

Home / Investors/ News Releases

## Study by Leading Economist Identifies Potential for \$378 Billion of Savings From Follow On Biologics

RICHMOND, Va., Feb 11, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- A report released today, commissioned by Insmed Inc. (Nasdaq: INSM), identifies potential cost savings of approximately \$378 billion over the next 20 years from making follow on biologics (FOBs) available in the U.S.

The econometric study by economist Dr. Robert J. Shapiro, former Under Secretary of Commerce in the Clinton Administration, found that "...generic versions of the top 12 categories of biologic treatments with patent protections that have expired or that are due to expire in the near future could save Americans \$67 billion to \$108 billion over 10 years and \$236 billion to \$378 billion over 20 years."

According to other published reports, an estimated \$10 billion worth of biologic drugs are expected to come off patent by 2010, with an additional \$10 billion by 2015. FOBs would provide safe and effective therapies at a reduced cost following the expiration of the original product's patent.

Dr. Shapiro's report, entitled The Potential American Market for Generic Biological Treatments and the Associated Cost Savings, also finds that "...the economic and medical benefits from generic biologics should be as great or perhaps even greater as those from generic forms of traditional pharmaceuticals... Moreover, the potential savings from the discounted prices that generics provide will be larger with biogenerics, because original biologics are so much more expensive than other brand pharmaceuticals..."

The scientific, regulatory and legal framework for the approval of small- molecule generic drugs is well developed, and a regulatory system for approving FOBs was established in Europe in 2006. However, no regulatory pathway currently exists for FOBs, which are also commonly referred to as biosimilars or biogenerics, in the U.S.

"Dr. Shapiro's comprehensive analysis presents a compelling case for the need for Congress to adopt legislation so patients can receive affordable access to life-saving biotech drugs in a timely manner," said Geoffrey Allan, CEO of Insmed, a developer of follow-on biologics and biopharmaceuticals. "The cost savings to the health care system have the potential to be enormous, while the environment for new market participants could introduce competition to these monopolistic markets, similar to that seen in the traditional pharmaceutical generics industry."

The release of Dr. Shapiro's report is part of Insmed's broad education campaign on the importance of establishing a regulatory pathway in the U.S. for large molecule protein-based drugs, known as follow-on biologics (FOBs), which are also commonly referred to as biosimilars or biogenerics.

Insmed is currently developing a portfolio of FOBs and intends to initiate clinical trials for its first two FOBs in 2008. Members of Insmed's skilled biologics team have worked on over 50 therapeutic proteins. Their focused protein-based drug development backgrounds, coupled with the Company's FDA- approved protein manufacturing facility, and clinical and regulatory expertise, positions Insmed, upon the establishment of a regulatory pathway, to be an initial entrant into the U.S. FOBs market with a broad range of medicines following the expiration of patents covering the innovator products.

Dr. Shapiro is the chairman of Sonecon, LLC, a private firm that advises U.S. and foreign businesses, governments and non-profit organization.

His full report is available on Insmed's website at: <a href="http://www.insmed.com">http://www.insmed.com</a>. Journalists may contact Dr. Shapiro by calling 202-213-7233 or e-mailing <a href="mailto:jprocter@gibraltar-llc.com">jprocter@gibraltar-llc.com</a>.

Insmed is currently developing a portfolio of FOBs and intends to initiate clinical trials for its first two FOBs in

2008, both of whose brand sales represent over \$3 billion in current sales world wide. Members of Insmed's skilled biologics team have worked on over 50 therapeutic proteins. Their focused protein-based drug development backgrounds, coupled with the Company's FDA-approved protein manufacturing facility, and clinical and regulatory expertise, positions Insmed, upon the establishment of a regulatory pathway, to be an initial entrant into the U.S. FOBs market with a broad range of medicines following the expiration of patents covering the innovator products.

## About Insmed

Insmed Inc. is a biopharmaceutical company with unique protein process development and manufacturing experience and a proprietary protein platform aimed at niche markets with unmet medical needs. Insmed has a state-of-the- art, FDA-approved biologic commercial manufacturing facility in Boulder, Colorado and a Corporate office in Richmond, Virginia. For more information, please visit <a href="http://www.insmed.com">http://www.insmed.com</a>.

## About Robert J. Shapiro

Robert J. Shapiro is the chairman of Sonecon, LLC, a private firm that advises U.S. and foreign businesses, governments and non-profit organizations. Dr. Shapiro has advised, among others, U.S. President Bill Clinton and British Prime Minister Tony Blair; private firms including Amgen, AT&T, Gilead Sciences, Google, MCI, Inc., SLM Corporation, Nordstjernan of Sweden, and Fujitsu of Japan; and non-profit organizations including the American Public Transportation Association, the Education Finance Council, BIO, and the U.S. Chamber of Commerce. He is also chairman of the Globalization Initiative of NDN, co-chair of the American Task Force Argentina, Policy Fellow of the Georgetown University School of Business, Senior Fellow of the Progressive Policy Institute (PPI), and a director of the Ax:son-Johnson Foundation in Sweden. From 1997 to 2001, Dr. Shapiro was Under Secretary of Commerce for Economic Affairs. Prior to that, he was co-founder and Vice President of PPI. Dr. Shapiro also served as the principal economic advisor to Bill Clinton in his presidential campaign, senior economic advisor to Albert Gore, Jr. in 2000, Legislative Director for Senator Daniel P. Moynihan, and Associate Editor of U.S. News & World Report. He has been a Fellow of Harvard University, the Brookings Institution and the National Bureau of Economic Research. He holds a Ph.D. from Harvard, an A.B. from the University of Chicago and a M.Sc. from the London School of Economics and Political Science. He is the author of numerous articles for scholarly and popular journals, and his forthcoming book is Futurecast: How Superpowers, Globalization and Populations Will Change the Way You Live and Work, to be published by St. Martins Press in April 2008.

## Forward-Looking Statements

This release contains forward-looking statements which are made pursuant to provisions of Section 21E of the Securities Exchange Act of 1934. Investors are cautioned that such statements in this release, including statements relating to planned clinical study design, regulatory and business strategies, plans and objectives of management and growth opportunities for existing or proposed products, constitute forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those anticipated by the forward-looking statements. The risks and uncertainties include, without limitation, risks that product candidates may fail in the clinic or may not be successfully marketed or manufactured, we may lack financial resources to complete development of product candidates, the FDA may interpret the results of studies differently than us, competing products may be more successful, demand for new pharmaceutical products may decrease, the biopharmaceutical industry may experience negative market trends, our entrance into the follow on biologics market may be unsuccessful, our common stock could be delisted from the Nasdag Global Market and other risks and challenges detailed in our filings with the U.S. Securities and Exchange Commission, including our Quarterly Report on Form 10-Q for the quarter ended September 30, 2007. Readers are cautioned not to place undue reliance on any forward-looking statements which speak only as of the date of this release. We undertake no obligation to publicly release the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances that occur after the date of this release or to reflect the occurrence of unanticipated events.