

# Biomanufacturing Operations on Upswing

## Biosimilars and Pharma's Growing Interest in Biologics Keep Manufacturing Plants Humming

Amit Agarwal and Michael Omartian

**T**he bioproduction market has been posting solid growth for years driven by increasing sales of biological

products. Pharma's increasing reliance on biological molecules to fill its pipelines has boosted this trend.

Scintia forecasts that biologics, with sales of \$110 billion in 2008, will grow

more than 8% through 2014, reaching sales of over \$178 billion. We believe the bioproduction market will keep pace with the overall biologics market and grow from \$18 billion in 2008 to over \$27 billion in 2014.

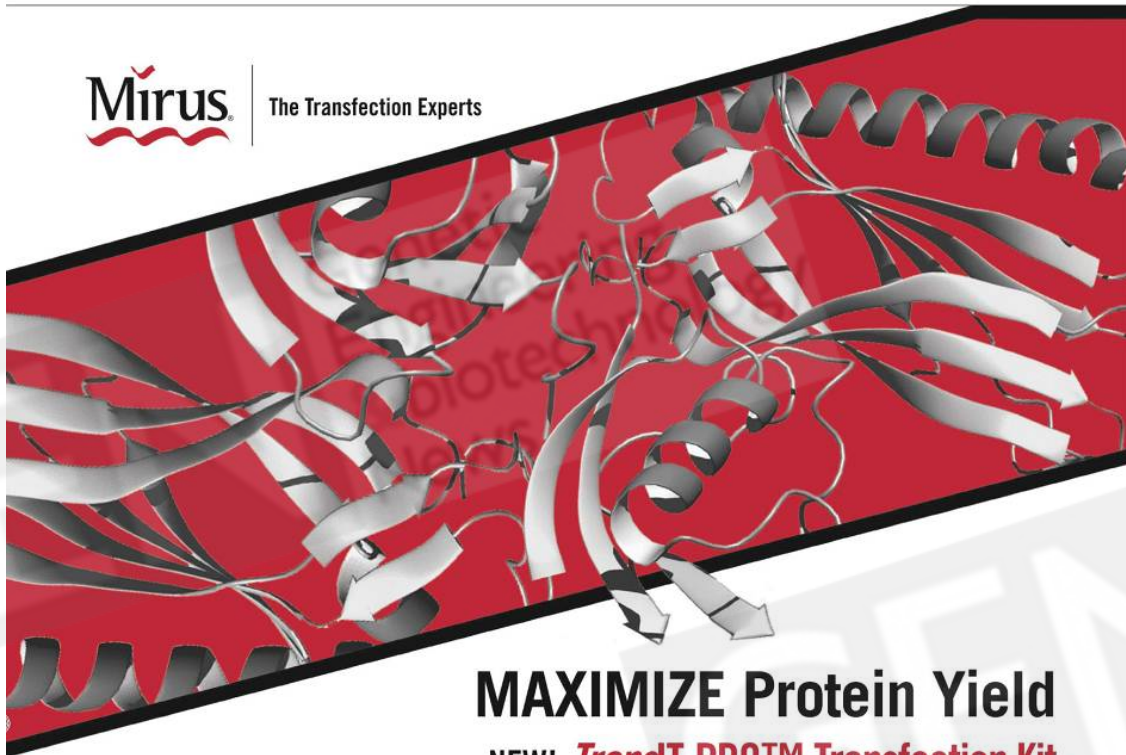
In contrast, chemically synthesized drugs are likely to see flat to declining revenues in the same time period.

In the past, most companies kept bio-

manufacturing in-house to control personnel, production schedules, intellectual property, quality issues, and to meet regulatory requirements. Outsourcing was used primarily by smaller companies lacking the financial and technical resources needed to manufacture their own products or by larger companies needing to supplement production capac-

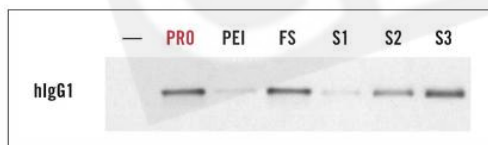
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Human IgG1 was produced by transient transfection using *TransIT-PRO*<sup>TM</sup>, linear PEI, or FreeStyle<sup>TM</sup> MAX transfection reagents. CHO-S cells were cultured in 20 ml of FreeStyle<sup>TM</sup> CHO Expression Medium in 125 ml shake flasks. Day 7 supernatants were analyzed by Western blot. Standard was 2-fold serially diluted (S3 = 6.3 mg/l).

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While the overall biologics market is predicted to grow from \$18 billion in 2008 to over \$27 billion in 2014, chemically synthesized therapeutics are expected to see flat-to-declining revenues in the same time period.

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ity for new, more sophisticated technologies. Even today, nearly 80% of bioproduction is performed in-house.

Going forward, however, we expect outsourcing to increase more than two-and-a-half-fold among both large and small players by 2013. The drivers for additional outsourcing are the increasing complexity of biologics and greater investment required for production.

As second-generation biologics such as monoclonal antibodies replace first-generation therapeutic proteins, sophisticated mammalian cell culture techniques are required. This type of production requires greater capacity and specially trained personnel, which makes outsourcing more attractive than in-house production.

Recognizing the market opportunity, contract manufacturing organizations (CMOs) will, by 2012, have augmented their mammalian cell culture production capacity by more than 90% over 2008 levels.

While many large drug developers will choose to outsource for economic reasons, smaller biotech companies will increasingly need CMOs to manufacture their products. In part, this is because, as a result of recent pharma mergers, there are fewer large pharma companies with which biotechs can partner for production.

In the past, most biologic alliance deals have transferred the manufacturing responsibility to the larger partner for later stage clinical trials and commercial quantities. These days, newly merged pharmaceutical companies have greater competition for finite manufacturing production capacity.

Amit Agarwal ([aagarwal@scintiaadu.com](mailto:aagarwal@scintiaadu.com)) is a partner, and Michael Omartian is a senior analyst at Scintia Advisors. Web: [www.scintiaadu.com](http://www.scintiaadu.com).