Imprimis Pharmaceuticals Registers its New Jersey Facility with the FDA as an Outsourcing Facility

October 28, 2016

SAN DIEGO, Oct. 28, 2016 /PRNewswire/ -- Imprimis Pharmaceuticals, Inc. (NASDAQ: IMMY), a pharmaceutical company focused on the production and dispensing of high quality innovative compounded medications, today announced that it has filed for registration of its recently-constructed New Jersey facility with the U.S. Food and Drug Administration (FDA) as a 503B outsourcing facility. The state-of-the-art facility is expected to begin manufacturing as an outsourcing facility in December 2016 and dispensing medications in early first quarter 2017.

The NJ based outsourcing facility will initially make and distribute Imprimis' proprietary sterile Dropless Therapy® injectable and LessDrops® topical formulations in accordance with current good manufacturing practices (cGMP). Imprimis designed the facility for the production of its core ophthalmology formulations, outfitting it with automated filling, labeling and other state-of-the-art equipment that should allow for improved production efficiencies. The ease of customer ordering for office use and stocking inventory should also increase administration and dispensing efficiencies. The company also believes ophthalmologists, surgery centers and other healthcare providers will benefit greatly by having the ability to simply order the quantities of Dropless Therapy and LessDrops formulations they require for inventory and office use without having to provide patient specific prescriptions.

Mark L. Baum, CEO of Imprimis, stated, "This is an important milestone for our company. We believe transitioning the production of our proprietary Dropless Therapy® injectable and LessDrops® formulations to an outsourcing facility environment should create additional 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. Based on our internal research and an April 2015 third party market research report, we expect that adoption of our core ophthalmology formulations will increase as a result of moving to an outsourcing facility environment, once customers are no longer required to provide patient-specific prescriptions. This is an exciting time for Imprimis and I am confident that with the investments in infrastructure, improvements in operating efficiencies and strengthening of our senior leadership team, we are well positioned to meet our existing and anticipated increase in demand for our innovative ophthalmic formulations."

The Drug Quality and Security Act (DQSA) was signed into law on November 27, 2013 and, as enacted, clarifies and strengthens the regulatory framework governing the compounding of FDA-approved pharmaceutical ingredients. Section 503B of the new law allows outsourcing facilities to register with and submit to inspection by the FDA, produce certain finished compounded drugs to cGMP (current good manufacturing practices) and ship across state lines without a patient-specific prescription.

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 pharmaceutical company dedicated to producing and dispensing high quality innovative compounded medications in all 50 states. The company's unique business model drives patient access and affordability to many critical medicines. Headquartered in San Diego, California, Imprimis owns and operates three dispensing facilities located in California, New Jersey and Pennsylvania. For more information about Imprimis, please visit the corporate website at www.ImprimisRx.com.

Forward-Looking Statements

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 our ability to make commercially available our compounded formulations and technologies in a timely manner or at all; physician interest in prescribing our formulations; risks related to our compounding pharmacy operations; our ability to enter into other strategic alliances, including arrangements with pharmacies, physicians and healthcare organizations for the development and distribution of our formulations; our ability to obtain intellectual property protection for our assets; our ability to accurately estimate our 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 our 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. 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.

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