



H I G H L A N D
THERAPEUTICS

www.highlandtherapeutics.com

For Immediate Release:

HIGHLAND THERAPEUTICS RECEIVES NOTICE OF ALLOWANCE FOR PATENT ON LEAD PRODUCT

TORONTO, Canada, November 13, 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 owned by the Company’s wholly owned subsidiary, Ironshore Pharmaceuticals & Development, Inc. (“Ironshore”).

The Notice of Allowance is for U.S. Patent Application No. 14/230,067, “Methods for Treatment of Attention Deficit Hyperactivity Disorder”, which relates to HLD-200, including its unique pharmacokinetic profile. Highland recently reported positive top-line Phase III data for HLD-200. A pivotal trial is anticipated to begin in the first half of 2015.

“A strong intellectual property estate has always been an overarching objective of the Company, and we are pleased by the Notice of Allowance for our lead product, the first of many we anticipate being issued,” said David Lickrish, Highland’s President and Chief Executive Officer. “As seen in the data from our Phase III study, our unique approach to the treatment of ADHD has the potential to expand the therapeutic window of currently available stimulants. We believe our development candidates, if approved, may represent the next generation of these important medications, with the potential to control symptoms of ADHD upon awakening and throughout the day.”

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 before the end of the year. 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.

Highland believes there is a growing appreciation about the critical importance of complex pharmacokinetic profiles on clinical outcomes, as evidenced by the FDA's *Draft Guidance on Methylphenidate Hydrochloride*, issued November 6, 2014.

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, or contact:

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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.