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Funding for biotech up in 2005

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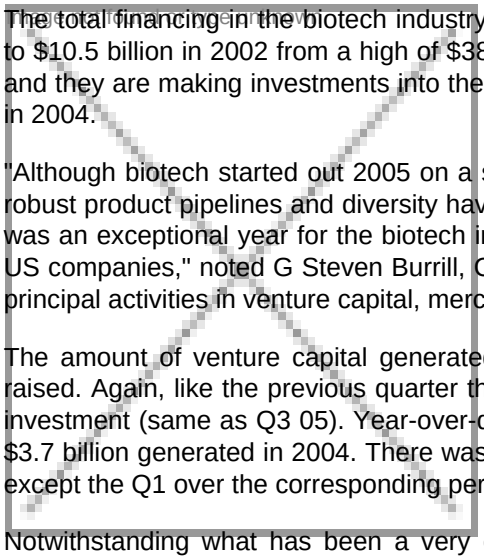
Funding for biotech up in 2005

The global biotechnology industry has attracted large investments in the last few years with a 12 percent increase in 2005.

A study by Irving Levin Associates, a research firm based in Norwalk, Connecticut, has revealed that venture capitalists increasingly placed their bets on healthcare and biotech during 2005. The number of dollars was up five percent from 2004 to $7.3 billion, and there were a larger number of deals.

The study noted that the biopharmaceutical sector scored $2.1 billion, based on 102 deals with disclosed prices. The medical device sector and the traditional pharmaceutical sector each accounted for approximately $1.4 billion in venture capital, although there were more deals in medical devices than pharma. "Corporate investors made up some of the VC funding in healthcare during 2005. The IPO market may be lackluster, but big pharma is hungry for novel, proprietary therapies," said Stephen M Monroe, senior editor, Irving Levin Associates.

Despite the increase in deals, the median investment size was slightly smaller. For the year ended December 31, the median investment size was $11.3 million, down from $12 million during 2004. However, the median investment size increased by nearly 19 percent during 2005, compared with 2003. According to the report from Irving Levin Associates, the top players in healthcare VC are also shifting. MPM Capital led the top 10 venture firms by number of investments during 2005, having participated in 17 investments, followed by Alta Partners, Domain Associates and HealthCap, each with 15 investments, according to the report from Irving Levin Associates.



The total financing in the biotech industry, according to Bio World, in the last few years has been on the rise after it dropped to $10.5 billion in 2002 from a high of $38 billion in 2000. After this slump, again the industry has been in the eye of investors and they are making investments into the industry. The industry saw a total financing of $16.9 billion in 2003 and $20.8 billion in 2004.

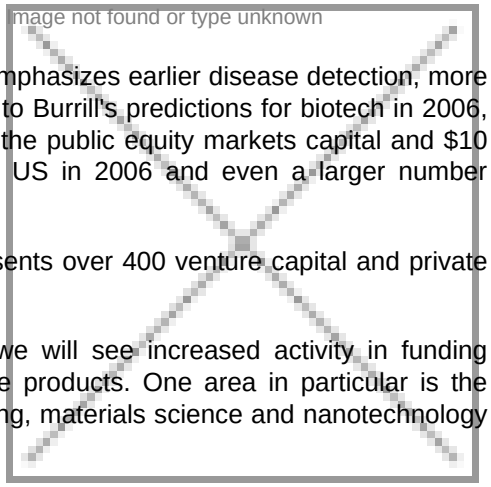
"Although biotech started out 2005 on a slow note, it has seen positive increases since April. But, large cap companies with robust product pipelines and diversity have led biotech's success in the capital markets. By any performance measures, 2005 was an exceptional year for the biotech industry in terms of financings and partnering, bringing in a record $35 billion for the US companies," noted G Steven Burrill, CEO of Burrill & Company, a San Francisco-based global leader in life sciences with principal activities in venture capital, merchant banking and media.

The amount of venture capital generated by biotechs was up a modest eight percent compared to the Q3 2005 amount raised. Again, like the previous quarter there were plenty of deals that got done - 47 in fact, averaging about $20 million per investment (same as Q3 05). Year-over-date, the venture capital raised $3.5 billion in 2005 that was slightly on lower side of $3.7 billion generated in 2004. There was a gradual increase in the flow of investments into the industry each quarter in 2005 except the Q1 over the corresponding period the previous year.

Notwithstanding what has been a very challenging year economically and a very tough equity market, $17.3 billion was invested in the biotech sector in 2005 with all forms of funding finding takers and $17 billion in partnering capital in 2005. US-based biotech funds raised approximately $7 billion in 2005 (up from $5 billion in 2004) and life science investments by the venture capital community have increased from 2004. Private Investments in Public Entities (PIPEs) and Secondaries remained flat while IPOs and debt financing fell short of the comparable 2004 totals. Public financings overall also remained flat.

The increase in the growth of biotech internationally continued to take place in 2005 with China and India emerging with the potential to become biotech "powerhouses" in the next five to ten years.

The prediction for 2006



Biotechnology will continue to fuel a major transformation in healthcare - one that emphasizes earlier disease detection, more targeted treatments, and adjunctive support through enhanced nutrition. According to Burrill's predictions for biotech in 2006, the industry will raise over $35 billion in 2006, with approximately $25 billion from the public equity markets capital and $10 billion in partnering. A reasonably robust public equity IPO market - 30+ in the US in 2006 and even a larger number internationally.

Even the members of the National Venture Capital Association (NVCA) that represents over 400 venture capital and private equity firms in US, expressed their optimism on life sciences industry.

Patrick Ennis, managing director, ARCH Venture Partners observed, "In 2006 we will see increased activity in funding interdisciplinary start-ups as markets converge and customers demand innovative products. One area in particular is the interface between Life Sciences and Information Technology. Advances in computing, materials science and nanotechnology are enabling life changing breakthroughs in the healthcare industry".

Sharing similar views Deepak Kamra, general partner, Canaan Partners noted, "In 2006, the rewards will come for the more adventurous venture firms. Silicon Valley and the US markets still have good opportunities but do not promise the kind of excitement and rapid market expansion that India, China, Europe and Israel do. The US venture industry will accelerate its advance towards worldwide penetration for it to get better returns. Bangalore and Shanghai beckon with lots of risk but higher returns."

EMEA issues guidelines for registering biosimilars

The European Medicines Agency (EMEA), a decentralized body of the European Union headquartered in London, has

adopted guidelines on similar biological medicinal products.

The EMEA felt the need to issue guidance on this emerging issue as the applicants of similar biological medicinal products, who have applied for scientific advice from the Committee for Medicinal Products for Human Use (CHMP), expressed the need for specific guidance. The advances as well as the limitations of methods and techniques available today for the full characterization of such medicinal products have already prompted the CHMP to initiate a number of specific guidelines relevant to quality, non-clinical and clinical issues, to be addressed within the development programs of similar biological medicinal products.

The CHMP issues specific guidelines concerning the scientific data to be provided to substantiate the claim of similarity used as the basis for a Marketing Authorization Application (MAA) for any biological medicinal product (see Section 3.2.1.1, Part I, Annex I to Directive 2001/83/EC), eg: medicinal products containing biotechnology derived proteins as active substance, immunologicals such as vaccines, blood-derived products and monoclonal antibodies. The CHMP guidelines addressing the planning and conduct of comparability studies should always be read in conjunction with relevant legislative and administrative provisions in force in the EU.

The guidelines will help to introduce the concept of similar biological medicinal products, outline the basic principles to be applied and will provide applicants with a 'user guide', showing where to find relevant scientific information in the various CHMP guidelines, in order to substantiate the claim of similarity.

The CHMP has or may develop additional guidance documents addressing both the quality, non-clinical and clinical aspects for the development of similar biological medicinal products. Product-class specific guidance documents on pre-clinical and clinical studies to be conducted for the development of defined similar biological medicinal products will be made progressively available.

It should be noted that the scientific principles described in quality and non-clinical/clinical guidelines applicable to similar biological medicinal products containing biotechnology-derived proteins, as active substance may also be useful when considering non biotechnology-derived biological medicinal products.

Guidelines applicable to all similar biological medicinal products

While developing a similar biological medicinal product and carrying out the comparability exercise to demonstrate that this product is similar to another one already authorized in the EU, some existing CHMP guidelines may be relevant and should therefore be taken into account. For example:

- CPMP/BWP/328/99 Development Pharmaceutics for Biotechnological and Biological Products - Annex to Note for Guidance on Development Pharmaceutics (CPMP/QWP/155/96)
- Topic Q5C, Step 4 Note for Guidance on Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products (CPMP/ICH/138/95 - adopted Dec. 95)
- Topic Q6B, Step 4 Note For Guidance on Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products (CPMP/ICH/365/96 - Adopted March 99)
- ICH Topic S6, Step 4 Note for Preclinical Safety Evaluation of Biotechnology-Derived Products (CPMP/ICH/302/95 - adopted Sept. 97)

Biological Products containing Biotechnology-Derived Proteins as active substance

- In addition to this guideline, the CHMP is developing further guidelines on Similar Biological Medicinal Products (see CHMP monthly report, May 2005), eg:
- Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substances: Quality issues (EMEA/CHMP/BWP/49348/2005).

- Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues (EMEA/CHMP/42832/2005).

- Annex guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues-guidance on biosimilar medicinal products containing recombinant human insulin (EMEA/CHMP/32775/2005).

- Annex guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues-guidance on biosimilar medicinal products containing somatropin (EMEA/CHMP/94528/2005).

Additional product-class specific annexes are envisaged to provide guidance for products containing rG-CSF and epoetin and others as the need arises and will be made available in the EMEA website.

The current guidelines, relevant to comparability and similar biological medicinal products will be complemented by the above guidelines for aspects concerning similar biological medicinal products.

In addition, the quality guideline (CPMP/BWP/3207/00) will be replaced by ICH Q5E for aspects concerning quality changes to the manufacturing processes of biotechnological/biological products by:

- The "Guideline on comparability of medicinal products containing biotechnology-derived proteins as active substance â€“ Quality issues (CPMP/BWP/3207/00)".

- The "Guideline on comparability of medicinal products containing biotechnology-derived proteins as active substance - Non-clinical and clinical issues (CPMP/Ad-Hoc group on (non)-clinical comparability of biotechnology products/3097/02)".

Immunologicals such as vaccines and allergens

Vaccines are complex biological medicinal products. Currently, it seems unlikely that these products may be thoroughly characterized at a molecular level. Consequently, vaccines have to be considered on a case-by-case basis. Applicants should take appropriate advice from the EU Regulatory Authorities.

Allergen products are similarly complex and the same approach should be taken.

In addition to the CHMP guidelines applicable to all biological medicinal products, the following guidelines should be taken into consideration:

The CHMP guidelines addressing the quality, non-clinical and clinical aspects of immunological such as vaccines are as follows:

- CPMP/BWP/477/97 Note for guidance on Pharmaceutical and Biological Aspects of Combined Vaccines, (CPMP adopted July 1998).

- CPMP/BWP/2490/00 Note for Guidance on Cell Culture Inactivated Influenza Vaccines (Adopted by CPMP January 2002) - Annex to Note for Guidance on Harmonisation of requirements for Influenza Vaccines CPMP/BWP/214/96

- CPMP/BWP/214/96 Note for Guidance on Harmonisation of Requirements for Influenza Vaccines (CPMP adopted March 97)

- CPMP/BWP/2289/01 Points to Consider on the Development of Live Attenuated Influenza Vaccines (CPMP Adopted,

February 2003)

- CPMP/BWP/243/96 Note for Guidance on Allergen Products (CPMP adopted March.96)
- CPMP/EWP/463/97 Note for guidance on Clinical Evaluation of New Vaccines (CPMP adopted 19 May 1999)

Blood or plasma-derived products and their recombinant alternatives

The BWP and BPWG guidelines listed below should be taken into consideration, in addition to the applicable CHMP guidelines (Section 3.1 and 3.2).

In view of the complex and variable physico-chemical, biological and functional characteristics of the products listed in the BPWG guidelines mentioned below, it will not be acceptable to submit a reduced clinical dossier when claiming similarity to a reference medicinal product. As a result, applications for such similar products will still need to satisfy the safety and efficacy requirements described in these BPWG guidelines for "new products".

For quality issues:

- CPMP/BWP/269/95 Rev.3 Note for guidance on Plasma -Derived Medicinal Products (CPMP adopted Jan. 2001).

For non-clinical and clinical considerations:

- CPMP/BPWG/283/00 Note for Guidance on the Clinical Investigation of Human Normal Immunoglobulin for Subcutaneous and Intramuscular use (Adopted July 2002)
- CPMP/BPWG/2220/99 Note for Guidance on the Clinical Investigation of Plasma derived Antithrombin Products (Adopted January 2002)
- CPMP/BPWG/198/95 Rev. 1 Note for Guidance on the Clinical Investigation of Human Plasma Derived Factor VIII and IX Products (Adopted October 2000)
- CPMP/BPWG/1561/99 Note for Guidance on the Clinical Investigation of Recombinant Factor VIII and IX Products (Adopted October 2000)
- CPMP/BPWG/388/95 Rev. 1 Note for Guidance on the Clinical Investigation of Human Normal Immunoglobulin for Intravenous Administration (IVIg) (Adopted June 2000)
- CPMP/BPWG/575/99 Note for Guidance on the Clinical Investigation of Human Anti-D Immunoglobulin for Intravenous and/or Intramuscular Use (Adopted June 2000)

Other biological medicinal products

Other types of biological medicinal products exist such as gene or cell therapy medicinal products. These products are of a complex nature and will be considered in the future in light of the scientific knowledge and regulatory experience gained at the time.

In any case, companies developing similar biological medicinal products are invited to contact the Agency to obtain further advice on their development.

The details of the CHMP guidelines are available at following links of the EMEA:

Website:

www.emea.eu.int/index/indexh1.htm

www.emea.eu.int/htms/human/bwp/bwpfin.htm

www.emea.eu.int/htms/human/bwp/bwpdraft.htm

www.emea.eu.int/htms/human/bpwg/bpwgfin.htm

www.emea.eu.int/htms/human/bpwg/bpwgdraft.htm

Biotech industry ends 2005 with breakthrough product approvals

The biotechnology industry ended 2005 with steady financial investments and product deliveries as companies succeeded in introducing novel therapies for patients suffering from some of the most devastating and deadly diseases. The year also marked significant advancements in agricultural and environmental biotechnology.

"The biotech industry has reached a maturity level capable of producing a steady stream of new and unique therapies. The goal is to produce even more targeted therapies that will result in more effective medicines," said Jim Greenwood, president and CEO of the Biotechnology Industry Organization (BIO).

The Food and Drug Administration (FDA) in 2005 approved seven recombinant biologics, as well as a number of first-in-class products and several "orphan drugs" â€“ or products that treat a rare disease affecting fewer than 200,000 Americans. About 45 percent of all recombinant and monoclonal antibodies cleared for marketing have been approved since 2000, demonstrating a very recent growing trend of industry market success.

Running slightly behind 2004, biotech companies last year raised about $20.1 billion in public and private financing, compared to $20.8 billion the previous year. Financings in 2004 and 2005 top all annual figures from the previous decade with the exception of the year 2000, when the industry raised a record $38 billion following completion of the draft sequence of the human genome.

Source: www.bio.org