

# **RenaMed Biologics and Genzyme Announce Worldwide Collaboration To Advance Investigational Treatment for Acute Renal Failure**

*Date: September 28, 2005*

## **Data from Phase II study, completed by RenaMed, to be presented at ASN in November**

RenaMed Biologics, Inc. (RenaMed™), formerly Nephros Therapeutics, Inc., and Genzyme Corporation (NASDAQ: GENZ) announced today that they have entered into a strategic collaboration to jointly develop and commercialize RenaMed's Bio-Replacement Therapy™ for the treatment of acute renal failure. The product utilizes physiologically active renal epithelial cells, administered ex vivo in a hollow-fiber cartridge, intended to treat a sudden loss of kidney function with the ultimate goal of improving survival rate. Genzyme and RenaMed will undertake a collaborative effort to advance the product through clinical development, manufacturing, and commercialization on a worldwide basis.

The joint development and commercialization agreement calls for a 50/50 sharing of costs and profits. Genzyme will contribute funding of approximately \$23 million through the third quarter of 2006 to support the next stage of clinical development, and may make additional payments to RenaMed upon completion of certain developmental milestones. These additional payments could total \$20 million. Thereafter, the agreement calls for shared program funding, and for potential additional milestone payments by Genzyme at approval. Genzyme also made an equity investment in a recent private financing completed by RenaMed in June 2005.

"We are pleased to be working with RenaMed to explore the potential of this therapy in addressing acute renal failure, a serious condition which is not well addressed by current treatments," said John P. Butler, president, Genzyme Renal. "Genzyme is committed to comprehensively meeting the needs of patients with the full spectrum of renal disease through our current products and our growing pipeline."

"Genzyme is the ideal strategic partner for this program and the collaboration creates substantial value for RenaMed," said Greg Phelps, chairman and CEO, of RenaMed Biologics, Inc. "Genzyme is a leading medical innovator, has a strong commitment to advancing renal disease treatments, and has proven expertise in developing and commercializing similar biologic therapies. This partnership provides important direct financial value to RenaMed, funds a large part of the development of our first product, and allows us to retain half of the worldwide economics for this important opportunity. This is a very strong endorsement of RenaMed and our lead program."

RenaMed recently completed a Phase II trial of its Bio-Replacement Therapy in patients suffering from acute renal failure. Data from this trial are scheduled to be

presented at the annual American Society for Nephrology (ASN) meeting in November 2005.

### **About Acute Renal Failure (ARF)**

Acute renal failure is the sudden loss of kidney function which can lead to multi-organ failure, systemic inflammatory response syndrome (SIRS) and death. The most common causes of ARF are sepsis, blood loss during major surgery or injury, medications and contrast agents. ARF occurs in approximately 5 percent of all hospitalized patients (over 700,000 patients). Severe ARF, which represents approximately 20 percent of all ARF cases, is treated in the ICU with renal replacement therapy. These patients require extensive hospitalizations, and the mortality rate is 55-70 percent. Current therapy is limited to dialysis and hemofiltration; while these treatments address waste and fluid imbalances they do not treat all the consequences of kidney failure.

### **About RenaMed Biologics**

RenaMed Biologics, Inc. is the leading clinical stage company focused on the development of proprietary Bio-Replacement Therapies for critical diseases involving severely compromised kidney function. The company's lead product is intended to replace the cellular biologic functions of the kidney that are lost in patients with acute renal failure. The product utilizes physiologically active human renal epithelial cells, administered ex vivo in a hollow fiber cartridge. Renal Bio-Replacement Therapy works in conjunction with existing hemofiltration systems and is designed to provide comprehensive kidney function support. Renal Bio-Replacement Therapy is intended to dramatically improve the clinical outcomes and cost of care for patients suffering from ARF. For more information, please visit [www.renamedbiologics.com](http://www.renamedbiologics.com).

### **About Genzyme**

One of the world's leading biotechnology companies, Genzyme is dedicated to making a major positive impact on the lives of people with serious diseases. Founded in 1981, Genzyme has grown from a small start-up to a diversified enterprise with 2004 revenues of \$2.2 billion and more than 7,600 employees in locations spanning the globe. With many established products and services helping patients in more than 80 countries, Genzyme is a leader in the effort to develop and apply the most advanced technologies in the life sciences. The company's products and services are focused on rare inherited disorders, kidney disease, orthopaedics, cancer, transplant and immune diseases, and diagnostic testing. Genzyme's commitment to innovation continues today with a substantial development program focused on these fields as well as heart disease and other areas of unmet medical need. For more information, please visit [www.genzyme.com](http://www.genzyme.com).

### **RenaMed Statement:**

Certain statements in this news release may be considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Any or all of the forward-looking statements in this press release may turn out to be wrong. They can be affected by inaccurate assumptions RenaMed might make or by known or unknown risks and uncertainties, including, but not limited to: the early stage of product development; the ability to secure necessary patents;

uncertainties as to the future success of ongoing and planned clinical trials; and the unproven safety and efficacy of products under development. Consequently, no forward-looking statement can be guaranteed, and actual results may vary materially.

**Statement:**

This press release contains forward-looking statements, including the statements regarding: a potential treatment of acute renal failure and the design of the product candidate; potential funding and other payments under the collaboration agreement, including potential milestone payments; the anticipated presentation of clinical data and timing thereof; and estimates concerning the acute renal failure patient population. These statements are subject to risks and uncertainties that could cause actual results to differ materially from those projected in these forward-looking statements. These risks and uncertainties include, among others, the timing of and safety and efficacy results from clinical trials and decisions made by the companies based on these results; enrollment rates for clinical trials; the ability to manufacture sufficient quantities of product for development and commercialization activities and to do so in a timely and cost efficient manner; the content and timing of decisions by regulatory authorities related to the development and commercialization of the potential therapy; the competitive environment for therapies for acute renal failure; the actual timing of the presentation of clinical data; the accuracy of the companies' information concerning the acute renal failure patient population; and the risks and uncertainties described in reports filed by Genzyme with the Securities and Exchange Commission. Please see the disclosure under the heading "Factors Affecting Future Operating Results" in the Management's Discussion and Analysis of Financial Condition and Results of Operations section of Genzyme's Quarterly Report on Form 10-Q for the period ended June 30, 2005 for a more complete discussion of these and other risks and uncertainties. Genzyme cautions investors not to place substantial reliance on the forward-looking statements contained in this press release. These statements speak only as of the date of this press release, and Genzyme undertakes no obligation to update or revise the statements.

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