

## Highland Therapeutics Inc.

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For Immediate Release:

## HIGHLAND THERAPEUTICS ANNOUNCES CLOSING OF US\$6.7 MILLION FINANCING

- Provides resources for up to five clinical programs planned for 2013, including studies in pediatric and adolescent ADHD patient populations
- World-class clinical, regulatory, intellectual property and commercial team in place to progress lead compounds through approval
- Market research being conducted to maximize commercial success of HLD-100, HLD-200
- Scale-up of manufacturing process ongoing; pivotal product batches to be run prior to yearend

TORONTO, Canada, August 15, 2013—Highland Therapeutics Inc. ("Highland"), a specialty pharmaceutical company leveraging its proprietary technologies to optimize the delivery of previously approved drug products, today announced that it has completed a US\$6.7 million offering of Class A common shares. Investors in the offering included Highland's Clinical Development group – an arm's length entity responsible for the manufacturing and clinical development of the Company's two lead compounds. Highland believes their substantial investment further aligns their interests with those of all shareholders and welcomes them as new shareowners.

The funds raised provide the necessary resources for Highland, through its wholly owned subsidiary, to (1) conduct up to five clinical studies with its two lead compounds – HLD-100 (a novel formulation of amphetamine) and HLD-200 (a novel formulation of methylphenidate), both being developed to treat the symptoms associated with Attention-Deficit/Hyperactivity Disorder (ADHD), (2) conduct market research to further develop commercialization strategies for the drug candidates, (3) scale-up manufacturing activities, and (4) use for general corporate purposes.

"The completion of this offering, in conjunction with the anticipated exercise of Warrants that were issued in an earlier financing, is expected to allow the Company to take its lead compound through to a pivotal trial," said David Lickrish, President and Chief Executive Officer of Highland Therapeutics Inc. "We have assembled a world-class team of leading clinical, regulatory, intellectual property and commercial experts with extensive experience in our target market. I believe that we are not only capable of securing FDA approval, but that we are developing new tools that could benefit physicians and patients, ultimately improving the quality of life for all persons affected by ADHD."

The first two studies, which will build upon the successful results seen in an adult population, will examine the optimized pharmacokinetics of Highland's amphetamine program (HLD-100) in adolescent and pediatric ADHD patients. Dosing of adolescent patients (13-17 year olds) has already begun in the Phase I/II study and the Company expects to initiate dosing of patients in the pediatric study (6-12 year olds) this week.

The methylphenidate program (HLD-200) is being run in parallel with the amphetamine program and follows the same established path. Dosing in the adolescent and pediatric patient studies for HLD-200 is expected to commence later in August and in September, respectively.

These Phase I/II studies have been designed to test up to three different experimental formulations of each lead compound. After dosing with the initial formulation, the Principal Investigator and the Company's Scientific Advisory Board (SAB) will review the pharmacokinetic (PK) data and determine if an optimal PK profile has been achieved. If so, the study will conclude and a meeting with the U.S. Food and Drug Administration will be requested to determine the optimal design of an efficacy / pivotal study.

"We are very pleased with the enthusiastic response from clinicians who view Highland's drug candidates as potential first-line therapies for the treatment of ADHD," said Dr. Bev Incledon, the Company's Senior Vice-President, Research & Development. "While Highland's drug delivery technology has thus far exceeded expectations, these Phase I/II studies represent the first time the technology has been used in pediatric and adolescent ADHD patients. The data will allow us to further optimize the delivery of these important medications in order to maximize their clinical effect while potentially mitigating some serious side effects."

Based on feedback from key opinion leaders (KOLs) and the Company's SAB, Highland believes that its drug delivery technology represents a platform technology that could have several

applications beyond ADHD. To this end, Highland has begun screening other compounds – in a wide range of indications – and expects to advance new drug candidates into its development pipeline in 2014.

Working with leading third-party consultants, Highland's subsidiary is in the process of determining what resources are required to realize the full potential of HLD-100 and HLD-200 upon commercial launch. The evolving dataset from both this market research and the clinical development programs will further increase the Company's understanding of how its lead compounds could be used in a clinical setting. Third-party market research conducted to date has confirmed that there is substantial pent-up demand for a product that can better control the symptoms of ADHD during the early morning routine – when the leading therapies are ineffective – while providing once-daily coverage of symptoms.

Recognizing that manufacturing is a key component of the drug-approval process, Highland, through its subsidiary, has invested heavily in the manufacturing process for its lead compounds. Working with its contract manufacturing partners, scale-up activities are ongoing and the Company expects to manufacture registration batches prior to year-end.

## About Highland Therapeutics Inc.

Highland Therapeutics Inc. is a specialty pharmaceutical company leveraging its proprietary technologies to optimize the delivery of previously approved drug products. The Company's lead products, HLD-100 and HLD-200, are novel formulations of the psychostimulants (amphetamine and methylphenidate, respectively) used to treat ADHD and are being developed to address a prevalent unmet medical need in the treatment of the disease – the lack of symptom control during the early morning routine.

Highland Therapeutics Inc. is a client of MaRS Discovery District's Life Sciences and Healthcare practice, which provides advisory services and support to help Ontario life sciences companies grow and commercialize their businesses.

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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.