

Home / Investors/ News Releases

Insmed Chairman And CEO Provides Positive Outlook in Special Letter to Shareholders

Insmed Chairman And CEO Provides Positive Outlook in Special Letter to Shareholders

RICHMOND, Va.--(BUSINESS WIRE)--April 1, 2003--Insmed, Incorporated (NASDAQ/NMS: INSM), a biopharmaceutical company engaged in the development of drug candidates for the treatment of metabolic diseases and endocrine disorders with unmet medical needs, today announced that it has issued a Special Letter to Shareholders in an effort to update existing Insmed investors on the current status of the Company, and more importantly, management's perspective on the Company's future growth outlook. The text from the letter follows:

"Dear Shareholder,

I am pleased to be writing to you today with good news about Insmed. The Company is well on its way toward meeting our strategic objective of getting a new drug to market by the second half of 2004. On the basis of our progress to this point, our financial resources and the robust science that stands behind our drug candidates, we now expect that target to be met.

As you recall, last year we underwent a restructuring that included the cessation of development of the investigational drug product, INS-1. At that time, we decided to focus on winning approval for our most advanced product, SomatoKine®. This is the rhIGF-I/rhIGFBP-3 complex, our proprietary delivery system of insulin-like growth factor-I, commonly referred to as IGF-I. In order to meet this goal, we have sharply cut our cash burn rate and have taken steps to start the key clinical trial required for approval of the rhIGF-I/rhIGFBP-3 complex.

Here's where we stand now on our key initiatives:

- Cash position. Our stated goal was to hold our burn rate to no more than \$1 million a month. So
 far in 2003, we're doing even better than this. We also ended 2002 with a larger than expected
 cash cushion. At \$27.3 million, it was up about \$1.5 million from our forecast at the time of the
 third quarter report. At current rates and projections, including all clinical trial expenses, we will
 easily have enough cash to fund at least two more years of full operation. This will be plenty of
 time to execute the strategy of getting the rhIGF-I/rhIGFBP-3 complex to market.
- Clinical trials and FDA approval. We are on track to initiate the pivotal Phase III trial of the rhIGF-I/rhIGFBP-3 complex as a treatment for growth hormone insensitivity syndrome (GHIS) in the first half of 2003. We plan to conduct a 6-month interim analysis of this study early in 2004. If the analysis is positive, we will then file for regulatory approval in both the U.S. and Europe. The final step will be to put the drug on the commercial market in the second half of the year.

We have several reasons for confidence that we can gain approval for this product within this timetable. First, the scientific evidence supporting the use of this drug in growth disorders is very compelling. Second, the rhIGF-I/rhIGFBP-3 complex has been designated an Orphan Drug by the FDA and we are currently seeking the same designation in Europe. Orphan Drug status provides many benefits to the Company, including seven years of market exclusivity, tax incentives and study design assistance. Another factor in our favor is our exclusive license to Pharmacia Corporation's portfolio of regulatory filings for rhIGF-I. Pharmacia had used this material in several European countries to obtain

marketing approval of rhIGF-I for the treatment of GHIS. With Pharmacia no longer producing rhIGF-I, we will use these filings to support the approval of the rhIGF-I/rhIGFBP-3 complex.

Drug Nears Debut With Patients, Physicians

Prior to approval, we plan to have the rhIGF-I/rhIGFBP-3 complex in use under a special license named patient program in Europe. This program will involve a small number of GHIS patients who have no alternative therapies for treatment of their condition. This program will provide benefit to those people with this serious growth disorder. In addition, it will put the drug into the hands of physicians who over time can begin to investigate its therapeutic potential in other serious medical conditions where there is no therapy currently available. This is one of a number of strategies towards identifying potential new markets for the rhIGF-I/rhIGFBP-3 complex.

As you probably know, GHIS is not a common disorder and therefore, the market for drugs to treat it will be rather small. However, we believe that a deficiency of IGF-I production in the human body contributes to a number of diseases. It is well established that IGF-I is vital to normal human growth and metabolism. Therefore, we see the initial approval of the rhIGF-I/rhIGFBP-3 complex for GHIS as opening the door to potentially very large markets approaching the billion-dollar range.

This year we have generated additional positive results from a dose-ranging trial of the rhIGF-I/rhIGFBP-3 complex in adolescents with type 1 diabetes. This study conducted at the University of Cambridge in England demonstrated that administration of the rhIGF-I/rhIGFBP-3 complex restored IGF-I levels and increased insulin sensitivity in a dose-dependent manner. As we announced in January, these results have been submitted for presentation to the 63rd Scientific Sessions of the American Diabetes Association June 13-17 in New Orleans.

Opening a Door to the Diabetes Market

The market potential of the rhIGF-I/rhIGFBP-3 complex will be particularly large if the drug continues to show positive effects in the diabetic population and wins approval. Several million diabetics currently take insulin therapy in the U.S. alone, and still do not achieve adequate control of their blood glucose levels. Furthermore, this disease is still widely under-diagnosed and is approaching epidemic levels in our population. Research such as the University of Cambridge study suggests that the rhIGF-I/rhIGFBP-3 complex works alongside with insulin to give these patients adequate control of their blood sugar. In this scenario, it will have a market with literally millions of customers in the U.S. alone.

IGFBP-3: A Naturally Occurring Anti-Cancer Agent

The World Health Organization estimates that by 2020, the number of annual worldwide cancer related deaths is expected to reach 10 million. Although there are several drugs available to treat cancer, the use of many of these drugs produces significant side effects and decreases the quality of life of the patient.

Our proprietary product, rhIGFBP-3 is a protein that is normally found in our bloodstream. Several studies have demonstrated that cancer risk increases with decreasing blood levels of IGFBP-3.

In January we announced the results of studies conducted by our collaborators at McGill University in Montreal and the Bristol Royal Infirmary in England. These studies demonstrated that rhIGFBP-3 caused a significant reduction in cancer cell growth and a marked inhibition of tumor growth in animals. These results will be presented at the annual meetings of the American Association for Cancer Research, April 5-9, and the American Society of Clinical Oncology, May 31-June 3.

This program is very focused and is moving forward at a rapid pace and we are truly excited about the progress we have made in this area.

Big Pharma Partnerships on the Horizon

Even at this early stage of research, rhIGFBP-3 has drawn favorable attention. In just one week earlier this year, we talked with three of the world's leading pharmaceutical companies about this project. Our objective is to reach an agreement with a large drug company in the next one to two years to assist us in the development and marketing of this novel anti-cancer agent.

A New Focus on the Investor

I would also like to say a few words about a topic of direct interest to you, the value and liquidity of your Insmed shares. In January of this year, the Company received a Nasdaq Staff Determination that

it was subject to delisting from the Nasdaq National Market because it had failed to meet the minimum bid price requirement of \$1.00 per share. We have appealed the delisting, and further action is on hold pending the results of a Nasdaq hearing. In the meantime, we have been moving aggressively to build demand for Insmed shares and bring the price up to levels that reflect the Company's true potential.

As part of this effort to reach out to more investors, including potential as well as existing shareholders, we have retained Investor Relations International (IRI), a firm that specializes in helping high-quality companies such as Insmed, that face delisting threats. IRI has a strong track record of raising the profile and price of companies through marketing efforts focused on sophisticated investors seeking value in overlooked lower-priced stocks. With the help of IRI, we will shortly be communicating a series of new developments that will make our growth prospects clear and should make the investing public stand up and take notice. Please feel free to contact our investor relations representative at Insmed, Baxter Phillips, at 804-565-3041 should you have additional questions regarding our increased investor communications program.

Looking Ahead

When I last wrote to you, in November 2002, I noted that we were in a tough market environment but were focused on moving forward. The environment is still tough, but we're also more focused than ever. Our forward progress has more than justified the decisions we made last year about the Company's strategic direction. We are on the right course and are, if anything, ahead of schedule in getting to our chosen destination. For you, as a shareholder, this means the Company is firmly on a wealth-building track. I'm convinced that once we reach our targets of regulatory approval for the rhIGF-I/rhIGFBP-3 complex and a marketing partnership for rhIGFBP-3, the true value inherent in Insmed shares will be fully apparent to Wall Street.

Sincerely, Geoffrey Allan, Ph.D. Chairman and Chief Executive Officer Insmed Incorporated"

About Insmed Incorporated

Insmed Incorporated develops pharmaceutical products for the treatment of metabolic and endocrine diseases with unmet medical needs. The Company's most advanced product candidate, SomatoKine® (rhIGF-I/IGFBP-3), is a novel delivery composition of IGF-I that regulates essential metabolic and anabolic (growth promoting) processes, such as glucose uptake and tissue regeneration. Insmed is developing SomatoKine® for the treatment of Growth Hormone Insensitivity Syndrome (GHIS) and both type 1 and type 2 diabetes. The Company's second product candidate, rhIGFBP-3, is a recombinant protein that is being developed as an anticancer agent targeted towards the inhibition of solid tumor growth. For further information, please visit the company's corporate website: www.insmed.com

Certain statements included within this press release and Special Letter to Shareholders, which are not historical in nature, constitute forward-looking statements for the purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements regarding expected financial position, results of operations, cash flows, dividends, financing plans, business strategies, operating efficiencies or synergies, budgets, capital and other expenditures, competitive positions, growth opportunities for existing or proposed products or services, plans and objectives of management, demand for new pharmaceutical products, market trends in the pharmaceutical business, inflation and various economic and business trends. Such forward-looking statements are subject to numerous risks and uncertainties, including risks that product candidates may fail in the clinic or may not be successfully marketed, the Company may lack financial resources to complete development of product candidates, competing products may be more successful, demand for new pharmaceutical products may decrease, the biopharmaceutical industry may experience negative market trends and other risks detailed from time to time in the Company's filings with the Securities and Exchange Commission. As a result of these and other risks and uncertainties, actual results may differ materially from those described in this press release.

CONTACT: Investor Relations International Haris Tajyar, 818/981-5300 Fax: 818/981-5303 htajyar@irintl.com or Insmed Incorporated Baxter Phillips, III, 804/565-3041 Fax: 804/565-3510 bphillips@insmed.com