

Foreword to the First Edition

Capital, whether it originates from venture, public equity, private, or government sources, continues to be biotech's source of sustenance. In fact, access to financing can make or break a company, regardless of whether it has Nobel Prize winning science or a top-flight business school management team.

In order to attract capital there has to be a "value proposition" that is sufficiently engaging and well constructed that will not only capture the imagination of investors but also make them want to ultimately invest.

This book recognizes that there is no consent on how to apply valuation methodologies in life sciences. One of the complicating factors is that, compared to other industries, valuation of biotech innovation is much more demanding. The long 10-15-year development and clinical trials process still represents the main risks faced by any biotech company. Added to that is the fact that getting a drug across the regulatory goal line and receiving Food and Drug Administration approval (or other regulatory agency approval in the United States or elsewhere in the world) for marketing is no longer good enough. Since the biotechnology industry is not isolated from the major influences affecting the overall healthcare industry, the reality of de facto healthcare cost controls will mean a significant reduction in "peak sales" for individual drugs. Science will no longer be the deciding factor; payor agents will play a far more activist role via reimbursement criteria, co-payment arrangements and similar rationing technologies. Reimbursement planning starts with clinical planning.

At the dawn of the biotechnology industry, early investors had very few metrics with which to base and compare their investment decisions and valuations of such fledgling companies as Amgen and Genentech were "negotiated events". Investors bought into the hopes, dreams and expectations that the scientists and entrepreneurs were selling.

Fast forward to today and the industry is still extolling those same hopes and dreams that its innovation can make a difference ... meet an unmet medical need with a breakthrough therapeutic; create better crops; improve the environment, or protect the population from the threat of bioterrorism.

By and large, the investment community and capital markets have liked what they have heard. For the comparatively short 30-plus year history, this industry has attracted almost \$400 billion. Capital continues to flow into biotechnology companies at incredible rates and this year alone we predict that a new milestone will be reached for the industry with \$40 billion being invested in the United States alone. We have come a long way in a very short space of time.

Those of us who fund innovative, but relatively immature enterprises not only have to recognize the best-in-class companies but also understand how the future will unfold in the light of constant technology change. The maturing industry that is now melding its scientific entrepreneurship with the needs and culture of its larger commercial reality is an ever-increasing challenge. In the early days, the dream of an emerging biotechnology company was to become a fully integrated pharmaceutical company and lever its intellectual property portfolio into a stream of blockbuster drugs.

To demonstrate how dramatically this business model and landscape can change – the focus on a one-size fits-all blockbuster drug is a strategy that may have run its course. The best selling drug of 2020 is somewhere between the bench and pre-clinic trials ... but who knows if big pharma, as we know it, will develop it. The successful companies of the future will be those that marry both molecular diagnostics with targeted drugs and deliver effective personalized therapies. We are witnessing an unprecedented rate of evolution and transformation in the life sciences and healthcare. We are in an era of personalized medicine where the promise is compelling for the future of health care ... personalized medicine offers earlier and more precise diagnoses, treatments tailored to the individual, reduction of side effects and adverse reactions to drugs, breakthroughs in treatment, and ultimately prevention of major diseases such as cancer, diabetes and Alzheimer's.

On the other side of the ledger the move to a more personalized, predictive and preventive medicine (the three "P's") world that will revolutionize the health care system, as we know it today, is challenging pharmaceutical and biotechnology companies alike to adapt. Up until recently, their focus has been on the discovery of blockbuster drugs. Now, with the convergence of IT and genomics, smarter drug delivery and "labs" on a chip are moving us down an inevitable path towards targeted personalized medicines – away from "blockbusterology" – and spotting "early warning" signs of impending health problems. Science is leading into a promising realm of new technologies such as theranostics, responder/non-responder effect of biomarkers, molecular diagnostics and the re-emergence of genomics and proteomics companies in an era of tougher regulations governing the safety of drugs with payors looking to decrease the costs of health care.

Creating a successful and profitable biotechnology enterprise is therefore just as complicated as the genetic and cellular innovations that the company is trying to commercialize. Conservative estimates tell us that a biotech company will need close to \$2 billion (according to recent estimates) and at least 12-15 years before any patient receives its novel drug therapy and returns on this massive investment can be generated. Along the way, the company will face many challenges: For its product – numerous and stringent regulatory hurdles; for the corporation – fickle financial markets; product competition; rapidly changing technologies; and difficulties in recruiting and retaining skilled staff. Taking all these factors into account small wonder that the chance of bringing a drug to market is about 1 in 1000!

Thus, as investors, we are taking a chance, it's true, but we view this as a very necessary investment in the future of mankind – and that gives us courage. Also, there is an opportunity for moving the science forward into commercialization, and for creating value. This, of course, requires a tremendous amount of due diligence and dogged research, but those of us who have stayed with this industry for decades know that the effort is well worth it.

While, as investors we have the courage to be part of a better future our investment decisions have to be tempered with reality and on arriving at appropriately calculated valuations of the company's worth ... after all investment comes at a price to the entrepreneur. As a long-time investor in life sciences and someone who has been involved in the process of "valuation" for many years this is where the rubber meets the road in the deal making process. Tension on both sides of the negotiation table might be ameliorated if there was one agreed on set of rules about what a piece of technology or biotech companies are actually worth.

The claim is made that the process of valuation in biotechnology is one part science and one part art. I would argue that there is a third essential ingredient, and perhaps the most important, and that is passion. Without it the biotechnology industry, perhaps would never have come into being.

Any assistance that can help us figure out, in a more rational way, the complexity of the "value proposition" will help both communities at the bargaining table reach more realistic valuations is welcomed. A company's value lies in its potential to generate a stream of profits in the future. Profits can be generated from sales of drugs, services but also from upfront, milestone and royalty payments. All valuation exercises are based on determining a company's future, which requires many assumptions such as: the state of the market targeted and the potential share obtainable; the

company's intellectual property and its freedom to operate; third, the ability of management to deliver on the business plan; and fourthly, the absolute size of the financing and what's needed to get to the next value inflection point. There is no "magic bullet" when it comes to valuation and it has remained a "black box" process for even the most seasoned investment professionals.

The authors have, therefore, done an admirable job in setting out a roadmap for valuation in life sciences. They take us from this often times subjective operation to the more rational scientific process. The detailed worked examples are particular helpful in reducing the process into a more practical operation. This text will become a useful addition to the reference shelves of both the entrepreneur and investment professional alike and must reading for anyone contemplating raising investment capital.

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