PROFITABLE BIOTECH COMPANIES Predicted TO DOUBLE in Next Few Years

Therapeutic proteins and therapeutic antibodies collectively comprise almost 75% of biotech drugs currently on the market. Protein drugs also represent one of the fastest-growth areas, with sales expected to reach $40 billion in 2003.

According to a review from Business Communications Company Inc. (BCC) titled, Biotechnology in Healthcare: Product and Market Review, protein-based therapeutics are expected to drive rapid growth in the industry during the next decade.

In 2002, the Food and Drug Administration approved 35 biotechnology-based drugs. According to BCC analysis, there are more than 40 biologic products (antibodies and non-antibody recombinant proteins) currently in Phase III clinical trials and about 60 in Phase II trials.

This research is expected to lead to more than 35 new products reaching the market during the next four to six years, according to BCC estimates.

The number of new biotech products expected to enter the market is projected to double the number of profitable biopharmaceutical companies by mid-decade.

BCC also predicts that sales of protein drugs will continue to grow faster than pharmaceutical's overall historic growth rate of 8% annually. The market for protein drugs is projected to grow at an average annual rate of 12.2% from 2003 through 2008 — reaching nearly $71 billion. Several important new drugs should receive FDA approval, and previously introduced biologics will continue to strip market share from older, less effective therapies.

Most notably, there are monoclonal antibodies in the last stages of clinical trials for the treatment of autoimmune disease and cancer that are expected to be blockbusters, BCC says.

Although the growth of protein drugs is expected to be healthy, industry participants in the market also face serious and new challenges, including lawmakers threatening to introduce bills governing the introduction of generic drugs, and the loss of patent protection for several leading protein drugs.

DRUG-DISCOVERY CRO/OUTSOURCING Relationships Seek to Improve PRODUCTIVITY

Pharmaceutical and biotechnology companies have begun to form strategic relationships with drug-discovery contract research companies, with the goal of alleviating some pressure to improve research productivity.

Analysis from Frost & Sullivan reveals that management of the drug-discovery process and technologies provides several market opportunities for drug-discovery companies.

These relationships have been found to be more significant with biotech companies working on technologies that complement the research done by pharma companies.

But, global outsourcing companies are bogged down by macroeconomic factors that hinder their efforts to collaborate with their drug-discovery partners. Understanding the needs of global pharmaceutical and biotechnology companies and developing infrastructure as well as technologies to suit them could involve prohibitive investments, Frost & Sullivan experts believe. Drug-discovery CROs that can overcome these challenges are likely to win outsourcing contracts for entire portfolios of drug-discovery requirements.

The workforce, past alliances, and domain expertise have been found to be critical factors in a sponsor's choice of a drug-discovery partner. The report, Drug Discovery Contract Research Markets: Profiles of the Top 50 Global Outsourcers, also finds that new entrant drug-discovery CROs have to flaunt the technical skill sets of their employees and the credentials of scientists employed.

Smaller biotechnology and pharmaceutical companies will find the passage into the drug-discovery contract-research value chain easier at the chemistry and screening end because these areas involve less infrastructure and technology investment. But drug-discovery CROs prefer to research a proprietary technology and team up with global outsourcers rather than work on chemistry-related contract research since the work on proprietary technology results in greater revenue.

Pharmaceutical COST-EFFECTIVENESS Evaluations May Be Based on Faulty ASSUMPTIONS

Faulty assumptions in econOMIC MODELS USED TO EVALUATE THE COST-EFFECTIVENESS OF Prescription drugs may incorrectly favor more expensive drugs, according to a study by Express Scripts. For example, Express Scripts' researchers set out to examine whether pharmacoeconomic models of *Helicobacter pylori* eradication direct decision makers to consider cost-effective therapeutic choices.

The researchers looked at treatments that combined antibiotics with either a generic bismuth drug

DRUG-DISCOVERY CONTRACT RESEARCH MARKETS: IMPACT OF TOP INDUSTRY CHALLENGES (GLOBAL) 2002-2010

Challenge	Years 1-2	3-4	5-8
Establishing Credibility	High	High	High
Developing Strategic Fit Between Outsourcers and CROs	High	High	High
Moving up the Value Chain	High	Medium	Medium

Source: Frost & Sullivan, San Antonio. For more information, visit frost.com.

DRUG-DISCOVERY CONTRACT RESEARCH MARKETS: RANKED IN ORDEROFIMPACT (GLOBAL) 2002-2010

Rank	Driver	Years 1-2	3-4	5-6
1	Global R&D Productivity	High	Medium	Medium
2	Cost Advantages Leading to Growth in Outsourcing	High	Medium	Low
3	Increase in Time and Labor-Intensive R&D Processes	High	Low	Low

Source: Frost & Sullivan, San Antonio. For more information, visit frost.com.

or a more expensive branded proton pump inhibitor. The researchers first replicated and then validated two models, replacing model assumptions with empirical data from a multipayer claims database.

The researchers assessed treatment of 435 commercially insured U.S. patients treated with bismuth-metronidazole tetracycline (BMT), proton pump inhibitor (PPI) clarithromycin, or PPI amoxicillin.

Patients met more than one of the clinical requirements, including ulcer disease, gastritis/duodenitis, stomach function disorder, abdominal pain, *H.pylori* infection, endoscopy, or *H.pylori* assay. Sensitivity analyses included only patients with ulcer diagnosis or gastrointestinal specialist care.

Outcome measures were rates of eradication retreatment; number of office visits, hospitalizations, endoscopies, and antisecretory medication; and cost per effectively treated (nonretreated) patient.

Model results overstated the cost-effectiveness of PPI-clarithromycin and underestimated the cost-effectiveness of BMT. Before empirical adjustment, costs per effectively treated patient were $1,001, $980, and $1,730 for BMT, PPI-clarithromycin, and PPI-amoxicillin, respectively.

Estimates after adjustment were $852 for BMT, $1,118 for PPI-clarithromycin, and $1,131 for PPI-amoxicillin. Key model assumptions that proved retrospectively incorrect were largely unsupported by either empirical evidence or systematic assessment of expert opinion.

The researchers' conclusions were that organizations with access to medical and pharmacy claims databases should test key assumptions of influential models to determine their validity and that journal peer-review processes should pay particular attention to the basis of model assumptions.

Leading Disease States Served by Specialty Pharmacies and their Corresponding Treatments

Disease	Leading Treatment(s)	Estimated Annual Specialty Drug Cost per Patient
Cancer	Herceptin, Rituxan, Mylotarg, Campath, Iressa, Novantrone	$10,000
Crohn's Disease	Remicade	$16,000
Gaucher Disease	Cerezyme	$242,000
Growth Hormone Deficiency	Humatrope, Nutropin	$18,000
Hemophilia	Clotting Factor	$125,000
Hepatitis C	Pegylated Intron (interferon)+ Rebetol (ribavirin), Pegasys	$30,000
HIV/AIDS	Combivir, Epivir, Zerit, Crixivan, Sustiva, Viracept, Fuzeon	$15,000
Immune Disorders	IVIG	$40,000
Infertility	Humegon, Pergonal, Repronex, Metrodin, Fertinex, Follistim, Gonal-F, Lupron	$15,000 (1)
Multiple Sclerosis	Betaseron, Avonex, Rebif, Copaxone, Novantrone	$15,000
Pulmonary Hypertension	Flolan, Tracleer, Remodulin	$65,000
RSV (Respiratory Syncytial Virus)	Synagis	$8,000
Rheumatoid Arthritis	Remicade, Enbrel, Humira	$15,000

(1) Estimated average cost per cycle is $4,000 to $7,000. Patients may engage in multiple treatment cycles each year.
Source: Raymond James & Associates Equity Research, St. Petersburg, Fla., Specialty Drug Distribution, July 2002, and AdvancePCS, Irving, Texas, SpecialtyRx pharmacy. For more information, visit rjcapitalmarkets.com or advancepcs.com.

ADVANCEPCS Report Reveals HIDDEN COST of Biotech Therapies and Injectable Drugs

A report by AdvancePCS reveals that specialty pharmaceutical drugs are increasing healthcare costs dramatically, but the financial impact remains hidden to many of the health plans paying for the products. Although specialty pharmaceuticals — biotech therapies and injectables — are used to treat small numbers of patients with rare, chronic conditions, the expense accounts for a disproportionate share of total healthcare costs. For example, the report notes that patients with chronic diseases requiring specialty drug care comprise just 1% to 5% of a typical health plan's population, yet account for 25% to 50% of the plan's total medical costs.

The AdvancePCS report states that specialty pharmaceuticals account for $22 billion of the national drug spend, representing 15% of the $150 billion pharmaceutical market. With annual costs per patient typically ranging from $10,000 to $1 million, specialty drug expenditures are projected to continue to accelerate at rates exceeding 20% annually, more than the 14% annual growth projection for the entire pharmaceutical market. The financial impact of this rapidly growing segment is compounded by the difficulties in monitoring, handling, and administering these unique drugs.

Most specialty drugs must be dispensed by the healthcare professional or require patient education for self-administration.

As a result, specialty drugs often are billed through the medical benefit as opposed to the pharmacy benefit.

Follow up

ADVANCEPCS, Irving, Texas, is an independent provider of health-improvement services, touching the lives of more than 75 million health-plan members and managing about $28 billion in annual prescription drug spending. For more information, visit advancepcs.com.

BUSINESS COMMUNICATIONS COMPANY INC., Norwalk, Conn., studies major market, economic, and technological developments that characterize industry. For more information, visit buscom.com.

EXPRESS SCRIPTS, St. Louis, provides integrated PBM services, including network pharmacy claims processing, mail-pharmacy services, benefit-design consultation, drug-utilization review, formulary management, disease management, medical and drug data analysis services, and medical-information management service. For more information, visit express-scripts.com.

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