



IRONSHORE

PHARMACEUTICALS & DEVELOPMENT, INC.

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For Immediate Release:

IRONSHORE PHARMACEUTICALS ANNOUNCES FDA ACCEPTANCE OF HLD200 NEW DRUG APPLICATION FOR TREATMENT OF ADHD

- If approved, HLD200 would be the first stimulant that is taken prior to bedtime to achieve a clinically meaningful effect upon awakening, throughout the day and into the evening
 - PDUFA date is July 30, 2017
- Pivotal trial program for HLD100 (under development for the treatment of ADHD), anticipated to begin in 2017

George Town, Grand Cayman, December 15, 2016 – Ironshore Pharmaceuticals & Development, Inc. (“Ironshore”), a wholly owned subsidiary of Highland Therapeutics Inc., today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for HLD200 (delayed-release and extended-release methylphenidate capsules), which was developed as a potential new option for physicians treating patients with Attention-Deficit/Hyperactivity Disorder (ADHD). HLD200 is the only stimulant medication intended for dosage administration in the evening, prior to bedtime, to target the control of ADHD symptoms and improve functioning from the time the patient awakens and throughout the day. The expected action date by the FDA under the Prescription Drug User Fee Act (PDUFA) is July 30, 2017.

“We are pleased to confirm the progression of HLD200 through the regulatory process at the FDA and look forward to collaborating with the Agency in 2017,” said Dr. Bev Inledon, Executive Vice President, Research & Development. “The NDA filed in support of HLD200 was substantive and included data from two pivotal Phase 3 trials, an exploratory Phase 3 study, and several pharmacokinetic trials in children, adolescents and adults. In addition to this rigorous clinical development program, the Company also completed several normative studies designed to further validate the Before School Functioning Questionnaire (BSFQ) and the Parent Rating of Evening and Morning Behavior-Revised (PREMB-R) morning (AM) and evening (PM) subscales, which may become important screening and assessment tools in the clinical setting.”

HLD200 is the first product that leverages Ironshore's proprietary DELEXIS® technology platform which could have a meaningful impact on health outcomes in a variety of therapeutic areas including, among others, central nervous system disorders and inflammatory bowel disease.

"It is important to recognize that while there are many effective medications for the treatment of ADHD, there still is widespread suffering among a substantial portion of families whose lives are materially and adversely affected. I believe we can improve clinical outcomes by attempting to optimize the delivery of stimulant medications," said Dr. Randy Sallee, Chief Medical Officer. "I would like to thank the patients, parents, clinical investigators and employees for their enthusiasm, dedication and perseverance over the eight years of development."

"In addition, based on the positive results from an open-label tolerability study in pediatric patients with ADHD, I am pleased to announce our plans to move HLD100 (a delayed-release and extended-release formulation of amphetamine) into a pivotal study in 2017. HLD100 could further broaden treatment options for patients and physicians, if approved."

While the NDA for HLD200 has been accepted for review by the FDA, such acceptance does not mean that HLD200 will be approved by the FDA for the treatment of ADHD.

About HLD200

HLD200 is a novel delayed-release and extended-release formulation of methylphenidate that utilizes Ironshore's proprietary drug delivery platform, DELEXIS®, designed to enable nighttime dosing of patients with ADHD to target the onset of clinically meaningful treatment effect upon awakening and lasting through to the evening, if approved.

About Ironshore Pharmaceuticals & Development, Inc.

Ironshore Pharmaceuticals & Development, Inc., a wholly owned subsidiary of Highland Therapeutics Inc., is a pharmaceutical company that is leveraging its proprietary technology, DELEXIS®, to optimize the delivery of previously approved drug products.

Highland Therapeutics Inc. is a client of MaRS Discovery District's Health Venture Services group, which provides advisory services, connections to talent, customer & capital networks, and market intelligence to high-impact, Ontario-based life sciences ventures, helping them commercialize their ideas and build globally competitive companies.

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Forward-Looking Statements

This press release contains forward-looking information, which reflects Ironshore's current expectations regarding future events. Forward-looking information is based on a number of assumptions and is subject to a number of risks and uncertainties, many of which are beyond Ironshore's control that could cause actual results and events to differ materially from those that are disclosed in or implied by such forward-looking information. These forward-looking statements are made as of the date of this press release and, except as expressly required by applicable law, Ironshore assumes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.