properties, and changes affecting how opioids are regulated and prescribed by physicians, changes in laws and regulations, including Medicare and Medicaid, affecting among other things, pricing and reimbursement of pharmaceutical products, the effect of recent changes in U.S. federal income tax laws, including but not limited to, limitations on the deductibility of business interest, limitations on the use of net operating losses and application of the base erosion minimum tax, on our U.S. corporate income tax burden, the success and pricing of other competing therapies that may become available, our ability to retain and hire qualified employees, the availability and pricing of third-party sourced products and materials, challenges related to the development, commercialization, technology transfer, scale-up, and/or process validation of manufacturing processes for our products or product candidates, the manufacturing capacity of third-party manufacturers that we may use for our products, potential product liability risks, the recoverability of the cost of any pre-launch inventory, should a planned product launch encounter a denial or delay of approval by regulatory bodies, a delay in commercialization, or other potential issues, the successful compliance with FDA, Health Canada and other governmental regulations applicable to us and our third party manufacturers' facilities, products and/or businesses, our reliance on commercial partners, and any future commercial partners, to market and commercialize our products and, if approved, our product candidates, difficulties, delays or changes in the FDA approval process or test criteria for ANDAs and NDAs, challenges in securing final FDA approval for our product candidates, including our oxycodone hydrochloride extended release tablets product candidate, in particular, if a patent infringement suit is filed against us with respect to any particular product candidates (such as in the case of Oxycodone ER), which could delay the FDA's final approval of such product candidates, healthcare reform measures that could hinder or prevent the commercial success of our products and product candidates, the risk that the FDA may not approve requested product labeling for our product candidate(s) having abuse-deterrent properties and targeting common forms of abuse (oral, intra-nasal and intravenous), risks associated with cyber-security and the potential for vulnerability of our digital information or the digital information of a current and/or future drug development or commercialization partner of ours, and risks arising from the ability and willingness of our third-party commercialization partners to provide documentation that may be required to support information on revenues earned by us from those commercialization partners. Additional risks and uncertainties relating to us and our business can be found in the "Risk Factors" section of our latest annual information form, our latest Form 20-F, and our latest Form F-1 and F-3 registration statements (including any documents forming a part thereof or incorporated by reference therein), as amended, as well as in our reports, public disclosure documents and other filings with the securities commissions and other regulatory bodies in Canada and the U.S., which are available on [www.sedar.com](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 (i) to "we," "us," "our," "Intellipharma," and the "Company" refer to Intellipharma International Inc. and its subsidiaries and (ii) in this document to share amounts, per share data, share prices, exercise prices and conversion rates have been adjusted to reflect the effect of the 1-for-10 reverse split which became effective on each of Nasdaq and TSX at the open of market on September 14, 2018. The common shares of the Company are currently traded on the OTCQB and the TSX.

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

The condensed unaudited interim consolidated financial statements, accompanying notes to the condensed unaudited interim consolidated financial statements, and Management Discussion and Analysis for the three and six months ended May 31, 2020 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)

	May 31, 2020	November 30, 2019
	\$	\$
<b>Assets</b>		
Current		
Cash	72,098	64,622
Accounts receivable, net	240,679	177,202
Investment tax credits	775,736	775,736
Prepaid expenses, sundry and other assets	191,966	156,616
Inventory	246,756	349,131
	<u>1,527,235</u>	<u>1,523,307</u>
Property and equipment, net	<u>2,036,015</u>	<u>2,273,406</u>
	<u>3,563,250</u>	<u>3,796,713</u>

**Liabilities**

## Current

Accounts payable	4,296,577	3,757,018
Accrued liabilities	1,513,429	927,698
Employee costs payable	1,628,580	893,864
Income tax payable	5,678	5,678
Promissory notes payable	154,379	159,863
Convertible debentures	1,772,034	1,744,813
	<u>9,370,677</u>	<u>7,488,934</u>

**Shareholders' equity (deficiency)**

## Capital stock

## Authorized

Unlimited common shares without par value

Unlimited preference shares

## Issued and outstanding

23,678,105 common shares

(November 30, 2019 - 22,085,856)

23,678,105 common shares (November 30, 2019 - 22,085,856)	46,144,402	45,561,222
Additional paid-in capital	44,265,141	44,167,721
Accumulated other comprehensive income	284,421	284,421
Accumulated deficit	(96,501,391)	(93,705,585)
	<u>(5,807,427)</u>	<u>(3,692,221)</u>

## Contingencies

	<u>3,563,250</u>	<u>3,796,713</u>
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**Intellipharma International Inc.**

Condensed unaudited interim consolidated statements of operations and comprehensive loss

For the three and six months ended May 31, 2020 and 2019

(Stated in U.S. dollars)

	Three months ended		Six months ended	
	May 31, 2020	May 31, 2019	May 31, 2020	May 31, 2019
	\$	\$	\$	\$
<b>Revenue</b>				
Licensing	395,740	399,696	773,294	664,247
Up-front fees	-	814,824	-	893,809
	<u>395,740</u>	<u>1,214,520</u>	<u>773,294</u>	<u>1,558,056</u>
<b>Cost of good sold</b>				
Cost of goods sold	-	-	-	33,068
	<u>395,740</u>	<u>1,214,520</u>	<u>773,294</u>	<u>1,524,988</u>
<b>Gross Margin</b>				
<b>Expenses</b>				
Research and development	635,326	1,655,039	1,583,171	3,787,300
Selling, general and administrative	548,232	1,476,013	1,071,463	2,683,256

Depreciation	102,423	126,776	205,122	252,060
	<u>1,285,981</u>	<u>3,257,828</u>	<u>2,859,756</u>	<u>6,722,616</u>
Loss from operations	(890,241)	(2,043,308)	(2,086,462)	(5,197,628)
Net foreign exchange gain	22,066	24,961	44,854	13,629
Interest income	-	843	-	854
Interest expense	(180,258)	(55,294)	(754,198)	(114,102)
Net loss and comprehensive loss	<u>(1,048,433)</u>	<u>(2,072,798)</u>	<u>(2,795,806)</u>	<u>(5,297,247)</u>
Loss per common share, basic and diluted	<u>(0.04)</u>	<u>(0.10)</u>	<u>(0.12)</u>	<u>(0.26)</u>
<b>Weighted average number of common shares outstanding, basic and diluted</b>	<u>23,678,105</u>	<u>21,037,532</u>	<u>23,445,792</u>	<u>20,047,972</u>

### Intellipharmaceuticals International Inc.

Condensed unaudited interim consolidated statements of cash flows

For the three and six months ended May 31, 2020 and 2019

(Stated in U.S. dollars)

	Three months ended		Six months ended	
	May 31, 2020	May 31, 2019	May 31, 2020	May 31, 2019
	\$	\$	\$	\$
<b>Net loss</b>	(1,048,433)	(2,072,798)	(2,795,806)	(5,297,247)
Items not affecting cash				
Depreciation	102,423	125,895	205,122	252,060
Stock-based compensation	12,232	160,016	65,981	162,289
Accreted interest	127,403	8,260	641,840	16,197
Unrealized foreign exchange loss	(5,484)	885	(5,484)	883
Change in non-cash operating assets & liabilities				
Accounts receivable	23,558	(79,846)	(63,477)	(55,761)
Investment tax credits	-	(45,000)	-	(90,000)
Inventory	-	-	102,375	31,723
Prepaid expenses, sundry and other assets	(19,654)	201,083	(35,350)	169,401
Accounts payable, accrued liabilities and employee costs payable	874,001	735,923	1,892,275	377,002
Deferred revenue	-	(817,784)	-	(892,784)
Cash flows used in operating activities	<u>66,046</u>	<u>(1,783,366)</u>	<u>7,476</u>	<u>(5,326,237)</u>
<b>Financing activities</b>				
Repayment of 2013 Debenture	-	-	-	(300,000)
Proceeds from issuance of shares on exercise of 2018 Pre-Funded Warrants	-	1,500	-	27,953



Cash flows provided from (used in) financing activities	-	1,500	-	(272,047)
<b>Investing activity</b>				
Purchase of property and equipment	-	(9,624)	-	(13,414)
Cash flows used in investing activities	-	(9,624)	-	(13,414)
Increase (decrease) in cash	66,046	(1,791,490)	7,476	(5,611,698)
Cash, beginning of period	6,052	2,821,669	64,622	6,641,877
<b>Cash, end of period</b>	<u>72,098</u>	<u>1,030,179</u>	<u>72,098</u>	<u>1,030,179</u>
<b>Supplemental cash flow information</b>				
Interest paid	-	44,331	-	90,754
Taxes paid	-	-	-	-

## CONTACT INFORMATION

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