Article

Strategic Planning for Financing and Growing Biotechnology Companies

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ABSTRACT

There are significant aspirations from both start-ups and existing biotechnology companies, as they endeavor to finance and grow their innovation. Growth demands substantial investments of time, energy and finance. Additionally, they face major risks and uncertainties in the process of growth and new product development in what is a dynamically changing environment. There is no question that the entrepreneurial spirit is core to biotechnology companies but without a congruent strategy for growth and a plan to secure the necessary finances to fund it they will most likely fail. This paper focuses on the process of strategic planning for financing and growing a biotechnology company. First, the strategic planning of biotechnology companies is discussed and a model of strategic congruence for innovation is proposed. Second, a framework for the process of financing a biotechnology innovation is presented. Third, examines the challenges of growing the biotechnology company. Following that final conclusions are drawn.

INTRODUCTION

Significant innovations and research in biotechnology has changed and will continue to change the practice of medicine. Biotechnology companies are continuously developing drugs, medicines and therapies as well as environmentally friendly chemicals, fuels and materials that address the growing needs of society. Biotechnology is one of the strongest growing industries of the 21st century. The future of biotechnology is strong. Millions of patients worldwide are benefiting from the discovery, development and delivery of innovative drugs, medicines and therapeutics to treat chronic diseases. The acceleration of change is driven by innovation and technological advancements that are core and critical to the biotechnology industry. Existing and future innovations and research in biotechnology will bring even further advances beyond our expectations that will help the growing needs of more people worldwide and become part of our lives. In addition, the population profile, workforce skills and roles, digital technologies and big data, and drugs and devices are highly influential in driving innovation. However, to succeed in this uncertain, dynamic and competitive environment there is a need to develop effective strategic planning for financing and growing tomorrow’s innovations today.

There are a number of key strategic components that are fundamental for biotechnology company’s growth and success. For many start-ups achieving positive net present value (NPV+) market returns and commercial success are short lived. The new product development process is extremely time consuming, complex, challenging and requires significant investment in both financial and human capital. There are high levels of risk and uncertainty in bringing any new product to fruition, developing, managing and protecting intellectual property, and challenges in meeting the regulatory process. Furthermore, there is significant cost required in gaining market approval for each individual product. For biotechnology companies to have any chance of success in terms of new product development they must have (1) proof of principle, (2) product efficacy and safety, (3) sufficient finance for clinical trials (for example through partnering), and (4) marketing channels: communication, distribution and service channels.

According to a recent MIT study almost 14 percent of all drugs in clinical trials eventually win approval from the FDA (Wong, Siah and Lo, 2018). This research was based on Informa’s Citeline dataset and contains over 400,000 entries corresponding to 185,994 unique clinical trials of over 21,000 compounds (Wong, Siah and Lo, 2018). With such a low success rate, it is important that companies incorporate appropriate strategies to reduce product development risk at each stage of development, from start-up capital through early stage capital and late stage clinical trials. Effective leadership and commitment from the board of directors and top management
Strategic Planning

Vision, mission and values of the biotechnology company drive strategic planning. Strategic planning should begin with the end in mind. Financing, investment, venture capitalists, strategic alliances, balance sheet and competencies for R&D are all fundamental for the strategic development and growth of the company.

As part of the strategic planning process key questions need to be considered include:

- Who are our key stakeholders?
- What are our stakeholders’ needs, wants and expectations in the short, medium and long term?
- What outcomes achieve our stakeholder needs?
- What changes do we need to make?
- How do we achieve continuous improvement and innovation?
- What actions are required today to achieve tomorrow’s innovations?
- How can we partner creatively to achieve optimal financial returns?

Additionally, as part of the process of strategic planning future trends and innovations must be closely reviewed. The future biotechnology will be an even bigger part of our life, from drugs, medicine and therapeutics to environmentally friendly chemicals, fuels and materials. Technologies including ICT-integrated biotechnology efficient disease prevention and wellbeing programmes, precision medicine, genome editing, organ production, and stem-cell therapy will contribute to support the health challenges brought about by an aging population. These trends and innovations are influenced by a number of factors that clearly need to be embedded into the strategic planning of biotechnology companies.

Future trends and innovations are influenced by:

- Competitive landscape
- Ageing populations with more diverse conditions and chronic diseases that need to be treated
- Financial pressures on government to provide high cost medications
- Technological advancement
- Innovation in genetics, biotechnology, material sciences and bio-informatics
- Public attitudes and expectations.

On this premise leaders of biotechnology companies must have a clear understanding of what influences these trends and innovations and the direct impact these have on their own company. Leaders are constantly challenged in their attempt to achieve the highest return for investors while maintaining a highly competitive company that is innovative with outstanding R&D and sustainable competitive advantage. They are under constant pressure to achieve timely project milestones within the allocated budget while meeting the expectations of investors.

To achieve a successful strategy, it is necessary to ensure that people and processes are in place for leadership, with the goal of executing ingenious financial strategies, and growth strategies, congruent with goals and objectives to develop and deliver future innovations in biotechnology. Congruence is essential to execute a strategy for innovation in the dynamically changing environment of biotechnology. As presented in figure 1 below this requires the following:

- **Management and People.** Strong management and leadership team and people with specific competencies and expertise that can generate scientific innovations that are core to biotechnology success.
- **Organization.** Ensuring that the organization supports and facilitates the utilization of internal competencies with the right structures and systems and R&D investment in place and develops a strong value add reputation and invaluable intellectual property.
- **Ingenious Financial Strategies.** Developing a financial strategy that supports and facilitates the vision, mission and values with appropriate funding, budget, investment and control system is paramount to support today’s business and tomorrow’s growth. In achieving this companies can consider partnering to reduce the level of investment required and share the risk.
- **Growth.** Achieving tomorrow’s innovations today. Growth through the vision, creativity, scientific innovation and discovery of product and service development using appropriate marketing initiatives to bring these innovations to fruition.
Strategic planning for competitive advantage in biotechnology companies requires:

- Utilizing all resources for generation of profit, growth and development.
- Maintaining high quality standards in R&D.
- Developing and executing a viable finance strategy, which can successfully fund and support advancement in innovation and R&D.
- Utilizing intellectual property, technologies and R&D to develop breakthrough innovations that can improve and save lives.
- Recruiting and retaining high caliber staff that can support and facilitate the executive of the strategic plan.

**Figure 1:**

Strategic planning for competitive advantage in biotechnology companies requires:

**THE FINANCING PROCESS**

Finance is core to the execution of any strategy. As presented in figure 2 the financing process can be divided into a number of core steps as follows:

- Step 1 – 2: this allows the biotechnology company to obtain a comprehensive view of the current business and management short, medium and long term plans. Step one undertakes a review of the business plan and the strategic goals and objectives. Step two is an in-depth analytical review of the current financial position of the company.
- Step 3 – 5: this focuses on company comparison to competitors in the field. Industry information is obtained to allow the company to assess and evaluate the direction and desirable outcomes of the business in relation to competitors. Scenarios need to be discussed and evaluated at this time in order to assess the
potential risks associated with achieving such outcomes.

- Step 6: identify a number of key valuations to allow the business to bring alignment among stakeholders. Determine target capital structure and ‘what if’ scenarios.
- Step 7: the market must be tested in order to identify potential success given the selected strategy. Assess the possibility of interest from potential investors, lenders and partners. This may be an iterative process.
- Step 8: when the financial strategy is initially tested the opportunity is presented in order to attract potential investment/lender/partner interest.
- Step 9 – 10: as part of the financing process management present to potential investors/lenders/partners.
- Step 11 – 14: potential investors/lenders/partners are evaluated to identify the best options for the company. Further negotiations may take place before agreements are finalized.

**CHALLENGES OF GROWING THE BIOTECHNOLOGY COMPANY**

Growth requires major changes in the company’s strategy. External environmental and competitive forces initiate the need to review the existing strategy in light of further growth and development. When seeking finance for growth, consideration needs to be given to the form of finance and if the company is focused on securing grants, for example government grants, working with accelerators, co-development with partners, speaking with family offices, or trying to crowd source, before approaching a traditional venture capitalist. Growth brings about new challenges for the company.

Small biotechnology companies are challenged due to the lack of capital and credibility, which takes time and effort to achieve and sustain. Patents are of significant benefit for biotechnology companies to attract the venture capitalist. Patents give the biotechnology company credibility, demonstrating that they have the core competencies, are properly engaged in R&D and developing the right innovations. Venture capitalists recognize patents as a critical indicator of the biotechnology company's potential.
company’s potential, and are more likely to support biotechnology companies that own strong, blocking patents. Venture capitalists provide endorsement for more significant long-term growth of the biotechnology company is their goal to attract the right strategic alliance. Biotechnology companies need to utilize their internal core competencies and R&D to achieve patents, this in turn will attract venture capitalists that will allow the company to grow further. At that point, the biotechnology company can be in a position to engage in a strategic alliance with a large biotechnology/pharmaceutical corporation that has the required financial resources, manufacturing, marketing and regulatory expertise, which provides the biotechnology company with full growth potential.

CONCLUSION

Scientists engaged in biotechnology are focused on innovations that meet the diverse needs of society. Essential elements in reaching this goal require strategic planning and building a team to ensure financing and growth that supports and facilitates leveraging new technologies, advanced data and analytics to ensure the best possible discoveries, development and delivery of innovative medicines and treatments. The key challenge facing leaders of biotechnology companies is the intense and continuous need to bring life-changing drugs, diagnostics, treatments to market in light of the regulations, funding, patents, FDA approval combined with the increasingly dynamic, complex and competitive external environment. Biotechnology companies need to be adaptable, flexible, and responsive to opportunities. Leaders of biotechnology companies must develop a congruent strategy that provides every possibility to identify and exploit opportunities of scientific discovery that will create enormous life changing benefits to society at large. However, in doing so they need to also focus on the financial returns and liquidity for shareholders in the short and medium term to attract and achieve continued investment and growth. Strategic planning for financing and growing a biotechnology company is not a one time implementation but a rigorous process that requires perseverance and flexibility.

REFERENCES:
