

News release

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Despite renewed growth in 2010, Biotech industry faces R&D challenges

Growing funding chasm between established players and early stage start ups

Kuala Lumpur, 17 June 2011 – The global biotechnology industry delivered solid top- and bottom-line growth in 2010, with the industry achieving aggregate profitability for the second year in a row.

Yet funding for research and development has grown increasingly scarce for the vast majority of firms in the sector, which tend to be pre-commercial stage companies that depend on years of funding to support drug development. This has placed new pressure on the traditional biotech business model, and may reshape how companies pursue R&D in the future, according to *Beyond borders: global biotechnology report 2011*, Ernst & Young's 25th annual report on the biotech industry.

"While the biotech industry's aggregate performance improved in 2010, there is now a widening gap between large, established companies and those at earlier stages for whom access to capital continues to be difficult," said Carol Wong, Ernst & Young Malaysia's Biotechnology and Healthcare Advisory Leader. "Biotech firms will need to adapt creatively to this environment by doing more with the funding that is available and by working from the earliest stages of development to demonstrate the potential value of their products to investors, payers and regulators."

Key results highlighted in the report include:

- ▶ **Record-breaking profitability:** Companies in the industry's established biotech centers of Australia, Canada, Europe and the US had a record-breaking aggregate net profit of US\$4.7 billion, a 30% increase from the previous year.

- ▶ **Aggregate funding rebounds:** Companies in Canada, Europe and the US raised US\$25 billion in 2010 — equaling the average for the four years before the global financial crisis.
- ▶ **Funding for innovation declines:** In the US, large debt financings by mature, profitable companies grew by 150% over 2009. Conversely, there was a 20% decline in the amount of “innovation capital” for the sector, defined as total funding minus large debt financings.
- ▶ **More skewed funding:** 82.6% of funding went to just 20% of US companies, up from 78.5% in 2009. The bottom 20% of companies raised 0.4% of funds, down from 0.6% in 2009.
- ▶ **Alliances remain strong, but not up-fronts:** The total potential value of strategic alliances remained strong, totaling more than US\$40 billion. However, up-front payments from partners to biotech companies dropped 37 percent to US\$3.1 billion.
- ▶ **Deal making slows:** Merger and acquisitions (M&As) involving European or US biotech firms dropped sharply from 58 deals in 2009 to 45 deals in 2010, while the aggregate value of these transactions remained relatively flat (after normalizing the 2009 numbers to exclude the mega-acquisition of Genentech).

Sustaining innovation

The *Beyond borders* report notes a confluence of challenges that will make it difficult for the industry to sustain its historical level of innovation. In addition to less available “innovation capital,” biotech companies face increased competition from other sectors for a smaller pool of venture capital.

Even with less capital available, companies are being asked to do more, as the process of discovering and developing drugs has become increasingly lengthy, expensive and risky. Drug approvals continue to be near historic lows and it is becoming increasingly common for regulators to request additional data for approval after a company has undertaken clinical studies, increasing the time, expense and risk of developing products.

Carol Wong also points out, “health care systems across the globe are under increasing pressure to rein in costs, creating continued downward pressure and uncertainty on the prices that innovators can secure for their products. This lack of sustainability in health care is also leading to a sweeping movement under which companies will need to move from simply producing new medicines to demonstrating improvements in health outcomes.”

The report identifies four complementary approaches for biotech companies to sustain innovation in this increasingly challenging environment:

1. **Prove it or lose it.** In an outcomes-driven ecosystem, companies will be under more pressure to prove that their products are truly differentiated. As a result, they will need to tailor their strategies from the early stages of development to demonstrate comparative effectiveness for regulators and be willing to engage in creative pricing approaches for payers including outcomes-based pricing approaches.
2. **Do more with less.** Companies will need to find new ways to conduct capital raising/deployment and R&D more efficiently. On the capital side, companies will need to be creative in raising, optimizing, preserving and investing scarce capital — from new ways of monetizing existing intellectual property to pursuing “virtual” company models to reduce fixed infrastructure. On the R&D side, targeted products for smaller populations can be more efficient, requiring smaller trials, less generic competition and fewer safety issues.
3. **Build new competencies.** To support the first two imperatives, managers will need different competencies: awareness of changing market dynamics (e.g., regulators, payers, pharma); project management discipline and performance measurement; the ability to measure value (e.g., analytical techniques) and communicate value; and the creativity to develop new models and approaches.
4. **Collaborate for coordinated action.** Sustaining innovation will also take changes that biotech companies cannot make alone, requiring coordinated action with other stakeholders. Examples include: encouraging a system of adaptive clinical trials and conditional drug approvals; realigning payment mechanisms around health outcomes; developing incentives to retain biotech investors; and working on transparency and access to build trust.

Key regional findings

United States

- ▶ Revenues of publicly traded biotechs grew to US\$61.6 billion, a 10% increase and equal to the growth rate of 2009 when adjusting for the acquisition of Genentech by Roche.
- ▶ Net income increased from about US\$3.7 billion in 2009 to US\$4.9 billion in 2010.
- ▶ M&A transactions involving US-based biotech companies turned in the lowest aggregate value in the last five years, totaling US\$12.6 billion.

- ▶ Total US industry funding reached US\$20.7 billion in 2010, up from US\$18 billion the previous year but driven largely by debt raised by profitable companies to refinance existing debt and for stock buybacks and acquisitions.
- ▶ Venture capital raised in the US totaled US\$4.4 billion in 2010, down slightly from the US\$4.6 billion reached in 2009.

Europe

- ▶ Revenues of European public biotechs grew 12% to €13 billion, a significant increase from the 2% growth seen in 2009.
- ▶ The combined net loss for biotechs in the region improved slightly, from €467 million in 2009 to €459 million in 2010.
- ▶ The value of M&A activity in Europe increased from €1.8 billion in 2009 to €3.5 billion in 2010.
- ▶ Total funding for the European industry was essentially unchanged from the previous year, with €2.9 billion raised.
- ▶ Venture capital raised in Europe totaled €1 billion, an increase from the €790 million raised in the previous year.

Canada/Australia

- ▶ The Canadian biotechnology industry raised more than US\$482 million in 2010, a decrease of US\$251 million compared to 2009. However, when removing the financing of US\$325 million from one company, the sector raised 18% more in 2010.
- ▶ Australian publicly traded biotech companies raised US\$129 million in 2010, less than half the amount raised in 2009.

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