

# TURING

PHARMACEUTICALS

1177 Ave of the Americas, 39<sup>th</sup> Floor  
New York NY 10036

October 30, 2015

The Honorable Elijah E. Cummings  
Ranking Member  
Committee on Oversight and Government Reform  
United States House of Representatives

The Honorable Bernard Sanders  
Ranking Member  
Subcommittee on Primary Health and  
Retirement Security  
Committee on Health, Education, Labor, and  
Pensions  
United States Senate

Dear Senator Sanders and Representative Cummings:

Thank you for your letter of September 21, 2015, regarding Turing Pharmaceuticals AG's ("Turing") acquisition of Daraprim (pyrimethamine). We share your commitment to providing patient access for this life-saving drug at an affordable price. Patient access is one of Turing's top priorities, and our response demonstrates that in the short time Turing has owned this drug we have taken tangible steps to increase access and offer a number of programs to ensure affordability.

In our response, we strive to answer your questions as comprehensively as possible. Because Turing is a privately held corporation, under the advice of counsel we are unable to provide certain numbers and data related to proprietary information. Furthermore, because Turing has only had ownership over Daraprim for fewer than three months – five weeks from the date of your letter, we do not yet have complete data to respond to certain inquiries. Nevertheless, we have attempted to provide you pertinent and useful information in order to respond as comprehensively as possible to your request.

## **Introduction to Turing**

As background, Turing Pharmaceuticals is a privately held pharmaceutical company that officially launched in February of 2015 with the acquisition of three products, an intranasal formulation of **ketamine**, **Syntocinon**<sup>®</sup> (oxytocin nasal solution) and **Vecamyl**<sup>®</sup> (mecamylamine HCl tablets). Turing focuses on developing and commercializing innovative treatments for serious diseases and conditions across a broad range of therapeutic areas for which there are currently limited or no treatment options.

On March 10<sup>th</sup>, 2015 Impax Laboratories, Inc. acquired Tower Holdings, Inc. (including operating subsidiaries CorePharma LLC and Amedra Pharmaceuticals LLC) (collectively, "Impax"). At the time, Amedra Pharmaceuticals LLC owned the rights to Daraprim<sup>®</sup>. On June 15<sup>th</sup>, Impax appointed a single specialty distributor for inpatient hospital pharmacies, government customers, and customers eligible for 340B pricing. A single specialty dispense pharmacy was also added to the distribution network to handle all non 340B outpatient prescriptions.

On August 7<sup>th</sup>, 2015 Turing acquired the rights to market and distribute Daraprim® (pyrimethamine) in the United States from Impax. As part of that transaction, Turing was assigned the distribution contracts previously entered into by Impax.

### **Research & Development**

Turing is currently conducting research regarding established parasite proteins for toxoplasmosis that would increase the efficacy of standard treatment for toxoplasmosis and decrease potential adverse events. Turing will begin animal studies of recently various synthesized molecules in 1Q2016 to research their efficacy in toxoplasmosis. Additionally, Turing is conducting research to identify treatments for the dormant state of toxoplasmosis. Outside of its toxoplasmosis research, Turing announced on October 23, 2015, FDA's acceptance of an Investigational New Drug Application and Fast Track Designation for Turing's drug product that would treat epileptic encephalopathies.

Currently, Turing Pharmaceuticals has 41 employees who are dedicated to the R&D of new and existing treatments. Seven (7) researchers are dedicated solely to toxoplasmosis research. There are currently 19 open positions within Turing's R&D department. This is not an exhaustive list or business plan of future R&D initiatives, but provides a sampling of current initiatives. Attached is a snapshot of the current pharmaceutical pipeline for Turing.

### **Response to request for information**

In the weeks since Turing's acquisition of Daraprim (August 7, 2015), we have been assessing the programs, distribution channels, and contractual agreements that Impax and Amedra had in place. Where appropriate we have maintained those agreements, for example honoring the lower price contract Amedra negotiated with the Department of Veterans Affairs and Department of Defense (\$7.13 per tablet). In those instances where we recognized a deficiency and believing we can do better and offer a more competitive rate or open channels of distribution, we have done so. For example, we have extended 340B discount pricing to Walgreens Specialty Pharmacy ("WSP") ensuring wider distribution and easier access than under the previous owner of this drug.

Having only recently acquired Daraprim, we are unable to provide gross sales figures at this time, and we believe gross revenue would not paint a comprehensive picture regarding the costs paid by patients and sales of the drug.

The current cost of Daraprim depends upon the specific population being served. For certain patient populations that qualify for charitable coverage, the cost of Daraprim is \$0. For government programs like Medicaid and Public Health Service (PHS)/340B programs, the cost of Daraprim is \$0.01 per tablet. Patients participating in these programs constitute nearly two thirds of the patients using Daraprim. Turing opted to maintain the price (\$7.13 per tablet) previously negotiated by Amedra with the Department of Veterans Affairs and the Department of Defense. Turing also expects to receive and pay quarterly invoices for Medicare Part D "coverage gap" rebates. For patients that have Commercial (private) insurance and are unable to afford the product, Turing has implemented a copay mitigation program and participates in a patient assistance program (currently run by Amedra Cares as part of the Asset Purchase Agreement with Impax), a patient bridge program, and a charitable foundation program for Medicare Part D patients. Lastly, while the wholesale acquisition cost (WAC) for Daraprim is \$750



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per tablet, by definition the WAC pricing does not include the very substantial discounts and rebates offered for this or any other like product. As you know, the WAC price rarely, if ever, reflects the actual cost paid by patients. To the best of our knowledge there are currently no instances for which a patient has actually paid the WAC of \$750/tablet for the product.

In addition to the discount programs and agreements we have in place to make Daraprim affordable for patients, Turing has been assessing distribution. This includes our recent work with WSP to enable any hospitals/entities participating in the 340B program to obtain the 340B pricing of \$1/bottle. Turing managed to do this within 48 hours of learning of the issue from the National Alliance of State & Territorial AIDS Directors ("NASTAD"). Turing has also made an effort to reach out to advocacy groups. Turing met with NASTAD as early as September 15, 2015, and has continued to speak with individual state AIDS Drug Assistance Programs ("ADAPs") to discuss the distribution and eligibility of rebates to these providers to alleviate any issues and concerns. Additionally, Turing has added a true specialty distributor to its distribution network that has existing accounts with a majority of the hospitals/contract pharmacies in the US. In situations where they are not the hospital's prime vendor, this distributor has the ability to supply product through its existing third party contracts.

Turing Pharmaceuticals is committed to ensuring that patients and hospitals have access to Daraprim. We hope that you find the responses above to be informative. In the event that Turing determines that any of the information above is inaccurate it will supplement its response. Should you have any additional questions please contact us at 646-356-5577.

Sincerely,



Nancy Retzlaff  
Chief Commercial Officer

cc: The Honorable Jason Chaffetz  
Chairman, House Committee on Oversight and Government Reform



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## R&D PIPELINE – FOR DISTRIBUTION

October 19, 2015

# Luring Pharmaceuticals' R&D Pipeline – For Distribution

