



PHARMACEUTICALS EXPORT PROMOTION COUNCIL

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FDA Decisions: Biotech Companies Waiting for FDA Approval

When a biotech company is developing a drug, the process can take ten years or more. There are many steps in the development process, including initial design, testing, changes in design, more testing, and application for federal approval. Even if this process is successful, leading to a newly approved drug, there is still no guarantee of its commercial success, which can depend on how Medicare, insurers, and doctors interpret the drug's use.

Despite all of these uncertainties, investors still heavily focus on whether a company's new drug will be approved by the FDA.

After all, if the drug is approved and does well after release, the company could see big revenue increases.

Business section: Investing ideas

For a closer look at companies that are about to receive the all-important FDA decision, we list below drug makers awaiting FDA decisions over the next three months.

Do you think these companies will receive FDA approval?

List sorted by market cap.

- 1. Pfizer** (NYS: PFE) : A biopharmaceutical company, offers prescription medicines for humans and animals worldwide. Market cap at \$164.34B
- 2. Bristol-Myers Squibb** (NYS: BMY) : Develops, and delivers innovative medicines that help patients prevail over serious diseases. Market cap at \$55.84B
- 3. Gilead Sciences**: Engages in the discovery, development, and commercialization of therapeutics for the treatment of life threatening diseases worldwide. Market cap at \$35.53B
- 4. Vertex Pharmaceuticals** (NAS: VRTX) : Engages in the discovery, development, and commercialization of small molecule drugs for the treatment of serious diseases worldwide. Market cap at \$8.61B
- 5. Salix Pharmaceuticals**: Develops, and commercializes prescription drugs for the treatment of gastrointestinal disorders in the United States. Market cap at \$3.11B
- 6. VIVUS** (NAS: VVUS) : Engages in the development and commercialization of therapeutic products

H.O.: 101, Aditya Trade Centre, Ameerpet, Hyderabad – 500038

Tel: 040-23735462/23735466, Fax: 91-40-23735464

Email: info@pharmexcil.com



for underserved markets in the United States. Market cap at \$2.04B

7. Cell Therapeutics: Engages in the development, acquisition, and commercialization of drugs for the treatment of cancer. Market cap at \$1.08B

8. ProtalixBioTherapeutics: Focuses on the development and commercialization of recombinant therapeutic proteins based on its proprietary ProCellEx protein expression system in the United States. Market cap at \$533.96M

9. MAP Pharmaceuticals: Focuses on the development and commercialization of inhalation therapies for patients suffering from migraine. Market cap at \$476.72M

10. Affymax: Engages in the development of drugs for the treatment of serious and life-threatening conditions. Market cap at \$456.27M

11. Progenics Pharmaceuticals: Engages in the development and commercialization of therapeutic products to treat the unmet medical needs of patients with debilitating conditions and life-threatening diseases in the United States and internationally. Market cap at \$329.16M.

12. Furiex Pharmaceuticals: Engages in the compound partnering business in the United States and Europe. Market cap at \$241.49M.

13. Chelsea Therapeutics International: A development stage pharmaceutical company, focuses on the acquisition, development, and commercialization of pharmaceutical products for the treatment of various human diseases. Market cap at \$233.97M.

14. Arena Pharmaceuticals (NAS: ARNA) : Focuses on discovering, developing, and commercializing oral drugs in the therapeutic areas of cardiovascular, central nervous system, inflammatory, and metabolic diseases. Market cap at \$233.11M.

Source: Daily Finance

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