For Immediate Release

Contacts:
Joel Ranck
202-832-0478
jranck@lincolnparkcom.com

Eric Langer, BioPlan Associates, Inc.
(301) 921-9074
elanger@bioplanassociates.com

34% of Biopharmaceutical Manufacturers Experiencing Capacity Constraints in 2005

September 27, 2005 (Washington, DC) – Despite an overall decrease in capacity utilization, and excess available industry capacity, according to a recently released study, 34% of biopharmaceutical developers are currently experiencing capacity constraints.

These results, from the *3rd Annual Report and Survey of Biopharmaceutical Manufacturing, Capacity and Production*, are part of a recently released annual industry survey by BioPlan Associates, Inc. This comprehensive, annual assessment of the state of worldwide biopharmaceutical manufacturing provides an on-going view of manufacturing capacity and production in this $80 billion global industry. The report details and analyzes industry benchmarks and trends: capacity utilization for production systems in mammalian, microbial, and yeast systems; factors causing capacity constraints; planned capacity expansions; outsourcing trends and factors; use of disposable manufacturing technologies; purification, and training benchmarks in the industry.

Coverage includes industry capacity, production trends, and benchmarks:

- In-depth analysis and summary of the key 2005 survey findings, trends and implications for industry-wide biomanufacturing capacity and biotherapeutic production
- Comparison of production by biotherapeutic developers and contract manufacturing organizations
- Current and future potential industry bottlenecks
- Trend analysis in this 3rd in a series of annual biopharmaceutical manufacturing industry evaluations
- Projected capacity bottlenecks, and how they might be resolved
- This edition includes the joint industry expertise from BioPlan Associates, and BioProcess Technology Consultants

Among the Key Findings:

- 34% of biotherapeutic developers and CMOs agree or strongly agree that their, *"organization is currently experiencing capacity constraints."*
- Nearly twice as many biotherapeutic developers are experiencing significant capacity constraints, compared to CMOs

- Average capacity utilization as % operating capacity for mammalian cell culture is 68.8%.
- The largest percentage of respondents, 39.6%, identified, "Lack of trained technical production staff" as a reason they will experience capacity constraints by 2010.
- A relatively low, 12% felt problems associated with downstream purification would cause capacity constraints by 2010.
- 24.3% felt that, to avoid capacity constraints, suppliers should "Develop cost-effective disposable/ single-use technologies."
- 52.8% of respondents who outsourced production felt that the most critical issue regarding outsourcing was that their CMO, *"must be able to establish a good working relationship."*

Areas covered:

- Overall industry capacity
- Capacity utilization at CMOs and biotherapeutic developers
- Current capacity, mammalian, microbial, yeast, and insect systems
- Capacity constraints, and expected capacity constraints by 2010
- Factors impacting future production
- Key areas to address to avoid capacity constraints
- Planned future capacity expansions by 2010
- Outsourcing, by production system
- Critical outsourcing issues when selecting a CMO
- Disposables and single-use systems, factors restricting use
- Current spending on disposables and single-use systems
- Downstream purification issues, problems involving microfiltration
- Training in biopharmaceutical manufacturing
- Suppliers to biopharmaceutical manufacturing, growth rates
- Customer expectations of suppliers

The study included responses from 187 biopharmaceutical developers and CMOs from 23 countries. It is published by BioPlan Associates, Inc., which has provided market assessment and market research to biopharmaceutical, biotechnology, and healthcare companies since1989. BioPlan Associates, Inc. 15200 Shady Grove Road, Suite 202, Rockville, MD 20850 Tel: 301-921-9074 (www.bioplanassociates.com).

###