

CRUNCH TIME

BIOPLAN SURVEY REVEALED

- Significant budgetary increases (greater than 20%) will be new facility construction (9.4%) and new capital equipment (8.4%)
- The budget data for outsourced biopharmaceutical manufacturing slowed to a 1.3% decline.

Finances, not technologies are shaping the future of biopharma, writes Eric S Langer, BioPlan Associates. With data gleaned from BioPlan's latest survey, he reveals the latest trends in manufacturing budgets.

Financial and funding worries top the list of fears at most global biopharmaceutical organisations. Rumours abound that corporate budgets will be squeezed or eliminated altogether. The Biotechnology Industry Organization published a report in late 2008 showing initial public offerings (IPOs) dropped 97% compared with 2007, and that 30% of all publicly traded biopharmaceutical companies have less than six months' cash on hand. If these fears result in budget contractions, then investors' expectations of mass consolidations and technology sell-offs may be realistic. Further, if development and production budgets are constrained, this will affect future drug innovation, and, thereby, company value.

Survey findings

To measure the impact on company value, BioPlan Associates included issues regarding budget shifts in 2009 in its survey of biopharmaceutical manufacturers and contract manufacturing organisations (CMOs). The results, included in BioPlan Associates' 6th Annual Report and Survey of Biopharmaceutical Manufacturing, provide a

Contributor profile



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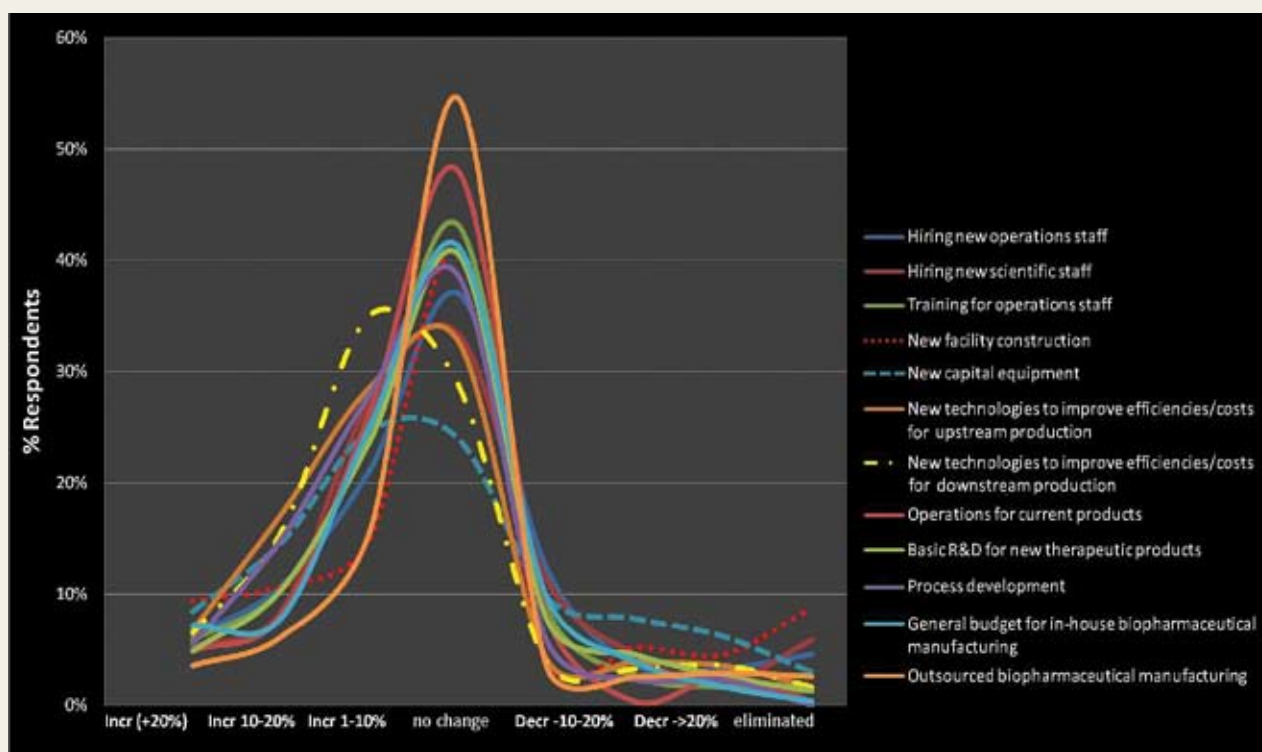
global perspective from executives at 443 biopharmaceutical companies. This year's survey elicited data on ten broad aspects of production and associated trends in 35 countries. One of the key areas of interest concerned budget issues, and the extent to which these budgets are being squeezed.

Respondents were asked to 'Consider the current economic situation today. By about what percent do you believe your budget and funding will change over the next 12 months?' (Figure 1, overleaf). Surprisingly, this figure shows that while there are some shifts in budgets, most respondents (of January and February 2009) indicate that budget areas are likely to remain unchanged over the next 12 months, which is good news for departments and their vendors. The bad news for some vendors is that these budgets will likely be spent more carefully than they have been.

While healthcare in general tends to have a certain degree of insulation from economic troubles, there has been increasing caution among decision-makers to commit to a project or purchase.

'As a contract manufacturer, we have found that our biopharmaceutical clients continue to have the budget for projects,' says Dr Robert Broeze, president and CEO at Laureate Pharma Princeton, NJ. 'However, they are being more deliberate in their decision-making. In the past, the need to get a project completed was the primary driving force. Today, that's been peppered with a healthy dose of financial analysis.'

Figure 1: Current economic situation: by what % will your budget/funding change over next 12 months? (Biomanufacturers and CMOs, n=308.)



Canny perspective

This caution in decision-making will likely result in delayed purchasing and more uncertainty. The decline in global economies is now beginning to express itself in a wait-and-see attitude among buyers. Vendors are beginning to experience this as their buyers try to determine what is going to happen in the economy. This could also be a self-fulfilling prophesy.

Despite BioPlan's data suggesting a relatively even ride over the next year, some vendors are concerned. A serious aspect is that all budgets are subject to change and could be adjusted mid-year. Some vendors are cutting prices, and this could get worse for weaker competitors. Given the caution in the industry, the question many vendors are asking is how much longer it might take to convert 'discussions' into contracts.

'We see a great deal of uncertainty in our pharmaceutical clients,' says Dr Richard Donaldson, VP Chemical Development at Ricerca, a drug development company in Concord, OH. 'We witnessed a fall-off in new proposals throughout the fourth quarter 2008. So far, in first quarter 2009, requests for proposals have returned to levels we enjoyed last year at this time.'

Donaldson believes that the fundamentals of the contract outsourcing business will remain strong over the next five years. 'For 2009, it will be a year of client retention, consolidation and no growth,' he says.

Budgets most affected

Many vendors had been experiencing the effects of the downturn as early as June 2008. However, some have found the impact increasing over the past six to nine months (pre-February 2009). So when areas of greatest change in biopharma budgets were examined, BioPlan wanted to assess where these effects, positive and negative, are greatest. Process development was found to be the area where the greatest budgetary increases are likely (an average of 3.8%). Following is budgetary increases for 'new technologies to improve efficiencies for downstream production' (2.5%).

From the biomanufacturers' perspective, the financial situation is creating a leaner purchasing environment. 'The process we use to acquire new process equipment has not changed,' says Adam Goldstein, senior manager, Clinical Operations Purification Development at Genentech in Oceanside, CA. 'However, we are evaluating our manufacturing strategies more closely as a result of the global financial situation. This means we're being more careful in scrutinising potentially less critical elements in our RFPs, and ensuring that what we acquire is vital to the production process. This could mean delaying equipment purchases, doing more thorough analysis on the cost implications of new capital or just negotiating harder with vendors.'²

Not unexpectedly, the areas of greatest budgetary decrease are in new facility construction (down 6.2%). Interestingly, the

change in budgets for new capital equipment appears to be relatively flat (down 0.6%); however, Figure 1 shows a bimodal distribution, where some companies are planning to decrease budgets, while others are planning increases. This suggests that decisions on capital equipment expenditures at some companies could have been made months or years before.

Similarly, while 8.8% of companies planned to eliminate their 'new facilities' budget, 9.4% planned large increases (more than 20%). So, expenditures on long-term items may be dependent on budget cycles and when construction decisions were made. Other areas targeted for budget elimination included hiring of new scientific staff (5.8% of respondents) and hiring of operations staff (4.5% of respondents).

Vendor sales growth

To evaluate the impact of the current economic situation on vendors to this industry, 160 vendors were asked about their average annual growth rates. This establishes a 'derived demand' for products used by biopharma, which in turn, provides insight into the growth rate of end users.

The study found relatively robust growth for 2008. On average, vendors reported an annual growth rate of 13.2%. This represents a slight flattening of growth from the previous two years (Figure 2) from sales in equipment and instrumentation, raw materials, and consumables and services (such as engineering, validation and CRO). This year, each of these segments hovered around 12-14%, while in 2007, equipment and instrumentation sales had grown by over 21%.

While it is possible current growth rates to the **healthcare?** industry are declining, this data shows that biopharma remains stronger than others segments into which these vendors may also be selling.

Summary

Economically, healthcare segments, including biotech, have generally enjoyed a certain degree of insulation from economic troubles – an aging population, long product cycles, the urgent need to treat diseases for which no other therapies are available and more risk-tolerant investors add to the segment's ability to grow in times of economic downturn.

Despite this, the current economic situation is having an impact. There has been increasing caution among decision-makers to commit to projects and purchases. Some companies foreseeing lost sales are attempting to generate business by reducing prices. Some buyers are expecting price declines, and are waiting to make necessary purchases (a classic formula for a deflationary economic situation). While purchasing agents

SURVEY METHODOLOGY

This sixth in the series of annual evaluations by BioPlan Associates, Inc yields a composite view and trend analysis from 443 responsible individuals at biopharmaceutical manufacturers and CMOs in 35 countries. The methodology also encompassed an additional 160 direct suppliers of materials, services and equipment to this industry. This year's survey covers issues such as current capacity, future capacity

constraints, expansions, use of disposables, trends and budgets in disposables, trends in downstream purification, quality management and control, hiring issues, employment and training. The quantitative trend analysis provides details and comparisons of production by biotherapeutic developers and CMOs. It also evaluates trends over time and assesses differences in the world's major markets in the US and Europe.

may welcome the prospect of falling prices, widescale price declines will accelerate the economic downturn. The fear of deflation was one reason the US Federal Reserve cut interest rates to near-zero in January. The decision to slash interest rates to below 0.25% was due to concern of a deeper economic catastrophe, according to one US economic forecaster.

'The message is one of fear: of a deep recession and of a debilitating deflationary spiral that would capsize a debt-laden economy,' says Joshua Shapiro, chief US economist at MFR Inc, New York.

However, biotechs continue to demonstrate an ability to secure capital and move forward. As recently as the third quarter 2008, some biotechs were still securing venture capital. According to financial adviser Moneytree, the San Francisco Bay Area generated \$555 million in 26 deals during the third quarter of 2008, almost double that in 2007. Although across the US, and across all industries, venture capital (VC) deals appeared to be running 7% below the number of deals generated in 2007, in comparison, IPOs have almost dried up.

Merger and acquisition activities have grown as the market for IPOs has shrunk over the past two years. It is likely that these will continue as larger companies find good science investments at later-stage companies, which may be less risky. It's also likely that earlier stage companies will need compelling science if they are to attract necessary capital. Valuations, as a result, will be down, which will significantly affect how budgets are spent at smaller companies.

Some analysts are recommending that startup life-sciences companies look overseas for VCs, investors, partners and capital. Perhaps some of this investment may come from the Middle East and Asia. As these regions mature, more organisations will likely become interested in investment. In addition, VC firms will likely hold onto their companies longer. As a result, they will be asking many to reduce cost and to review their cash situations. For many companies, this will require flexibility and a different approach to R&D spending.

However, if the economic situation worsens, partnering activities are likely to grow when traditional sources for financing dry up. Given the current financial markets, many smaller biotechs realise that survival will depend on developing partnerships. **WPF**

Figure 2. Supplier segment to manufacturers of biopharmaceuticals (average annual vendor sales growth rate, 2006-08).

