

www.ironshorepharma.com

# IRONSHORE PHARMACEUTICALS ANNOUNCES AGREEMENT FOR \$143 MILLION IN SENIOR SECURED NOTES FINANCING

George Town, Grand Cayman, August 14, 2018 – <u>Ironshore Pharmaceuticals & Development, Inc.</u> ("Ironshore"), a wholly owned subsidiary of <u>Highland Therapeutics Inc.</u>, today announced that it has entered into agreements with purchasers to raise approximately US\$143 million at a purchase price of 98% by way of a private placement of Senior Secured Notes. Morgan Stanley & Co. LLC is acting as sole placement agent for the offering. The completion of the offering is subject to customary conditions and it is anticipated that closing will occur on or about August 22, 2018.

"With the FDA approval of JORNAY PM™ in hand, our primary focus has shifted to ensuring an optimal commercial launch of this innovative drug with its unique value proposition. JORNAY PM is the only stimulant medication that is dosed once daily in the evening and was developed to help patients with Attention Deficit Hyperactivity Disorder (ADHD) obtain better control over the disruptive impairments they typically experience during the early morning routine and throughout the day," said David Lickrish, President and Chief Executive Officer. "This financing, in conjunction with the funds raised in 2017, will provide the necessary resources for Ironshore to fully support the launch of a blockbuster drug and fund the anticipated costs of all planned commercialization and marketing initiatives with the launch of the drug projected to occur in the first half of 2019."

#### **WARNING: ABUSE AND DEPENDENCE**

See full prescribing information for complete boxed warning.

- CNS stimulants, including JORNAY PM, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence
- Assess the risk of abuse prior to prescribing, and monitor for signs of abuse and dependence while on therapy

See additional safety information below

JORNAY PM (methylphenidate) extended-release capsules CII were approved by the U.S. Food and Drug Administration (FDA) on August 8, 2018 for the treatment of ADHD in patients 6 years and older.

Stimulant medications have been a cornerstone of ADHD treatment for decades and more than 67.3 million prescriptions were written for these products in the U.S. in the twelve months ended June 30, 2018<sup>1</sup>. The leading brand, Vyvanse<sup>2</sup>, reported U.S. net revenues of US\$2.0 billion over the same period. Ironshore has developed a product for this market that represents a differentiated value proposition for the treatment of ADHD. JORNAY PM is the only stimulant medication that is dosed in the evening with demonstrated improvement in the severity of ADHD symptoms in the early morning and throughout the day. Please see additional dosing information in the full prescribing information at <a href="http://ironshorepharma.com/labeling.pdf">http://ironshorepharma.com/labeling.pdf</a>.

Goodmans LLP is acting as Lead Counsel, King & Spalding LLP is acting as U.S. counsel and Solomon Harris is acting as Cayman Islands counsel for Ironshore in connection with the offering.

## **ABOUT JORNAY PM**

JORNAY PM is a central nervous system (CNS) stimulant prescription medicine used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in people 6 years of age and older. JORNAY PM may help increase attention and decrease impulsiveness and hyperactivity in people 6 years of age and older with ADHD. It is not known if JORNAY PM is safe and effective in children under 6 years of age.

JORNAY PM is dosed once daily in the evening and should be initiated at 8:00 p.m. Timing of administration of JORNAY PM may be adjusted between 6:30 p.m. and 9:30 p.m. to optimize the tolerability and the efficacy the next morning and throughout the day. Please see additional dosing information in the full Prescribing Information for JORNAY PM at <a href="http://ironshorepharma.com/labeling.pdf">http://ironshorepharma.com/labeling.pdf</a>.

## IMPORTANT SAFETY INFORMATION

#### WARNING: ABUSE AND DEPENDENCE

CNS stimulants, including JORNAY PM, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy.

#### **CONTRAINDICATIONS**

- Known hypersensitivity to methylphenidate or other components of JORNAY PM
- Concurrent treatment with a monoamine oxidase inhibitor (MAOI), or use of an MAOI within the preceding 14 days

#### **WARNINGS AND PRECAUTIONS**

- Serious Cardiovascular Reactions: Sudden death has been reported in association with CNS stimulants at recommended doses in pediatric patients with structural cardiac abnormalities or other serious heart problems. In adults, sudden death, stroke, and myocardial infarction have been reported. Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious heart arrhythmias, or coronary artery disease.
- Blood Pressure and Heart Rate Increases: Monitor blood pressure and pulse. Consider the benefits and risks in patients for whom an increase in blood pressure or heart rate would be problematic.
- Psychiatric Adverse Reactions: Use of CNS stimulants may cause psychotic or manic symptoms in patients with no prior history, or exacerbation of symptoms in patients with pre-existing psychiatric illness. Evaluate for bipolar disorder prior to JORNAY PM use.
- Priapism: Cases of painful and prolonged penile erections and priapism have been reported with methylphenidate products. Immediate medical attention should be sought if signs or symptoms of prolonged penile erections or priapism are observed.
- Peripheral Vasculopathy, including Raynaud's Phenomenon: CNS stimulants used to treat ADHD are associated with peripheral vasculopathy, including Raynaud's phenomenon. Careful observation for digital changes is necessary during treatment with ADHD stimulants.
- Long-Term Suppression of Growth: Monitor height and weight at appropriate intervals in pediatric patients.

## **ADVERSE REACTIONS**

Based on accumulated data from other methylphenidate products, the most common (>5% and twice the rate of placebo) adverse reactions for pediatric patients and adults are: appetite decreased, insomnia, nausea, vomiting, dyspepsia, abdominal pain, weight decreased, anxiety, dizziness, irritability, affect lability, tachycardia, and blood pressure increased.

Additional adverse reactions (>5% and twice the rate of placebo) in pediatric patients 6 to 12 years treated with JORNAY PM: headache, psychomotor hyperactivity, and mood swings.

Please see additional safety information in the full prescribing information for Jornay PM at <a href="http://ironshorepharma.com/labeling.pdf">http://ironshorepharma.com/labeling.pdf</a>.

## 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. For more information, visit Highlandtherapeutics.com

### **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

<sup>&</sup>lt;sup>1</sup> As reported by IQVIA

<sup>&</sup>lt;sup>2</sup> Vyvanse is a registered trademark of Shire LLC

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.

## For further information, please contact:

Nelson F. Isabel, Chief Financial Officer Ironshore Pharmaceuticals & Development, Inc. (345) 749-8170