



## Imprimis Pharmaceuticals Registers its Texas Facility with the FDA as an Outsourcing Facility

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SAN DIEGO, April 12, 2016 /PRNewswire/ -- Imprimis Pharmaceuticals, Inc. (NASDAQ: IMMY), a pharmaceutical company focused on the development and commercialization of proprietary and customizable drug formulations, announced today that it has filed for registration of its ImprimisRx TX pharmacy, located in Allen, Texas, with the U.S. Food and Drug Administration (FDA) as a 503B outsourcing facility. The Drug Quality and Security Act (DQSA), signed into law on November 27, 2013, created this pathway in which a compounding pharmacy can voluntarily register with the FDA as an outsourcing facility under Section 503B of the federal Food, Drug and Cosmetic Act, comply with the DQSA and avail itself of the operational benefits the law provides.



The ImprimisRx TX facility will make and distribute compounded drugs according to current good manufacturing practices (cGMP), which are the same standards used for the manufacture of FDA-approved drugs. ImprimisRx TX will initially distribute the company's proprietary sterile Droplless Therapy® injectable formulations, which are administered following ocular surgery, primarily cataract surgery. Once operating as an outsourcing facility, ophthalmologists will have the ability to simply order the quantities they need for inventory and office use, without providing patient specific information that is required today. The company expects to begin distributing from the facility towards the end of the second quarter of this year.

Mark L. Baum, CEO of Imprimis, stated, "This is an important milestone for our growing company. We believe transitioning our Droplless Therapy® injectable formulations to an outsourcing facility environment is good for our number one constituent – our patients. And if it is good for our patients, it is good for Imprimis and its shareholders. Importantly, operating as a 503B outsourcing facility should create new revenue opportunities by simplifying the ordering process with existing and new potential customers, including hospitals, group purchasing organizations, and surgery centers, that desire, or in some cases, require purchasing from an FDA-registered outsourcing facility. According to internal research and an April 2015 third party market research report, adoption of our core ophthalmology formulations is expected to increase as a result of moving to an outsourcing facility and once customers are no longer required to provide patient-specific prescriptions."

Mr. Baum concluded, "We believe increased adoption of cGMP production standards, the same manufacturing standards that FDA-approved drugs are held to, will ensure public confidence in quality and patient safety for compounded drugs. We have also been engaged in efforts to improve the DQSA so that more compounded drugs are made in a cGMP environment. We fully expect that the FDA will remain a supportive partner as outsourcing facilities continue to operate and build quality-made finished pharmaceuticals under FDA scrutiny. We look forward to being a part of the outsourcing facility community and using the provisions of the DQSA to better serve the many thousands of patients we serve each week."

*Other than drugs compounded at a registered outsourcing facility, all Imprimis compounded formulations may only be prescribed pursuant to a physician prescription for an individually identified patient consistent with federal and state laws governing compounded drug formulations.*

### ABOUT IMPRIMIS PHARMACEUTICALS

Imprimis Pharmaceuticals, Inc. (NASDAQ: IMMY) is a national leader in the development, production and dispensing of novel compounded pharmaceuticals. The company's two business programs, *Imprimis Cares™* and *Custom Compounding Choice™*, focus on patient outcomes and affordability by offering high quality custom compounded drugs in all 50 states. Headquartered in San Diego, California, Imprimis owns and operates four dispensing facilities located in California, Texas, New Jersey and Pennsylvania. For more information about Imprimis, please visit the corporate website at [www.ImprimisPharma.com](http://www.ImprimisPharma.com).

## SAFE HARBOR

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Any statements in this release that are not historical facts may be considered such "forward looking statements." Forward looking statements are based on management's current expectations and are subject to risks and uncertainties which may cause results to differ materially and adversely from the statements contained herein. Some of the potential risks and uncertainties that could cause actual results to differ from those predicted include risks and uncertainties related to Imprimis' ability to make commercially available its compounded formulations and technologies in a timely manner or at all; physician interest in prescribing its formulations; risks related to its compounding pharmacy operations; its ability to enter into other strategic alliances, including arrangements with pharmacies, physicians and healthcare organizations for the development and distribution of its formulations; its ability to obtain intellectual property protection for its assets; its ability to accurately estimate its expenses and cash burn, and raise additional funds when necessary; risks related to research and development activities; the projected size of the potential market for its technologies and formulations; unexpected new data, safety and technical issues; regulatory and market developments impacting compounding pharmacies, outsourcing facilities and the pharmaceutical industry; competition; and market conditions. These and additional risks and uncertainties are more fully described in Imprimis' filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K and its Quarterly Reports on Form 10-Q. Such documents may be read free of charge on the SEC's web site at [www.sec.gov](http://www.sec.gov). Undue reliance should not be placed on forward-looking statements, which speak only as of the date they are made. Except as required by law, Imprimis undertakes no obligation to update any forward looking statements to reflect new information, events or circumstances after the date they are made, or to reflect the occurrence of unanticipated events.

### Investor Contact

Bonnie Ortega  
[bortega@imprimispharma.com](mailto:bortega@imprimispharma.com)  
858.704.4587

### Media Contact

Paul Rabin  
[paul@pascalecommunications.com](mailto:paul@pascalecommunications.com)  
516.503.0271

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