Highland Therapeutics, Inc.

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

For Immediate Release:

HIGHLAND THERAPEUTICS ANNOUNCES POSITIVE CLINICAL RESULTS FOR HLD-200 – A NOVEL ADHD THERAPEUTIC

- Positive results achieved in Phase 1 HLD-200 study ; confirm second pipeline product
- Results further validate Highland's drug-delivery technology as potential platform technology
- Study highlights include class-leading low variability with respect to T_{max}
- Consistent delay in initial drug release, in conjunction with a long absorption window, further support HLD-200's commercial potential

TORONTO, Canada, June 25, 2013—Highland Therapeutics, Inc. ("Highland"), a specialty pharmaceutical company based in the MaRS Discovery District in Toronto, today announced that its wholly owned subsidiary has generated positive Phase-1 results for HLD-200 – a novel formulation of methylphenidate being developed to treat the symptoms associated with Attention-Deficit/Hyperactivity Disorder (ADHD). The study was conducted in collaboration with the Harvard Clinical Research Institute (HCRI) and Massachusetts General Hospital (MGH), and with Dr. Joseph Biederman as Senior Study Adviser and Medical Monitor. Dr. Biederman is Chief of the Clinical and Research Programs in Pediatric Psychopharmacology and Adult ADHD at MGH, and Professor of Psychiatry at the Harvard Medical School.

Consistent with the observations from the HLD-100 (amphetamine) Phase-1 trial, Highland's proprietary drug-delivery technology performed exceptionally well in delivering the active pharmaceutical ingredient consistently across the entire group of healthy adult volunteers. In addition, the study data revealed an absorption window for HLD-200 that is longer than that of the leading methylphenidate product on the market today.

The study, "A Phase 1, Single-Center, Single-Dose, Open-Label, Randomized, Crossover, Comparative Bioavailability Study to Compare Two Methylphenidate HCl Modified Release and an Immediate Release Methylphenidate HCl Marketed Formulation in Healthy Adult Volunteers", examined the pharmacokinetics of HLD-200 and represented the first study in

humans for HLD-200. A total of 12 patients were enrolled in the study – six men and six women – each of which received the three different methylphenidate formulations after a washout period between treatments.

While the data are strong overall, Highland is particularly pleased by the class-leading low level of variability seen with respect to the time to maximum concentration, or T_{max}. This parameter is critical given Highland's unique approach to dosing its drugs. The low coefficient of variation (CV%) seen in the HLD-200 study is similar to that seen in the HLD-100 Phase-1 study; demonstrating the robustness of Highland's drug-delivery platform. According to the article "Pharmacokinetic Variability of Long-Acting Stimulants in the Treatment of Children and Adults with Attention-Deficit Hyperactivity Disorder" by James C. Ermer *et al*, published in CNS Drugs, HLD-200's level of variability is significantly lower than that of the leading stimulants, including Vyvanse (marketed by Shire US Inc.), Concerta (Janssen Pharmaceuticals, Inc. – a Johnson & Johnson company) and Focalin XR (Novartis Pharmaceuticals Corporation).

Commenting on the study, Dr. Biederman said, "The data suggest that Highland has developed a potential new treatment option for ADHD that could consistently deliver the medication so that the symptoms of ADHD can be controlled immediately upon wakening while also providing once-daily coverage."

Dr. Bev Incledon, Highland's Senior Vice-President, Research & Development added, "We are pleased to once again see such low levels of variability with our technology. The consistent delivery of their medication is a great benefit for patients as it enhances the predictability of their response, which is clinically desirable."

"The data we have generated for both our amphetamine and methylphenidate programs suggest our drug-delivery technology is a platform technology, applicable to other active ingredients in a wide range of therapeutic categories," said David Lickrish, Chief Executive Officer of Highland Therapeutics, Inc. "In ADHD, our products are designed to address a significant unmet medical need in the treatment of the disease. The third-party market research we have conducted indicates substantial pent-up demand for Highland's products, which could become first-line therapy in both the adult and pediatric/adolescent patient populations."

"We are grateful for the support of MaRS, which provides an ideal environment for innovative life sciences companies to thrive. MaRS has been instrumental in Highland's success to date," added Mr. Lickrish.

Based on the strength of the Phase-1 data, Highland anticipates initiating Phase-2 studies with both HLD-100 and HLD-200 in the third quarter of 2013. The Phase-2 trials will be conducted in two stages – one in adolescent patients (ages 12-17), the other in pediatric patients (ages 6-11) with ADHD. Data from these studies are expected in the fourth quarter of 2013 and will be critical in guiding the design of the Phase-3 clinical trial programs, anticipated to begin in the first quarter of 2014.

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.

For further information, please contact Nelson F. Isabel at (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.