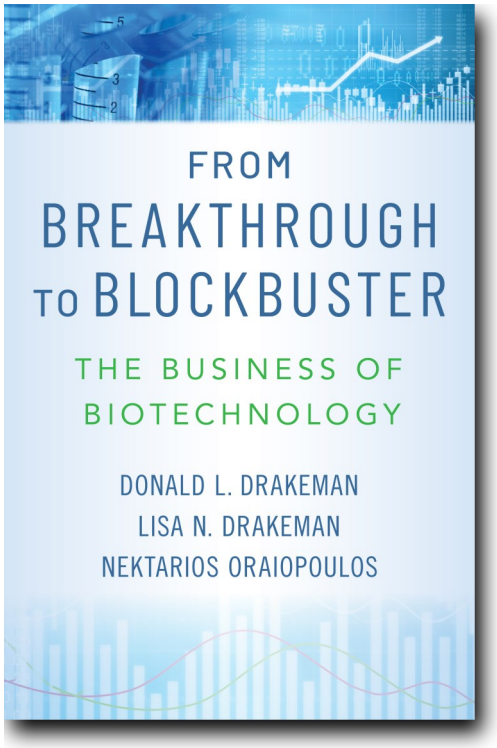

FROM BREAKTHROUGH TO BLOCKBUSTER:

THE BUSINESS OF BIOTECHNOLOGY

MEDIA KIT

From Breakthrough to Blockbuster: The Business of Biotechnology is an essential resource for students, scientists, investors, entrepreneurs, physicians, policy makers, and all others interested in how new medicines come into being, why the process is so breathtakingly expensive, and how small entrepreneurial ventures can compete in one of the world's most expensive and heavily regulated industries. Beyond that, the account of how a vast collection of inexperienced, underfunded, and unprofitable small companies have created more life-changing new medicines than the largest global pharmaceutical firms is a *David-and-Goliath* story well worth reading.

Co-authored by a Cambridge professor and the CEOs of successful biotech companies, one of which pioneered the cancer treatments recognized in the 2018 Nobel Prize for Medicine.

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www.thebusinessofbiotechnology.com

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ABOUT THE BOOK

Beginning in the 1970s, several scientific breakthroughs promised to transform the creation of new medicines. As investors sought to capitalize on these Nobel Prize-winning discoveries, the biotech industry grew to thousands of small companies around the world. Each sought to emulate what the major pharmaceutical companies had been doing for a century or more, but without the advantages of scale, scope, experience, and massive resources.

How could a large collection of small companies, most with fewer than 50 employees, compete in one of the world's most breathtakingly expensive and highly regulated industries?

This book shows how biotech companies have met the challenge by creating nearly 40% more of the most important treatments for unmet medical needs. Moreover, they have done so with much lower overall costs.

The book focuses on both the companies themselves and the broader biotech ecosystem that supports them. Its portrait of the crucial roles played by academic research, venture capital, contract research organizations, the capital markets, and pharmaceutical companies shows how a supportive environment enabled the entrepreneurial biotech industry to create novel medicines with unprecedented efficiency. In doing so, it also offers insights for any industry seeking to innovate in uncertain and ambiguous conditions.

Looking to the future, it concludes that biomedical research will continue to be most effective in the hands of a large group of small companies as long as national healthcare policies allow the rest of the ecosystem to continue to thrive.

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Chapter abstracts are available at www.thebusinessofbiotechnology.com/the-book

PRAISE FOR THE BOOK

"A fascinating guide to the complex business of biotechnology, with deep insights into the key factors, players, interactions and behaviours that have shaped the success of this industry. Suitable as a primer for those with no knowledge of the field, or as a refresher for the cognoscenti. Trigger warning: contains material that may distress pharma management."

- Sir Gregory Winter, CBE, recipient of the 2018 Nobel Prize in Chemistry, and founder of several biotech companies

"This is a remarkable synthesis and analysis of the Biotech industry from the viewpoint of individuals who thoroughly understand it based on their own seminal achievements. Their analysis of the key components is a must-read for those either trying to develop new life-saving medicines or interested in furthering these enterprises."

- Margaret A. Liu, M.D., DSc*hc*, MD*hc*, FISV, CEO of Pax Therapeutics, and board member, Ipsen, S.A.

"A must read for all biotechnology leaders, this is a state-of-the-art analysis of the industry from two of its most successful entrepreneurs and a top business school professor, bringing rigor and actionable insight."

- Dr Richard Mason, CEO of Apollo Therapeutics and former head of Johnson & Johnson's London Innovation Center

"Anyone who wants to understand how to leverage ecosystems for innovation in the face of uncertainty must read this rigorous analysis of how biotech companies, investors, government and big pharma have worked together to achieve some of the biggest scientific and commercial breakthroughs of the last century."

- Arnoud De Meyer, Professor Emeritus and former President, Singapore Management University

"An outstanding overview of the science and the business of innovative drugs. Students, researchers and policy makers will be immensely benefited from this book."

- Mahmud Hassan, Ph.D, Director, The Blanche and Irwin Lerner Center for the Study of Pharmaceutical Management Issues, Rutgers Business School

"A must read for everybody interested in the medical biotech industry, practically relevant and theoretically sound."

- Jürgen Mihm, Professor of Technology and Operations Management, INSEAD

"How is it possible that a few thousand small companies, many of them short-lived, can out-compete the mighty pharma majors at their own game? Understanding this puzzle is of fundamental importance for industry leaders and policy makers alike. This marvelous insider analysis is a must-read."

- Stefan Scholtes, Dennis Gillings Professor of Health Management, Cambridge University Centre for Leadership & Enterprise

ABOUT THE AUTHORS

Donald Drakeman, PhD, was the founding CEO of the US biotech company that pioneered the development of the checkpoint inhibitor cancer treatments recognized in the Nobel Prize for Medicine 2018. These products, YERVOY and OPDIVO, are being used to treat many different forms of cancer. He is a Fellow in Operations and Technology Management at the Cambridge Judge Business School, Distinguished Research Professor in the Program on Constitutional Studies at the University of Notre Dame, and a Venture Partner at Advent Life Sciences. His publications have been cited in numerous patents and by the Supreme Court of the United States. He is a Fellow of the Royal Society of Biology. A graduate of Columbia Law School, he received a PhD from Princeton University.

Lisa Drakeman, PhD, was the founding CEO of one of Europe's most successful biotechnology companies. Under her leadership, the company set numerous financing records, including a record setting IPO, and inaugurated research programs leading to the new FDA-approved medicines DARZALEX (multiple myeloma) and KESIMPTA (multiple sclerosis). She is a Fellow of the Centre for Health Leadership and Enterprise at the Judge Business School, University of Cambridge, and Vice Chair of the board of the Zucker Institute for Innovation Commercialization at the Medical University of South Carolina. She has received numerous industry honors, including the Sol J. Barer Award for Vision, Innovation, and Leadership. She has been a faculty member at Princeton University and regularly lectures on entrepreneurship at universities in the US and Europe. She received a PhD from Princeton University.

Nektarios Oraiopoulos, PhD, is Professor of Operations and Technology Management at the Cambridge Judge Business School of the University of Cambridge. His research on innovation and R&D management has appeared in the leading journals of the field. He has won multiple awards and has been invited to make presentations at both academic and industry conferences. In addition to his academic work, he has advised entrepreneurial start-ups and has worked closely on research projects with numerous executives from the biopharmaceutical industry. He holds a Diploma in Electrical and Computer Engineering from the National Technical University of Athens and a PhD in Business Administration from the Georgia Institute of Technology.

Learn more about the authors

AUTHOR Q+A

How did *The Business of Biotechnology* come about?

Over the years, we have had the opportunity to speak to students in science, engineering, business, and even the humanities at Princeton, Oxford, Cambridge, Notre Dame, and other universities. These students have been interested in learning more about entrepreneurship and biotechnology not only from an academic perspective, but also as a potential career direction. In many respects, this book represents the extended version of those talks we have given – our sense of what someone entering the industry might want to know. At the same time, we have tried to analyze the industry, especially as to the origins of important new medicines, in a number of ways that we believe may provide insights for both practitioners and scholars into how the business of drug development has changed over the last half century.

Why did you want to write this book?

"My hope in writing this book was that everyone touched by the biotech industry — scientists, managers, investors, policy makers, physicians and patients — could understand better how the amazing breakthroughs of the last half century of biomedical research have been converted into important new medicines."

- Don Drakeman

"I didn't know I was an entrepreneur. Working in biotech was a happy accident! I hope this book helps others find out if entrepreneurship is the right career path for them."

- Lisa Drakeman

"I am a firm believer of Kurt Lewin's saying: 'There is nothing more practical than a good Theory'. Over the past decades, business school academics and management scholars have made great contributions in our understanding of the biotech industry, but more often than not these contributions have not made the transition to the executive world. A key objective, and in fact, driving force, when we set out to write this book was to bring together the complex reality of running a biotech company with the insights offered by the academic literature on the topic. We hope that our work will motivate a dialogue that will strengthen the symbiotic relationship between theory and practice. Doing so will help entrepreneurs and investors to better navigate the biotech ecosystem, while it will allow management scholars to work on topics that can make an impact in an industry that affects all of us."

- Nektarios Oraiopoulos

EXCERPT: CHAPTER SEVEN

How GSK Missed a $32B Opportunity with the Covid-19 Vaccine

At the outset of the COVID-19 pandemic, scientists around the world set out to design an effective vaccine as rapidly as possible. No one knew what technological approach would be the most successful. The goal was to prompt vaccinated people's bodies to generate a strong immune response to an essential part of the virus called the "spike protein." Then, upon exposure to the virus, the immune response would neutralize or eliminate it before the infection could set in. The key question was how to get the spike protein in the body in a way that would lead to a rapid and effective immune response.

No one was better positioned to answer that question than GlaxoSmithKline (GSK), the world's leader in vaccines. With over $8 billion in vaccine sales, GSK had opened a dedicated global vaccines research center just a few years before. In those new labs, GSK researchers had been working with a promising new vaccine technology called mRNA. With that approach, they could potentially deliver the genetic code for the spike protein directly to the patients' cells. To get the resources to work on an mRNA-based COVID vaccine, the researchers, following the standard approach common to many pharmaceutical companies, presented the idea to the series of GSK committees that needed to approve research programs. After the proposal finally found its way to senior management, it was rejected on the grounds that mRNA technology was not "ready for prime time."

At the same time, two small biotech companies set out to design mRNA COVID vaccines. Later recounting that it took one of them an afternoon, and the other just two days, the biotech companies pressed forward with the unproven technology. One of them, Moderna, developed the product on its own, while the other, BioNTech, partnered its vaccine with Pfizer for on-going development.

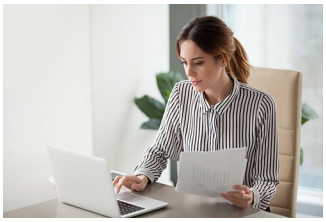
Eventually, the Moderna and BioNTech/Pfizer vaccines were authorized for sale in many countries, and became the leading COVID vaccines. Analysts projected total 2021 sales of over $13 billion for the Moderna vaccine, and over $19 billion for the BioNTech/Pfizer vaccine. Their willingness to bet on an unproven, potentially not-ready-for-prime-time technology propelled them well past GSK, which would no longer be the #1 vaccine company.

This story illustrates many of the themes of chapter seven. Biotech and pharmaceutical companies frequently have access to the same technologies and are working on the same diseases. But there are very significant differences in how decisions are made to allocate resources to the various research programs, leading to different levels of tolerance for risk. Those differences can help explain why **the biotech industry has been able to create more high priority, pathbreaking medicines with less experience and far fewer resources than the pharmaceutical industry.**

Read more excerpts at www.thebusinessofbiotechnology.com

EXCERPT: CHAPTER SIX

Are You an Entrepreneur?



Who is the biotech entrepreneur? Is a biotech entrepreneur necessarily an accomplished scientist bent on improving human health by discovering a paradigm-shifting scientific insight? Some accounts of the industry certainly give that impression, and there have certainly been many biotech entrepreneurs who have been outstanding research scientists. However, the CEO's task is far more extensive than managing scientific research projects, no matter how innovative or complicated they may be. A biotech company is an extremely complex business. It requires the application and coordination of scientific, regulatory, financial, and management expertise to operate effectively. Fundraising and communications capabilities, the ability to negotiate and manage business partnerships, problem solving skills, strategic thinking, and perseverance are all essential for the company's success. So, while scientific knowledge is one critical aspect of building a successful biotech company, it is not the only one. This need for multidisciplinary leadership abilities helps explains why, as the industry has developed, individuals with a variety of backgrounds have ended up with overall management responsibility.

While there are many guides offering advice on being a successful entrepreneur, there are fewer resources available to help potential entrepreneurs think about whether it is the right career path for them. In other words, "How do I know if I'm an entrepreneur?"

To shed further light on the qualities and traits that are helpful for biotech entrepreneurship, we have developed a set of questions to help people consider whether they might find a career in biotechnology entrepreneurship fulfilling and a good match for their personality and inclinations. There may be other important considerations, but these represent a good place to start, and they are basically an entrepreneurial version of the Delphic Oracle's injunction to "know yourself."

Do you always think there is a better way to do things?

When biotech CEOs are not working to raise money, they often describe their jobs as creative problem-solving. Their companies are trying to succeed in the same task being pursued by the research deivisions of large pharmaceutical companies, but with a tiny fraction of the resources. Creativity is essential, and since the industry is subject to countless laws and regulations, that creative spirit needs to be channeled into pathways that will work effectively in a very carefully regulated environment.

Are you willing to take on just about anything, even if you don't know much about it?

In a nearly constant state of having insufficient resources, biotech companies cannot afford to have staffs of experts in every possible area. Entrepreneurial employees need to banish the phrase, "That's not my job," and replace it with enthusiasm for the opportunity to learn – and master – something completely new and difficult whenever necessary.

EXCERPT

Are you comfortable taking risks?

Success is not along a defined path, and obstacles are the norm. Many highly credentialed graduates have succeeded in their academic work by having a detailed and comprehensive understanding of a particular field, and they are used to seeking and finding the "right" answers. That is not always – in fact, not often – possible in biotech company leadership. Plans need to be made, and often changed, without adequate amounts of information being available, and many of those plans will go wrong usually in unexpected ways. For some, that opportunity to juggle many things in unpredictable environments sounds exhilarating; for others, it would be a highly unattractive way to devote countless hours each week.

Do you like to do new things, or do you prefer routine?

As with all of the earlier questions, there is no right or wrong answer, just the one that suits an individual's preferences. It is not uncommon for biotech senior executives to find that their day goes in completely unexpected ways on a regular basis. Whether the surprises are good (the stock jumps up in a way that may lead to a new financing opportunity) or not (the FDA calls to place a "clinical hold" – that is, stop patient enrollment – on your most important product in clinical trials), there are a lot of them.

Can you accept rejection and failure?

Perseverance is a must in an industry with a 90% failure rate and a financing environment in which most potential investors (sometimes all investors) say "no" most of the time. Multi-hundred-million-dollar corporate alliances can, and often will, fall apart at the last minute after a year or longer spent in detailed negotiations. Being able to plot a course towards success is important, but it is just as essential to be able to figure how to bounce back from disappointment or failure.

There is no guaranteed formula for success as a biotech entrepreneur. However, potential biotech entrepreneurs would probably do well to be able to answer "yes" to these questions, and in fact, entrepreneurs in almost any field should probably be able to answer in the affirmative to most of them. Novel ideas, creative thinking, clever new approaches – the stock-in-trade of entrepreneurs everywhere – are an essential component of success. But, at the same time, all of that creativity needs to be exercised and managed in ways that will gain the support of the investors and regulatory bodies that are crucial to the company's success. For example, carefully maintaining meticulous, detailed written records in full compliance with the impressively complex and comprehensive regulations established by the FDA and other similar bodies around the world is as important for successfully launching a new medicine as creating the product in the first instance. Managing this delicate balance in a constantly changing environment requires an exceptional level of adaptability as well as the ability to learn new things quickly. While no specific academic discipline can claim ownership of this skill, it is arguably one of the main benefits of advanced education. This could help explain the unusually high levels of education of the biotech leaders and the striking diversity of the educational and professional backgrounds of those leaders. Whatever their backgrounds may be, those who enjoy the type of environment we have described, and who are

able to tolerate operating in a risk-laden environment of complexities and uncertainties, can find biotech entrepreneurship to be an exciting career path. They will have the rewards of working with a group of incredibly smart people who single-mindedly focus on building a successful business by bringing important new medicines to the patients who need them.

As we conclude this section on entrepreneurial characteristics, it is worth noting that there is very little research in this area, and that developing a better understanding of the relationship between personality traits and successful entrepreneurship is an important area for future study. To the best of our knowledge, there are no studies that specifically examine such connections in the context of the biotech industry. Given the variety of the different tasks and stakeholders involved, it would be interesting for further studies to shed light on how certain qualities and traits (or lack thereof) affect the processes and outcomes of those interactions. For example, are some traits more effective in managing the company's own board or shareholders versus negotiations with a potential licensee such as a large pharmaceutical company, or vice versa? As discussed in the references in the notes to this chapter, the vast majority of studies on the personality traits of entrepreneurs do not account for industry characteristics, and the performance measures are quite generic, if they are captured at all.

PROMOTIONAL INFO

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Book

- Biotech vs Pharma is a David-and-Goliath story well worth reading.
- The exciting story of disruptive technologies giving birth to biotech.
- Inexperienced, underfunded, and unprofitable small companies have created more new medicines than big pharma. Read how they did it.
- Learn how biotech entrepreneurs created the most breakthrough medicines of the past two decades.
- Biotech companies have created nearly 40% more of the most important treatments for unmet medical needs than Pharma companies.
- Did you know that each new medicine costs over $2.5B to develop? Find out why.
- This book offers insights for any industry seeking to innovate in uncertain conditions.

Audience

- An essential resource for students, scientists, investors, entrepreneurs, physicians, and policy makers interested in creating new medicines.
- An essential resource for anyone interested in how new medicines come into being.

Entrepreneurship

- Would you find a career in biotechnology entrepreneurship fulfilling and a good match for your personality? Find out.
- An essential text for anyone starting a business and wondering, *how do I know if I'm an entrepreneur?*

Biotech-Pharma Alliances

- Did you know that biotech-pharma alliances are more effective when the biotech company retains control?

Authors

- Co-authored by CEOs of successful biotech companies, one of which pioneered cancer treatments recognized in the Nobel Prize for Medicine 2018
- Co-authored by a professor at the Judge School of Business, Cambridge.

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