The Complete Handbook for Life Science Companies

MAKE YOUR BUSINESS STRONGER AT ANY STAGE

THE SCIENCE OF SUCCESS
The six fundamentals of launching a biotech startup

DEMYSTIFYING BUSINESS MANAGEMENT
Real world guidance from those who’ve done it

PLUS RESOURCES, CHECKLISTS, ASSOCIATIONS
Connect with organizations that help you succeed
FOREWORD .................................................. 3
A STARTUP PHILOSOPHY ................................. 3
Credibility ...................................................... 4

CHAPTER 1: FORMING A COMPANY ..................... 5
Registering the company ................................... 5
Incorporating style ......................................... 6
Company specifics ......................................... 6
An operations agreement ................................. 6
A tactical company name ................................ 7
Business Planning ........................................ 7
Executive Summary ...................................... 7
The Market .................................................. 7
The Science .................................................. 8
Strategy .................................................... 8
Management .............................................. 8
Financial Projections .................................... 8
A Workable Document .................................. 9

CHAPTER 2: FINANCIAL CONSIDERATIONS ...... 9
1. Government Grants .................................... 10
2. Outside Investment ..................................... 10
Credibility and Leadership .............................. 11
Investment Strategy ...................................... 11
3. Turning a Profit ........................................ 12
Chief Financial Officers ................................ 13
Advisory Boards ......................................... 14
Conclusion ............................................... 14

CHAPTER 3: LEGAL MATTERS ......................... 16
Intellectual property ...................................... 16
Patents ...................................................... 17
Licensing ................................................... 18
What to do if a patent is blocked ..................... 19
How to secure the best attorney ...................... 19
Financing early legal fees .............................. 20

CHAPTER 4: OPERATIONS AND LOGISTICS ...... 20
Life Science Incubators ................................. 20
Managing the Numbers .................................. 21
Finding a Fit .............................................. 21
Going Virtual ............................................ 22
Having a Voice in the Industry ....................... 23
Joining Forces .......................................... 23
Direct Benefits ......................................... 23
The Value of Making Connections .................. 23

CHAPTER 5: BUILDING THE RIGHT BRAND ...... 24
Branding Basics ......................................... 25
Selecting a Company Name ............................ 25
Logo Logistics .......................................... 25
Online Presence ........................................ 26
It’s All About Credibility ............................... 27

CHAPTER 6: HUMAN RESOURCES .................. 27
Preparing to Bring Employees on Board ............ 27
Compliance with Labor Laws ......................... 27
The Logistics ............................................ 28
Payroll .................................................... 29
Benefits and Perks ..................................... 29
Background and Reference Checks .................. 29
Negotiation .............................................. 30
Managing Employees ................................... 30
Terminating or Ending Employment ............... 30
Conclusion ............................................ 31
Appendix: Checklist .................................... 32
Chapter 1: Forming a Company ...................... 32
Chapter 2: Financial Considerations ............... 32
Chapter 3: Legal Matters ............................... 32
Chapter 4: Operations and Logistics ............... 32
Chapter 5: Building the Right Brand ............... 32
Chapter 6: Human Resources ....................... 33
Appendix: Resources .................................. 33
About TriNet ........................................... 35

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Foreword

For scientists with a breakthrough idea, those who need help transitioning from the lab to the life science/biotech boardroom, and everyone in between, this guidebook is for you.

Academic success requires years of commitment and specialization, leaving little time for M.B.A.s and business development seminars. As a result, many experienced scientists are unfamiliar with the fundamentals of launching a biotech startup. Despite being the source of endless innovation, they often struggle to bridge the gap between discovery and the marketplace with all of its diverse challenges and unknowns.

This handbook demystifies the various aspects of business management and shares key insights and best practices for managing the growth of biotech companies. To prepare scientists for the challenges ahead, it draws on interviews with law firms, HR providers, life science associations, startup incubators, and other entities that guide startups through this process every day. It also brings to the table some hard-earned wisdom from scientists who have successfully made the leap from idea to execution.

Common themes emerged from the expert interviews. Most believe the greatest misstep biotech founders make is that they don’t set up to succeed. From day one, newly-minted CEOs need to be thinking about the end product—what exactly are they going to make? How will it be administered? Who and where is the eventual market? And most importantly—what value will it bring and what is the reimbursement strategy? Every decision life sciences founders make should be directed toward the ultimate product or service, rather than short- or mid-term goals. Investors need to see a feasible path to market to consider parting with their funds.

A Startup Philosophy

The purpose of this guide isn’t just to lay out all the steps needed to achieve startup success. It’s also about the shift in mindset—from scientist to businessperson—that needs to occur before scientists can achieve success in the life sciences world.

Hand-in-hand with this are two mental shifts required to transition from the laboratory to the boardroom. Founders need to recognize that their job has expanded far beyond science. It now involves building value for customers and investors—a far more multi-disciplinary pursuit. This handbook offers a series of recommendations for systematically building value within and around a scientific idea. It also arms biotech leaders with strategies for protecting that value as their business develops.

The second paradigm shift relates to balancing figures. It can be hard for scientists to move from managing research grants to spending tens of thousands of dollars on legal, financial, marketing, and operations fees. This handbook attempts to differentiate what matters from what doesn’t—drawing on experts in many fields to pinpoint the best places to invest hard-earned funding dollars.

That being said, there is no getting around the fact that extra zeroes are useful—cheap work will stand out in a bad way. From half-complete patent protection to sloppy letterheads and domain names, there are many red flags that will send investors running. Scientists intending to make the translational leap must be prepared to leap at full force.
Credibility

A biotech startup launches with a clean slate. For the most part, no one has a negative impression of the people or the science—but no one has a positive opinion either. The immediate challenge faced is attracting investors, top legal and financial advisors, talented employees and other crucial business-building personnel, without any sort of track record.

The common denominator across all fields is the image of the company. From the outset, founders should be thinking about the public face of their business and how interested parties may be perceiving them. For better or worse, public opinion will shape the way a company’s science and potential are viewed. A feed-forward circle soon develops. Well-presented companies find it easier to gain representation from top law firms, secure spots in incubators and receive reputable investment dollars. This encourages other leading services and groups to follow suit.

With this in mind, scientist-founders should develop clean, air-tight patents alongside marketing and branding that signal professionalism and success. Few people can dive into the complex mechanisms of a modern science company. But many, many groups can judge the outward face of a biotech startup, especially competing forces waiting to pounce.

This guide isn’t intended to be the final word on commercializing an idea or technology for profit. It is meant to help scientists understand what to expect as they build a business from the ground up. The chapters that follow outline company formation, financial considerations, legal matters, operations and logistics, marketing and public relations, and human resources.

This is only the beginning. This guidebook provides an overview of topics, which founders must then start exploring on their own, focusing on the areas most relevant to their business. Included at the end of the book is a list of resources that delve deeper into each field.

The road to building a successful life science business is long, but every journey begins with a single step.

Is the Timing Right?

In 2008, Kim Lim put her own money on the line to found Ultimate Labs, a clinical laboratory service based in San Diego. Lim was recently divorced, had two young children and her new business venture coincided with the great recession. Growth was slow in the beginning but, eight years on, the company is thriving. Which begs the question: is there a right or wrong time to start a biotech?

“At the time there was very little investment, even SBIR (Small Business Innovation Research) grants were really hard to come by,” says Lim.

Banks were extremely reluctant to lend, making it difficult to grow and expand in line with the initial business plan. With a lack of outside investment, the team focused on keeping costs low and worked to turn a profit early on.

“We just did it ourselves, creating revenue and adding services one by one,” recalls Lim.

At the time, biotechs weren’t hiring, which fueled the need for outsourced services. Ultimate Labs set out to meet this demand, developing new, more efficient processes. Instead of trying to save money with capital purchases, Lim positioned the company as a top quality service provider.
“Our approach was to search out the latest technology and that was to our advantage. At the time, systems were getting smaller, but larger biotechs were hanging onto their equipment to cut costs. They had the gigantic HPLCs and the gigantic spectrophotometers, when the latest products were really being miniaturized. We took advantage of all of that when we started.”

Many scientists hold off from establishing a company because of economic factors, life events or a lack of financial security. However, with innovation, specialization, and an ability to adapt, life science entrepreneurs can overcome adverse situations.

“I’ve been on a couple of panels for young college and graduate students, and their main question is how do you do it? Where do you start? I think really the starting point is being brave. You just have to do it. You have to try it and not be afraid that you’ll make a mistake. It’s going to be OK in the end. If you really want it you will get there.”

Chapter 1: Forming a Company

Introduction

An academic scientist may work for years on a proof-of-concept. Once it’s validated, the challenge turns to translating the scientific idea into a novel, valuable product. This is the commercialization stage. There may be endless potential, but it’s hard to know where to begin. Startups first need to officially form a company. This step is vital for protecting personal assets. After that, founders must learn how to put together a comprehensive business plan that gives their company a competitive edge in the marketplace.

Registering the company

Establishing as a third-party entity is an important translational leap and one that should be made early on. The number one reason for incorporating is that it protects any personal assets as well as the owner in an individual capacity. Without a third-party entity, founders are personally liable for all business activities. That alone justifies the ~$200 registration fee and associated time. Beyond that, there are other reasons to establish a single corporation:

- Easier administration and taxes
- Intellectual property, financial and legal filings are directed to one consistent place
- Tidy, transparent financial and legal picture, which is favorable to investors
- Meets prerequisite to secure funding; a venture capitalist is unlikely to consider depositing funds into a personal bank account

Incorporating is also when the exact structure of a business should be formalized. If this is undefined, the limits of any lawsuits against the founders are equally expansive. Beginning any commercial transactions before registering, for example, might inadvertently create an “unintended partnership.” Anyone who helps or participates in the business—even a friend or spouse—will involuntarily put his or her assets on the line.

The good news is that establishing a company is a straightforward process. Transitioning scientists can proceed without running into a minefield of potential hazards. Do-it-yourself legal websites walk users through the basics for around $150. As the business progresses, it’s wise to hire an attorney to establish a more detailed operations structure. But unlike patents and many financial decisions, it’s OK to start off basic.
Incorporating style

Beyond the name, there are several executive decisions that need to be made during the formation of a company. Foremost is the incorporation style. Founders need to choose between registering as a limited liability company (LLC) or as a C corporation. There are other options (namely an S corporation, or state-specific options), but the majority of startups favor LLCs and C corporations.

“Usually, if you’re expecting funding quickly, you form a Delaware C corporation,” explains Kevin Buckley, a San Diego-based biotech attorney. “If not, you’ll form an LLC so that you can write-off the losses individually, on your individual taxations.”

A limited liability company protects the owner’s(s’) personal finances and assets. It also establishes a flow-through entity (FTE), aka pass-through taxation, whereby the company’s income is treated as that of its investors or owners.

A C corporation places a taxation gap between the company and the owner. As such, the business would be subject to standard corporation tax rates, even before it turns a profit.

Why Delaware? According to USA Corporate Services Inc., over one million startups, LLCs and corporations from all over the United States are currently registered in Delaware. There are financial incentives to do so: Companies registered in Delaware pay no state income tax and there is no out-of-state operating fee. Day-to-day administration is also user-friendly, run by the Division of Corporations, which allows for easy filing and approvals online.

The primary reason to choose Delaware, however, is that the state’s securities and management law is extremely business-friendly. Delaware’s General Corporation Law is continuously updated and considered biased against regulation. The state also instituted a Court of Chancery as far back as 1792, which created jury-free courts with judges that specialize in business disputes and are well-versed in business law. For this reason, many investors strongly favor the predictability of a Delaware-registered startup.

Company specifics

Founding a company is relatively hassle-free, but as the startup progresses there are some areas that need attention. A sound, transparent company structure is a must-have for investment. A strong startup will also include:

An operations agreement

It’s fairly common to approach a new startup as part of a two-person partnership. The instinctive business arrangement would be to formalize a 50/50 split of shares, responsibilities, and executive decisions. But what happens if the partners disagree? Many companies and friendships have fallen into a litigious mess because there is no provision in the operating agreement for how to settle a head-to-head dispute. Venture capitalists also want to avoid conflict and have seen this scenario play out negatively. If the business filings do not stipulate how a 50/50 dispute will be resolved, investors will either direct the founders to the door or begin implementing their own provisions. At that point, the company seeking funding loses leverage. Investors may take a majority share of the board seats or rewrite the management rules.
A tactical company name

To file a registration, there needs to be a company name. Often, the founders have a name pre-determined but it’s always important to audit the field before making a submission. In the Internet age it’s not that hard, but it is vital to ensure that trademark rights, domain name, and social media handles are available. For companies still in the brainstorming phase, see Chapter 5: Building the Right Brand for best name selection practices.

Another option is to register a legal name, with an intention to later file a DBA, “doing business as.” The term refers to the operating name of the company, as opposed to the fixed legal name. While it’s not ideal, it does achieve many incorporating goals, such as channeling paperwork to a single location and reducing the risk of forced rebranding if a good naming fit is yet to be determined.

Business Planning

A business plan is a company’s guiding document. It’s the blueprint for how it will grow from a fledgling startup to a full commercial enterprise. Although business plans vary according to the industry and type of company, they all contain key elements.

Executive Summary

A business plan starts with the executive summary, a two- to five-page overview of your business. Founders should strive to make the summary as effective and compelling as possible without giving away too much proprietary information.

The Market

One critical element of writing a business plan is defining the target market. This helps focus efforts towards 1) what the company is actually selling, 2) those who are most likely to buy the product/service, and 3) how to best communicate the company’s value proposition to the customer.

Investors want to see that startups have identified the key sector in which the company will operate. When pitching to investors, founders need to show 1) that there is demand for the product/service, 2) that the demand is sizeable and growing, and 3) that demand can be captured by your product/service. This research can be done independently or the founders can obtain strategic market insights from a firm—there are some that specialize in the life sciences. They help determine where a company fits in the marketplace and where the biggest competition lies. This information can help to identify points for differentiation and how the startup plans to be unique.

The main objective of a business plan is to highlight how the product will address a current unmet need in the market better than anyone else. It should pool information to support the case that there is demand for what the startup is offering. It should also include an estimation of how long the startup will have a competitive advantage once patents are secured. (See Chapter 3: Legal Matters for how to apply for patents.)
Identifying the customer

Market research matters. It’s important for startups to gain insight into the customers and marketplace they’re trying to reach as they roll out a new idea. This is when founders should ask, “Who are my customers and why should they care about what I’m selling?” Figuring out the target audience is a critical step in launching a biotech business. It shouldn’t be skimmed over in the interests of time and money. When talking to potential users of a conceptual product, startups should ask questions and really listen to what they have to say. Putting the focus on the customers’ problems—not the product—should help the company better understand customer behavior. It’s better to present new technologies as a much-needed “solution” rather than innovation for innovation’s sake.

The Science

This part may seem like a walk in the park to most scientists, but a special skillset is required to pitch the business plan to outside investors, who may or may not have a science background. Scientists should avoid writing this section like they would a peer-reviewed journal article. When explaining how a discovery works, clear, familiar terms work best, avoiding science jargon as much as possible. Analogies are helpful when it comes time to explain complex concepts. Founders are typically passionate about their science, having lived and breathed it for years. As such, it is wise to ask a detached third party to read over the science to guarantee it’s readable and comprehensible.

Strategy

This is arguably the most important part of the business plan, as it outlines exactly how the startup plans to accomplish its goals and how long it will take. To excel at this, founders should decide on important milestones that can gauge the company’s ongoing success. A strategy should cover each phase of development, with a breakdown of how much capital is needed along the way. To stay organized, it’s wise to map out all of the activities needed to achieve those goals, tying in a cost to each activity.

Management

A management section seeks to introduce all of the people involved in a given company, from senior management to key advisors, with a brief overview of their relevant experience and skills. It’s not necessary to take up space by including resumes or CVs. Only short biographies are necessary. Spotlighting management capabilities shows that the team of people driving the business has the right know-how and is committed to success.

Financial Projections

Once the market has been analyzed and clear objectives set, startups can begin to put the final financial pieces of the puzzle in place. This part may be intimidating to many founders. As an early-stage company trying to get seed funding or turn a profit, it’s inherently hard to predict financial performance several years down the road. Founders should strive to tackle it objectively, with an aim to be specific. Investors want to see that a startup has a good grasp on what’s involved, even if the exact figure is a ballpark estimate.
Breaking down the financial data required for a sound business plan, startups should aim to include the following:

- Financial projections—monthly or quarterly for year one, and quarterly and/or yearly for years two through five
- Forecasted income statements, balance sheets, cash flow, and capital expenditure budget
- A projected balance sheet breaking down the assets, liabilities, and owner’s equity
- A cash flow projection revealing the actual movement of cash through the company in a given period

These projections should align with the amount of money being requested. Failure to do so can look suspicious to investors. For efficiency and peace of mind, many startups choose to pull in an accountant to review financial projections. Either way, this section of the business plan needs to be as reasonable and as clear as possible in order to recruit investors.

**A Workable Document**

It’s a challenge to find a company in any industry sector that has followed its business plan precisely. Things happen. So much of what is in store will be unforeseeable. However, despite countless iterations, it’s critical to have a business plan in place. It builds credibility with investors, keeps the company on track with spending, and serves as a baseline document for all other aspects of the business.

“We tried to create a business plan, but it never works out the way you think it will,” says Kim Lim, CEO and founder of Ultimate Labs. “But it’s an idea, the basics; you have to have a good handle on your finances, you have to have a good handle on your customer base and sales. I knew from the beginning that we would need marketing to help grow our sales, so that was in the business plan, too.”

A business plan is a flexible document that will need to be revisited and revised from time to time. It’s not written in stone. Executed well, it can help raise capital, while also serving as an internal roadmap for expansion.

**Chapter 2: Financial Considerations**

**Introduction**

Scientists are more than familiar with how to apply for grants and how research funding works. But securing funds to run a for-profit business is an entirely different endeavor. Once a startup is incorporated, armed with a business plan, and has intellectual property pending or finalized, the next challenge is securing sufficient funding.

There are three basic financial paths a new biotech can take:

1. Operating with National Institute of Health (NIH), Small Business Innovation Research (SBIR), or related government grants
2. Seeking outside investment, whether venture capital, angel funding or crowd-based
3. Selling products or services to generate an independent revenue stream

Each has pros, cons and quirks, and understanding how to approach them is necessary to avoid breaking the bank early on.
**Top tip:** The kind of funding a startup should go after is largely determined by the company’s offering and how long it takes to develop. Life science reagents have a short time to market because there are no FDA requirements. A therapeutic or medical device, on the other hand, takes years. This path may require angel investors, and possibly venture investment, to sustain the startup through the long product cycle, according to Lisa Johnson, CEO of BioForward, a Wisconsin biotech association. Federal SBIR grants are very beneficial in supporting life sciences startups, but they are time-consuming and offer little flexibility.

Worth noting is that communication with investors is fundamentally different from grant applications. Whereas grant organizations want science specifics, investors focus primarily on the value proposition. What value does this company bring to the industry? Providing a simple, concise answer to that question is critical when dealing with investors. Founders need to present a strong business plan that helps investors understand the value of the science.

1. **Government Grants**

Small business grants, which are largely government funded, may be the most natural progression from research funding. The United States government offers Small Business Innovation Research (SBIR) grants to businesses looking to commercialize a product or discovery, thus seeding a new business and creating jobs. Hundreds of open grants are posted on the SBIR website and span a breadth of opportunities. Grant allotments vary but multiple can be held at once.

The Department of Defense is another major funding source that extends to early businesses. Applicants are required to connect their science to the Department of Defense’s mission, but their inclusion range is surprisingly large. Other government departments, including agriculture, energy and environment, all offer small business grants, which can be searched for in this central database.

“Government grants are great because you’re not giving anything away and you’re still moving your idea forward,” says Nicole DeBerg, COO of J. Craig Venter Institute. “The key is to move your idea as far along as you can before involving too many investors, and grant funding stretches your ability to do this.”

Surviving on government grants alone is challenging, but it does allow startups to persevere without compromising on their vision or priorities. When it is time to sell the idea or products, the founders will have retained full equity. Funding from grant sources can also be supplemented with credit lines. Chapter 4: Operations and Logistics discusses ways to minimize startup costs and draw on different resources (payment for many services can be negotiated or contracted on a deferred basis).

2. **Outside Investment**

Venture capital funding is notoriously fickle. Depending on when a company starts out, where it’s located and what field it’s in, there will be significant hurdles to getting investment dollars. The good news: The process teaches a founder to refine their business plan and set realistic expectations.

It can be overwhelming for scientist-founders looking to gain a foothold in the for-profit sector. A good place to start is by joining a regional business/venture group. Startups situated in a life sciences hotbed can access a wealth of influential people through these open-invite associations. Organizations such as the San Diego Venture Group (SDVG) are a melting pot of investors, executives, startups, and more, working to initiate new business partnerships. Most can be found through a basic Google search or via their LinkedIn page or group.
**Credibility and Leadership**

Potential investors need to believe in a startup’s science, but much more importantly, they need to believe in the people. For first-time biotechs, it can be hard to establish a good reputation. In most regions, this can be overcome quickly by doing homework and seeking outside help.

“If you are going to attract capital, you need to know how to present to investors and ideally you have a very strong management team,” says Lisa Johnson, CEO of Wisconsin’s BioForward.

To secure investors, founders should:

- Network and ask mentors and peers for an introduction to venture capitalists. A startup that comes referred already has one vote of confidence.
- Work hard to show the company is operating by the book, with a high quality attorney, a sensible business plan, operations agreement and a well-crafted patent estate. With their money on the line, investors don’t want to join forces with a “wildcard.”
- Know the subject. If a founder doesn’t know the competitors in his or her space, or the major financial challenges, they’ll quickly lose the respect of a credible investor audience.
- Outline the best-case scenario as well as some backup plans, which will inevitably come into play. Founders need to show that the value of their company will not be lost when things don’t go as planned.
- Present clear markers of success that speak for themselves. Examples might include placing in a startup competition, securing prior investment, showing outstanding science potential or achieving early milestones.

Newly-minted CEOs might be surprised to find the conversation does not revolve around their science. It’s easy to romanticize startup science companies and the potential for breakthrough treatments. However, there are more basic principles on the minds of investors, such as whether the particular science field is under- or over-invested in. This means market value, not science potential or the potential benefit to patients.

**Investment Strategy**

Securing private capital investment dollars may seem like the holy grail of funding, but it’s important for founders to pause and consider the package deal before committing. All money is not the same. A startup’s main investors (of whom there could be several) will likely take a seat on the board. This could prove crucial for long-term success or it could create internal challenges that impair the company as it moves toward commercialization. The outcome depends on the people and the company-investor cultural fit.

For this reason, startups should be cautious when seeking angel investment. An orthodontist may be independently wealthy and successful, but their experience probably does not translate to that of a science company’s. Inexperienced board members can contribute to fatal business mistakes. If nothing else, their presence on the board might deter future investors. On the flipside, having reputable, resourceful investors and board members can hugely fortify a business.

Securing the first round of funding doesn’t mean a startup has made it. That’s just the beginning. It also comes at a cost. The high risk associated with these investments means that the investor will demand a substantial equity stake in the company. Founders should discuss value and negotiate terms with that in mind. If they can prove the worth of their business, with a clear path to market and financial potential, they’ll have a lot more leverage to bargain with.
A word of caution: Before signing an agreement that puts their company on the hook, startups should always speak with a financial consultant and an attorney. These are important decisions, so it’s best to have the documents reviewed by a professional. It’s worth the peace of mind to know that terms and conditions won’t end up hurting the business long-term. These professionals can be considered part of a startup’s wider advisory team, helping make sound business decisions so that the startup can succeed.

“You want the right advisors from a business, legal, and accounting perspective early on,” says Nicole DeBerg. “When you first bring money in, you have to be really careful, and your attorneys will be your best friends.”

**Risk and Commitment**

Scientists are trained to be risk-averse. Money in academia is not easy come, easy go. Grants are hard-fought and tightly budgeted. Yet to commercialize an idea, scientists must engage the private sector. Money is on the table and bets must be placed.

Do founders need to commit their personal funds into the project?

“It’s a very difficult conversation when you get in front of a venture investor and say, ‘I want five million dollars of your money but oh, by the way, I’m unwilling to put 20 to 30 thousand of my own money into my own company,’” says Kapila Viges, director of EnterpriseWorks Chicago, University of Illinois and visiting director of the Proof of Concept Fund for IllinoisVENTURES.

Many scientists are very reluctant to invest their own money, given the number of startup ventures that fail. But if a scientist is not prepared to put their own money on the line, can they expect others to put theirs?

“Every investor wants to know that everybody’s got skin in the game. They need to know that everybody is invested,” says Viges, though she acknowledges each case is different. “These aren’t hard and fast rules, but it’s an example of the mindset.”

Even if a founder believes strongly in his or her idea, they are still entering a risky business. In drug development, for example, what works in a petri dish and even yields convincing pre-clinical data often does not produce the same results in humans. This is a disappointing—yet very real—outcome in life science startups.

“If you don’t have a lot of money and you have a family to take care of, use other people’s money!” says Nicole DeBerg, COO of J. Craig Venter Institute.

In essence, this relates to the much bigger fundamental shift for scientists-turned-business people. They are now entrepreneurs, not scientists, and need to show an understanding of what success in business means.

### 3. Turning a Profit

Not every life science startup requires years of investor or grant-funded research and development. Some, particularly services, can begin selling immediately. As with the other funding routes, executives will need to carefully calculate the numbers before they begin.

How much money does a startup require? Founders should consider writing a detailed list of everything they’ll need to buy, with an aim to build a more complete picture of the startup and operating costs. It can start with equipment needs and costs and run through to big-ticket items like office space, manufacturing and computer equipment as well as smaller purchases like office supplies and software. There are other costs that founders
might not readily think about, such as employee compensation and marketing spend. They should also think about any wages or fees the startup could incur for legal, financial or tax advice/services, as well as special licenses and permits specific to their business.

The second part of the equation is how likely the company is to begin selling significant amounts of products and services. It’s hard to predict, but startups should do their best to research and consult as many experts as possible, to prevent the executives from biasing their own business predictions.

**A word of caution:** When a scientist leaves a stable position to start their own company, they are taking a giant leap of faith. While it can be a very exciting time, it’s important for them to closely and regularly review their own household balance sheet. Staying on top of how the new business venture impacts their personal finances can help a founder remain realistic about what they can and cannot afford when it comes to both personal and business needs and wants.

### Protecting the Investment

Business insurance may not be front and center on a startup’s list of priorities, but it will be if something goes wrong. It’s best to preempt any disasters with solid insurance coverage. A policy will help a new biotech protect its investments by minimizing risks associated with unexpected events, like a lawsuit, a natural disaster, the death of a business partner or an injured employee.

Furthermore, depending on the type of business owned, founders may have special or additional requirements and considerations. To determine if this applies, startups can check with the state government to learn more about insurance requirements for local businesses. Lenders may also require certain business insurances to protect their investment. Securing initial coverage involves the most work, but it’s also vital that the policies be maintained. Executives should review their policies annually to ensure they still fit with the company’s growing needs, keeping pace with business growth.

To obtain professional liability insurance, executives can contact an insurance carrier and learn about the different options that exist. In general, a $1 million policy is going to end up costing around $2,000 a year for each individual, according to Michael Mojabi, partner/principal at Ryan Financial Services.

“Speak with a professional insurance broker to determine your needs for whatever jurisdiction you’re in and what it is your company is trying to do,” says Mojabi.

### Chief Financial Officers

Chief financial officers (CFOs) are critical players in Fortune 500 companies, but for a startup with one or two people, it’s a hard role to fill. Do they need one?

“I think at the outset you don’t need one,” says David J. Parker, general partner at Ampersand Capital Partners, a private equity firm. “Typically, when the company is taking in institutional money from venture investors, they’ll look for a CFO or at least a VP of finance that is credible and has some experience.”

For a startup to decide what talent it needs, it should first consider its existing skillsets, particularly those of the CEO. “If it’s an individual that has built a company before and has some of the critical financial skills, then you can get away with an outside resource—they call them ‘rent a CFO’ outfits—and that’s certainly an option,” Parker says.

Specialized firms have CFOs on staff that can be contracted to provide outside CFO services. This is a practical way of bridging roles as the company scales and is not considered a red flag by investors.
Advisory Boards

One independent step startups can take to build credibility is to establish a scientific advisory and/or business advisory board.

“We recommend that everybody has an advisory board,” says Kapila Viges, director of EnterpriseWorks Chicago, University of Illinois and visiting director of the Proof of Concept Fund for IllinoisVENTURES. “We even have some programs where we provide advisory board mentorship for them. I think the challenge is that scientist-entrepreneurs try to do everything by themselves.”

Having a well-crafted board confers many benefits, including:

1. Additional guidance, connections and areas of expertise
2. It shows the startup is open to collaboration and appreciates the need to bring in extra help
3. Having respected board members adds legitimacy and credibility to the business
4. It makes the logistics of running a startup more feasible, as there are more people to carry the load

With that said, there are some words of warning. Many founders look to experts in their science field as a first port of call. Instead, they should look for individuals with experience commercializing scientific ideas. A smart scientist in another lab adds very little additional strength to your business team.

Startups should also exercise due diligence when it comes to selecting boards. Many trusting CEOs have had their intellectual property taken from beneath them by advisory board members who see opportunities for themselves. A fellow scientist who helps develop or troubleshoot a startup’s technology may decide they want to run with that idea themselves. If specific legal precautions weren’t taken, there may be few legal routes to stop them. To play it smart, founders should choose trustworthy people, have them sign confidentiality agreements, and set the scope and limits of their participation in stone from day one.

Conclusion

Each funding option has its place. Investors offer potentially huge resources, but will want control of certain business functions. Grants offer funds without taking equity, but are competitive and require stringent applications. Understanding how to present and pitch a company in each context will help founders secure the necessary investment.
Achieving Company Milestones

In 2008, before finishing his Ph.D., Jim Ross secured a Phase I Small Business Innovation in Research (SBIR) grant from the National Institute of Health (NIH) for $349,000. The company that would become Axion Biosystems hired one full-time employee that year (it now has 36), using lab space at the Georgia Tech bio-incubator to develop technology for commercial use. It would be three years before their first product, the Maestro, was introduced to the market.

“I would suggest that for scientific products, companies explore whether they can get NIH funding to support development,” says Tom O’Brien, CEO of Axion Biosystems. The company focuses on solving problems related to human heart and brain activity, and the Maestro is a multiwell microelectrode array (MEA) platform which can be used to screen complex human functions and disease states in a dish, such as the arrhythmias and seizure activities that emerge between networks of human cells.

Phase I NIH funding was critical during early development but was not, on its own, enough to go to market. For that, Axion turned to further grants and private investors, soliciting over $6 million in investments from people known to their small team. Ross, now the chief technology officer (CTO), was instrumental in making that happen.

“Our CTO has a way of articulating our vision that gets people excited. Also, he executes on product development, giving us products to sell, and that always makes investors happy,” O’Brien comments.

Many scientists struggle to present their vision to investors in a way that builds understanding and appreciation. Axion’s detailed business plan and well-articulated vision enabled them to excite investors and then later back up that excitement with results.

What were some of the key milestones for Axion Biosystems as it went through technology commercialization?

• Securing an SBIR grant from the NIH
• Securing seed grants of $50,000 and $100,000 from the Georgia Research Alliance in 2008 and 2009 respectively
• Getting an exclusive license to their technology from Georgia Tech
• Receiving eight non-dilutive NIH grants for a cumulative $7 million, $4 million of which went to development of the first product
• Selling the first Maestro
• Moving to private facilities from the Georgia Tech bio-incubator

Axion Biosystems represents a funding success story, even though they still have not turned a profit.

“We will be close this year, but we are more focused on topline growth and operating cash flow than we are on profitability,” says O’Brien.

With their intelligent and excited approach to grant applications and investors, Axion Biosystems was able to take their first product to market. Now they rapidly add functionality to the software and applications to the platform. Using the same core technology, they are developing a non-invasive platform to functionally image peripheral nerves and an implantable MEA that that can be used to stimulate, block, and control peripheral nerves.
Chapter 3: Legal Matters

This chapter details why and how startups should:

- Clearly define intellectual property and regulatory path
- Search and audit the intellectual property landscape
- License or collaborate with existing patent holders
- Find a capable patent lawyer to draft the best possible patent estate

Introduction

In the early stages of a life science company, two legal tasks demand immediate attention: intellectual property (IP) filings and licensing agreements. Both are time-sensitive and extremely important for long-term business success.

Once again, the path to market should be influencing every tactical move a startup makes. Downstream considerations, such as the intended regulatory route, will determine where and how it should make its patent filings. Will it be seeking the approval of the FDA, ISO, or EMA? How international is the intended market?

Now is also the time for founders to diversify their possible revenue channels. San Diego patent attorney Kevin Buckley likens this to a “shotgun approach” to exploring business opportunities. The reason: It’s nearly impossible for a startup to fully develop a “silver bullet” novel therapeutic.

Failure rates are extraordinarily high. A 2014 Nature paper found that just one in 10 clinical trials succeeds. On the other hand, many startups succeed in developing a product for experimental/research use only (RUO), bypassing clinical trials altogether. Likewise, an idea for a diagnostic could be turned into a technology platform or a lab testing service. Buckley says the idea is to patent as many development paths as possible, so the business model can adapt and evolve as challenges arise. Well-placed intellectual property may also be licensed out to fund the primary R&D.

Intellectual property

Patents are at the heart of many life science startups. However, other entrepreneurs seed companies with an idea to provide a service rather than develop a novel therapeutic. While patents may not be relevant in these situations, there are other intellectual property options. The five key rights include:

- **Patents**—essentially a 20-year legal monopoly on a novel idea or approach
- **Trademarks**—a word, phrase, symbol or design that identifies a commercial entity
- **Copyrights**—proprietary text, audio or visual content
- **Trade secrets**—less specific product or service information that provides a competitive edge
- **Know-how**—tacit knowledge that is difficult to communicate and define

Many startups overlook intellectual property claims if they’re not dealing with definable patents. If this is the case, trade secrets and know-how are especially important. A biotech service is highly dependent on protocol and people. If a startup spends time experimenting with new approaches or training staff, its leaders should simultaneously ensure that their investment is protected.
Unlike other forms of intellectual property, trade secrets aren’t registered and won’t expire. Unfortunately, this makes establishing a claim a little less clear-cut. The World Intellectual Property Organization (WIPO) lists three criteria for achieving trade secret status:

- The information must be secret (not generally known or accessible)
- It must have commercial value because it is secret
- The rightful holder must have taken reasonable steps to keep the information secret

The second claim is for know-how. If a company hires and trains an employee to complete a certain task, it’s likely that over time he or she will develop an intrinsic understanding of how that procedure is performed—for example, the nuanced shake of a bottle or a response to a color change in a solution. That understanding cannot be patented but the executives should consider establishing contracts with the employees to protect that know-how and insight. That might entail a non-compete clause in the contract or even a stake in the company’s success.

**Patents**

Patents are similar to insurance in that every life sciences business needs full, overlapping, and up-to-date coverage. Also like insurance, they can be a little intimidating. Things really get tested in the worst-case scenarios.

Thankfully, patents can be managed successfully. More than that, they are critical building blocks when it comes to building value. Done well, they can vouch for the professionalism of a company’s science and the legitimacy of the business. They can also stand alone as IP to be licensed, creating a revenue stream for future science endeavors.

San Diego-based biotech patent attorney Kevin Buckley suggests keeping these key principles in mind when building an airtight patent:

1. **Enabling**—A patent should enable a startup’s science, research and development growth for years.
2. **Broad**—Science is a gigantic field of gray. Every receptor has multiple targets and every antibody binds uniquely. Founders should patent as much as they can, so the intellectual space is protected from all angles—existing and soon-to-be discovered. Patents should stand beside a biotech as the science iterates.
3. **Angled toward the intended product**—The best IP approach is not to cover the science at hand. The goal is to anticipate the end product, crafting patents for what is ahead. Once again, investors want to see a clear path to market that includes downstream patent claims.
4. **Novel and not obvious**—The U.S. Patent and Trademark Office makes the rules on this one.

Companies starting out at a university may be required to work through the institution’s tech transfer office (TTO) to file the initial patents. The institution will own any intellectual property developed within their organization. Founders will have to license it back if they want to spinout a standalone company.

For academic scientists who believe they are on to something with commercial potential, it’s common practice to file a pre-publication patent—essentially a placeholder for the intellectual property. The next day, when the paper is published, the IP pressure will begin. It’s important for scientists to know that a “placeholder” patent will not stand. A concerted effort from any substantial life sciences or pharma company will quickly unravel its intellectual claims. To secure their patents and business, founders need to make a decisive move.
To begin licensing technology or science away from a university, founders need to have established an independent corporation (see Chapter 1: Forming a Company). Through that, they can contract with a patent attorney to begin negotiating with the institution for rights to develop the idea or discovery.

A word of caution: Fast-tracking patent approvals through a university is a dangerous move. While they may get intellectual property transferred and secured faster, the terms of the licensing agreement are typically much worse. Scientists opting for this route won’t be able to negotiate down the percentage of royalties that the institution will take and they may be charged a fee.

Confidentiality agreements

Confidentiality or non-disclosure agreements (CDAs/NDAs) aren’t rocket science, but they are important. Many smart scientists have inadvertently given away their business by not having one in place. Founders should think about when and where they might need them. An attorney can provide additional advice and will often have a template that can be used as a basic, one-way NDA (they’re typically only a few pages in length).

Perhaps the bigger point to underscore is for startups to always be savvy. Even verbally sharing an idea or approach before the company’s patents are filed is enough to invalidate its intellectual property rights around the world. This can happen years after the fact and is a horrible waste of both the work completed and the potential of the science in development. Startups should secure confidentiality before they share any thoughts and refrain from publishing any enabling documents, such as white papers or abstracts, until the patents are finalized. When networking or seeking guidance, founders should be mentally prepared to discuss the logistics of the company without ever disclosing the novel approach or science.

One caveat: Venture capitalists don’t appreciate the request for a CDA. They see hundreds and hundreds of pitches a year and could not possibly manage the conflicts of interest. A startup that presents one will simply be disclosing that they don’t understand the mechanisms of the life sciences industry. The NDA relationship with investors is one of trust. Considered logically, some of these investors will end up on the startup’s board. If the founders can’t trust them with their intellectual property, then they wouldn’t want them on their team at all. To avoid any issues, life sciences entrepreneurs should stick to pitching credible venture capital firms and investors.

Licensing

Once a startup’s patent applications are drafted for all the necessary therapeutic variants, it’s time for it to move on to licensing. The aim for founders here is to identify two different groups of people: the people that are blocking their science and those that present an opportunity for a merger, collaboration or acquisition. Without an understanding of what is blocking them or what they can license to somebody else, biotechs are unable to secure and realize the true value of their business.

Searching and indexing these collections of patents or “estates,” is a project that savvy scientists can undertake themselves. A good place to start is with the U.S. Patent and Trademark Office, through which a lay-person can canvas the national patent landscape. If the end goal is to sell the eventual product or service in overseas markets, the startup founders will also need to conduct an international search. The World Intellectual Property Organization (WIPO) website can mine all the major databases, but the data presented may require complex interpretation. For a fee, companies such as the Sherman Patent Search Group provide a more user-friendly service. They specialize in this field, with access to licensing databases that span the globe, penetrating complex and obscure filings to deliver comprehensive results. They also translate the findings into English. Through these groups, it’s possible to run specific searches, such as freedom-to-operate and infringement clearance.
What to do if a patent is blocked

For eventual funding, startups need to show investors that they have covered and understand the intellectual property in their field. Depending on the results, they may also need to take countermeasures.

If patents already exist and are blocking an intended filing, the countermove is to draft a patent estate that closely borders the existing claim. As an example, a scientific team may have discovered an antibody with potential therapeutic benefits. Upon searching international databases, they find patents already lodged in that space, perhaps detailing the same molecule but binding a different epitope. By leveraging their up-to-date expertise in this field and bringing in a top patent attorney, the new startup can claim every related molecule and mechanism. If they have multiple epitopes, they can claim use of a combination of epitopes, or four out of five of the possible epitopes, in all available regions. By doing so, they will restrict any potential competition while establishing themselves in a commanding position with room to grow and evolve.

Inevitably, this approach will attract the attention of those in the field. A new IP claim made on the boundaries of existing patent estates will trigger alerts on their end. Provided the new patents are constructed soundly, this is a positive thing for the startup.

"It’s a business opportunity," Buckley explains.

The new filings are likely to induce a “why didn’t I think of that reaction!” which readily morphs into an opportunity for collaboration or licensing. For this reason, startups that bump into a large life science company as they file intellectual properties rights may have found the ticket to a successful exit. Once again, if the patents are sound, the most a competitor can do is try to acquire the new player.

On the other hand, a founder may find some patented ideas, techniques or technologies that could help their science succeed. If others have made breakthroughs, they can consider licensing those findings in-house to fortify the life science business.

How to secure the best attorney

Many legal considerations can be managed independently. At some point, however, life science startups will need to hire an attorney. They can help establish and fortify the company as a third-party entity. A good attorney will also help scientists navigate the patent world and negotiate the necessary licensing. They bring credibility, an established network, and offer all sorts of advice. They’ve seen the set-up many times before.

The following best practices can help startups find and hire a suitable attorney:

- Choose an experienced law firm/attorney that specializes in life sciences and biotechnology. They have the necessary skills and experience, familiarity with the industry and startup situation; and their networks are relevant (for everything from funding to outsourcing work).
- Consider hiring one of the big eight patent law firms for some much-needed industry clout. A lot of premier biotech law firms select the clients they take on. Passing their screening is an important first step toward industry credibility. They know the important people within the field and any introductions or recommendations they make will carry weight.
- Look for integration. Startups that contract a patent lawyer, a transactional lawyer and an insurance lawyer that all operate independently will find a lot of the work falls on them. It’s important to have continuity to realize a long-term business plan. A patent lawyer needs to be preparing downstream for what the regulatory lawyer will ultimately submit. They need to be cohesive. A good approach for startups is to work backward from the end product, rather than approaching each step individually.
Avoid hiring a family friend who specializes in divorce law. Even if they did have the resources and reach, it’s a major red flag for investors. Patent law is technical and fails surprisingly often. It’s a dog-eat-dog world. A smart investor will not give money to a business that does not appear legally fortified.

Financing early legal fees

It’s all very well to chase quality, but what about the services cost? Another advantage to working with one of the eight major biotech law firms is that they can absorb initial costs and are familiar with a startup situation. Most will offer different payment models to help a startup grow their business. It’s in their interests to build a startup into a substantial client as well.

That said, not all innovative offers are a deal. Some will negotiate equity of the company, which can cause certain conflicts of interest, while others will donate the first $20,000 of legal work for free—before billing the founders $1,000/hour thereafter. Startups should hold out for a good deal and be prepared to negotiate. The important thing for founders to remember is that they can afford the highest quality legal counsel and those holistic services should prove worth it in the early stages.

Chapter 4: Operations and Logistics

Introduction

Previous chapters dealt with many of the business steps required to get a venture off the ground. Now it’s time to talk details. What will the day-to-day operations of the business look like? Where is the company going to set up shop? And how does a startup obtain lab supplies and materials?

There are more options than ever for effective research and development, from do-it-yourself affordable lab space to incubators to fully virtual startups that move projects through different contract research organizations. How does a startup know which route to take and how to make the journey a sustainable one? In this chapter, the pros and cons of different operations and logistics set-ups are outlined to help life sciences startups find the best fit for their one-of-a-kind company.

Life Science Incubators

Startup accelerators and incubators are increasingly popular throughout the business world, with some of the biggest uptake in the life sciences sector. The reason is simple: Establishing a laboratory with state-of-the-art equipment is extremely expensive, and for startups with one or two people, those mass spec or FACs machines might only be used once or twice a day. Why not share resources?

Beyond shared equipment, most incubators seek to offer a comprehensive startup package. They provide resources and guidance in many fields, with the goal of aiding companies in the initial stages of development.

Some specific offerings include:

- **Laboratory space**—with everything from wet labs to Internet connections
- **Advanced/expensive equipment**—from centrifuges to sequencers
- **Professional space**—for conference calls or investor meetings
- **Business training**—for wider business acumen
• Media training—and connections to journalists
• Legal counsel—or connections to reputable biotech law firms
• Financial support—though there may be poor terms and conditions
• Experience—formal or informal mentoring programs
• Connections—to investors, future staff or possible acquirers
• Credibility—nearly all incubators screen applicants, which makes placement an achievement in itself
• Morale—working for a life science startup can be a rollercoaster of ups and downs. It helps to have people nearby who can empathize, offer advice, and inspire.

For all of their benefits, incubators come with some caveats. First, they vary wildly. Some are extensions of existing research and development programs. Others are for-profit rental spaces that can prove to be a dead end. The package deals can be a drawback. They provide users with access to a lab at lower cost, but without control over what the lab contains. Logistics could also be a deciding factor. Incubators typically have fixed locations and durations, leaving little flexibility for a company’s growth.

Managing the Numbers

Incubators mitigate costs by providing access to common, and sometimes specialized, equipment. They are also relatively low risk—the buy-in is low, and it’s easier to walk away without long-term leases and ongoing equipment payments. An added benefit is that the costs are weekly, not loaded upfront. This can be critical, as early investors don’t pay with briefcases of cash. The money typically comes in installments. Paying deposits and buying capital at the outset can therefore be difficult. A good incubator will appreciate a startup’s financial situation and work to make the payment process as manageable as possible.

There are financial caveats when it comes to incubators. The terms and conditions can be stiff, especially if they require equity in a company or limit its future movements. The incubator may stipulate that it gets first right of refusal for any successful products the startup develops or it may close off access to competing investors or companies. This is not a given. There are plenty of incubators that are proudly “no strings attached,” such as Johnson & Johnson Innovation’s JLABs, which now runs six biotech facilities. Startups should do their homework and ask around to see how past tenants rate their experience.

Finding a Fit

There is no one “premier” life sciences incubator. Rather, selection is all about finding the right scientific and cultural fit. Perks vary from incubator to incubator, but may include direct financial contributions and research assistance time, as well as access to field-specific experts that can provide direction and validation for concepts.

Startups should make sure the managers (or the overarching company) are familiar with their science specialty. A medical device company, for example, should look for an incubator that has experience with devices and software. As another example, a company that is working on an NGS diagnostic tool should look for an incubator with sequencing experience.

Alternatively, companies should go straight to the source. A number of established life science companies run their own in-house incubators. Illumina, for example, allows access to their sequencers and nonexclusive access to Illumina intellectual property. They claim 10 percent of their tenant’s equity, but the companies do gain a front-row seat to one of the world’s greatest sequencing innovators.
Going Virtual

The incubator route won’t make sense for many startups, especially those taking a non-traditional route. Startups may choose to bootstrap it, leasing and operating their own space. A third option is to actively outsource different facets of R&D.

Outsourcing in the life sciences industry has surged in recent years due to three converging factors:

- **Macroeconomics.** Funding sources declined drastically during the Great Recession for both startups and established companies. Without upfront investment, companies were forced to stay light on their feet, passing work to contract research organizations (CROs).

- **At the same time, pharmaceutical companies laid off thousands of employees in an effort to keep costs low.** This created a skilled labor force that seeded new consulting firms and CROs, and staffed myriad others.

- **Despite these hurdles, science continued to advance and became ever-more complex.** The industry shifted from small molecule drug development to biologics and on to advanced therapeutics, such as antibody drug conjugates (ADCs). To handle these complex, potentially hazardous molecules, companies need specialized teams and expertise, familiar with highly involved regulatory guidelines. In 2016, the science alone can make outsourcing to CROs a necessity.

Nicole DeBerg, COO of J. Craig Venter Institute, recommends keeping the company virtual as long as possible. It’s hard to go back once a company is saddled with overhead expenses. “Virtual companies have been the going trend for a very good reason,” she says. “Find turnkey lab spaces where everything you need is already there and consider farming everything out as much as you can so you’re not taking away from your core business.”

She adds that biotech founders can think about hiring people to take care of running the business for them once their company grows big and successful enough (See Chapter 6: Human Resources).

**A word of caution:** Be careful about hiring too many independent contractors. According to Michael Mojabi, Partner/Principal at Ryan Financial Services, both the state and the Internal Revenue Service scrutinize 1099 forms, the way contract workers are paid. If a company intends to make people employees but starts out paying them as independent contractors, they can end up losing money because they didn’t establish their set-up properly at the beginning. Employee misclassification is an issue that can land a lot of companies in trouble with fines, so be sure to classify workers clearly.

One of the perks of outsourcing is that it’s not all or nothing. While so-called “virtual startups” choose to fully delegate their work (even the research process), others keep everything in-house or outsource individual services. A company may, for example, choose to outsource one or two routine services, such as water purity testing, which can be inefficient for the in-house team to run.

As always, the issue of funding is a big one. CROs are specialized, save time, and reduce the need for capital investments. But they do come at a cost. Predicting the costs associated with different scenarios is difficult but vital for startup business success.

One resource to keep in mind is the CRO itself. Many of the largest CROs have investment arms that offer science services in exchange for an equity stake. It’s certainly low risk. If the startup doesn’t make it, there is no debt to be paid. On the flipside, it may lower potential rewards, particularly if the company has already given away large shares in its business.
Having a Voice in the Industry

Joining a biotech association is another possibility for new companies. A life science industry association brings together all the major players—large and small companies, academic institutions, service providers and others—who are interested in building an environment that fosters life science success in a region. (See a comprehensive list of life science/biotech associations in the Appendix: Resources section.)

There are several important benefits offered by life science associations, including educational opportunities, professional development, networking, legislative advocacy and group discounts for common supplies.

Joining Forces

Although it may seem one step removed, advocacy at the local, state, and federal level is what keeps life science communities thriving. Biotech organizations help a region retain and attract talented people and develop a climate that favors business.

Lisa Johnson, CEO of Wisconsin’s biohealth association, BioForward, says the biotech industry assumes most people know the benefit that life science companies provide. However, legislators are often misinformed and view the industry as harmful rather than beneficial. Johnson believes life science companies, both big and small, need to come together as an industry to advocate and influence.

“A CEO of a small company needs to stay very focused on their business, yet at the same time they need to be aware of what could ultimately impact their company,” she says. “We can’t put our heads in the sand. We need to be more engaged as an industry.”

Direct Benefits

Many biotech associations, such as San Diego-based BioCom, operate a purchasing consortium to help companies save money on lab and office supplies, insurance and other expenses. BioCom currently provides members with access to 35 negotiated contracts as part of their purchasing group. This bulk-purchasing model reinforces the idea of power in numbers, allowing negotiation of discounts and rebates as a collective. Associations may also mediate member-to-member discounts. Combined, BioCom estimates it saved its 750 members $90 million in 2014 alone.

“The larger companies benefit if our innovative, emerging growth [startup] companies are more financially stable because they could ultimately be partners or customers in the future,” Johnson says. “We all benefit from a strong, innovative ecosystem.”

The Value of Making Connections

Biotech organizations also support entrepreneurs and life science businesses through access to experienced life science professionals for mentoring, guidance, potential board and scientific advisory board members, and academic institutions.

Johnson imparts this wisdom to early-stage companies: Look to the community and state for financial resources. Reach out to as many people as possible when forming a team to launch a business. Look for good mentors, and maybe an accelerator program. Connect and learn from people. Seek advice from resources that are available in the community.

Startup companies ultimately need to develop their own hybrid operations and logistics model, but tapping diverse resources can prepare them with the information required for that development.
Chapter 5: Building the Right Brand

Introduction

Image is everything when attempting to gain funding, attract talent and compete in the marketplace. The product or invention developed by a company may be exciting and compelling, but how is its business perceived by outsiders looking in?

Many startup life science companies get caught up in product development and forget to drive value through a clear, consistent brand identity. This chapter provides an overview of the steps required to establish a startup company’s position as a leading, recognizable brand in the life science sector.

[CALL-OUT BOX]

Marketing Checklist

Top priorities:

• A unique company name and associated URL
• A short explanation of the company’s unique value proposition
• The foundations of a brand—what the company is and the impression it wants to make

Secondary priorities:

• A logo
• A brand color palette
• Company email addresses and signatures (on-brand)
• Business cards
• A written overview of the business (short and impactful)
• A layman’s explanation of the science and what it achieves (without compromising intellectual property)
• A website or basic landing page

Tertiary priorities:

• Letterhead and creative templates with brand colors, name and logo
• An “About us” section for the website
• Valuable web content
• Sales collateral, brochures, etc. for tradeshows and events
• LinkedIn and/or Twitter founder and company pages (these social channels are the most valuable for businesses at this time)
• A voice. Whether contributing editorial articles to trade publications or participating in webinars, new companies need to get their opinions out there and communicate their company’s core messages
• A networking/tradeshow strategy to expand the business in person
Branding Basics

Building the right brand for a company is integral to its expanding growth and success. It takes years to develop a solid and reputable brand—a “household name.” The first steps are creating a brand identity with the right name and logo.

Selecting a Company Name

Coming up with a name can be challenging if multiple parties are involved but there are some basic principles to follow. Think about what the product or technology accomplishes and play the word association game (go ahead and cheat with a thesaurus). What type of impression will the name make? Be sure the name matches the appropriate category, target audience and tone. A light-hearted name does not suit a company that is selling a serious product. A small, customer service-oriented company, on the other hand, may be able to have more fun.

Jot down all the brainstormed names on a piece of paper. Say them out loud. The ideal names are easy to pronounce, easy to remember and neutral (without negative connotations). Choose potential names that won’t be confused with competitors and clearly indicate the industry sector (this is why there are so many “XYZ Technologies,” “XYZ Devices,” “Molecular XYZs” and so forth).

It’s important for companies to conduct wide Internet searches for their candidate names to determine whether they’re already taken or associated with something off-point. Think through any acronyms or sounds that are made if the words are run together. Search for the domain name, handles and usernames on social networks. These should all be secured for a company’s brand.

Once the list is whittled down to three prospects, write a two-sentence description for each name. Take the three names with descriptions and test them with a handful of prospects. Getting quick market feedback shows how a brand would be perceived externally. Think about scalability. Will the name still be relevant as the company grows and expands? Pick a name that will stay true even as the company evolves.

Top tip: It’s good to have input from a wide variety of groups, but it’s hard for a committee of five or more people to reach a consensus. Limit the number of people with an executive vote.

Logo Logistics

Once a name has been finalized, a creative visual identity should follow. A well-designed logo helps a company stand out from the crowd. It is a foundational element of brand strategy. Take some time to look at other company logos that are admirable but resist the urge to imitate. Logo design should be original.

The good news is that logos can be updated later on. Google recently updated its logo, proving that companies of any size can re-brand. A company’s initial logo concept is a starting point, but it does help if some of the aesthetics (color or font) can stay with the company over time.

Outsource it: Introducing Fiverr. This website burst onto the scene in recent years, bringing together an Internet of creative professionals prepared to work for a fiver ($5 USD). Contract three or four different designers with good reviews to ensure high-quality results. Provide as much direction as possible and hope that one will deliver your perfect logo. Also be aware that many charge extra for high-resolution logos or other add-ons. It’s best to keep the investment as low as possible until you find a logo that truly resonates.
**Bring it in-house:** With some artistic inclination and a vision of what the logo should look like, companies can use available online resources to guide them through the design process. These include websites that help businesses choose a cohesive color palette (e.g., design-seeds.com) or pick a creative font (e.g., DaFont.com). Putting the two together can provide the basics of a brand.

**A word of caution:** Companies should be careful not to get carried away with beautiful calligraphy and color designs if they don’t communicate their life science brand. They should choose their name and logo wisely, because a strong brand identity will allow people to instantly recognize what the company does, what it offers and what they can expect.

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**Marketing Strategy**

A startup’s marketing approach should be tailored to its business model. Broadly speaking, there are two major categories:

1. **Revenue.** A company is ready to sell. It has a core product or service that is ready to market and its financial plan is to drive revenue from sales. A company in this category needs to develop brand awareness and audience reach through a variety of different channels, actively pursuing marketing tactics from day one.

2. **Investment.** The company is facing many years of research and development. The owner may initially choose to fly under the radar as the patents and legal situation are finalized. Once this is achieved, the company’s next step is to curate a small number of very professional marketing pieces to add credibility to its brand and drive investment. The approach will focus on investor relations over product marketing.

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**Online Presence**

A website is often the first interaction potential customers or investors have with a brand, so it’s important to make a good impression. Managing website development and associated costs before revenue or serious investment has come in can be a challenge. A substantial, customized website can cost anywhere from $50,000 upwards. Consider the following approach for budget-conscious startups:

1. **Invest in one high-quality home page.** It’s not necessary to have a full website with dozens of pages and blog posts early on. Companies should instead build one decent page for visitors to land on and include a short intro, explaining who the company is and what it does. They should also consider embedding a contact form that encourages interested investors or collaborators to email them directly.

2. **Prioritize content.** Clear, engaging copy that demonstrates what a company does and how it can benefit visitors is what makes a lasting impression on a website.

3. **Keep records.** A best practice in establishing an online presence is to document everything, every username, password, the company that hosts the website, and the contact details of any outside help. At some point, a company may contract a professional website/marketing service. Retrieving usernames and passwords can waste days of their time (and a company’s money).

4. **Set up a company page on LinkedIn and Twitter.** Neither costs money and these social networking platforms increase a company’s chances of being found.

5. **Consider selling through third-party sites.** Many customers prefer to buy online, but establishing a website with secured payment options is a significant expense. If a company needs to do this early on in their startup journey, it may be better for them to use an established site, such as Amazon Lab, to sell their life science goods or services.
It’s All About Credibility

When embarking on a branding journey, it’s important that companies remember that the goal is to communicate value. With a strong brand, they can project their company’s image and attract investors, customers and employees. Their brand helps them stand out from the crowd and adds credibility to all they do. During the early years, many people will evaluate the potential of a company. Few will be able to truly understand the nuances of the science in a short amount of time, but everyone will understand the basic marketing cues that signal professionalism.

Chapter 6: Human Resources

Introduction

At some point, a company has sprouted from a seedling idea into one with potential for upward growth. The sky’s the limit, but it takes a team of dedicated people to make success a reality. Now is the time for startup companies to think about ways to attract and retain talented employees while preparing for human resources issues that inevitably crop up in any business.

Preparing to Bring Employees on Board

Expanding and hiring new employees is an important milestone for a young company. It may seem daunting to take responsibility for new individuals, especially if this is someone’s first foray into business ownership. Play it safe by planning in advance, protecting the company from any liability, and creating a happy and rewarding workplace for new team members. Third-party resources are available to assist companies find talented people to join their ranks.

Before starting the employee process, companies should consider these three human resource pillars:

Is there a long-term need? Before committing to hiring their first full-time employee, company owners should ask themselves if the company’s needs are project-based. If that’s the case, they may want to outsource help until they’ve built up enough work and revenue to justify bringing on an employee long term.

Timing is important. Cash flow is precarious in the early days and wages are a significant overhead. It’s important to run the numbers before hiring a new employee to ensure that the business is ready. Business owners should maintain this mindset throughout the company’s early years. Do they need a sales team and secretary now or is that in the next phase of their business plan? Development is step by step.

Remain flexible. Humans are among a company’s greatest variables, and there are many things out of an employer’s control. Part of the hiring process involves constantly tweaking as a company attempts to find the right people. Companies ready to hire should do their best but be prepared to iterate and part ways when things don’t work out.

Compliance with Labor Laws

Before beginning, one must seek out advice and research the labor laws in their state. The number of labor laws and regulations affecting small businesses is expanding, and startups are no exception. As regulations increase, so do the documents required to prove compliance. It is difficult for early-stage company owners to jump in and navigate the landscape on their own unless they have a high tolerance for risk, notes Jackie Breslin, Director of Human Capital Services at TriNet, a leading provider of outsourced HR products and services.
“It’s not unusual for us to catch mistakes that companies have made relating to labor law compliance,” Breslin says. “In fact, a lot of companies come to us because they have had to settle a claim.”

In California, for example, even a one-person company needs to abide by recent changes to the Paid Sick Leave law. As a company grows, relevant laws become greater and more complex, but there are plenty of laws that start at the one-employee mark, especially in states that are heavily regulated, such as California, Oregon, New York, New Jersey and Massachusetts. “Those happen to be states where it’s popular for life science companies to spring up,” notes Breslin.

In order to assure compliance with these ever-changing state, federal, and municipal labor laws, many organizations outsource their HR. This means engaging a third party to handle human resources functions, such as recruiting, payroll, benefits, and workers’ compensation. Outsourcing models range from services that handle a single process to “co-employer” approaches in which the vendor provides an array of services and becomes the employer of record for the company’s staff. A partnership with a human resources consultant or professional employer organization, such as TriNet, allows entrepreneurs to devote more energy to mission-critical tasks.

Kim Lim, CEO and founder of Ultimate Labs, a contract laboratory service that specializes in analytical testing for life science companies, outsourced to multiple experts when she started her company in 2008.

“You can do anything yourself, but you have to weigh up: is it worth your time or your money at that point? It’s those decisions that you have to make. I almost wish I utilized more of the outsourced services than I had and not tried to take it on myself,” says Lim.

The Logistics

Before diving into recruitment, companies should spend time thinking about the skillset and experience they are seeking. Map out what the employee will be doing and be as clear as possible when writing the job description, advises Breslin.

With a job description in place, consider logistics. Where will the person be working? Do they have a desk or wet lab space? Can they work remotely? What kind of office supplies and equipment will he or she need to perform the job? Will this person need to relocate?

Next they should decide how to go about recruitment. Will they use a recruiter or headhunter or find candidates on their own? They may network with other scientists or already have somebody in mind.

However, building a position around a person could be a risky move. Many startups have folded because the people hired were a poor fit for the company—perhaps a friend who lacked truly relevant skills or brought conflict into the office. It is important to have qualified people working at a startup, so human resources need to be approached as objectively as possible.

Breslin recommends companies think about what they need and fulfill that position. They should be very explicit about what they’re seeking. Recruiting is time-consuming and expensive, so they want to be sure that their hiring decisions are made carefully and with thought.

Another important point is to consistently revisit the hiring plan as the business grows. One approach is to combine hiring with company milestone achievements, such as product approval or revenue growth.

A word of caution: companies shouldn’t hire based purely on the age of their company nor should they simply try to “fill out the ranks.” They need to ensure that they have a business need for every new hire.
Payroll

Before extending an offer to a candidate, companies will want to make sure they have benefits and payroll in place. First and foremost, they will need a payroll provider to work with and prepare employee paychecks.

“It’s critical from a compliance standpoint that an organization will be able to pay people on time,” says Breslin.

Additionally, every business needs to have a license, tax ID number, employment insurance and workers’ compensation in place. A dedicated founder can manage a lot of this, but flying solo involves many risks and detracts from their true business goals.

“I’ve always sought out people with more expertise than me in specific areas,” says Lim. “We outsource most of our bookkeeping services, and our payroll is actually outsourced as well [because] I don’t need to spend time running payroll.”

Benefits and Perks

There are offerings a company needs to provide in order to abide by the law and there are benefits that entice top talent. Working at a startup requires long hours and frustrating dead ends. Companies need to compensate their employees well if they want to attract the cream of the crop. Money is a finite resource, so it’s best to put together packages creatively. A startup will need to go above and beyond the norm to make a position attractive.

“If you don’t offer benefits, you risk missing out on some of the best qualified candidates, especially if you’re asking someone to leave a nice, secure position to come work for your organization,” Breslin says.

Perks such as paid company holidays and time-off policies are quality-of-life concerns that a new employee will want to know about before accepting a position. As the organization grows, Breslin advises employers to prioritize people and invest in their employees. It’s also the best way to prevent employee burnout.

Before engaging in new-hire negotiations, a company should know what they can provide. An important facet is developing an employee handbook that outlines expectations. Is there a travel policy? How does expense reimbursement work? The handbook should cover all relevant perks and benefits to ensure that employees understand the terms of their employment and feel their needs are met. If an employee needs a medical leave of absence, can the company provide one? If not, is this something an insurance policy could cover? Companies should have a plan in mind for how they would manage these situations and include them in the handbook.

Background and Reference Checks

One step that many small companies overlook is performing background and reference checks on new hires, especially because it is common for early-stage companies to hire someone familiar. It may seem overly prudent to take these extra precautions, but Breslin strongly discourages companies from forgoing this important step of the hiring process.

“You’ll never regret doing a background check to determine if someone is the right hire,” she says. “You don’t want to find something out six months later that could have been found with a background check.”

Although a background check is usually outsourced to a third party, it is good practice for a manager to check references. As the saying goes, better safe than sorry.
Negotiation

Determining compensation is an important part of bringing people to the team. Because it’s often challenging to obtain a salary survey, Breslin recommends that companies do their own research by talking to other people in the industry who are hiring for similar roles. Both sides should arm themselves with as much information as possible.

When it comes to salaries, companies should keep in mind what they can afford and leave some room for negotiation. Early-stage companies will probably need to make some concessions to convince people to give up their job security, especially if this is the entrepreneur’s first business.

*A word of caution: This is a slippery slope. With the first hire, a company is setting a precedent of what happens with all of their future employees. As such, it is important for employers to be careful to not make overly generous concessions that they can’t sustain. They need to think about what it takes to get someone in the door without compromising their finances long term.*

Managing Employees

A startup owner’s work doesn’t end once an employee has joined their team. Managing employees requires constant communication and coaching. The onboarding process begins with a full explanation of the employee’s roles and responsibilities. Be sure to include priorities, objectives, goals and how they’ll be measured, the company vision, etc. Breslin recommends regularly conducting performance reviews, as well as setting goals and checking in with the employee frequently. Even two- and three-person businesses need to invest in professional HR practices.

As the ranks grow, a company must ensure that all managers are well-trained and understand the rules of HR. It may be worth investing in the leadership training needed to coach people effectively. Breslin recommends taking leadership classes to better understand how individual employees prefer to interact and receive feedback. For example, will managers have one-on-one meetings with employees? How often will they communicate? All of this training helps troubleshoot potential issues before they become a reason for someone to leave.

Terminating or Ending Employment

A reality of working with human resources is that there are times when employees will leave the organization, either of their own accord or by way of termination. In either case, Breslin says it is best to end the relationship with the worker as amicably as possible.

“It is important to treat employees well when they come to an organization and as they’re exiting,” she says. “You want them to have a great onboarding and offboarding experience.”

An exit interview is helpful to understand if there are ways to improve the workplace and keep lines of communication open. Also take care to remind exiting employees of relevant confidentiality agreements. They maybe be bound by such agreements even though they’re no longer an employee. Ask the payroll provider to help you navigate the rules for delivering the final paycheck.

Finally, ensure comprehensive documentation. No one wants an ex-employee to sue because a huge chunk of the company was promised in exchange for services, based on an agreement sealed only with a handshake.
“The big surprises in starting a company have really been about people,” says Lim, who has encountered a full range of employee outcomes, lawsuits and finally, loyal and top-performing staff. “Those are things you just can’t anticipate.”

Conclusion

Running a business is a marathon, not a sprint. As demonstrated throughout this handbook, there are numerous factors that need to be taken into consideration before launching a business. No matter how compelling the science, what makes or breaks a business is whether it can be translated to the real world. If there is no demand for a product or technology, or if another company is doing it better, the venture will fail.

If founders understand their company’s value to the marketplace and use the right resources to help tap into market share, they will see their growing business generate returns. As tempting as it is to measure success by other parameters, profitability is paramount. With a business plan as their guiding star, startup founders can find their footing in the market and differentiate from the competition.

What happens after the company is established as a credible life science business? For many scientists, the exit strategy is to be acquired by a larger company. Others wish to remain involved for the long haul, and the best-case scenario for staying power is to base their company around a market need that allows them to continually develop a suite of products in service of a particular solution. Either way, they can look back with pride at the company they built from day one.

Turning a scientific discovery into a full-fledged business takes hard work, preparation and partnership with the right people. It is a risky endeavor, but it can also be one of the most rewarding opportunities of someone’s career and life.
Appendix: Checklist

As you’re starting your business, refer to this checklist to guide you through the steps to successful commercialization.

Chapter 1: Forming a Company

• Know the market
• Create a business plan
• Register the company
• Name the company
• Write a solid business plan

Chapter 2: Financial Considerations

• Purchase business insurance
• Write out a list of startup business expenses
• Speak with a financial consultant and attorney
• Join a regional business/venture group
• Apply for government grants or seek outside private funding
• Establish an advisory board

Chapter 3: Legal Matters

• Clearly define the IP and regulatory path
• Search and audit the IP landscape
• License or collaborate with existing patent holders
• Find a capable patent lawyer to draft the best possible patent estate

Chapter 4: Operations and Logistics

• Find a space to run the business
• Join a biotech association

Chapter 5: Building the Right Brand

• Come up with a brand platform
• Shape the identity
• Choose a creative campaign
• Build a website
• Develop sales collateral
• Public relations launch

Chapter 6: Human Resources

• Obtain license, tax ID number, employment insurance, and worker’s compensation
• Research the labor law environment within the state
• Create positions based on need
• Consider outsourcing HR services for payroll and benefits
• Recruit qualified candidates and negotiate compensation
• Conduct background and reference checks
• Set expectations by creating an employee manual
• Take management courses, if necessary
• Conduct exit interviews and honor confidentiality agreements

Appendix: Resources

Biotech Organizations

BioAustin  
www.bioaustin.com
BioNebraska Life Sciences Association  
www.bionebraska.org
BioCom  
www.biocom.org
BioFlorida  
www.bioflorida.com
BioForward  
www.bioforward.org
California Life Sciences Association (CLSA)  
www.califesciences.org
Georgia Bio  
www.gabio.org
Illinois Biotechnology Industry Organization (iBIO)  
www.ibio.org
Kentucky Life Sciences Council (KLSC)  
www.kysciencecouncil.org

Life Science Connect  
www.lifescienceconnect.com
Life Sciences South Florida  
www.lifesciencesssf.org
Life Science Tennessee  
www.lifesciencetn.org
Life Science Washington  
www.lifesciencewa.org
Massachusetts Biotechnology Council (MassBio)  
www.massbio.org
New York Bio  
www.newyorkbio.org
The North Carolina Biosciences Organization  
www.ncbioscience.net

Other resources

TriNet  
www.trinet.com
The Chempetitive Group  
www.chempetitive.com/chemunity
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About TriNet

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