



HIGHLAND
THERAPEUTICS

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For Immediate Release:

HIGHLAND THERAPEUTICS ANNOUNCES EXPANSION OF PIPELINE INTO INFLAMMATORY BOWEL DISEASE

- **Agreement with Quotient Clinical Expands Pipeline Beyond Neuroscience Franchise**
- **Proof of Concept Study Designed to Demonstrate Preferential Delivery of Drug to Initial Site of Damage in IBD to Position HLD-400 as Potential First-Line Therapy**

TORONTO, Canada, May 26, 2016—Highland Therapeutics, Inc. announced today that its wholly owned subsidiary Ironshore Pharmaceuticals and Development, Inc. (“Ironshore”) has entered into an agreement with Quotient Clinical (“Quotient”) to conduct scintigraphy imaging of a new drug candidate, HLD-400, for Inflammatory Bowel Disease (IBD) using Quotient’s RapidFACT® (Rapid Formulation development And Clinical Testing) program.

Under the terms of the agreement, Ironshore will provide Quotient with technical support and access to Ironshore’s propriety drug delivery platform, DELEXIS®. In return, Quotient will provide its GMP manufacturing facility and clinical expertise in scintigraphy to demonstrate preferential delivery of the active pharmaceutical ingredient to target the initial site of tissue damage, the distal part of the colon, in patients with IBD.

David Lickrish, President and Chief Executive Officer stated, “Ironshore continues to demonstrate industry leadership, growing its pipeline organically while remaining focused on drugs that have the potential to be market-leading assets with best-in-class clinical effect. In treating IBD, management believes that by optimizing the delivery of the drug throughout the colon – but specifically to the initial site of tissue damage – physicians may be able to more effectively treat the disease during the initial onset of symptoms and, hopefully, stop the progression of tissue damage to other areas of the colon. In contrast, currently available oral therapies for IBD preferentially deliver drug to the early part of the bowel, which is only affected when the disease has progressed, leaving many patients unable to adequately control their condition or remain in remission. As such, if approved, we believe our product could naturally become a first-line therapy.”

Commenting on the agreement, Dr. Bev Incedon stated, “We are just scratching the surface of what might be possible by leveraging DELEXIS® beyond Neuroscience and we continue to find exciting applications for this novel technology in other therapeutics areas. Innovative partnerships like this one with Quotient Clinical allow us to expand our earlier stage programs and maintain our focus on the three other new drug candidates that are either already in pivotal trials, or that could be later this year.”

Mark Egerton, Quotient’s Chief Executive Officer said, “We are delighted to be working with Ironshore on this exciting program, which highlights the versatility of our collaborative approach to working with different segments of the pharmaceutical industry. In leveraging our Translational Pharmaceuticals® platform, Ironshore has access to formulation development, real-time GMP manufacturing and clinical testing capabilities at a single site, from a single company, as opposed to separate service providers. Our approach has been proven to shorten drug development timelines and improve financial performance by making R&D investments more efficient.”

Ironshore anticipates that the scintigraphy testing results will be available in early 2017.

About Highland Therapeutics Inc.

Highland Therapeutics Inc. is a 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 Nelson F. Isabel, Chief Financial Officer at (647) 260-7875.

About Quotient Clinical

Quotient Clinical offers unique services – based on its Translational Pharmaceuticals® platform – that integrate formulation development, real-time drug product manufacturing and clinical testing, significantly reducing the time and cost of bringing a drug to market.

For more than 20 years, Quotient Clinical has brought innovation to drug product development programs for pharmaceutical and biotechnology customers worldwide. The company is based in purpose-built, fully integrated facilities in the UK, where formulation development, real-time GMP manufacturing and early clinical trials are performed in the same facility. It employs over 320 staff, offering a full range of support services, from study set-up right through to data analysis and reporting. Quotient Clinical was recently acquired by specialist healthcare investor GHO Capital who will support the future development of the company.

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.