Intellipharmaceutics International Inc.
Form 424B5
October 13, 2017

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Registration No. 333-218297

PROSPECTUS SUPPLEMENT
(To Prospectus dated July 17, 2017)

# INTELLIPHARMACEUTICS INTERNATIONAL INC.

3,636,364 Common Shares

We are offering 3,636,364 common shares, no par value. In a concurrent private placement, we are also selling to purchasers of our common shares in this offering, warrants to purchase up to 1,818,182 common shares which represent 50% of the number of our common shares being purchased in this offering. The warrants and the common shares issuable upon the exercise of the warrants are not being registered under the Securities Act of 1933, as amended, or the Securities Act, are not being offered pursuant to this prospectus supplement and the accompanying prospectus and are being offered pursuant to the exemption provided in Section 4(a)(2) under the Securities Act and Rule 506(b) promulgated thereunder.

Our common shares are listed for trading on the Toronto Stock Exchange (the "TSX"), and on The NASDAQ Capital Market ("NASDAQ"), under the symbol "IPCI". On October 11, 2017, the closing sale price of our common shares as reported by the TSX and NASDAQ was Cdn$1.35 and $1.08, respectively. On October 11, 2017, the aggregate market value of our outstanding common shares held by non-affiliates was $29,020,743, based on our 31,073,151 outstanding common shares as of such date, of which 25,235,429 common shares were held by non-affiliates, and a per share price of $1.15, the closing sale price of our common shares on October 10, 2017 (which is the highest closing sale price of our common shares in the last 60 days). We have sold or offered securities having an aggregate market value of approximately $4,951,860 pursuant to General Instruction I.B.5 of Form F-3 during the prior twelve calendar month period that ends on and includes the date of this prospectus supplement.

Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading "Risk Factors" contained in this prospectus supplement beginning on page S-3, and under similar headings in the other documents that are incorporated by reference into this prospectus supplement.

We have retained H.C. Wainwright & Co., LLC, or Wainwright or the placement agent, to act as our exclusive placement agent. The placement agent has agreed to use its "reasonable best efforts" to arrange for the sale of the common shares offered by this prospectus supplement. The placement agent has no obligation to buy any of the common shares from us or to arrange for the purchase or sale of any specific number or dollar amount of the common shares. There is no required minimum number of common shares that must be sold as a condition to completion of this offering. We have agreed to pay the placement agent fees set forth in the table below, which assumes that we sell all of the common shares we are offering.

| | PER SHARE | TOTAL |
|---|---|---|
| Public offering price | $1.100 | $4,000,000.40 |
| Placement agent fees(1) | $0.077 | $280,000.02 |
| Proceeds to us before expenses(2) | $1.023 | $3,720,000.38 |

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(1)
In addition, we have agreed to reimburse the placement agent for offering expenses in the non-accountable sum of $25,000 and for legal fees and expenses up to $40,000. We have also agreed to issue to the placement agent warrants in an amount equal to 5% of the number of shares placed in this offering and issued on closing. See “Plan of Distribution” on page S-26 of this prospectus supplement for more information on the placement agent’s compensation.

(2)
Does not include proceeds from the exercise of the warrants in cash, if any. We estimate total expenses of this offering, excluding the placement agent fees, will be approximately $264,626.

The offering price of the common shares will be payable in U.S. dollars. All of the net proceeds of this offering will be paid to us in U.S. dollars.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus supplement. Any representation to the contrary is a criminal offense.

We expect to deliver the securities being offered pursuant to this prospectus supplement on or about October 13, 2017.

H.C. Wainwright & Co.

Prospectus Supplement dated October 11, 2017

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Prospectus Supplement

PROSPECTUS

About this Prospectus Supplement

You should rely only on the information contained in or incorporated by reference in this prospectus supplement, the accompanying prospectus and in any free writing prospectus that we have authorized for use in connection with this offering. We have not, and the placement agent has not, authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the placement agent is not, making an offer to sell common shares or seeking offers to buy common shares in any jurisdiction where the offer or sale is not permitted. You should assume that the information in this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, and in any free writing prospectus that we have authorized for use in connection with this offering, is accurate only as of the date of those respective documents. Our business, financial condition, results of operations and prospects may have changed since those dates. You should read this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, and any free writing prospectus that we have authorized for use in connection with this offering, in their entirety before making an investment decision. You should also read and consider the information in the documents to which we have referred you in the section of this prospectus supplement entitled “Where You Can Find More Information; Incorporation by Reference” and the section of the accompanying prospectus entitled “Where You Can Find More Information; Incorporation by Reference.” In this prospectus supplement, the “Company,” “Intellipharmaceutics,” “we,” “us” and “our” refer to Intellipharmaceutics International Inc. and its subsidiaries.

This prospectus supplement and the accompanying prospectus form part of a registration statement on Form F-3 that we filed with the Securities and Exchange Commission, or SEC, using a “shelf” registration process. This document contains two parts. The first part consists of this prospectus supplement, which provides you with specific information about this offering. The second part, the accompanying prospectus, provides more general information, some of which may not apply to this offering. Generally, when we refer only to the “prospectus,” we are referring to both parts combined. This prospectus supplement may add, update or change information contained in the accompanying prospectus. To the extent that any statement we make in this prospectus supplement is inconsistent with statements made in the accompanying prospectus or any previously filed documents incorporated by reference herein or therein, the statements made in this prospectus supplement will be deemed to modify or supersede those made in the accompanying prospectus and such documents incorporated by reference herein and therein.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference into this prospectus supplement or the accompanying prospectus were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreement, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

References to “$,” “U.S.$” or “dollars” are to U.S. dollars, and all references to “Cdn$” are to the lawful currency of Canada. In this prospectus supplement, where applicable, and unless otherwise indicated, amounts are converted from U.S. dollars to Canadian dollars and vice versa by applying the closing rate of exchange of the Bank of Canada on October 11, 2017. See “Exchange Rate Information.” Except as otherwise indicated, our consolidated financial statements and other information are presented in U.S. dollars.

In this prospectus supplement, we refer to information regarding potential markets for our products, product candidates and other industry data. We believe that all such information has been obtained from reliable sources that are customarily relied upon by companies in our industry. However, we have not independently verified any such information.

Any reference in this prospectus supplement to our “products” includes a reference to our product candidates and future products we may develop.

Whenever we refer to any of our current product candidates (including additional product strengths of products we are currently marketing, no assurances can be given that we, or any of our strategic partners, will successfully commercialize or complete the development of any of such product candidates or future products under development or proposed for development, that regulatory approvals will be granted for any such product candidate or future product, or that any approved product will be produced in commercial quantities or sold profitably.

In this prospectus supplement, the accompanying prospectus and/or the documents incorporated by reference herein or therein, we refer to information regarding potential markets for our products, product candidates and other industry data. We believe that all such information has been obtained from reliable sources that are customarily relied upon by companies in our industry. However, we have not independently verified any such information.

This prospectus supplement does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

Trademarks

Intellipharmaceutics™, Hypermatrix™, Drug Delivery Engine™, IntelliFoam™, IntelliGITransporter™, IntelliMatrix™, IntelliOsmotics™, IntelliPaste™, IntelliPellets™, IntelliShuttle™, Rexista™, nPODDDS™, PODRAS™ and Regabatin™ are trademarks. These trademarks are important to our business. Although we may have omitted the "TM" trademark designation for such trademarks in this prospectus supplement, all rights to such trademarks are nevertheless reserved. Unless otherwise noted, other trademarks used in this prospectus supplement are the property of their respective holders.

SUMMARY

This summary highlights information contained elsewhere in this prospectus supplement or incorporated by reference herein. This summary is not complete and may not contain all of the information that you should consider before deciding whether or not you should purchase the securities offered hereunder. You should read the entire prospectus supplement and accompanying prospectus carefully, including the section entitled “Risk Factors” beginning on page S-3 of this prospectus supplement and the section entitled “Risks Factors” in our annual report on Form 20-F for the fiscal year ended November 30, 2016, and all other information included or incorporated herein by reference in this prospectus supplement and the accompanying prospectus before you decide whether to purchase our securities.

Our Company

We are a pharmaceutical company specializing in the research, development and manufacture of novel and generic controlled-release and targeted-release oral solid dosage drugs. Our 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, we have developed several drug delivery systems and a pipeline of products (some of which have received U.S. Food and Drug Administration, or FDA, approval) and product candidates in various stages of development, including abbreviated new drug applications, or ANDAs, filed with the FDA (and one Abbreviated New Drug Submission, or ANDS, filed with Health Canada) in therapeutic areas that include neurology, cardiovascular, gastrointestinal tract, or GIT, diabetes and pain.

We also have new drug application, or NDA, 505(b)(2) specialty drug product candidates in our development pipeline. These include the Company’s oxycodone hydrochloride extended release tablets (previously referred to as Rexista™)(“Oxycodone ER”), an abuse deterrent oxycodone based on our 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). The NDA 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.

Our Corporate Information

We were incorporated under the Canada Business Corporations Act by certificate and articles of arrangement dated October 22, 2009. Our registered principal office is located at 30 Worcester Road, Toronto, Ontario, Canada M9W 5X2. Our telephone number is (416) 798-3001 and our facsimile number is (416) 798-3007. Our website address is http://www.intellipharmaceutics.com. Information on or accessed through our website is not incorporated into this prospectus supplement and is not a part of this prospectus supplement. Our common shares are listed for trading on the TSX and on NASDAQ under the symbol “IPCI”.

Recent Developments

NASDAQ Compliance

In September 2017, the Company announced that it has received written notification (the "Notification Letter") from The NASDAQ Stock Market LLC ("Nasdaq") notifying the Company that it is not in compliance with the minimum market value of listed securities requirement set forth in Nasdaq Rules for continued listing on The Nasdaq Capital Market. The Notification Letter does not impact the Company's listing on The Nasdaq Capital Market at this time. Nasdaq Listing Rule 5550(b)(2) requires listed securities to maintain a minimum market value of US $35.0 million,

and Listing Rule 5810(c)(3)(C) provides that a failure to meet the minimum market value requirement exists if the deficiency continues for a period of 30 consecutive business days. Based on the market value of the Company's common shares for the 30 consecutive business days from August 8, 2017, the Company no longer meets the minimum market value of listed securities requirement. In accordance with Nasdaq Listing Rule 5810(c)(3)(C), the Company has been provided 180

calendar days, or until March 19, 2018, to regain compliance with Nasdaq Listing Rule 5550(b)(2). To regain compliance, the Company's common shares must have a market value of at least US $35.0 million for a minimum of 10 consecutive business days. In the event the Company does not regain compliance by March 19, 2018, the Company may be eligible for additional time to regain compliance. If not, our securities may be delisted from NASDAQ.

The Offering

| | |
|---|---|
| Common shares we are offering: | 3,636,364 shares |
| Public offering price: | $1.10 per share |
| Common shares outstanding before this offering: | 31,073,151 shares |
| Common shares to be outstanding after this offering: | 34,709,515 shares |
| Concurrent private placement: | In a concurrent private placement, we are selling to the purchasers of common shares in this offering, warrants to purchase one-half the number of common shares purchased by such purchasers in this offering, or up to 1,818,182 of our common shares. The warrants will be exercisable six months after issuance at an exercise price of $1.25 per share and will expire on the 30 month anniversary of the initial exercise date. The warrants and the common shares issuable upon the exercise of the warrants, are not being offered pursuant to this prospectus supplement and the accompanying prospectus and are being offered pursuant to the exemption provided in Section 4(a)(2) under the Securities Act and Rule 506(b) promulgated thereunder. See “Concurrent Private Placement Transaction.” |
| Use of proceeds: | We currently intend to use the net proceeds from this offering for general corporate purposes, which may include working capital, capital expenditures, research and development, accounts payable and other commercial expenditures.<br><br>See “Use of Proceeds” beginning on page S-10. |
| NASDAQ and TSX symbol: | IPCI |
| Risk Factors: | Investing in our securities involves substantial risks. You should carefully review and consider the “Risk Factors” section of this prospectus supplement for a discussion of factors to consider before deciding to invest in our securities. |

The number of common shares shown above to be outstanding after this offering is based on 31,073,151 shares outstanding as of October 11, 2017 and excludes, as of that date:

an aggregate of 5,345,305 common shares issuable upon the exercise of outstanding options, with a weighted average exercise price of U.S.$3.45 per common share;

up to 525,950 additional common shares that have been reserved for issuance in connection with future grants under our stock option plan;

an aggregate of 1,979,797 common shares issuable upon the exercise of outstanding common share purchase warrants, with a weighted average exercise price of U.S.$2.03 per common share;

an aggregate of 94,131 deferred share units;

an aggregate of 450,000 common shares issuable upon the conversion of an unsecured convertible debenture held by Drs. Isa and Amina Odidi, our principal stockholders, directors and executive officers, or the Debenture;

an aggregate of 1,818,182 common shares issuable upon the exercise of the warrants to be issued in the concurrent private placement. See “Concurrent Private Placement Transaction;” and

an aggregate of 181,818 common shares issuable upon the exercise of the warrants to be issued to the placement agent as described in “Plan of Distribution.”

RISK FACTORS

Our past experience may not be indicative of future performance, and as noted elsewhere in this prospectus supplement and documents incorporated by reference into this prospectus supplement, we have included forward-looking statements about our business, plans and prospects that are subject to change. In addition to the other risks or uncertainties contained in this prospectus supplement and the accompanying prospectus and documents incorporated by reference into this prospectus supplement, the following risks may affect our operating results, financial condition and cash flows. If any of these risks occurs, either alone or in combination with other factors, our business, financial condition or operating results could be adversely affected. Moreover, readers should note this is not an exhaustive list of the risks we face. Some risks are unknown or not quantifiable, and other risks that we currently perceive as immaterial may ultimately prove more significant than expected. Statements about plans, predictions or expectations should not be construed to be assurances of performance or promises to take a given course of action.

The “Risk Factors” beginning on page 6 of the accompanying prospectus are incorporated by reference in this prospectus supplement.

Risks Relating to this Offering

Our management will have broad discretion in allocating the net proceeds of this offering, and may use the proceeds in ways in which you disagree.

Our management has significant flexibility in applying the net proceeds we expect to receive in this offering. Because the net proceeds are not required to be allocated to any specific product, investment or transaction, and therefore you cannot determine at this time the value or propriety of our application of those proceeds, you and other shareholders may not agree with our decisions. In addition, our use of the proceeds from this offering may not yield a significant return or any return at all for our shareholders. The failure by our management to apply these funds effectively could have a material adverse effect on our business, results of operations or financial condition. See “Use of Proceeds” for a further description of how management intends to apply the proceeds from this offering.

You will experience immediate dilution in the book value per share of the common shares you purchase.

Because the public offering price per common share is substantially higher than the book value per share of our common shares, you will suffer substantial dilution in the net tangible book value of the common shares you purchase in this offering. Based on the public offering price of $1.10 per share, if you purchase shares in this offering, you will suffer immediate and substantial dilution of approximately $1.02 per share in the net tangible book value of the common shares you acquire. See “Dilution” below for a more detailed discussion of the dilution you will incur if you purchase securities in this offering.

In addition to this offering, subject to market conditions and other factors, it is likely that we will pursue additional financings in the future, as we continue to develop our business. In future years, we will likely need to raise significant additional capital to finance our operations and to fund bioequivalence studies and clinical trials for the advancement of product development, as well as for regulatory submissions and the development, manufacture and marketing of other products under development and new product opportunities. Accordingly, we may conduct substantial future offerings of equity or debt securities. The exercise of outstanding options and warrants and future equity issuances, including future public offerings or future private placements of equity securities and any additional common shares issued in connection with acquisitions, will result in dilution to investors. In addition, the market price of our common shares could fall as a result of resales of any of these common shares due to an increased number of common shares available for sale in the market.

There can be no assurance that our common shares will continue to trade on the Nasdaq Capital Market or another national securities exchange.

From and after September 20, 2017, we have failed to meet the market value standard of the continued listing standards for NASDAQ Capital Market companies. There can be no assurance that we will be able to meet the market value or any of the other NASDAQ Capital Market listing standards. If we are unable to do so before March 19, 2018, and if we are unable to regain compliance with the standards within the time frame set by NASDAQ, our common shares may be delisted. There can be no assurance that we will be able to comply with all applicable NASDAQ Capital Market continued listing standards. If we are unable to do so, our common shares may no longer be listed on NASDAQ Capital Market or another national securities exchange and the liquidity and market price of our common shares may be adversely affected.

If our common shares are not listed on a national securities exchange, compliance with applicable state securities laws may be required for subsequent offers, transfers and sales of the common shares and warrants offered hereby.

Because our common shares are listed on NASDAQ Capital Market, we are not required to register or qualify in any state the subsequent offer, transfer or sale of the common shares. If our common shares are delisted from NASDAQ Capital Market and are not eligible to be listed on another national securities exchange, subsequent transfers of our common shares offered hereby by U.S. holders may not be exempt from state securities laws. In such event, it will be the responsibility of the holder of common shares to register or qualify the common shares for any subsequent offer, transfer or sale in the United States or to determine that any such offer, transfer or sale is exempt under applicable state securities laws.

There may be future sales or other dilution of our equity, which may adversely affect the market price of our common shares.

We are generally not restricted from issuing additional common shares, including any securities that are convertible into or exchangeable for, or that represent the right to receive, common shares. The market price of our common shares could decline as a result of sales of common shares or securities that are convertible into or exchangeable for, or that represent the right to receive, common shares after this offering or the perception that such sales could occur.

Future sales of our common shares may cause the prevailing market price of our common shares to decrease.

We have registered a substantial number of outstanding common shares and common shares that are issuable upon the exercise of outstanding warrants. If the holders of our registered common shares choose to sell such shares in the public market or if holders of our warrants exercise their purchase rights and sell the underlying common shares in the public market, or if holders of currently restricted common shares choose to sell such shares in the public market, the prevailing market price for our common shares may decline. The sale of shares issued upon the exercise of our warrants (and options) could also further dilute the holdings of our then existing shareholders. In addition, future public sales by holders of our common shares could impair our ability to raise capital through equity offerings.

Risks Relating to our Company

Our business is capital intensive and requires significant investment to conduct R&D, clinical and regulatory activities necessary to bring our products to market, which capital may not be available in amounts or on terms acceptable to us, if at all.

Our business requires substantial capital investment in order to conduct the R&D, clinical and regulatory activities necessary to bring our products to market and to establish commercial manufacturing, marketing and sales capabilities. As of August 31, 2017, we had a cash balance of $0.7 million. As of October 11, 2017, our cash balance was $0.3 million. We currently expect to satisfy our operating cash requirements until December 2017 from cash on hand and quarterly profit share payments from Par Pharmaceutical, Inc., or Par, and Mallinckrodt LLC, or Mallinckrodt, supplemented by, if necessary, utilization of the equity markets if available. Should our marketing and distribution partner, Mallinckrodt, continue to grow sales of our generic Seroquel XR® at anticipated rates, then we expect to be cash flow positive around the middle of fiscal 2018. 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 remaining two strengths of its generic Focalin XR® and, if launched, whether they will be successfully commercialized, or if sales of generic Seroquel XR® will continue to grow at expected levels. If necessary, we expect to utilize the equity markets, if available, to bridge any funding shortfall and to provide capital to continue to advance our most promising product candidates. 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. Although there can be no assurances, such capital may come from revenues from the sales of our generic Focalin XR® capsules, from sales of our generic Seroquel XR® tablets, from proceeds of this offering and from potential partnering opportunities for approved products, or from, if necessary, utilization of the equity markets if available. Other potential sources of capital may include payments from licensing agreements, cost savings associated with managing operating expense levels, other equity and/or debt financings and/or new strategic partnership agreements which fund some or all costs of product development. Our ultimate success will depend on whether our product candidates receive the approval of the FDA or Health Canada and whether we are able to successfully market approved products. We cannot be certain that we will be able to receive FDA or Health Canada 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. The availability of equity or debt financing will be affected by, among other things, the results of our R&D, our ability to obtain regulatory approvals, our success in commercializing approved products with our commercial partners and the market acceptance of our products, the state of the capital markets generally, strategic alliance agreements and other relevant commercial considerations. In addition, if we raise additional funds by issuing equity securities, our then existing security holders will likely experience dilution, and the incurring of indebtedness would result in increased debt service obligations and could require us to agree to operating and financial covenants that would restrict our operations. In the event that we do not obtain sufficient additional capital, it will raise substantial doubt about our ability to continue as a going concern and realize our assets and pay our liabilities as they become due. Our cash outflows are expected to consist primarily of internal and external R&D, legal and consulting expenditures to advance our product pipeline and selling, general and administrative expenses to support our commercialization efforts. Depending upon the results of our R&D programs, the impact of the Purdue litigation (as defined below) and the availability of financial resources, we could decide to accelerate, terminate, or reduce certain projects, or commence new ones. Any failure on our part to successfully commercialize approved products or raise additional funds on terms favorable to us or at all, may require us to significantly change or curtail our current or planned operations in order to conserve cash until such time, if ever, that sufficient proceeds from operations are generated, and could result in our not taking advantage of business opportunities, in the termination or delay of clinical trials or our not taking any necessary actions required by the FDA or Health Canada for one or more of our product candidates, in curtailment of our product development programs designed to identify new product candidates,

in the sale or assignment of rights to our technologies, products or product candidates, and/or our inability to file ANDAs, ANDSs or NDAs, at all or in time to competitively market our products or product candidates.

We have a history of operating losses, which may continue in the foreseeable future.

We have incurred net losses from inception through August 31, 2017 and had an accumulated deficit of $69,362,523 as of such date, and have incurred additional losses since such date. As we engage in the development of products in our pipeline, we may continue to incur further losses. While our commercial prospects have improved and our revenue base is growing, there can be no assurance that we will ever be able to achieve or sustain profitability or positive cash flow. Our ultimate success will depend on how many of our product candidates receive the approval of the FDA or Health Canada and whether we are able to successfully market approved products. We cannot be certain that we will be able to receive FDA or Health Canada approval for any of our current or future product candidates, or that we will reach the level of sales and revenues necessary to achieve and sustain profitability.

Approvals for our product candidates may be delayed or become more difficult to obtain if the FDA institutes changes to its approval requirements.

The FDA may institute changes to its ANDA approval requirements, which may make it more difficult or expensive for us to obtain approval for our new generic products. For instance, in July 2012, the Generic Drug Fee User Amendments of 2012, or GDUFA, were enacted into law. The GDUFA legislation implemented substantial fees for new ANDAs, Drug Master Files, product and establishment fees and a one-time fee for back-logged ANDAs pending approval as of October 1, 2012. In return, the program is intended to provide faster and more predictable ANDA reviews by the FDA and more timely inspections of drug facilities. For the FDA's fiscal years 2016 and 2017, respectively, the user fee rates are $76,030 and $70,480 for new ANDAs, $38,020 and $35,240 for "Prior Approval Supplements," and $17,434 for each ANDA already on file at the FDA. For the FDA's fiscal year 2016 and 2017, there is also an annual facility user fee of $258,905 and $273,646, respectively. Effective October 1, 2017, for the FDA's fiscal year 2018, the FDA will charge an annual facility user fee of $226,087 plus a new general program fee of $159,079. Under GDUFA, generic product companies face significant penalties for failure to pay the new user fees, including rendering an ANDA not "substantially complete" until the fee is paid. It is currently uncertain the effect the new fees will have on our ANDA process and business. However, any failure by us or our suppliers to pay the fees or to comply with the other provisions of GDUFA may adversely impact or delay our ability to file ANDAs, obtain approvals for new generic products, generate revenues and thus may have a material adverse effect on our business, results of operations and financial condition.

We operate in a highly litigious environment.

From time to time, we are subject to legal proceedings. As of the date of this prospectus supplement, we are not aware of any pending or threatened material litigation claims against us, other than as described below and under the caption "Legal Proceedings" in this prospectus supplement. Litigation to which we are, or may be, subject could relate to, among other things, our patent and other intellectual property rights or such rights of others, business or licensing arrangements with other persons, product liability or financing activities. Such litigation could include an injunction against the manufacture or sale of one or more of our products or potential products or a significant monetary judgment, including a possible punitive damages award, or a judgment that certain of our patent or other intellectual property rights are invalid or unenforceable or infringe the intellectual property rights of others. If such litigation is commenced, our business, results of operations, financial condition and cash flows could be materially adversely affected.

There has been substantial litigation in the pharmaceutical industry concerning the manufacture, use and sale of new products that are the subject of conflicting patent rights. When we file an ANDA or 505(b)(2) NDA for a bioequivalent version of a drug, we may, in some circumstances, be required to certify to the FDA that any patent which has been listed with the FDA as covering the branded product has expired, the date any such patent will expire, or th