



[Home](#) / [Investors](#) / [Press Releases](#)

Insmmed Provides Response to United States Patent Lawsuit; Seeks Immediate Dismissal or Summary Judgment for All Claims

RICHMOND, Va., Feb 22, 2005 (BUSINESS WIRE) -- Insmmed Incorporated (NASDAQ: INSM) today announced that the Law Firm of Foley & Lardner LLP has filed on behalf of Insmmed a motion to dismiss a complaint alleging infringement of method of use and method of manufacture patents brought by Tercica and Genentech against Insmmed in the United States District Court for the Northern District of California.

In response, Insmmed's motion to dismiss asserts that all alleged activities fall within the statutory safe harbour provided by 35 U.S.C. ss. 271(e)(1), commonly called the Clinical Trial Exemption. This exemption prevents patent infringements from being filed against activities reasonably related to obtaining FDA approval of a product, such as when the product is still being tested in Clinical Trials. Insmmed further asserts, among other things, that the plaintiff's have failed to state a claim for the requested relief, have not sued the proper party, have failed to name all the proper plaintiffs and have failed to establish the existence of a sufficiently real and substantial controversy between the parties. Insmmed seeks immediate dismissal or Summary Judgment against the plaintiff's allegation on these grounds.

The initial complaint filed on December 23, 2004 was amended on February 16, 2005. In the Amended Complaint Tercica and Genentech challenge Insmmed's right to commercialize SomatoKine(R) and added allegations of infringement of an additional patent. Geoffrey Allan, Ph.D., Insmmed's President and Chief Executive Officer commented, "We believe that this litigation is clearly an attempt to interfere with our ongoing business activities designed to bring IGF-I therapy to patients with medical need. We continue to maintain our belief that we do not infringe any valid patent claims and do not believe that Tercica will succeed in their efforts to prevent our proprietary IGF-I therapy, SomatoKine(R) from reaching patients with orphan diseases." Allan continued, "We perceived that their original December 23, 2004 complaint was filed in an attempt to interfere with our upcoming New Drug Application and other important business activities. The filing and timing of this amendment validates our perception. We strongly reiterate our belief that these allegations are without merit and we intend to vigorously defend our position and right to make SomatoKine(R). We will not allow these repeated interferences to hinder our intent to bring SomatoKine(R) to children with unmet medical need."

About Insmmed Incorporated

Insmmed is a biopharmaceutical company focused on the discovery and development of drug candidates for the treatment of metabolic diseases and endocrine disorders with unmet medical needs. For more information, please visit www.insmed.com.

Statements included within this press release, which are not historical in nature, may constitute forward-looking statements for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this press release include, but are not limited to, statements regarding the expected results of litigation regarding the validity of our patents and our future ability to conduct our business as now conducted and as it is currently proposed to be conducted; clinical trials and goals, our regulatory and business strategies and growth opportunities for existing or proposed products. Such forward-looking statements are subject to numerous risks and uncertainties, including the uncertainty of the outcome of any litigation, the risk that product candidates may fail in the clinic or may not be successfully marketed or manufactured, the company may lack financial resources to complete development of product candidates, the FDA may interpret the results of our studies differently than we have. We can give no assurances that we would be successful in any litigation or that such litigation would not have a material adverse effect on our business, financial condition and results of operation. Furthermore, we may not be able to afford the expense of defending against such a claim. As a result of these and other risks and uncertainties, actual results may differ materially from those described in this press release. For further information with respect to factors that could cause actual results to differ from expectations, reference is made to reports filed by the Company with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended. The forward-looking statements made in this release are made only as of the date hereof and Insmmed disclaims any intention or responsibility for updating predictions or financial guidance contained in this release.

