



HIGHLAND  
THERAPEUTICS

[www.highlandtherapeutics.com](http://www.highlandtherapeutics.com)

For Immediate Release:

## **HIGHLAND THERAPEUTICS RECEIVES SECOND NOTICE OF ALLOWANCE FOR PATENT ON LEAD PRODUCT**

TORONTO, Canada, November 20, 2014—Highland Therapeutics Inc. (“Highland”), a pharmaceutical company, today announced that the U.S. Patent and Trademark Office (“USPTO”) has issued a Notice of Allowance for a patent application for HLD-200, a novel formulation of methylphenidate designed to be taken once-daily in the evening with the objective of controlling symptoms of ADHD immediately upon awakening and throughout the day.

The Notice of Allowance is for U.S. Patent Application No. 14/230,053, “Compositions for Treatment of Attention Deficit Hyperactivity Disorder” owned by Highland’s wholly owned subsidiary, Ironshore Pharmaceuticals & Development, Inc. (“Ironshore”) and is the second Notice of Allowance received this month that relates to HLD-200.

“The pending issuance of these two important patents validates the tremendous effort of our team over the past several years, and underscores the novelty of our drug delivery platform,” said David Lickrish, Highland’s President and Chief Executive Officer. “The positive top-line data from our recently completed Phase III trial highlight the potential benefits of nighttime dosing in order to obtain meaningful control over symptoms of ADHD in the morning and throughout the day. Although our technology was specifically developed to address the significant challenges faced by families that struggle with ADHD during the morning routine, we believe there are several important applications beyond methylphenidate and amphetamine, and expect to broaden our development pipeline in 2015.”

The Notice of Allowance signals the end of the substantive examination of the patent application by the USPTO. After the administrative processing period is complete, a U.S. patent will be issued, likely early in January 2015. The U.S. patent scheduled to issue from this application will expire in 2032. After issuance, Ironshore plans to list the patent in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book, upon US regulatory approval of HLD-200.

## **About Highland Therapeutics Inc.**

Highland Therapeutics Inc. is a specialty pharmaceutical company that, through its wholly owned subsidiary Ironshore Pharmaceuticals & Development, Inc., is leveraging its proprietary technology, DELEXIS™, to optimize the delivery of previously approved drug products. The Company's lead product candidates, HLD-200 and HLD-100, are novel formulations of the psychostimulants (methylphenidate and amphetamine, respectively) used to treat ADHD and are being developed to address a prevalent unmet medical need in the treatment of the disease – inadequate symptom control during the morning routine. Intended for nighttime dosing, DELEXIS™ is designed to provide a consistent delay in the initial release of the active drug, followed by a period of extended release; with the objective of providing control of ADHD symptoms immediately upon waking and throughout the day.

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 further information, please visit the Company's website at [www.highlandtherapeutics.com](http://www.highlandtherapeutics.com), or contact:

Nelson F. Isabel  
Chief Financial Officer  
(647) 260-7875

## **Forward-Looking Statements**

This press release contains forward-looking information, which reflects Highland'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 Highland'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, Highland assumes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.