

# Investment Report 0005

## Investments in Biotech stocks

#Investment

#Biotech

- This is not financial advice!
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## Understanding the Biotech industry

- A biotechnology company uses living organisms such as bacteria or enzymes to make drugs. The use of living organisms differentiates biotechnology companies from pharmaceutical companies, which research and develop chemicals to invent drugs.
- Investors should pay close attention to each phase of a biotech company's drug candidates. Drugs in later phases are more likely to succeed, making investing in that company less risky. There are four major steps and three phases that biotech companies follow to develop new drugs:
  1. Drug discovery: A biotech company first identifies a drug candidate and the diseases that it potentially can target.
  2. Preclinical testing: The company tests the drug candidates in vitro (test tubes) and/or in vivo (living animals such as mice).
  3. Clinical testing: The drug candidate is tested on humans. Clinical testing generally occurs in three phases:
    - i. **Phase 1**: Small studies are conducted to find a safe dose for the drug candidate and determine how the drug affects humans
    - ii. **Phase 2**: Larger studies involving around 100 or more patients are conducted with a focus on safety and short-term side effects and to determine the optimal dose for the drug.
    - iii. **Phase 3**: Even larger studies, with hundreds or even thousands of patients, are conducted to demonstrate how effectively and safely the experimental drug treats the target disease.

4. Regulatory approval: A biotech company must obtain regulatory approval before it can sell a drug. The biotech company files for regulatory approval from the FDA, using the clinical testing data it has generated.
- Most biotech companies have many drugs simultaneously under development, which provides multiple revenue streams. The safest biotech investments are focused on more than just a few experimental drugs.
  - Many growing biotech companies often generate cash by issuing new shares of stock, which dilutes the value of the existing shares. Some biotechnology companies also receive, and may be heavily dependent upon, money obtained via partnerships with larger drugmakers or grants from government agencies and nonprofit organizations. Mergers and acquisitions are common in the biotech sector, which means that any of the most promising biotech companies could be acquired by their larger competitors
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## **Should you invest in biotech stocks?**

- Investing in biotech stocks can be risky because it's possible that the company's drug candidate proves ineffective or worse in clinical testing. And, even if testing goes well, biotech companies have no guarantee that a drug will be approved by the FDA.
  - The least risky biotech companies have drugs already commercially available and many drugs in later phases of testing. The best biotech companies also develop drug candidates with peak annual sales that are forecast to be high.
  - You can reduce your investment risk by focusing on biotech companies with strong financial positions. Biotech companies that already sell one or more drugs are much more likely to be profitable, and they are less likely to use creative means to generate the significant amounts of cash required to fund drug research and development.
  - The best biotech companies are well-positioned to deliver tremendous returns over long periods of time, making them well-suited for buy-and-hold investors.
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## **Investing in CRISPR Therapeutics, Axsome Therapeutics and Amgen (Long-term Investment Plan)**

## 1. CRISPR Therapeutics

- CRISPR Therapeutics is on a roll. The company recently earned approval for its first product, Casgevy, a gene-editing therapy for a couple of rare blood diseases. Developed in collaboration with biotech giant [Vertex Pharmaceuticals](#), Casgevy should have massive commercial success. CRISPR and Vertex estimate a total patient population of at least 35,000, and the treatment costs \$2.2 Million per patient in the U.S. Even grabbing just 30% of that target market would mean billions of dollars in revenue. There aren't many competitors to contend with, either, so things are looking good for CRISPR and Vortex.
- On the other hand, Vertex, which makes multiple cystic fibrosis (CF) drugs, enjoys a near-total monopoly over sales and treatments for the underlying cause of CF. Its pipeline also includes promising CF therapy in phase 3 testing.
- While Vertex's CF franchise has room to grow, the company has its sights set beyond CF as well. Vertex and CRISPR await regulatory approvals for Casgevy.
- The company expects to wrap up a late-stage study of non-opioid pain drug VX-548 by early 2024. It's also evaluating Inaxaplin in a pivotal study as a treatment for APOL 1-mediated kidney disease.
- Vertex is already profitable, which provides a large cash stockpile it can use to further bolster its drug candidate pipeline.

## 2. Axsome Therapeutics

- Axsome Therapeutics has experienced significant clinical and regulatory process over the past three years, culminating in the approval of Auvelity, a treatment for depression, in 2022. Axsome's lineup also features narcolepsy therapy Sunosi, acquired in 2022 from Jazz Pharmaceuticals.
- These two medicines are generating growing sales. Last year, Axsome Therapeutics' revenue came in at about \$270 Million, much better than the roughly \$50 Million reported in 2022.
- Meanwhile, Auvelity is being tested in Alzheimer's disease agitation (aggressive and restless symptoms) and should soon start a pivotal study in smoking cessation. Sunosi will soon kick off late-stage studies in depression, binge eating disorder, and shift work sleep disorder (disruptions in sleep rhythms caused by unconventional working hours); it has an ongoing late-stage study targeting ADHD.
- And there's more good news: Axsome has a rich late-stage pipeline that should yield more clinical and regulatory wins in the next few years. It's running a phase 3 study for AXS-12 targeting narcolepsy, while it plans to submit regulatory

applications for AXS-07 for migraine and AXS-14 for fibromyalgia (a chronic disease that causes pain and trouble sleeping).

- The company's lineup should be transformed in the next three years, setting up a solid foundation for consistent revenue growth and stock-market performance through 2034.

### 3. Amgen

- Amgen is a well-established biotech company with a long list of marketed products. However, the drugmaker has been dealing with slow or nonexistent revenue growth due to competition.
- The biotech has a plan to turn things around. It's developing new therapies, and this includes the highly promising weight-loss area. Sales of anti-obesity drugs are projected to skyrocket in the coming years, and Amgen hopes to capture a piece of this market. Amgen also acquired Horizon Therapeutics for \$28 billion last year, a move that significantly expanded its lineup and pipeline.
- Furthermore, the drugmaker has been making a push in the biosimilars market, another promising industry considering that most people think prescription drugs are too expensive. Amgen is working on biosimilar versions of several blockbusters, from Regeneron Pharmaceuticals' Eylea, a treatment for wet age-related macular degeneration (an eye disease), to Bristol Myers Squibb's cancer drug Opdivo.
- Amgen has a deep pipeline and a long history of developing newer and better medicines, so it should do just fine. Then there's the fact that it boasts a solid dividend program. Whether it's to boost returns over the next decade or for passive income, Amgen is an excellent pick for income-seeking investors.

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## Trends

- [Is Amgen a Good Dividend Stock to Buy right now?](#) **Its diverse product mix and strong fundamentals make a decent case.**

### Note

- \* "Amgen's earnings are reliable and derived from a bunch of different medicines."
- \* "It spends a relatively small proportion of its resources on developing new drugs."

\* "Expect this business to continue returning capital to shareholders for a long time."

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- [CRISPR Therapeutics](#)
  - [Vertex Pharmaceuticals](#)
  - [Axsome Therapeutics](#)
  - [Amgen](#)