TESTIMONY OF NANCY RETZLAFF
CHIEF COMMERCIAL OFFICER, TURING PHARMACEUTICALS

Before the

THE HOUSE COMMITTEE ON OVERSIGHT AND
GOVERNMENT REFORM

ON

"DEVELOPMENTS IN THE PRESCRIPTION DRUG MARKET: OVERSIGHT"
JANUARY 26, 2016

HEARING BEFORE THE HOUSE COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

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Chairman Chaffetz, Ranking Member Cummings, and members of the Committee, thank you for giving me the opportunity to share with you additional information regarding Turing's business practices, its product Daraprim®, and its commitment to ensuring that every patient in need has access to Daraprim®. I am Nancy Retzlaff, the Chief Commercial Officer of Turing Pharmaceuticals LLC. Turing is a small, research-focused, pharmaceutical company that began commercial operations on February 24, 2015. It is committed to helping patients who often have limited or no effective treatment options by investing in and developing pharmaceuticals that treat serious and neglected diseases. As the Committee is aware, since this fall, Turing has received significant attention about its decision to raise the price of a recently acquired drug, Daraprim®, which is primarily used to treat a parasitic infection called toxoplasmosis that most often affects patients with compromised immune systems. Toxoplasmosis is considered a "neglected" parasitic infection by the CDC, and a priority for public health action based on the number of people infected, the severity of the disease, and the ability to prevent and treat it. It is important to highlight that there has been no pharmaceutical innovation or research in the treatment of toxoplasmosis for over 50 years. With my testimony today, I hope to dispel certain misconceptions of Turing's business practices and provide any additional details that the Committee may find helpful.

Turing purchased the sole rights to manufacture and sell Daraprim® in the United States and Puerto Rico from Impax Laboratories on August 7, 2015, for $55 million. Impax had owned Daraprim® since March 2015. During its time of ownership, Impax raised the wholesale acquisition price, or WAC, of the drug from $13.55 to $17.63 per pill. In connection with the acquisition of Daraprim®, Turing assessed the market for similarly situated pharmaceuticals and found that despite Impax's decision to increase the price, Daraprim® was still being sold for a price that was well below its market value. Daraprim® is a lifesaving medication that is not only widely accepted as the preeminent treatment for toxoplasmosis, but also the only approved treatment (in conjunction with a sulfonamide) for toxoplasmosis in this country. After considering the extremely small patient population of approximately 3,000 patients per year, mandatory statutory discounts and rebates like those in the 340B and Medicaid programs, and the costs to manufacture and distribute Daraprim®, Turing made the decision to raise the WAC to $750 per pill. This decision also reflected Turing's business goals of funding improved access programs and services for patients in need, and importantly, research and development into alternative treatments for the disease that Daraprim® is used to treat, as well as other diseases that have been neglected by the pharmaceutical industry. To reiterate, there has been no new pharmaceutical approved for treatment of toxoplasmosis in over 50 years. This pricing decision was spearheaded by Turing's then-Chief Executive Officer.

As this Committee knows, pricing of pharmaceuticals is complex, given the many participants in the distribution and payment system. The WAC is only the published price and does not reflect the actual net cost of Daraprim® or any other drug to patients, hospitals, health plans, or government programs. Significant discounts or rebates are customary, or often mandatory, but are not typically disclosed to the public. The actual net price of Daraprim® ranges from $0.01 (one cent) per pill ("penny-pricing") to $750 per pill. Less than a quarter of the sales occur at the higher-end of this range. Although actual patient out-of-pocket costs are typically set by insurers and government programs and therefore may vary, the vast majority of Daraprim® sales (over 60 percent) are associated with either Medicaid or the 340B program. Those programs receive penny-pricing and have the ability to pass these savings through to patients. However, these penny-pricing programs do not lower our overhead, manufacturing, or distribution costs. Rather, Turing voluntarily participates in these programs because it wants to ensure that all patients who need Daraprim®, particularly the most vulnerable who need this life-saving drug, are able to access it.

At this point, I would like to discuss various steps that Turing has taken to improve patient access to Daraprim®, as well as the programs that are funded, in part, by Turing's sales of the drug.

I. Further Changes in Pricing

After consulting with patient advocacy groups and toxoplasmosis thought leaders around the country about how to strike the appropriate balance between the cost of treatment and the need for innovation in toxoplasmosis therapies, and in response to concerns raised about the cost of Daraprim®, Turing announced on November 24, 2015 that it had discounted the price of the drug by up to 50 percent for hospitals. This is in addition to the "penny pricing" that many hospitals already enjoy as covered entity participants in the 340B program. Notably, hospitals are the first to treat about 80 percent of patients with toxoplasmosis encephalitis – the most common form of toxoplasmosis in the United States – which means that a significant number of patients will benefit from this decrease.

Turing also learned that another major barrier to keeping Daraprim® stocked in hospital pharmacies was that it was only offered in bottles of 100 tablets for purchase. After learning of this issue, the company worked quickly to make available a new 30-pill bottle, which allows hospitals to purchase a more manageable volume of Daraprim® if needed. To be clear, hospitals may still receive a 50 percent discount on the new 30-pill bottles.

Patient Access and Affordability Programs

Ensuring patient access is, and always has been, our top priority– regardless of a patient's ability to pay. To this end, Turing has implemented and/or expanded several programs that make Daraprim® available to all patients, including the most vulnerable.

First, as previously noted, approximately two-thirds of Daraprim® sales are associated with federal and state government programs like Medicaid and the Public Health Service Section

340B programs. These programs have access to Daraprim® at penny-pricing. Turing also offers Daraprim® at a reduced price of $2,216.26 per bottle, or $22.16 per pill, to the Department of Veterans Affairs and Department of Defense under the Veterans Health Care Act for distribution to their patients.

Second, the Daraprim® Patient Assistance Program ("PAP") provides Daraprim® free of charge to qualified, uninsured patients with demonstrated income that is at or below 500 percent of the federal poverty level. Until recently, the assistance income limit for the Daraprim® PAP was only 150 percent of the federal poverty level. Therefore, Turing has substantially expanded the qualifying income eligibility for this PAP, and increased it to a level that is well-above industry standards.

Third, Turing supports patients who have commercial insurance through a co-pay support program, under which eligible patients may receive cost sharing support under which they are not obligated to pay more than $10 out of pocket for Daraprim® prescriptions.

Fourth, Turing offers a "bridge" program that provides patients who have commercial insurance with a supply of Daraprim® at no charge during the period of a benefits investigation by their commercial insurer, or during the pendency of their appeal from a commercial insurer's denial of coverage. This ensures that a patient will have timely access to Daraprim®.

Fifth, Turing contributes to Patient Services, Inc. ("PSI"), a longstanding independent charity that provides financial assistance to help cover the cost-sharing obligations of financially needy patients for toxoplasmosis therapies in a manner consistent with PSI's advisory opinion from the HHS Office of Inspector General.

Turing actively supports these programs now, and is committed to continuing and expanding these programs in the future, because patient access is Turing's top priority.

II. Disease Awareness and Education

In addition to its assistance programs, Turing also supports people at risk from toxoplasmosis by making a significant investment in a national team of health educators.

Toxoplasmosis is a rarely-seen, sometimes forgotten disease, so diagnosis can be delayed or missed. Time lost allows the infection to progress towards harmful, and sometimes life-threatening consequences. Recognizing this danger, Turing's team offers unbranded, non-promotional education to allied healthcare professionals, who are then able to use this information to raise awareness of toxoplasmosis, and more effectively screen patients for changes in health related to this disease in order to allow for early diagnosis.

The educators, and their well-referenced, simple-to-follow programs, have been welcomed at many hospitals, health centers and community-based organizations. Just last week at a major inner-city hospital, one of our team members learned of a patient whose toxoplasmosis had initially been missed. With this in mind, the hospital has recognized the urgency to improve

their caregivers' understanding of toxoplasmosis and has adjusted its training schedule to allow prompt delivery of toxoplasmosis education by Turing.

III. Distribution

When Turing acquired Daraprim®, it also assumed the distribution channels, organizational decisions, and contracts that its predecessor, Impax, had put in place. Some of these decisions and operations were perceived to have limited, or at least changed, patient access to the drug. To address customers' concerns, Turing took decisive action within a few weeks of acquiring Daraprim®, including initiating a broad, multi-channel communication initiative to ensure providers were aware of how to access Daraprim®. Further, Turing engaged and hired experts to expand and alleviate access issues.

Turing engaged a specialty distributor to improve access with institutions and hospitals. Before the acquisition, Impax used a third party logistics provider to handle all institutional sales. This led to unnecessary bureaucratic inefficiencies in the distribution system that resulted from the third-party logistics provider's need to register each hospital as a new account. Turing's new specialty distributor has pre-existing contracts with upwards of 90% of hospitals in the United States, which affords institutions more streamlined access. This distributor is also able to quickly establish agreements with the few entities with which it does not have a pre-existing relationship. Simply adding a third party logistics provider to an experienced specialty distributor has greatly improved Turing's ability to get Daraprim® to those in need. Let me point out that this distribution change primarily benefits recipients of the 340B program that Turing participates in at a financial loss.

To further improve the distribution system, Turing also began proactive outreach to state AIDS Drug Assistance Programs (ADAPs) and other patient advocacy organizations within weeks of acquiring Daraprim®. These patient advocacy organizations expressed dissatisfaction with the access issues caused by the Impax model. Turing representatives have been traveling the country to meet with various ADAPs, HIVMA, and other organizations in order to ensure state-by-state access for patients who comprise a large percentage of severe toxoplasmosis population.

Through this outreach, Turing was made aware that Walgreens Specialty Pharmacy ("WSP") was not able to facilitate access to 340B pricing under the original agreement with Impax. When Turing learned of this obstacle on September 15, 2015, it immediately met with WSP, and within 48 hours, it had the necessary distribution channels and chargeback procedures in place to offer 340B through WSP. This process normally takes months to finalize, but Turing was able to make the necessary changes in a matter of days. That very weekend, the New York ADAP was able to fill an order through WSP, which would not have been possible previously.

IV. Research and Development

Turing Pharmaceuticals is focused on developing and commercializing innovative treatments for serious diseases and neglected conditions. I want to take this opportunity to

emphasize Turing is a research-based company that is committed to innovation and reinvests 60 percent of its net income from the sale of Daraprim® into research and development – a figure that far exceeds industry standards. Toxoplasmosis research is particularly important to Turing, and the company's current pipeline includes product candidates that might be the only advance in toxoplasmosis treatment in 50 years. I would like to highlight that among our R&D programs, is one specifically focused on addressing a main adverse event of current treatment for toxoplasmosis. This program has advanced to a stage that gives us confidence in our ability to potentially improve patient outcomes in the not too distant future. As of December 2015, Turing had 13 research and development programs in its pipeline. For your reference, I have supplied as attachments to our written testimony both: (1) a summary of our R&D pipeline as of December 2015; and (2) our 2015 Quarter 3 report, which discusses our R&D philosophy and several efforts.

V. Conclusion

On behalf of the dedicated employees of Turing who strive to bring new advances to rare and neglected diseases, and fulfill our pledge "that no patient needing Daraprim® will ever be denied access," I thank you for the opportunity to testify today. I hope that my testimony has helped show the Committee that Turing's business practices have found a way to fund innovative research for a neglected disease. At the same time, the company has and will continue to offer comprehensive patient assistance programs to ensure all patients can access Daraprim® regardless of ability to pay. Turing looks forward to providing improved treatments for patients in the future.

As Turing has done over the past several months, it will continue to work with the Committee and its members to answer any additional questions that it may have. Thank you for your time.

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Press Release

Turing Pharmaceuticals AG Announces Third Quarter Business Highlights and Financial Results

Zug, Switzerland, November 12, 2015 - Turing Pharmaceuticals AG, a privately-held biopharmaceutical company focused on developing and commercializing innovative treatments for serious diseases and conditions, today announced financial results and operational highlights for the quarter ended September 30, 2015.

Research and Development

- Toxoplasmosis is on the Center for Disease Controls' list of neglected parasitic infections (NPIs) as a priority for public health action. We intend to file Investigational New Drug applications with the FDA for new candidate medications, currently in preclinical studies. The most advanced pipeline products are dihydrofolate reductase (DHFR) inhibitors with improved pharmacological profiles relative to pyrimethamine. Turing is also actively engaged in licensing opportunities for toxoplasmosis therapeutics.
- Epileptic encephalopathies are a diverse group of severe epilepsy disorders in which uncontrolled epileptic activity contributes to a progressive decline in cognitive and motor function. Beginning in November, we are initiating the Phase I clinical program for TUR-004, our new candidate for this group of disorders. The first trial will be a randomized, double-blind, placebo-controlled, single ascending dose study to evaluate the safety, tolerability and pharmacokinetics of an oral

formulation of TUR-004 in healthy young adult subjects. TUR-004 has received Fast Tack Designation from the FDA.

- We are developing, TUR-002, an intranasal formulation of ketamine for the treatment of Posttraumatic Stress Disorder (PTSD) and Major Depressive Disorder (MDD). Ketamine, which has been extensively used as an anesthetic, may also be used as rapid treatment for these disorders as suggested by experimental studies. It is estimated that more than fifteen million adults in the United States suffer from MDD and more than seven million from PTSD over a given year, many of whom will experience suicidal ideation. In addition, a World Health Organization report indicates that by 2030 depression will be the leading cause of disease burden globally. We plan to initiate Phase I trials for TUR-002 by the first quarter of 2016.
- TUR-007 is a preclinical drug candidate targeting pathological mechanisms associated with Canavan Disease. Canavan is a neurological disorder that manifests in early infancy and is caused by an inherited genetic abnormality. This genetic aberration leads to a deterioration of myelin in the brain, thereby preventing proper transmission of nerve signals. Symptoms include intellectual disability and the inability to crawl, walk, sit or talk. Some patients suffer from paralysis, blindness and seizures with a life expectancy limited to early adolescence. There is currently no approved treatment. Turing has initiated preclinical work in Q3 '15 at an industry-leading CRO to aid in the development of TUR-007.
- TUR-005 is a preclinical drug candidate for Lafora Disease, a fatal autosomal recessive neurological disorder typically diagnosed in adolescents. Dysfunction of one or more key proteins involved in glycogen processing leads to the presence of hallmark Lafora bodies and is associated with neurodegenerative myoclonic epilepsy for which no disease-modifying treatments exist. Turing also initiated preclinical work in Q3 '15 at an industry-leading CRO to aid in the development of TUR-005.
- Cross reacting material 197 (CRM197) is a non-toxic variant of diphtheria toxin, which we believe is an ideal platform technology capable of intracellular delivery of cargo proteins into cytosol and across the blood-brain-barrier. We are developing CRM197 fusion constructs with therapeutic proteins of up to 1,000 amino acids in length as a proof of concept before assessing even larger delivery systems. Our initial focus is on monogenic diseases with validated animal

models and a firmly established connection between the defective protein and associated disorder. Turing entered a Sponsored Research Agreement in Q2 '15 with the Hospital for Sick Children in Toronto to discover and develop new treatments based on this technology.

Due to the high cost of pursuing these development objectives, Turing expects to spend at least 60% of its revenue on research and development for the foreseeable future.

Martin Shkreli, founder and CEO of Turing said, "Our Research and Development organization, led by Dr. Eliseo Salinas, has surpassed my expectations in advancing TUR-004 for epileptic encephalopathies and TUR-002 for depression with the FDA." Dr. Salinas remarked, "We are very excited about the potential for Turing's pipeline of new drug candidates to help patients in need of better medications."

With respect to Daraprim®, after consulting with patient advocacy groups and infectious disease doctors, Turing understands that toxoplasmosis patients are primarily concerned with timely access and minimal out-of-pocket costs. We are committed to continuing the expansion of our distribution partnerships in order to facilitate optimal patient access. In addition to participation in federal and state programs with costs as low as 1 penny per pill, and patient savings programs under which patients' out-of-pocket expenses do not exceed $10 per prescription, Turing contributes to Patient Services, Inc. (PSI), a longstanding independent charity that provides support for financially needy patients' cost-sharing obligations for any toxoplasmosis therapies, consistent with PSI's advisory opinion from the HHS Office of Inspector General. In order to better address the needs of physicians and patients, Turing will be introducing a 30-count bottle to address the needs of hospitals as well as a sample package to ensure physicians have timely and affordable access to therapy in emergency situations.

Financial Update: Quarter Ended September 30, 2015

For the third quarter of 2015, net revenue was $5.6 million representing Daraprim® and Vecamyl® sales. Research and development spending of approximately $7 million reflects Turing's progress advancing TUR-002 and TUR-004 with the FDA and multiple preclinical programs.

The following represents expectations for selected financial figures in the quarter ended September 30, 2015.

Turing Pharmaceuticals AG and Subsidiaries

(amounts in thousands, unaudited)

	Three Months Ended 30-Sept-15	**Nine Months Ended 30-Sept-15**
Net revenues	$5,657	$5,975
Research and Development	6,969	11,467
Net loss	**($14,590)**	**($27,729)**

The September 30, 2015 financial information is subject to independent auditor review. Accordingly, the amounts set forth above are estimates based solely on currently available information, which is subject to change and has not been reviewed by our independent auditors. We have not finalized our review of financial statements for the quarter ended September 30, 2015 and during the course of our review we may identify items that would require us to make adjustment to our preliminary operating results described above. As a result, the discussion above constitutes forward-looking statements and, therefore, we caution you that these statements are subject to risks and uncertainties, including possible adjustments to our preliminary operating results. Unless otherwise noted, Turing is providing this information as of November 12, 2015 and disclaims any duty to update the information contained herein.

About Turing

Turing Pharmaceuticals AG is a privately-held biopharmaceutical company with offices in Zug Switzerland and New York, New York. 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. Products being developed include intranasal ketamine for a variety of mood

disorders and Syntocinon® (oxytocin nasal solution) for multiple indications. Daraprim®(pyrimethamine) for the treatment of Toxoplasmosis in combination with sulfonamide and Vecamyl® (mecamylamine HCl tablets) for hypertension are Turing's first commercial products.

For more, visit www.turingpharma.com (http://www.turingpharma.com).

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Safe Harbor

In addition to historical facts or statements of current condition, this press release contains forward-looking statements within the meaning of "Safe Harbor" provisions of The Private Securities Litigation Reform Act of 1995, including statements regarding the initiation of product development activities, including but not necessarily limited to clinical trials. Forward-looking statements provide Turing Pharmaceuticals' current expectations and forecasts of future events. Turing Pharmaceuticals' performance and financial results could differ materially from those reflected in these forward-looking statements due to general financial, economic, regulatory and political conditions affecting the biotechnology and pharmaceutical industries. Given these risks and uncertainties, any or all of these forward-looking statements may prove to be incorrect. Therefore, you should not rely on any such factors or forward-looking statements. Turing Pharmaceuticals undertakes no obligation to update publicly any forward-looking statements.

For media inquiries, contact:
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R&D PIPELINE – FOR DISTRIBUTION

October 19, 2015

Turing Pharmaceuticals' R&D Pipeline – For Distribution

Product	Indication	Preclinical	Phase I	Phase II	Phase III	Marketed
DARAPRIM®	Toxoplasmosis					
VECAMYL®	Hypertension					
VECAMYL®	New Indication					
TUR-001 (Syntocinon)™	Lactation					
TUR-001 (Syntocinon)™	New Indication					
TUR-002 (IN Ketamine)	Suicidality					
TUR-002 (IN Ketamine)	New Indication					
TUR-004	Epileptic Encephalopathy					
TUR-004	Epilepsy					
TRP-001	Glycogen Storage Disorders					
TRP-002	Rare Genetic CNS Disorder					
TRP-003	Pediatric Leukodystrophy					
TRP-004	Toxoplasmosis					
TRP-005	Next Generation Epilepsy					
TRP-011	Congenital Metabolic Disorder					

(Ph3 estimated Q3, 2016)

(Ph3 estimated Q3, 2016)

(Ph3 estimated Q2, 2016)

Committee on Oversight and Government Reform
Witness Disclosure Requirement – "Truth in Testimony"
Required by House Rule XI, Clause 2(g)(5)

Name: Nancy Retzlaff

1. Please list any federal grants or contracts (including subgrants or subcontracts) you have received since October 1, 2012. Include the source and amount of each grant or contract.

None

2. Please list any entity you are testifying on behalf of and briefly describe your relationship with these entities.

Turing Pharmaceuticals

Currently employed as Chief Commercial Officer

3. Please list any federal grants or contracts (including subgrants or subcontracts) received since October 1, 2012, by the entity(ies) you listed above. Include the source and amount of each grant or contract.

None

I certify that the above information is true and correct.

Signature: 

Date: 01/22/2016

Nancy Retzlaff
Chief Commercial Officer

Nancy Retzlaff is the Chief Commercial Officer at Turing Pharmaceuticals. Prior to joining Turing, Ms. Retzlaff was the VP of Global Marketing / Commercial at Mesoblast Inc. in New York City. Previously with Pfizer, she held the lead regional commercial role in Japan, Australia, Canada and Korea. Also with Pfizer she held a global role in Neurosciences. In addition to her time at Mesoblast Inc. and Pfizer, Ms. Retzlaff has worked at Schering-Plough and Bayer. Ms. Retzlaff received a Bachelor of Commerce; Marketing & General Business at the University of Saskatchewan.