

Preface

My journey into this fascinating field of biotechnology started about 26 years ago at a small biotechnology company in South San Francisco called Genentech. I was very fortunate to work for the company that begat the biotech industry during its formative years. This experience established a solid foundation from which I could grow in both the science and business of biotechnology. After my fourth year of working on Oyster Point Boulevard, a close friend and colleague left Genentech to join a start-up biotechnology company. Later, he approached me to leave and join him in of all places – Oklahoma. He persisted for at least a year before I seriously considered his proposal. After listening to their plans, the opportunity suddenly became more and more intriguing. Finally, I took the plunge and joined this entrepreneurial team in cofounding and growing a start-up biotechnology company.

Making that fateful decision to leave the security of a larger company was extremely difficult, but it turned out to be the beginning of an entrepreneurial career that forever changed how I viewed the biotechnology industry. Since that time, I have been fortunate to have cofounded two other biotechnology companies and even participated in taking one of them public. During my career in these start-ups, I held a variety of positions, from directing the science, operations, regulatory, and marketing components, to subsequently becoming CEO. During the past two and a half decades, I have learned more than I thought was possible about starting, building, and operating a biotechnology company. I experienced the joys and disappointments that come with this unique merger of science and business. Biotech entrepreneurs experience firsthand the transformation of a scientific idea into a real product, the challenge of building a company infrastructure, issues in dealing with regulatory requirements, manufacturing, and market issues. They learn how to overcome challenges in such a way that is both satisfying and rewarding. Until you have been a part of a biotech start-up, you will never know the thrill that comes from creating and bringing to market a life-saving product, conceived and developed in part, from your own ideas, and the work of your hands, and those of a talented team. Surprisingly, the most important lessons are usually learned, not from successes, but from apparent “failures,” as you work through them to transform these situations into something better than was expected or anticipated.

When I first journeyed down this career path, I had no formal guidance or background in being a biotechnology entrepreneur. Although I was prepared for scientific rigor through my PhD training, then operationally through my MBA qualification, I did not appreciate the breadth and complexity of these issues until I faced these challenges on a daily basis. Consequently, I had to learn on-the-job while shouldering the scientific and the business needs of a company.

Biotechnology Industry Limitations

A severe limitation to the expansion and maturation of this industry is the availability of seasoned entrepreneurs and team members, who understand what it takes to establish and grow successful life science companies. Most of the training for biotech entrepreneurs comes from firsthand experiences while on-the-job. This learn-as-you-go method is not an ideal way to ensure success of these organizations because the product development process is complex, and the financial stakes are extraordinarily high. Several universities and business schools now offer programs specializing in training biotech leaders and entrepreneurs – yet the availability of experienced life science entrepreneurs is still in significant deficit. In the US, numerous states have biotechnology initiatives supported by government funding to foster the creation of biotech and life science companies. Sadly, however, all admit a dearth of seasoned biotech leaders to shepherd these fledgling organizations. To fill this void, most organizations support an “Executive-in-Residence” or “Entrepreneur-in-Residence” program, hoping to find experienced biotech leaders to spawn and nurture development of these new biotechnology companies. These programs plan to recruit and relocate seasoned biotechnology leaders from other states to lead their newly developed biotech companies. Unfortunately, each organization is vying for the same limited resource of individuals, with no state having an excess of experienced biotech leaders to keep up with the demand in this industry.

Who This Book Is for?

The Business of Bioscience: What Goes into Making a Biotechnology Product is for all those fascinated by the biotechnology industry, and those who want to know of the challenges and rewards that accompany the development of a biotechnology product. It is for those interested in beginning, or joining, a development-stage biotechnology company, such as the entrepreneur, or would-be entrepreneur, and interested team members. It is for the critical support groups, those whose work and efforts support and partner with biotechnology, such as patent attorneys, executive recruiters, and regulators to name a few. This information will be of interest to those who finance this industry, such as venture capitalists and angel investors. This book was also written for other professionals who have an interest in this industry.

You may be an investor, analyst, or someone yearning to learn what goes on behind the scenes in the building of a biotechnology company. No matter who the reader is, you will learn things applicable to help work effectively with, and in the biotechnology industry.

Those who seek guidance and practical insight into the challenges that lie ahead in building a biotechnology company will find this information invaluable. You may be a former pharmaceutical executive with many years of experience; you may be a professor, scientist, or physician with the gnawing desire to build a business based on a breakthrough medical technology. This book can be a road map for the life science entrepreneur to help navigate the labyrinth of starting and building a successful biotech company. Even experienced biotech professionals will gain additional insight by seeing the world from the eyes of an entrepreneur, to better understand what they can do to participate in the growth of their biotech companies. Finally, for those who just want to know the inner workings, challenges, and opportunities within such an organization, they will find that the process of developing a biotech product is not as straightforward as one may think.

It is my hope that *The Business of Bioscience* will also serve as a teaching guide and companion for business schools and universities with programs focusing on the entrepreneur in the biotechnology industry. Most business schools today have an entrepreneurial focus, and some are developing programs specifically supporting the life science industry with its unique set of issues and needs. This book is intended to serve as a resource for institutions teaching a growing number of students in the emerging, and life-changing field of biotechnology entrepreneurship.

Why I Wrote *Business of Bioscience*

During my years as a formative biotech entrepreneur, I painfully recognized a void of knowledge within myself about how to establish and build a biotechnology company. To fill this void, I voraciously read dozens of books on various topics that I believed would help me as a biotech entrepreneur. These books covered topics on general business development, basic marketing, project management, writing business plans, employee hiring practices, leadership principles, high-tech company histories, corporate alliances, fundraising, regulatory affairs, in addition to my regular scientific journals and biotech industry publications. Although each of these self-help books contained a component that could be applied to my entrepreneurial interests, none spoke directly to my situation as a biotech entrepreneur. Portions of these books contained bits of information that were generally applicable to all industries. These topics included: “how to write a winning business plan,” “how to hire good people,” “raising money,” and other general entrepreneurial topics. But like a wrong-sized glove, nothing exactly fit my situation. What was missing from these books was the integration of these topics, within the context of the biotechnology industry, with examples of real-life challenges the biotech entrepreneur faces on a daily basis.

Over the years, my desire was to summarize my learning experiences, and to write a book that was encompassing and relevant to equip future biotech entrepreneurs. I wanted this book to be practical, with insight that could be applied to various stages of biotech business development. In addition, I wanted this book to be enjoyable to read, not for entertainment sake, but to help the reader remember the information and apply it to the right situation.

What Is Covered in This Book

In *The Business of Bioscience* you will be introduced to many key aspects of the biotech and product development process. This includes: the characteristics of a biotech entrepreneur, how to establish an organization, raising many forms of capital, selecting development milestones, dealing with personnel issues, the significance and impact of a business model, market strategies and their impact on raising money, regulatory compliance issues, and why you must manage differently at different life-stages of the organization. I have included background information at the beginning of each chapter so as not to take for granted the readers' understanding of all subject matter; yet we quickly move to in-depth discussions of these subjects so that those with more experience in these areas will also benefit. Knowledge is essential for success, and most biotech entrepreneurs are very knowledgeable. However, a distinguishing difference between a good biotech leader and a great biotech leader is having wisdom – the ability to apply specific knowledge at the right time, in the right situation. This aspect is an overarching theme of this book.

As you read this volume, you will learn the mechanics and some business strategy of how to establish and grow a life science company. You will come away with an understanding of the expectations of biotech investors, and also gain insight on how to use this information to give you the best opportunity to raise the needed capital for a growing company. Securing funding for a biotechnology company is a crucial requirement if you hope to have any opportunity for business success. As a result, I have devoted two chapters to multiple aspects of the fundraising and financing process. Since there is literally not enough money available to fund all good ideas in this industry, it is important for you to understand the expectations of investors, and what constitutes a fundable company.

In this book, I touch on development life-stages in a biotech company and the parallel to life-stages of individuals. This analogy is helpful to understand how and when to transition a management style to meet the changing needs of an organization during company development. To be successful, you need information specific to the precise stage of growth of an organization. A company's needs have differing priorities based on the life-stage of the organization. For instance, you can read books on how to set-up proper financial accounting and compliance measures for Sarbanes-Oxley, which are always essential; however, if an organization does not have operating capital for more than 90 days, financial accounting compliances are

not a high priority at this stage. Conversely, understanding how to write an effective business plan is important, but if the organization is having morale issues because of poor hiring decisions, it is time to address these before losing staff or seeing their motivation disappear.

The future of a start-up biotechnology company relies on decisions made at critical junctures. The consequences of some choices may seem subtle but can have a dramatic impact on the company. It is essential that the biotech entrepreneur have a working knowledge in all areas of company and product development, to make wise decisions, and ensure the future success of an organization. I have referenced additional materials on particular topics should you desire more in-depth knowledge on these subjects. In the future, provided that there is sufficient interest in this subject matter, it is my intent to add a workbook to support more formalized instruction suited to an academic course curriculum.

Throughout *The Business of Bioscience*, you will be learning technical information coupled with strategy, and placed into a context of the “bigger picture.” This information is directly applicable to establishing and growing your organization, and developing your product and team, such that there is continuity in growth regardless of the size of your company. No matter how comprehensive a book, there will always be additional aspects of biotechnology entrepreneurship that can be covered; however, what is contained here, are the essentials that you will need to establish and grow your biotechnology company, and move your product development thorough to commercialization. The information in this book will help guide you through the rough spots and avoid a few detours along the way, and serve as a ready resource for help when you need it.

Summary

The biotech industry is in great need of seasoned biotechnology leaders who have the knowledge, wisdom, and desire to lead others to accomplish something greater than they themselves can do alone. This industry needs strong value-based leaders and teams of individuals who can see the future of medicine, and help usher the changes that genomics, proteomics, molecular biology, and personalized medicine can bring to human health. The overarching goal of this book is to equip, train, and prepare future leaders in the biotech industry, such that their products and services can advance medicine, that more may live longer, healthier lives. My desire has been to combine strategy, operational guidance, and practical wisdom in this book. My hope is that you will find this information valuable, as you join the ranks of entrepreneurs, visionaries, and scientific teams in establishing and building a biotechnology business. If I succeed in helping you avoid potential pitfalls in the entrepreneurial process, it will have been worthwhile. I am a firm believer in an ancient proverb, “learn from the mistakes of others, because you will never live long enough to make them all yourself.”

I welcome any comments that you, the reader, may have on ways to improve this resource so that biotech leaders and entrepreneurs can be better equipped to lead our industry into the future. Additional information can be found on various topics helpful to the biotech entrepreneur at my website, www.businessofbioscience.com

Best Wishes for Your Success!

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The Business of Bioscience

What goes into making a Biotechnology Product

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