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**FOR IMMEDIATE RELEASE**

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**Repligen Announces Submission of New Drug Application for SecreFlo™ for Improved Pancreatic Imaging In Patients with Pancreatitis**

**WALTHAM, MA – December 21, 2011** – Repligen Corporation (NASDAQ: RGEN) announced today that it has submitted a New Drug Application (NDA) for SecreFlo™ (RG1068, synthetic human secretin) to improve detection of pancreatic duct abnormalities in combination with MRI in patients with pancreatitis. Structural abnormalities of the pancreatic ducts are a common cause of pancreatitis and may result in significant abdominal pain. In the pivotal Phase 3 study, the addition of SecreFlo™ to an MRI led to highly statistically significant improvements in sensitivity, image quality, ability to visualize the full length of the pancreatic ducts and diagnostic confidence when compared to MRI alone. A radiologist's ability to more confidently identify the presence or absence of pancreatic duct abnormalities has the potential to improve patient triage and care. The SecreFlo™ NDA was filed with a request for priority review of the application which, if granted, would result in a 6 month review period.

"I would like to express my deep appreciation to our employees, clinical investigators and consultants for their dedication and hard work to accomplish this pivotal milestone for the Company," stated Walter C. Herlihy, President and Chief Executive Officer of Repligen Corporation. "SecreFlo™ has the potential to be an important diagnostic tool to help radiologists and gastroenterologists confidently plan the best course of treatment for their patients."

"We are very pleased to have filed Repligen's first NDA and we look forward to continuing to work closely with the FDA to advance SecreFlo™ through the review process," stated Dr. Michael L. Hall, Chief Medical Officer at Repligen Corporation. "We currently expect to hear back from the FDA in 60 days if our application is accepted for review and whether FDA will grant the NDA priority review."

SecreFlo™ has previously been granted Fast Track Designation based on the need to develop safer, non-invasive alternatives to diagnostic ERCP, an invasive endoscopic procedure used to diagnose and treat diseases of the pancreas which is potentially harmful for patients. The product has also been granted Orphan Drug Designation which qualifies Repligen to receive seven years of marketing exclusivity in the United States if we are the first company to obtain approval for SecreFlo™ in combination with MRI. There are more than 300,000 MRI procedures conducted in the U.S. and Europe each year that could directly benefit from the addition of SecreFlo™. We plan to file a Marketing Authorization Application in Europe next quarter.

SecreFlo™, a synthetic version of the hormone secretin, stimulates secretion of watery fluid into the pancreatic ducts. When the pancreatic ducts are filled with water they are more effectively visualized

by MRI. The pivotal Phase 3 study was a multi-center, baseline controlled, single dose study in which 258 patients enrolled at 23 clinical sites within the U.S. and Canada received an MRI of the pancreas with and without SecreFlo™, and separately an ERCP. The MRI images were randomized and independently reviewed by three radiologists for evaluation of the presence or absence of 10 pre-specified pancreatic duct abnormalities, image quality, visualization of the main pancreatic duct and confidence in diagnostic findings. The analysis of the Phase 3 radiographic images was a “re-read” which was agreed to by the Food and Drug Administration and European Medicines Agency based on the determination that the original analysis was flawed and therefore inconclusive.

### **Pilot Study in Pancreatic Cancer**

A pilot study is currently being conducted to evaluate the ability of SecreFlo™ to improve detection and characterization of pancreatic cancer in combination with contrast-enhanced MRI and computed tomography (CT). This study harnesses the second biologic property of SecreFlo™ to increase blood flow to the tissues of the pancreas. Early detection of pancreatic cancer will increase the identification of patients who are candidates for surgery and may improve patient outcomes. We expect to release initial results from this study in the first half of 2012.

### **About Repligen Corporation**

Repligen Corporation is a leading supplier of critical biological products used to manufacture biologic drugs. Repligen also applies its expertise in biologic product development to SecreFlo™, a hormone which is being developed as a novel imaging agent for the diagnosis of a variety of pancreatic diseases. In addition, we have two early stage CNS rare disease programs which are advancing into Phase 1 clinical trials. Repligen’s corporate headquarters are located at 41 Seyon Street, Building #1, Suite 100, Waltham, MA 02453. Additional information may be requested at [www.repligen.com](http://www.repligen.com).

*This press release contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The forward-looking statements in this release do not constitute guarantees of future performance. Investors are cautioned that express or implied statements in this press release which are not strictly historical statements, including, without limitation, statements regarding, our expectations for and the potential timing of the FDA’s review of and response to the NDA, and plans and objectives for product development, regulatory approval, and product sales constitute forward-looking statements. Such forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from those anticipated, including, without limitation, risks associated with: the FDA’s evaluation of and response to our NDA filing, our compliance with all Food and Drug Administration and EMEA regulations, and other risks detailed in Repligen’s filings with the Securities and Exchange Commission. Repligen assumes no obligation to update any forward-looking information contained in this press release or with respect to the announcements described herein except as required by law.*