

## Profile Sheet

### Regeneron Pharmaceuticals, Inc.

Founded in 1988 on the principle that strong science will result in important new medicines, Regeneron (Nasdaq: REGN) is a fully integrated biopharmaceutical company that discovers, develops, manufactures, and commercializes important new medicines that address serious medical conditions. For more information, visit Regeneron at its worldwide website at [www.regeneron.com](http://www.regeneron.com).

### History of Industrial Operations and Product Supply (IOPS) – Rensselaer, New York

The Industrial Operations and Product Supply (IOPS) group is responsible for the manufacture, distribution, and quality assurance of all finished drug products (vials, syringes, devices, etc.) through both its own internal drug substance manufacturing capabilities and a network of contract partners. Regeneron purchased the Rensselaer, NY site for large-scale bioprocess manufacturing in early 1994.

In 2007, global healthcare leader Sanofi-Aventis and Regeneron entered into a collaboration with the stated goal of putting several Regeneron designed fully human monoclonal antibody drug candidates into clinical development each year. The antibody collaboration has driven tremendous operational growth for Regeneron. The traditional biopharmaceutical approach of manufacturing one or two products per plant would need to stretch to 15-30 bulk products and over 100 final product forms (SKUs) in less than five years. This could not be accomplished without unprecedented flexibility, high throughput, and seamless quality.

In response, the Rensselaer site has quickly adapted to produce as many as five different medical products simultaneously or more than 20 in a single year within a 400,000 sq. ft. facility on a 38 acre campus that employs over

500 technicians, managers, scientists, engineers, training and quality professionals. The site is now an industry leader in the use of disposable technology for bioprocessing and is among the top 15 biopharmaceutical facilities worldwide in terms of total cell culture capacity. New technologies and daily continuous improvements have become the strategic enablers of unprecedented operations growth.



### Our Products and Distribution Channels

Regeneron has one of the biopharmaceutical industry's most robust product pipelines with 13 drug candidates in clinical development as of February 2013, all of which were discovered in our own internal research labs. IOPS clinical products are distributed to medical facilities across the world.

In addition, Regeneron currently has three products approved for marketing by the United States Food & Drug Administration (FDA). The majority of sales are distributed by third party logistics providers to specialty pharmacies in the U.S., and in some cases, abroad:

- ARCALYST® (rilonacept) was introduced in February 2008 as the first approved drug for Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS), a group of rare autoimmune disorders



- EYLEA® (aflibercept) injection was launched in November 2011 for treatment of neovascular age-related macular degeneration (wet AMD), the leading cause of acquired blindness for people over the age of 65 in the United States and Europe. The first year launch has dramatically exceeded initial forecasts to become one of the top five drug launches in biopharmaceutical industry history with 2012 sales of \$828 million.
- ZALTRAP® (ziv-aflibercept) was approved in August 2012 as a treatment for patients with metastatic colorectal cancer (mCRC) that is resistant to or has progressed following an oxaliplatin-containing regimen.

## IOPS Achievements & Recognition

### Quality

- 94% reduction in Overdue Training Assignments, 2010-2012
- 92% reduction in Bioburden, 2009-2012
- 95% reduction in the Number of Unplanned Events per Lot, 2007-2010
- 36% increase in First Pass Yield of Manufacturing Records, 2010-2012

### Productivity

- 200% increase in Labor Productivity, 2007-2011
- Industry Pioneer in Disposable Technology using 2,000 L in-process mixing bags as early as 2008

### Delivery

- Launched EYLEA® within 1 business day of FDA approval
- 10x increase in Kilograms of Protein produced per year, 2008-2012
- 10x increase in Supply Chain Events per year, 2008-2012
- 40% reduction in EYLEA® Product Release Cycle Time, 2009-2011

- 40% reduction in Raw Material Release Cycle Time, 2011-2012

## Flexibility & Customer Satisfaction

- 92% decrease in Product Changeover Time, 2007-2011
- 8x increase in the Number of Different Product Forms Manufactured, 2008-2012
- 80% reduction in Document Workflow Cycle Time, 2008-2012
- 80% reduction in Stability Testing Cycle Time, 2010-2011
- 47% reduction in Bioburden Testing Cycle Time, 2010-2011
- 4 Regulatory Agency Inspections with Zero Observations, 2011-2012

## Environment, Health & Safety

- 15% increase in the number of employees recommending IOPS as a “Great Place to Work”, 2010-2012
- OSHA Recordable Rate nearly 70% less than the industry average, 2009-2012
- Center for Economic Growth (CEG) - Economic Award, 2009
- Hess C-Neutral Certificate for Carbon Reduction Program, 2010-2011
- Hess C-Neutral Certificate for Supporting Renewable Energy Sources through Green Purchases, 2011



**For more information please contact:**

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