BIOTECHNOLOGY ENTREPRENEUR HOW TO BE SMART!

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While starting any business is daunting, biotechnology start-ups present unique technological, business, financial, regulatory and legal challenges for the entrepreneur. A thorough plan is essential. Below are some tips for the biotech entrepreneur.

Business Plan

A complete business plan should include intellectual property strategy, a regulatory and market analysis, the responsibilities of each member of the company team, and financial and exit strategies.

Intellectual Property

Protection of the company's intellectual property, including securing patent, trademark, and copyright protection for key intellectual property, executing invention assignment agreements and confidentiality agreements with key employees, contractors and advisors, and obtaining professional review of and advice on all these documents and filings, is critical to building an innovative company and attracting the necessary financing to commercialize its products and services.

Employ a Responsible Team

The company needs a structured team to help realize its commercial goals and be successful. At the company's inception, it is not uncommon for a biotechnology entrepreneur to be the company's main scientist. As the company matures, the responsible team will require different sets of skills to satisfy changing needs.

Generally, management monitors the day-to-day operations, oversees corporate governance and accounting issues, guides the development and marketing of technologies and products, and raises funds. Scientists must be employed, since appropriate skills and experience are necessary to carry out the research and development that lead to commercial success.

Biotechnology companies also often have scientific or medical advisors with experience in the industry to help guide and direct the company on approaching scientific and medical issues.

A strong Board of Directors is important to a successful company. The Board has the responsibility to protect the interests of and guide the company and its shareholders, help determine a company's goals and strategy, and monitor performance of the company and its executives.

Approaching legal accounting and regulatory matters proactively from formation, including surrounding the company with experienced professionals, can build trust with employees, investors, partners and customers. Being unprepared may cost the company delays and substantial amounts of money in accomplishing its goals, securing financing and in obtaining a smooth liquidity event.

Financing the Company

Along with proprietary technology, business plan, and strong management, a company needs to be capitalized properly. A typical drug takes $900 million and 15 years to develop, so companies need to raise large sums of money long before they can commercialize a product or receive revenues. The sources of financing available to the company may vary from time to time, depending upon a variety of factors, including the stage of the company's product and technology development.

Entrepreneurs often start a company with their own assets, including mortgaging their homes, to gain the initial capital required for a biotechnology business. Early-stage funding is also provided by angel investors (wealthy individuals who invest in private companies), friends and family, university grants, private foundations, bank loans and venture capitalists. Various federal, state, and regional programs also provide funding opportunities to biotechnology companies to promote entrepreneurial growth.

Collaboration (licensing or development) agreements with pharmaceutical companies or "strategic partners" may also be available to the company at various stages of research and development of a product. Furthermore, an equity investment by these corporate partners or other investors often allows companies to use royalty streams to fund additional development.

Subsequent funding rounds are required to support the company's operations and product development until commercialization can occur, and thereafter. These stages require financing from individuals or entities who can raise larger funds, and provide guidance and networking contacts. Venture capitalists, institutional and angel investors, and pharmaceutical companies, and "strategic partners" have the ability to provide this support.

The entrepreneur should consider the differences in the goals of the company and of the investors and partners when determining the company's objectives, including financing and liquidity opportunities.

Exit Strategy

Though perhaps not on the mind of the entrepreneur, an entrepreneur should consider an exit strategy at the beginning of the venture. This will certainly be important to employees, investors, potential partners and customers.

As a company succeeds in its plans, including having strong and protected intellectual property, products and technology in development, and developed products, the risk of failure decreases and the valuation increases. This may entice an acquisition or merger by larger firms (private or public) or a sale of shares on public markets.

Selling ones company may be emotionally difficult for the entrepreneur; however, if your business is a valuable asset and a larger company is willing to purchase it, this could be a good decision. A merger, assuming compatibility, may, among other things, enhance your ability to raise capital, and allow expansion of research and development efforts while allowing the entrepreneur to maintain some degree of control in the company.

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Selling shares of the company on public markets generally allows for conversions to cash for the entrepreneur and other investors and partners, and carries prestige, credibility and publicity for your company. Becoming a public company also allows shares to be used in lieu of cash in forming partnerships or purchasing equity in other companies. However, public companies are often still in need of securing financing for the realization of the company's goals, must meet extensive reporting requirements, and sacrifice internal control.

Conclusion

Given the risks and difficulties addressed herein, it is no surprise that biotechnology companies are often unsuccessful. However, with innovative proprietary technology, committed leadership, sufficient funding, and careful planning and execution a biotechnology company may be on its way to a successful business.

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