

Operationalizing Your Therapeutics Spinout

ENTREPRENEURIAL SCIENTIST PLAYBOOK

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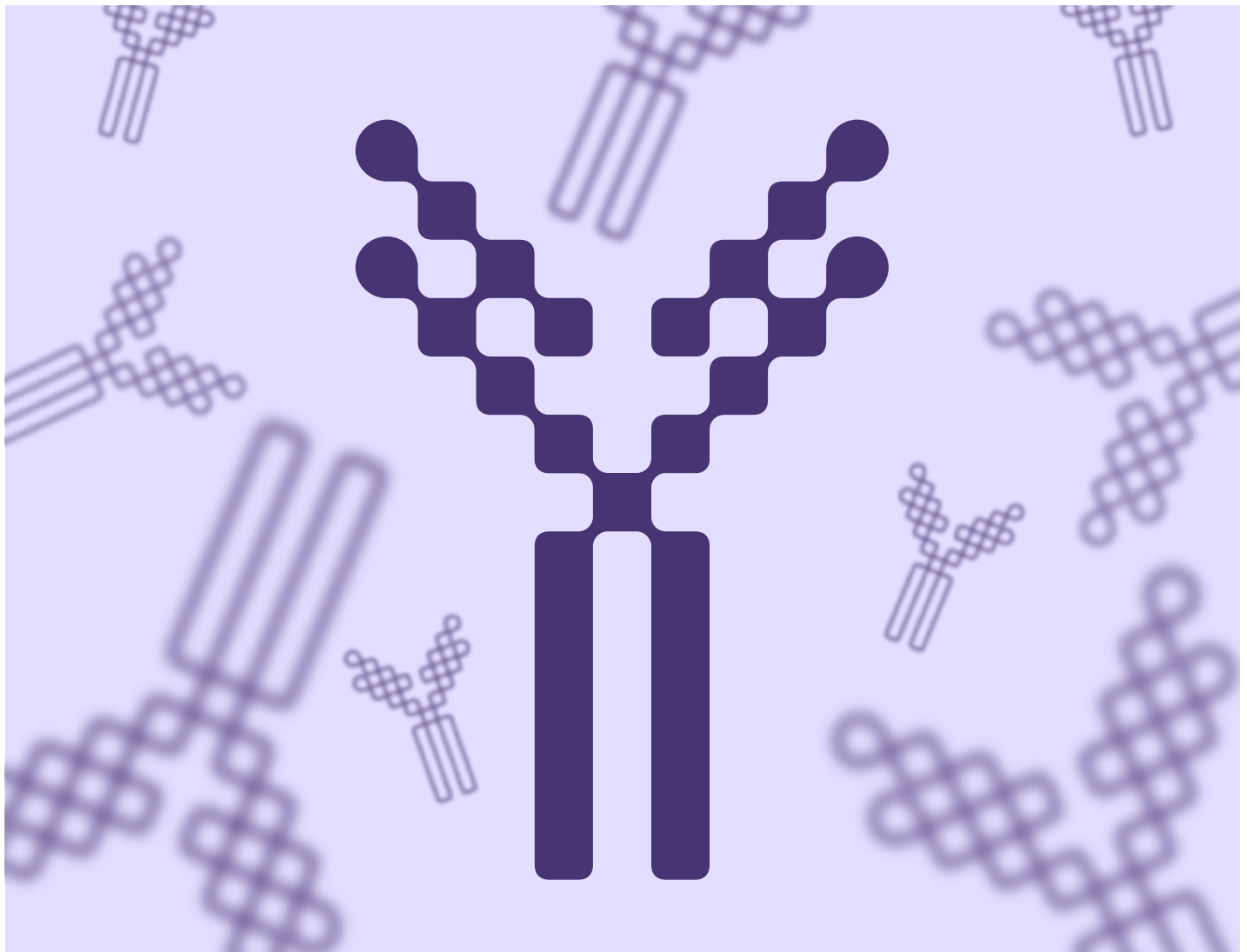


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Foreword

Welcome to Nucleate's Operationalizing Your Therapeutics Spinout Playbook for entrepreneurial scientists, the second of three playbooks to be produced by Nucleate's Research Initiative and supported by Schmidt Futures. This playbook explores the process of operationalizing a therapeutic spinout as you grow out of an academic lab into independent lab space.

Nucleate is a nonprofit organization committed to educating today's academic trainees and empowering tomorrow's biotech leaders. Together with the *Partnering with Pharma* and *Licensing from a University* Playbooks, this playbook aims to address the key knowledge gaps that PhD students and postdoctoral fellows experience when transitioning academic lab projects to viable companies.

We are excited to provide open-access resources to the community through the Nucleate Research Initiative, a global effort that provides context and understanding to the complex landscape of biotech education. In line with Schmidt Futures' mission to support exceptional people working to solve hard problems in science and society, we aim to support the next generation of life science talent from academic labs worldwide to tackle the world's pressing biomedical and ecological challenges.

We hope this playbook becomes an essential guide for startup founders ready to operationalize their spinout and serves as a practical resource for those considering the leap from academic research to entrepreneurship. While we provide strategies for common obstacles, we recognize that there is no one-size-fits-all solution in the dynamic process of company operationalization. Please consider this playbook a starting point—a collection of initial advice rather than a definitive solution. Every founder and startup is unique; what works for one may not be appropriate for another. We encourage you to engage with mentors and seek diverse opinions for all significant decisions. Great companies are built by teams, not individuals.

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Motivation + Methodology

The goal of this playbook is to provide actionable advice for the academic founder. Our hope is that this resource can accompany you from company ideation stage to securing Series A funding and preparing to move into independent lab space as you scale your company, providing potential solutions for common problems that founders face as they operationalize a spinout.

With the playbook in hand, founders will understand:

1. The benefits of spinning out life science companies from academia
2. Basic archetypes and business models of therapeutics spinouts
3. How to build a team, define an organizational structure, and manage people
4. Operational strategies to run your company with a positive culture
5. When to implement operational strategies throughout the lifecycle of an early stage spinout
6. Key considerations and timelines for transitioning from an academic lab to shared lab space to independent lab space
7. How to manage relationships with Contract Research Organizations

This playbook was compiled from a review of existing resources, as well as extensive interviews with spinout founders and executives, early employees, venture capitalists, executives at incubators and accelerators, and other experts in various aspects of company formation and building. This playbook would not have been possible without the generosity of these people, who took time to speak with us as well as edit and review different parts of the playbook. Thank you to:

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Chapter

01

Introduction

This playbook is written for you, the entrepreneurial scientist interested in translating your research into transformative technologies that enhance human health. Whether you are already in an accelerator or still preparing to embark on your entrepreneurial journey, this guide is designed to assist academic founders in transitioning scientific innovations from the academic laboratory into a successful company. We will explore the key issues you'll face as you evolve from an academic researcher to a startup founder, and further, as you expand your company into independently leased laboratory space. Our emphasis in this playbook is therapeutics spinouts. While the biotech industry is broad and includes other major verticals, therapeutic development is one of the primary ways for academic scientists to translate their innovations into treatments that improve human health. Whether or not you are developing a therapeutics spinout, this playbook will have useful information for entrepreneurs across all areas of biotech.

What is a Therapeutic?

As we will be discussing **therapeutics**, it's helpful to have a basic understanding of the relevant terminology. A therapeutic is a pharmaceutical drug that prevents, diagnoses, treats, or cures a disease. Therapeutics interact with biological systems and may target disease-causing mechanisms, alleviate symptoms, or restore otherwise disrupted physiologic functions. Therapeutics are often broadly categorized as either **small molecules** or **biologics**. Small molecules bind to proteins or other targets, are synthesized chemically, and are often taken orally as pills or tablets. Biologics are protein-based drugs produced in living cells and are generally administered as injectable solutions or infusions. Small molecules can often enter cells, whereas biologics are frequently limited to extracellular targets. Small molecules are easier to manufacture than biologics because they can often be produced with straightforward chemistry; biologics are manufactured from living cells, which is more difficult. An overview of different therapeutic modalities is provided in [Figure 1](#). While challenges differ between small molecule and biologic development, the operational strategies discussed in this playbook are largely generalizable across domains.

With various therapeutic approaches in mind, we set out to create a comprehensive playbook for aspiring academic entrepreneurs. Throughout this playbook, you will also find

references to additional resources. Regardless of your background or level of technical expertise, there is something valuable in these pages for you. We hope you will find reading it as rewarding as we found creating it.

Accelerators and Incubators

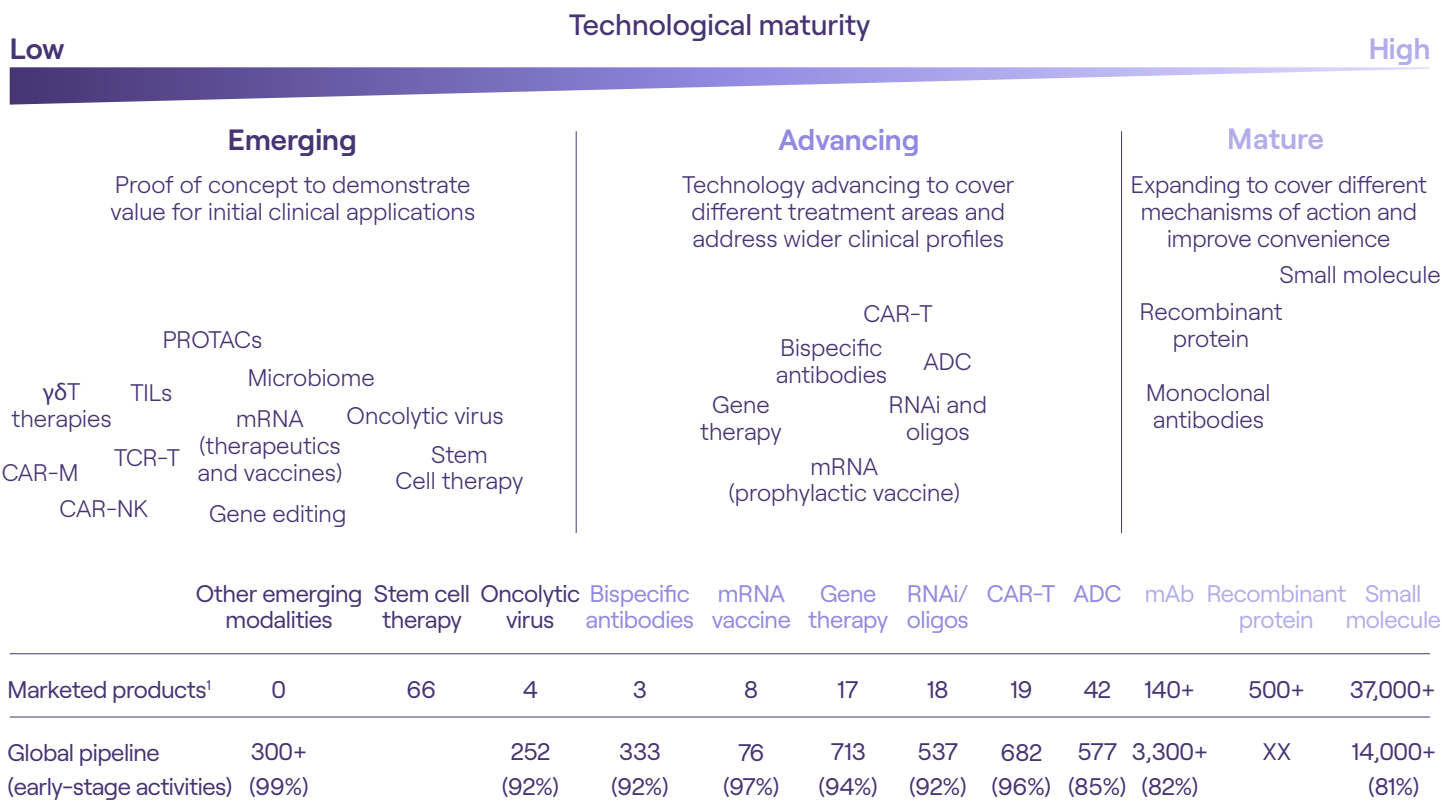
You will find this playbook especially helpful as you prepare to spinout of academia or go through early stage entrepreneurship programs, such as Nucleate's Activator. The Activator represents a new class of entrepreneurial resources, and functions as an equity-free educational program upstream of traditional accelerators and incubators, aimed at lowering the activation energy for aspiring entrepreneurs to explore to commercial potential of their technologies or research in human health (Bio) or planetary health (Eco). Outside of Nucleate, there are numerous companies that are dedicated to running accelerator or incubator programs. (Y Combinator is among the most well known), and many universities and companies also have accelerator or incubator programs. Before we dive into the specifics of spinning out life sciences companies, it's important to clarify the distinction between accelerators and incubators. These are general guidelines, but the terminology is often used interchangeably, so be sure to understand the target audience and mission of a program before applying.

Accelerators typically work with individuals or teams who already have a well-defined business concept or technology and are ready to rapidly advance it. These programs usually offer focused mentorship, access to networks, and seed funding to accelerate the development of your startup and business plans. If you have a clear idea and are poised for rapid growth, an accelerator is likely the right path for you.

Incubators, on the other hand, are often more suited for individuals or groups in the early stages of ideation and technology development. These programs provide a nurturing environment for brainstorming and refining concepts. They offer resources and support to help you transform your initial ideas into a solid foundation for a startup. Life sciences incubators often also provide lab space and core facilities. If you are still in the process of formulating your business concept and iterating on your science, an incubator is a better fit.

Figure 1: More Than 17 New Drug Modalities Have Been Developed in the Past 20 Years

There are multiple drug modalities with varying technological maturity. This graphic from the Boston Consulting Group gives an overview of some of the major ones. Within small molecules, there are many classes of molecule (e.g. kinase inhibitors, calcium channel blockers, etc.), generally defined by the molecule's function. There is a large diversity of modalities within biologics such as CAR T-cell therapy, mRNA vaccines, antibodies, etc.



¹ Not including products that are inactive or have been withdrawn from market as of October 2022.

Adapted from Boston Consulting Group (www.bcg.com/publications/2023/benefits-and-risks-of-new-drug-modalities)

While it's worth noting that accelerators are not strictly necessary to launch your biotech venture, they can be instrumental in providing the network, funding, and community needed to succeed. Many of the founders we interviewed had previously gone through an accelerator program, and noted it was exceptionally useful for first time founders and for building lasting connections. Nevertheless, each founder has their unique path, and it is certainly possible to build a company without an accelerator.

As you navigate your entrepreneurial path, we encourage you to seek out experienced mentors and allies who resonate with your ideas and identity, as these individuals can become your champions for years to come. We highly recommend leveraging Nucleate's Activator, accelerator, and incubator programs, in addition to complementary resources, to help build this network and maximize your chances of success.

Why Spinout

Before embarking on the journey of starting a company, it's helpful to take a step back and think about why you want to start a life sciences company. There are many career paths, and many places where one can do meaningful life sciences research; starting a company is only one route. The major benefit of starting a company is that you can focus on translating your research from papers into tangible products, and commercializing those products. In academia, research is often focused on discovering new knowledge and early stage translation (which involves converting your discoveries into prototypes and testing them in the lab). In most cases, academia is not a good place for finishing that translational process (going from prototype to final product), running clinical trials, going through regulatory processes, or selling a product. If you are working on science that can form the

basis of a new therapeutic, diagnostic, or other platform and are deeply passionate about working hard over the next 5–10 years (or longer!) to develop that science into a product that touches patient lives, starting a company may be right for you.

The Valley of Death

One of the challenges with spinning out therapeutic projects is the translational valley of death, which refers to the challenge of translating pre-clinical research into marketed therapeutics. Some of the challenges that contribute to this problem are scientific. For example, basic biology research often does not consider **druggability** of targets; if the activity of a protein is difficult to modulate with a small molecule, then it's not appealing for therapeutic development. Other challenges are non-scientific. Designing a candidate molecule, optimizing it to have desirable, **drug-like properties** in people, and rigorously testing it in animal models can take years and millions of dollars. Many academics (and their funders) focus on other areas of basic and translational science, and big pharmaceutical companies tend to be more interested in projects with a de-risked drug candidate with strong **Intellectual Property (IP)** and clinical proof of concept. There are a few potential solutions for advancing projects at this stage.

The first is an **SBIR/STTR** grant. These are NIH grants that provide **non-dilutive funding** to both an academic lab and a company. You need to form a **corporate entity** to apply for an

SBIR/STTR grant, but don't necessarily need to work out all the details of equity splits, licensing IP, etc. at the time you apply. The second option is to seek investment from a **seed-stage venture capital** fund or **angel investor**. These funds often invest in projects at the earliest stages in return for ownership of the company in the form of **equity** and sometimes seats on the company's **board of directors**. You need to be committed to spinning out your company, and likely need to negotiate licensing of IP, etc. before or shortly after getting funding. There are pros and cons to both approaches. SBIR/STTR grant review cycles are lengthy (6–9 months) so may not be a good option if you're graduating or ready to move on from academia soon. While it may be faster to get seed funding from a VC, the **valuation** of your company may be low without strong proof of concept data, meaning you give away more equity.

Universities are also aware of the challenge of the valley of death. A successful drug can generate billions of dollars of revenue (tens or hundreds of millions of which may flow back to a university if based on work done there), and so universities are exploring other options to support early stage therapeutic development (see [this](#) STAT news article for an example).

As you consider whether you prefer to continue developing your project in academia or spinout a company, it's helpful to consider the differences between the two. There is extreme heterogeneity; however, we've tried to capture the major contrasts in the **table below**.

Differences Between Working in Academia and Spinouts

Aspect	Academia	Spinout Company
Primary Focus	Knowledge generation and dissemination	Product development and commercialization
Freedom	Relative freedom in research direction	Scientific work directed by product strategy and market needs
Publication	Emphasis on publishing	Possible to publish, but priority is protecting company intellectual property
Collaboration	Most people have their own set of goals and priorities	Work together towards company goals
Resources & Equipment	Access to institutional facilities and shared resources	Need to secure own equipment; more autonomy in setup
Career Progression	Traditional academic ladder, all scientific roles (either postdoc/staff scientist or PI)	Opportunities across different functional areas
Skill Development	Emphasis on deep expertise in a specific field	Broader skill set including business, marketing, regulatory

Spinning out in the worst of times

There is never a “right time” to spinout your biotech company. At the time of publishing this playbook, you may be discouraged by the austere macroeconomic environment. In less startup-friendly macroeconomic environments, you will need to be conservative in your approach to fundraising and business development. This may require more robust proof of concept data, tighter term sheets, higher comparative expectations, less capital for non-lead asset exploratory science, and longer time horizons.

When the market is low, consider taking smaller check sizes from VCs and angel investors, or exploring some of the non-dilutive federal funding sources such as the SBIR/STTR programs mentioned above. An advantage of market lows is that they are typically preceded by market highs, where other startups have taken on more than they can chew, resulting in market availability for independent lab space and equipment via subleases that would otherwise be more costly.

Spinning out in the best of times

In contrast, when the landscape is flush with capital it can be easy to raise large amounts of money at appealing valuations. Benefits include faster scaling with more capital and high valuations leading to lower equity dilution for startups. However, these high valuations and large amounts of capital can come with inflated expectations relative to your stage of technological development, which can be overwhelming for a first time founder. Lessons can be learned from the biotech boom related to investments in COVID-related technologies in 2020. Many of these companies are now struggling, having taken on more capital and real estate than they can use efficiently or responsibly. In many cases, this excess capital has also created unrealistic expectations, leading to downrounds when those expectations are unmet. Others pivoted their technologies towards diagnostics while sacrificing core platform development, and ultimately found themselves in a space heavily saturated with competition. While it is generally easier to raise capital for a company when macroeconomic conditions are favorable, such conditions are transient and shouldn't play a major role in your decision.

Spinning out wisely

As you consider spinning out your company, it's essential to engage with investors early and frequently, as outlined later in our Networking section. Many investors are naturally curious and open to coffee chats, especially when you possess a concrete idea, current data, and initial proof of concept. However, it's vital to be mindful of what information you can safely disclose, and you should consult with your university's tech transfer office first as a prudent step.

Aligning your vision as a founder with investor motivations is critical. Investors continually construct and refine a mental model of your company's growth, from initial investment to eventual exit. This foundation is built on trust and backed by supporting data, ultimately propelling your biotech's development. Together with investors, you'll work to generate data that garners enthusiasm and secures the commitment of time, resources, and energy into your company's evolution.

For those without prior industry or startup experience, it's unwise to assume you know precisely what data will attract future investors, entice talent, and support Food and Drug Administration (FDA) approval and clinician adoption of your therapeutic. Early interactions with venture capitalists and mentors can help you shape a robust business plan that minimizes risks before launching your company and provides insights into the market landscape.

Do not be discouraged if in the end you realize it is not the right time to start your company due to scientific, business, or personal circumstances. Life is long and entrepreneurship is rarely a question of now or never, but instead now—or a little bit later. Whether or not the answer is “now” depends on your personal circumstances and the stage of the science. Your conversations with investors will help you understand if your science is sufficiently mature to spinout a company.

Regardless of the state of the market, or the flashiness of the science, it's important to understand the basics of how therapeutics spinouts operate and make money. The following chapters will go through the basic archetypes of therapeutics spinouts (single-asset vs platform) and discuss how they make money.



Chapter

The Business Basics

Drug Development Process Overview

The Basics of Drug Development

As a therapeutics founder, it's important to understand the basics of the drug development process. The first step to developing an approved drug is identifying a **drug target**. A drug target is a molecule in the body that is associated with (or causes) a disease or symptoms of disease. The drug target must have properties such that "drugging" the target alleviates symptoms (symptomatic treatment) or alters the progression of the disease itself (disease-modifying). Most drug targets are proteins. Drug targets can be identified through a variety of mechanisms, but those with **human genetic evidence** are more likely to lead to an approved drug¹.

For example, in genome-wide association studies (GWAS) researchers leverage population datasets to identify genetic variants statistically associated with a given disease, highlighting specific genes or genomic regions as potential drug targets. Signals from GWAS provide a starting point, but oftentimes require integration with other genetic, functional genomic, and clinical knowledge about the disease². Drug discovery efforts leveraging GWAS have been particularly successful when targeting rare variants. A notable example is the development of PCSK9 inhibitors for hyperlipidemia, motivated by the identification of a rare loss-of-function variant in the PCSK9 gene³. Other approaches to generating human genetic evidence for drug targets is presented in **the table on page 12**.

Although a drug target may show promise based on human genetic evidence or demonstrate a strong link to a disease in lab or animal studies, it remains challenging to predict its relevance in humans. For this reason, companies pursuing novel drug targets are often more risky to investors as this **biological risk** takes many years and tens of millions of dollars to overcome (you usually can't rigorously validate that drugging a novel target will successfully modify a disease until you see data from a Phase 2 clinical trial). Because of the nature of biological risk, one strategy for therapeutics spinouts is to select druggable targets with clinically validated connections to a specific disease. Generally, **chemical**

risk (i.e. if your drug meaningfully modulates your target) is easier to de-risk in the lab with preclinical in-vitro and in-vivo data by demonstrating your drug candidate engages with the target.

After identifying a drug target, the next step is hit identification. **Hit identification** usually starts with a chemical library, which are datasets of millions or billions of drug-like molecules that may be good starting points for your drug. If your company is developing therapeutic modalities with novel or relatively unexplored chemistry, you may need to design your own chemical library. The chemical space is massive (there are an estimated 1060 molecules that could be drugs!) and existing libraries represent a very small fraction of that universe. From these libraries, companies will often choose molecules to synthesize and test in an assay that characterize the molecule's activity with respect to your target of interest. This experimentation is often done with high-throughput assays, allowing one to test thousands or even millions of these molecules quickly. Molecules with the best results from these assays are called hits.

One example of technology that enables high throughput screens is DNA Encoded Libraries (DELs). In DELs, small molecules are tagged with unique DNA barcodes. The target protein is then captured (e.g. with streptavidin beads); millions of molecules are then incubated with the protein to determine which ones bind most effectively. One can then use PCR to identify the DNA barcode of the molecule(s) that have bound to the target protein. This allows for the simultaneous screening of many potential molecules to find hits with good binding affinity to the target of interest.

The most promising hits are then progressed through **lead optimization**. This process is driven by medicinal chemistry with the goal of improving **absorption, distribution, metabolism, excretion, and toxicity (ADMET properties)** of the hit, along with the activity of the molecule with respect to the drug target. There are various in-vitro and in-vivo experiments one can use to iteratively test these properties as you refine the molecule.

¹ Nelson, Matthew R., et al. "The support of human genetic evidence for approved drug indications." *Nature genetics* 47.8 (2015): 856-860.

² Ochoa, David, et al. "Human genetics evidence supports two-thirds of the 2021 FDA-approved drugs." *Nat Rev Drug Discov* 21.8 (2022): 551. (<https://www.nature.com/articles/d41573-022-00120-3>)

³ Uffelmann, Emil, et al. "Genome-wide association studies." *Nature Reviews Methods Primers* 1.1 (2021): 59. (<https://www.nature.com/articles/s43586-021-00056-9>)

Assays and Analyses for Human Genetic Evidence

Assay/Analysis	Description	Application in Therapeutic Development
Genome-Wide Association Studies (GWAS)	Analyzes genetic variations across the entire genome to find associations with specific diseases or traits	Target identification of genes and genetic variants associated with a given disease
Mendelian Randomization	Uses genetic variants as natural experiments to infer causal relationships between modifiable risk factors and diseases	Target prioritization to understand causal links between genetic variants and diseases, aiding target selection
Linkage and Pedigree Analysis	Identifies disease-associated genetic variations by studying the inheritance patterns in families	Trace the genetic basis of diseases in families to identify potential drug targets Useful for highly heritable and rare diseases
Quantitative Trait Loci (QTL) Mapping	Correlates genetic variants with variation in other biological data (e.g. gene expression, methylation, open chromatin)	Understand gene function and disease associations for target identification and prioritization
CRISPR-Cas9 Screens	Precise editing of genes to study their function and dysfunction	Experimental validation of gene function in models of disease, aiding in the identification of novel drug targets Multiplexed CRISPR/Cas9 editing systems enable high-throughput target identification by screening multiple genes simultaneously
Single-Cell Omics	Analyzes molecular species (RNA, protein, chromatin, etc.) at the level of individual cells	Elucidate the role of cell type and cell state variability in disease for target discovery
Spatial Omics	Characterizes molecular species in their spatial context	Identify the presence and localization of molecular species for tissue-specific targets and mapping of the microenvironment

By this point in the process, there is one molecule that is considered your **lead program**. A lead program at a therapeutics spinout often refers to the most advanced molecule, and typically receives the most scrutiny from investors. After optimizing your lead, the next step is preclinical testing and **investigational new drug (IND)** enabling studies. **Pre-clinical testing** refers to in-vivo studies performed by the company to gain confidence in the efficacy of the molecule. An IND is an approval from the FDA to begin human studies with your drug and requires completion of a mostly standard set of safety experiments in animals (IND enabling studies), to ensure your drug is safe for humans. These experiments must be done according to **good lab practice (GLP)** standards with **good manufacturing practice (GMP)** quality drug. These experiments cost millions of dollars, so

before embarking on these safety studies it's important that you have confidence in the molecule's efficacy, which is why companies frequently perform their own pre-clinical testing in addition to the required IND enabling studies.

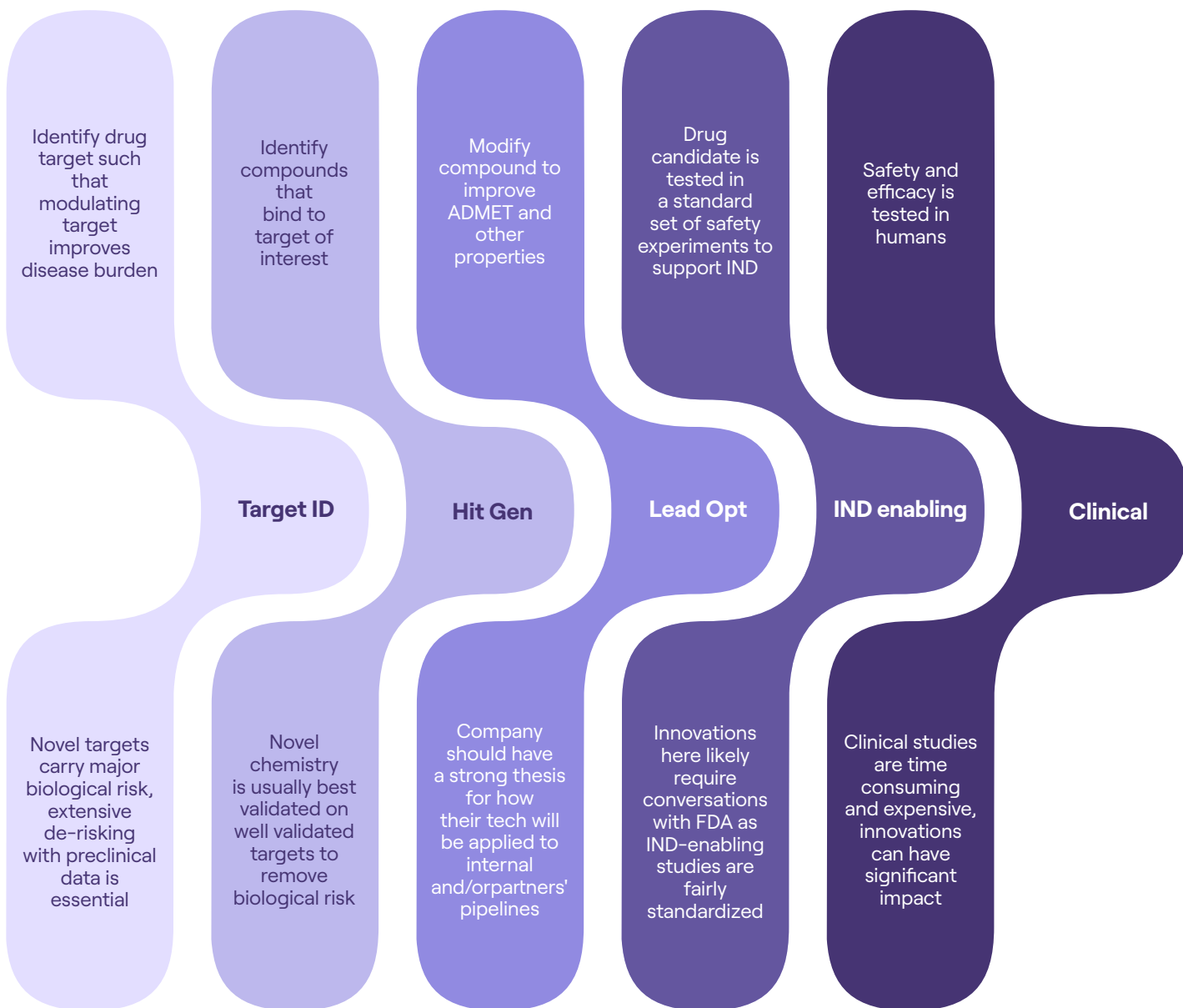
If your molecule is shown to be safe through all of these studies and you are granted an IND, you are ready to move into human trials. The first human trial is called a **Phase 1** trial and generally consists of 10s of patients with the goal of assessing the drug's safety. If your drug is safe, you can progress to **Phase 2** trials which are usually larger and assess the efficacy of the drug. The last step in clinical development is a **Phase 3** trial, which compares your drug to the standard treatment for patients with the disease you're trying to treat with your drug. If your drug is better (or in some cases, equivalent to) standard treatment,

then you can submit a **New Drug Application (NDA)** or **Biologics License Application (BLA)** to the FDA, which, if approved, means you can market your drug in the United States. A simplified version of the entire drug development process is shown

in [Figure 2](#). Even after approval, there is still commercial risk associated with selling the drug. For this reason, it's important that you understand the minimum efficacy necessary for a clinically meaningful improvement that will convince clinicians to use your product instead of the current standard of care.

Figure 2: Overview of major phases of drug development and considerations for spinouts

Major Goal



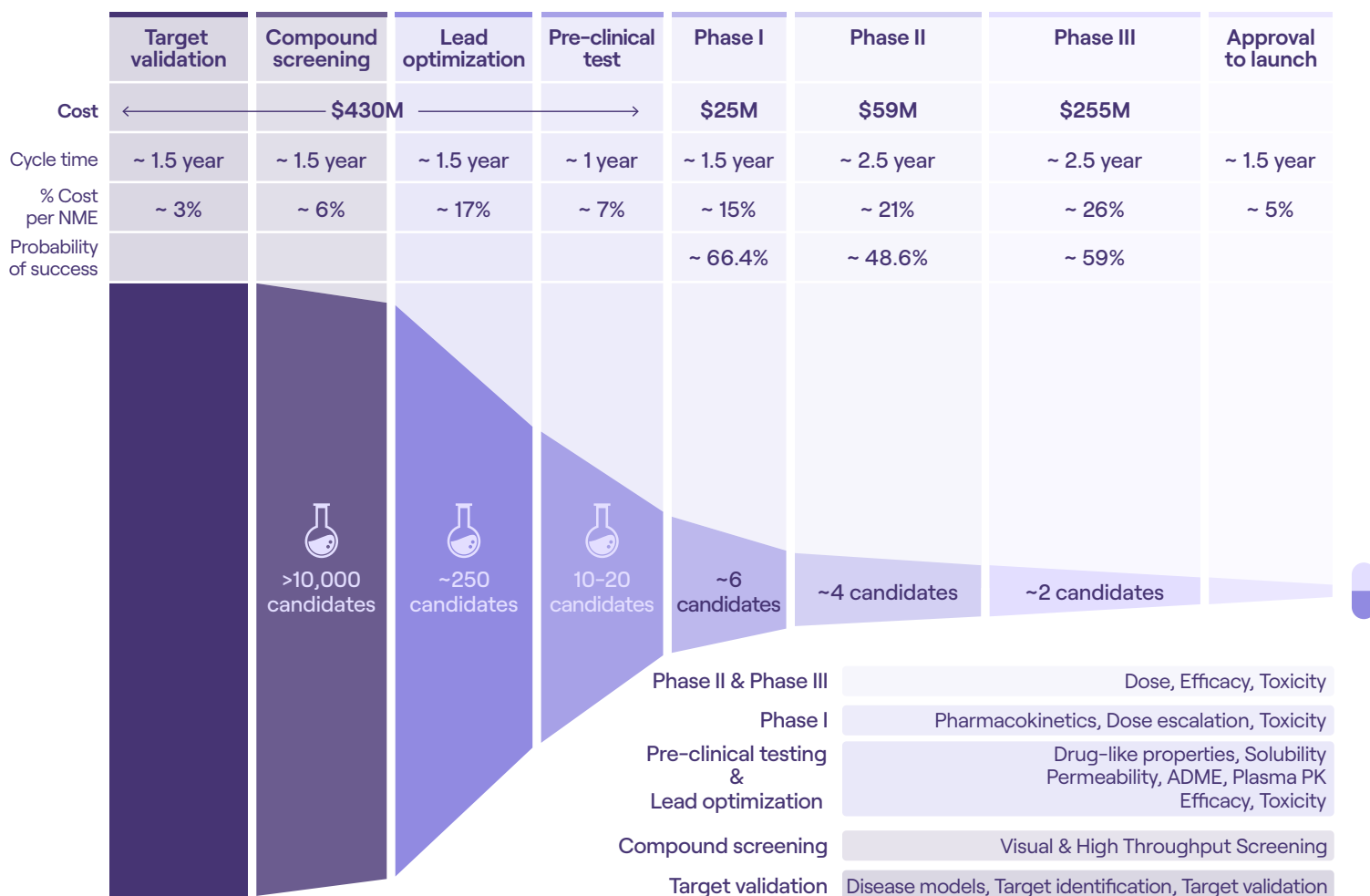
Spinout Considerations

It's helpful to keep in mind that your company doesn't necessarily need to build expertise in all of these areas. There are many **Contract Research Organizations (CROs)** to which you can outsource parts of this development process. It can be helpful to identify where your company's innovations sit in the drug development process. In general, it's better to work on science related to your company's primary innovations in-house, whereas it's easier to outsource standardized assays or experiments to CROs. By outsourcing, you can free up your scientific team to focus on the science that differentiates your company. CROs can also perform certain experiments more cheaply than your company, especially if they require expensive or specialized equipment that you otherwise don't need to purchase. These cost savings can be especially valuable if you have some seed

funding to generate key proof of concept data, and cannot afford to spend that funding on equipment. *For more information, see [Chapter 7: Contract Research Organizations](#).*

To develop a drug takes hundreds of millions of dollars and at least 7-10 years. Even with stringent pre-clinical criteria, only about 10% of drugs that enter clinical studies end up getting approved.¹ The timeline and costs of each major stage is broken down in [Figure 3](#). For this reason, it's helpful to identify in-vitro or in-vivo experiments you can do very early in the process to gain confidence in the drug's likelihood of success. This can also include experiments that will allow you to quickly determine the drug is unlikely to succeed, saving yourself years of time and your investors tens or hundreds of millions of dollars.

Figure 3: Cost and Success of the Drug Development Process



Adapted from Duxin Sun et. al (<https://www.sciencedirect.com/science/article/pii/S2211383522000521#fig1>)
 Sun, Duxin, et al. "Why 90% of clinical drug development fails and how to improve it?" *Acta Pharma Sinica B* 12.7 (2022): 3049-3062.

¹ Congressional Budget Office. "Research and Development in the Pharmaceutical Industry". (<https://www.cbo.gov/publication/57126>)

As a biotech founder, you will inevitably interact with the FDA. We will not go into the regulatory process in depth, as it can vary considerably for different products in different indications. You will need to work with a regulatory expert to understand the exact requirements, and it's helpful to engage these experts early in the drug development process. It's also helpful to have a pre-IND meeting with the FDA to ensure you have an accurate understanding of what the FDA expects to see in your IND application.

Business Models

Single Assets vs. Platforms

When spinning out your research, determining whether your work is better suited to a single asset or platform model is crucial. Single assets can be more easily out-licensed to existing companies or lead to an early acquisition; platforms typically require sustained efforts to generate assets.

A **single asset company's** primary product is a drug that will ultimately capture monetary value for curing or alleviating a given disease indication if approved. These companies are generally formed from either:

- i. A novel biological insight leading to a novel drug target
- ii. A novel chemical insight around how to drug a target better than existing approaches

Although the risk of single asset companies as a founder and employee can be quite large (if your lead program fails, the company may have difficulty continuing), investors can diversify their portfolio, spreading risk by investing in multiple single asset companies.

A **platform company's** primary scientific innovation is a process that enables the development of therapeutics. A platform can improve many aspects of the drug development process. Some platforms are computational and can consist of:

- i. Novel approaches to analyzing clinical or biological data to improve target identification
- ii. Algorithms to generate drug candidates (or predict properties of drug candidates) to improve hit identification
- iii. Algorithms to redesign molecules to improve ADMET properties as part of lead optimization
- iv. Methods to identify patient subgroups that may be more likely to respond to drugs to help clinical development
- v. Methods to discover new therapeutic modalities.

Other platforms consist of biological or chemical innovations. These can include:

- i. Cellular manufacturing platforms modifying cell lines or microbial cultures to produce therapeutic proteins and vaccines at scale
- ii. Tissue engineering to create tissues and organs for transplantation and drug discovery
- iii. Chemical synthesis and catalysis platforms that enable more efficient synthesis of active pharmaceutical ingredients
- iv. Cell therapy manufacturing platforms to isolate, expand, and improve the quality of therapeutic cells administered to patients such as in CAR-T cell therapy
- v. Novel chemical modalities such as mRNA therapeutics

How Single Assets and Platforms are Evaluated

It's important to note that each potential investor, pharma partner, and advisor considers different aspects of a platform as they assess your company and its technology. Some are thesis-driven, and may be enthusiastic about your platform if they agree with your theories about how your platform will improve drug development. Others may recognize that the value in platforms lies in their ability to develop drugs, and may completely disregard your platform and only use assets generated by your platform to make their assessment. In spite of this heterogeneity, the lists below provide some of the major aspects of a platform that folks will commonly consider as part of their diligence.

Single Assets Evaluation:

1. **Clinical Data and Efficacy:** Preclinical and clinical data to gauge the asset's effectiveness, safety profile, and potential for improving the current standard of care.
2. **Market Opportunity:** The size of the target patient population, the unmet medical need, and the asset's potential to address a compelling market demand.
3. **Competitive Landscape:** The asset's differentiation from existing or potential competitors, as well as its potential advantages in terms of efficacy, safety, or delivery mechanisms.
4. **Regulatory Pathway:** The likelihood of successful regulatory approval and the associated development timeline, considering potential challenges and risks.
5. **Commercialization Strategy:** The asset's potential pricing, reimbursement prospects, market entry, and clinical uptake strategy to ensure a clear path to commercial success.
6. **Intellectual Property:** The strength of intellectual property protecting the asset and its potential to secure market exclusivity.

Platform Assets Evaluation:

1. **Potential Asset Pipeline:** The ability of the platform to yield a portfolio of valuable therapeutic assets. This includes the diversity, novelty, and potential market impact of the assets your platform can generate. Platform companies with capital will typically pursue multiple potential indications as a derisking strategy due to the importance of demonstrating the platform's ability to generate assets.
2. **Technology Strength:** The platform's scientific soundness, technological depth, and competitive advantages.
3. **Intellectual Property:** A robust intellectual property portfolio protecting the platform technology, its exclusivity, and long-term competitive advantage.
4. **Development Timeline and Costs:** The efficiency and cost-effectiveness of asset generation using the platform.

A streamlined development process and lower costs are attractive attributes.

5. **Scalability and Market Impact:** The platform's ability to address a broad range of diseases, and its potential to disrupt or transform therapeutic development in the industry.

Partnering with big pharma companies who pay startups to use the platform and generate drugs can serve as powerful validation for investors. *Much more detail is available in our "Partnering with Pharma" playbook.* For a deeper dive into the business strategy of platforms, we also recommend Elliot Hershberg and Patrick Malone's piece [linked here](#).

In contrast, single assets are valued on clinical potential, market fit, and competitive edge. These criteria also apply to assets developed from platforms, so platform companies should be aware of them too.

What makes therapeutics valuable?

Therapeutics spinouts capture market value by selling approved drugs. Unlike business in many other industries, this means it often takes 5-10 years (or longer) for therapeutics spinouts to become profitable. There are a few things your company needs to sell approved drugs:

1. An approved drug

As we discussed, this is an extremely lengthy and challenging process!

2. Compelling Clinical Value

Not every drug approved by the FDA provides meaningful value to patients and generates profit. One recent example is Biogen's Alzheimer's drug Aduhelm. Aduhelm was given accelerated approval in June 2021 among much controversy; the FDA's approval was largely based on the fact that Aduhelm reduces amyloid beta plaques in the brain. However, reduction of plaques via a monoclonal antibody did not result in significant cognitive improvements. Clinical concerns around side effects and effectiveness made Aduhelm a commercial failure; in 2022, Aduhelm sold less than \$5M (which is less than the cost of a Ph3 clinical trial).²

3. Compelling Payer Value

In the US, many Americans are insured by private companies whose primary mandate is to make money. Medicare also has a process for determining if a new drug is "reasonable and necessary" as part of deciding if Medicare will provide coverage. As such, the amount you charge for the drug must still represent cost savings for the payer. Consider the world's most expensive medicine, Hemgenix. Hemgenix is a gene therapy used to treat patients with hemophilia B – it costs over \$3 million. However, hemophilia B patients require regular prophylactic treatment to replace missing blood clotting factors, and patients often experience complications requiring hospitalization. Therefore, Hemgenix actually saves health insurance companies money, justifying the price tag.

4. Lack of Competition

When the FDA approves a drug that represents a new chemical entity, they agree not to approve identical drugs for 5 years as a regulatory incentive to encourage companies to develop new drugs. This lack of competition allows pharma companies to charge high amounts for drugs for a period of time, helping them to recover the massive costs associated with research and development (R&D). Similarly, this potential for high revenue is what attracts biotech investment at the early stage in spite of the risk, as an approved drug often results in significant profit. Patents and other regulatory incentives can help extend this exclusivity further.

² STAT News. Inside 'Project Onyx': How Biogen used an FDA back channel to win approval of its polarizing Alzheimer's drug. 2021. (<https://www.statnews.com/2021/06/29/biogen-fda-alzheimers-drug-approval-aduhelm-project-onyx/>)

Although a drug must be sold to patients (which usually requires a clinician to prescribe and a provider to reimburse), this value can be captured through diverse streams. For example, licensing agreements, strategic partnerships, and acquisitions by larger pharma companies can generate revenue without requiring you to commercialize the drug yourself. *For more information, see our Pharma Partnerships Playbook.* It is common for platform companies to develop their own assets in-house while partnering with larger pharma companies to advance others. Revenue from partnerships is continually generated as milestones are met, making it possible for a platform company to invest in developing their own assets.

Regardless of your company's plans to commercialize therapeutics, your storytelling should clearly convey the biological or chemical innovations of your proposed therapeutic, and how you believe those innovations will result in compelling clinical and financial value. As a drug progresses through preclinical and clinical trial stages of development, its potential for clinical impact becomes increasingly tangible, amplifying its intrinsic value and the company's valuation.

Target Product Profile

A **Target Product Profile (TPP)** is a great tool to summarize how your therapeutic will provide clinical value. Throughout the drug development process, you have to make many decisions that can have a significant impact on the end product. As such, it's valuable to have an understanding of the important properties of the drug you are trying to develop. A TPP is a pivotal tool used in the pharmaceutical industry to achieve clarity on the goals and expectations for a drug you are developing, while facilitating effective communication among employees at the company, regulatory authorities such as the FDA, and other relevant stakeholders. TPPs outline intended use, target populations, safety, efficacy, and various other aspects of a therapeutic product. It serves as a dynamic blueprint, shaping the product's value and competitive advantage while providing a structured foundation for R&D decisions. It also plays a crucial role in communicating with investors and partners. For reference, the World Health Organization offers [publicly available](#) TPPs for major diseases and we have provided an example template an example template on [page 18](#).

You can start creating a TPP as soon as you have a potential indication for your asset. For platform-based companies without a specific lead program, this can be more challenging as your platform can potentially be applied to develop drugs across many indications. As your platform matures and begins producing drug candidates, you should consider creating a distinct TPP for each indication you believe your platform can viably address. One way to help narrow down potential applications of your platform is to outline your platform's competitive advantages over historical drug development approaches and technologies. Then, you can identify indications where

therapeutics are limited due to the problems that you help solve. This exercise can help you prioritize candidates and indications with the added benefit of demonstrating to VCs that you understand how your platform fits into the overall landscape of drug development. You can also apply the concept of a TPP to your platform as a whole, though the specific details will be different from a standard asset TPP.

To develop your TPP, gather input from **key opinion leaders (KoLs)** like clinicians, patients, regulators, payors, and industry experts. VCs and your Scientific Advisory Board can help make these connections. You should thoroughly understand the current **standard of care**, and how your proposed therapeutic will solve limitations of the standard of care. For example, if you have a platform to develop therapeutics taken as a once-a-month oral pill for a disease where the current standard of care is a daily injectable, you would significantly improve the patient experience, and likely patient compliance.

A TPP should include both the minimal acceptable criteria as well as the optimal or "dream" product characteristics. The minimal criteria represent the threshold that would allow the product to be usable and commercially viable in the current market. The optimal criteria represent an ambitious target that would represent a significant improvement over standard of care. For example, a minimal efficacy criteria for a cancer therapeutic could be a 20% improvement in progression-free survival compared to standard of care. The optimal efficacy criteria might be 40% improvement in overall survival.

Putting together a robust TPP takes a team with diverse areas of expertise. Your initial TPPs may include educated guesses as you build your network of experts to help with specific aspects of the TPP. Remember that the TPP is a dynamic document and it should change as you learn more about the indication (current medical opinion and treatment options generally affect the minimal criteria) and your own company's capabilities (which generally affect the optimal criteria). At a minimum, you should revisit the TPP after the completion of each major category of pre-clinical experiments, such as completion of toxicology studies, in-vivo studies, and receiving your IND.

Regulatory Incentives

In addition to reviewing drug applications for safety and efficacy, the FDA also provides various regulatory incentives to drug developers. The most important incentive is regulatory exclusivity. After approving your drug (assuming it is a new molecule and not a generic version of an existing drug), the FDA provides **New Chemical Entity (NCE)** exclusivity for 5 years, meaning they will not approve a generic version of your drug, even if you have no patents to protect the IP. The FDA also has an orphan drug designation program for rare diseases that affect less than 200,000 people in the US. If your drug is given orphan drug designation, you will have 7 years of regulatory exclusivity.

In addition to regulatory exclusivity, there are a few programs that can help speed up the regulatory process, some of which are discussed here. The first is a breakthrough therapy designation. If you are working on a drug for a serious condition and have preliminary data showing your drug is a substantial improvement over standard of care, you are eligible for this program. This program includes fast track designation which includes more frequent meetings with FDA as well as faster response times. The FDA has another program called priority review where vouchers are given to pharmaceutical companies who gain approval for drugs to treat orphan disease drugs, neglected tropical diseases, rare pediatric diseases, and “medical countermeasures” to bioterrorism threats. With these vouchers, the FDA aims to complete review of applications in less than 6 months, instead of the standard 10 months. These four months may not seem like a lot, but some drugs sell billions per year, and these months can be immensely valuable. These vouchers can be sold to other pharma companies, often for over \$100M.

Once your regulatory exclusivity and patents have expired, your drug sales will drop dramatically as generics enter the market. Manufacturers of generics for small molecules do not need to go through clinical studies, but instead must only prove that their drug is equivalent to yours. For small molecules, this is a fairly standard process. Unlike small molecules, biologics such as monoclonal antibodies are much more complex and cannot be chemically reproduced. Biosimilars are versions of original biologics approved by the FDA that are highly similar but not identical. Because it’s not possible to reproduce the same molecule for biologics due to manufacturing complexity compared to small molecules, biosimilars are much less common than generics. In most cases, biosimilars need to go through clinical studies showing no clinically meaningful differences from the original biologic in terms of administration, dosage, efficacy, and side effects. Because clinical studies are so expensive, and revenue from generics / biosimilars is lower than the novel molecules, companies rarely pursue them.

Target Product Profile

Parameter	Minimal Profile	Optimal Profile
Indications	Primary Indication	Broader range of indications (if applicable)
Patient Population	E.g. Patients aged XX years of age; Clinical diagnoses of YY condition/disorder via ZZ criteria; Inclusion criteria based on specific sub-populations for targeting	
Therapeutic Modality	E.g. Antibody (biologic)	
Efficacy	E.g. > 30% responder rate (measured as patients achieving a score of < X on a clinical scale) within 3 months post-treatment	E.g. > 70% responder rate (measured as patients achieving a score of < X on a clinical scale) within 6 weeks post-treatment
Safety	E.g. < 20% incidence of Y adverse effect	E.g. < 5% incidence of Y adverse effect
Dosing/Administration	E.g. Solution in pre-filled syringe, subcutaneous injection, Daily	E.g. Solution in pre-filled syringe, subcutaneous injection, Monthly
Approach	E.g. Treatment – disease modifying	
Mechanism of Action	E.g. Antagonist – inhibition of XX receptor resulting in reduction in YY signaling	
Biological Activity	E.g. Reduction in severity of XX symptoms	

Adapted from BioCurate (www.biocurate.com/resources/constructing-a-target-product-profile-industrys-perspective/)



Chapter

People Management

Even with exciting science and a clear business model, building a successful company requires a team of smart, motivated people whom you can trust to complete important tasks independently. Additionally, the best teams are supported by insightful advisors, scientific advisory board members, investors, and board directors. It's often easier to recruit people to join or support your company if you already know each other. Networking is an essential skill for any working professional, but is especially important for entrepreneurs.

Networking

Networking 101

Building a strong network is not just about exchanging business cards or collecting contacts; it requires genuine interest, curiosity, and a willingness to establish meaningful connections. Our recommendations for how to network successfully are shown in **the table below**.

Networking Strategies

1. Authenticity is Key

Successful networking begins with a sincere interest in what others are doing and saying. Networking must come from a place of curiosity; otherwise, it may come across as insincere and inauthentic. Engage in conversations with a genuine desire to learn about the other person's interests and endeavors. Make time to inquire about the interests, hobbies, and passions of others outside of their work. By creating personal connections, the relationships become stronger and more enduring.

2. Quality over Quantity

Rather than pursuing numerous superficial connections, founders should seek out individuals who genuinely intrigue them. Be kind to everyone, but be wary of spending too much time on interactions that lack substance. Your focus should be building relationships with like-minded individuals who share common goals and passions, ensuring that networking efforts yield valuable connections. Sometimes, you'll quickly realize you don't have overlapping interests with someone you meet – that's ok! Be respectful, but recognize it's ok to wrap up the conversation and not force a relationship.

3. Build a Network of Founders and Learn from Peers

Networking with other founders plays a crucial role in a biotechnology startup's growth. Sharing experiences with peers who face similar challenges can lead to invaluable insights and advice. Other founders can often relate to your struggles during difficult times, since many have experienced similar challenges themselves.

4. Overcome Fear of Idea Theft

While it is essential to be mindful of what information is shared, networking remains vital. You should be able to paint a clear picture of your technology to someone without needing them to sign a confidentiality agreement. The implementation of

ideas is often the most challenging part, and conversations with new people can offer support and strategies for execution.

5. Tailor Your Pitch

Networking involves talking to various people, each with different interests and backgrounds. Developing different pitches to cater to different individuals and "phenotypes" can help you make a more significant impact during networking interactions. You should be able to explain your technology to a scientist, investor, and your grandmother.

6. Track and Improve

Formalizing the data collection process and tracking conversations can help you refine and improve your pitch over time. If people seem engaged and you want to connect, set up regular conversations to strengthen the relationships. For industry veterans, this can mean a quarterly call. For potential investors, employees, and mentors, monthly calls.

7. Attend Events and Expand Your Network

A broad and diverse network becomes an invaluable asset for fundraising and recruiting top talent. It's impossible to predict the nonlinear effects of network building, and the person you bump into at a biotech event may very well become your lead investor when you start fundraising. Attend nearby networking events and fireside chats hosted by accelerators and VC firms alongside industry conferences like the annual J.P. Morgan Healthcare Conference. Ask people "Who are 1-2 people that you recommend I talk to? Could you introduce me?" – then your network becomes an actual network, not just second degree connections from you. Identify people that act as network hubs; you don't need to know everyone at first, just the superconnectors who do.

8. Embrace Cold Outreach

While introductions through mutual connections are ideal, founders should not shy away from cold outreach. Requesting a short introductory call based on shared interests can be more successful than you might believe. Acknowledge your familiarity with their work, and why you think a connection with you and your company would be mutually interesting.

9. Engage with VCs Early

You can mingle with VCs at biotech events, set up one-on-one meetings, and attend office hours sessions. Trust takes time to develop, and VCs want to see that as a founder you have both the technical and leadership skillset to be successful. You can reach out as soon as you have early data, even before you officially start fundraising.

How to Introduce Yourself

Introducing yourself effectively is a critical aspect of successful networking. A well-crafted introduction sets the tone for the conversation and leaves a lasting impression on the person you are meeting. Some key strategies on how to introduce yourself are shown in **table below**.

How to Introduce Yourself

1. Start with a Warm Greeting

Begin by offering a friendly and warm greeting. A simple "Hello" or "Hi, I'm [Your Name]," with a firm handshake and smile is a great way to initiate the conversation on a positive note.

2. Provide Context

Immediately provide context about who you are and what you do. Be concise but clear in describing your role and the company you represent. For example, "I'm the CEO of a therapeutics spinout that focuses on targeting X mechanism for Alzheimer's Disease," or, "I'm a PhD candidate in biophysics working on novel methods for allosteric binding pocket identification exploring turning my research into a company."

3. Highlight Your Expertise

Emphasize your expertise or any unique aspects of your background that could be relevant to the person you are talking to. Briefly mention your accomplishments or key projects to establish credibility.

4. Express Your Purpose

Clearly state the purpose of your introduction. Whether you are looking to connect for potential collaboration, seeking advice, or simply expanding your network, conveying your intention upfront helps the other person understand how they can best engage with you.

5. Engage and Hold Conversation

Avoid delivering a rehearsed speech. Instead, be engaging and conversational in your introduction. Show genuine

interest in the other person by asking questions and actively listening to their responses. If you're attending a networking event focused around a specific topic or problem, come up with a few introductory questions before attending, such as "How did you get interested in X?"

6. Elevator Pitch

Craft a concise and compelling "elevator pitch" that sums up your company or project in a brief and impactful manner. This pitch should be easy to remember and deliver, capturing the essence of your venture in just a few sentences.

7. Show Enthusiasm

A genuine excitement for your venture is contagious and can leave a positive impression on the person you are talking to.

8. Be Mindful of Body Language

Maintain eye contact, offer a firm handshake (if in person), avoid fidgeting, and display open and approachable body language.

9. Get Contact Info & Follow Up

If there is mutual interest, suggest connecting on LinkedIn and/or text; a phone number is typically an indication of personal interest. Follow-up with a message or email within 24 hours (ideally the morning after) expressing gratitude for your conversation at the event and ask to find time for a longer 1:1 meeting or coffee chat. When you meet, be sure to ask about any upcoming events relevant to your mutual interests for an opportunity to sustain contact and broaden your network.

An effective introduction not only captures attention but also showcases your enthusiasm, expertise, and the unique value you bring to the table. With practice and genuine engagement, you can make a lasting impression on potential investors, collaborators, and future employees.

Founding Team

While it's possible to start a company on your own, most have multiple founders. Building a strong founding team is one of the most important activities as you spinout your company. The best co-founders will be people from your network, ideally people with whom you have worked with extensively. One of the most common reasons startups fail is because of misalignment between co-founders, knowing you work well with someone can mitigate that risk. In this chapter, we will discuss strategies for putting together a founding team, starting with understanding your role within the founding team.

Your Role on the Founding Team

Founders can have multiple roles within a company. Although founder-CEOs like Bill Gates are often in the media as the face of their companies, being a CEO is not always the right fit for a first-time founder. Generally speaking, a CEO is responsible for leading the entire company. In the early stages of a startup, most of a CEO's time is split between selling the company:

- i. To investors to raise money
- ii. To potential employees to convince them to join
- iii. To potential partners while making strategic decisions about the company's direction.

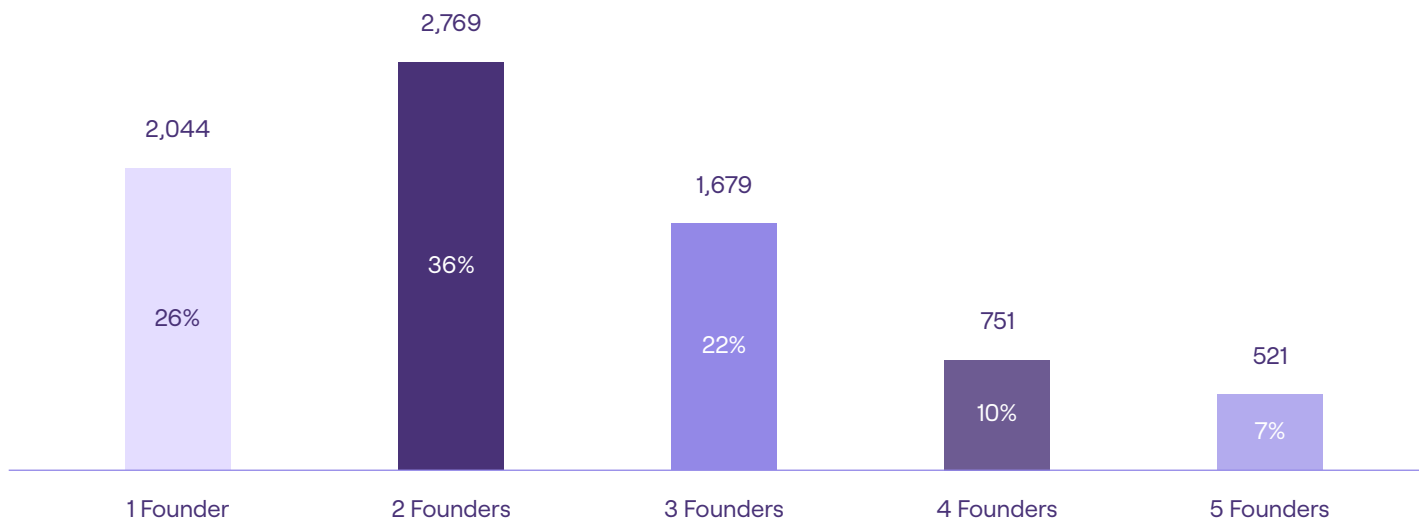
If you choose to be CEO, quickly developing the necessary skills to be a successful CEO will be a major determinant of your therapeutic spinout success. It's worth having the conversation with yourself and your co-founders early to figure out who will be the best CEO

for the company, both now and in the future (one possible answer is that none of you would make the best CEO in the long run!)

In addition to CEO, there are multiple other important executive level roles. A Chief Scientific Officer (CSO) is responsible for envisioning, developing, and executing on a research plan that aligns with the company goals, which are set in conjunction with the CEO, board of directors, and rest of the management team. A Chief Operating Officer (COO) manages daily business operations, working with various teams to ensure their work aligns with the company's goals. A Chief Business Officer (CBO) is responsible for understanding the value of the product or platform, communicating that value to different stakeholders, and making partnerships happen. If you're a first-time solo founder, all these different responsibilities can be overwhelming. Therefore, most founding teams consist of 2-3 people, who typically have worked together before (though many different types of founding teams go on to build great companies).

"For cofounders, if you don't already know each other, get to know each other fast! Make sure you can trust each other - eventually, there will be too much for one person to manage and you will need to be OK trusting them to make decisions without consulting you."

Figure 4: Distribution of founding team size from Carta data



Source: <https://info.carta.com/rs/214-BTD-103/images/Cofounder%20Equity%20Report.pdf>

When a company first starts, specific titles are not particularly meaningful as most co-founders and employees wear many hats; the important part is to have a plan for who will lead which categories of tasks. As the company grows, the roles will become increasingly separate and the day-to-day responsibilities are likely to change. For example, when a company is first founded, the CSO may be in the lab doing experiments, analyzing the

data, changing the experimental plan, and acting as technical lead in investor conversations. As the scientific team grows, the role shifts to people management, setting a long-term research plan to meet the company's goals, and ensuring the scientific team is making consistent progress towards those goals. Some examples are below in **table below**.

Examples of executive responsibilities within therapeutics spinouts

	Business	Scientific	Operational
Early stage	- Fundraising through VC, grants, and angel investors - Building partnerships with pharmaceutical companies for R&D collaboration (usually more relevant for platform companies) - Identifying and analyzing market needs for specific indications - Crafting a compelling company story and vision to attract investors and talent	- Conducting preclinical studies on drug candidates - Developing a patent strategy for novel discoveries - Attending scientific conferences to present research and network - Assisting with data interpretation and low level experimental design	- Establishing laboratory protocols and safety guidelines - Recruiting and training a core team of scientists and support staff - Implementing initial financial and HR systems - Navigating regulatory requirements for lab setup and initial trials
Growth stage	- Launching IPO or securing secondary funding rounds for expansion - Exploring and executing strategic in-licensing or out-licensing partnerships - Developing global marketing strategies and distribution networks for product launch - Negotiating with insurance companies for drug pricing and reimbursement	- Designing and overseeing clinical trials - Making go/no-go decisions on programs to build a robust pipeline - Collaborating with regulatory bodies for drug approval processes - Designing a high level R&D plan	- Scaling production facilities and processes to meet clinical and market demand - Enhancing IT infrastructure for larger scale data management and security - Expanding team across various departments, including sales, marketing, and regulatory affairs - Potentially establishing satellite offices to manage growing team

Please note that these lists will vary significantly based on the specifics of the company

To help determine the best role for you, it can be helpful to go through a road map exercise. What are the major goals for the company in the next 12-24 months? What are the major tasks that a person in each of the above roles needs to perform to help the company meet those goals? What are the skills and competencies needed to perform those tasks well? It can be helpful to do this exercise with co-founders, advisors, or even early investors. With this template, you can list out your strengths

and interests to determine where there is significant overlap. You may find that you don't feel you have the skills and experience to fill any of the roles. If that's the case, think about what role may be the closest fit, what skills you are missing, and how you might develop those skills. Alternatively, you can look for another co-founder, or hire someone else to complement your experience. You may also realize it's not the right time in your career to have an executive role, which is also OK. It's normal for founders to

take on mid-level scientific management (or lab scientist!) roles within their own companies after they help get it off the ground.

Regardless of your past experience and strengths, being an executive at a company is challenging! Even experienced executives need support from peers, mentors, board members, advisors, and sometimes executive coaches. Building a community that can support you and your company is even more important as a first-time founder.

Principal Investigators as Cofounders

With academic spinouts, your PI is often a co-founder. In order to understand their role within the company, you need to have a candid conversation about their goals. Are they interested in leaving their academic role to join the company full time? If so, it's appropriate for them to consider an executive role, possibly long term. Most commonly, your PI will keep their day job at your university. Some PIs are willing to spend time with the company part-time. In this case, they can certainly be an interim executive, but you will need to find someone else to take over that role full-time as the company gains traction and attracts funding (or convince your PI to take on the role at a later date). Some universities have policies that restrict faculty from serving as executives at other companies. A person's title is not particularly important as you go out and fundraise (e.g. your PI can have a title like "lead scientist" instead of CSO); most incubators and seed investors understand that titles are often transient at this point in the company.

As with your co-founders, the important thing is to make sure you and your PI are in agreement about **what** they will be doing. Some PIs will not be interested in being significantly involved. In this case, it's appropriate to label the PI as a **scientific founder**, including a small amount of equity (discussed in *Initial Equity Splits*). It's often helpful to ask the PI to serve as a scientific advisor, which can be very little time commitment (e.g. one 30 minute meeting per month).

Collaborators as Cofounders

Although there are examples of successful companies led by solo founders, the challenging journey of starting a company can be made easier with cofounders. Collaborators make natural cofounders because they are often equally as knowledgeable and as invested in the success of the technology. Importantly, you will already know if you work well together. If you have collaborators who contributed significantly to the science, but they are not interested in joining the company, it may be appropriate to label them as scientific founders with a small amount of equity for serving as a scientific advisor. If they are interested in helping to build the company full-time, have a conversation about what types of roles they may be interested in based on the descriptions above. If they are not interested in an executive

role, you will also need scientists at the bench doing the work, which may be a good fit for folks not interested in management level roles, or those who feel that they don't have the skills and expertise to succeed in those roles.

Other Cofounders

If none of your collaborators are interested in becoming full-time co-founders or you want to recruit a bigger founding team, you can think about alternate ways of finding co-founders. As we have previously mentioned, the best co-founders are often people you've worked with in the past. Another good way to find co-founders is recommendations from someone you trust (i.e. your trusted contact has worked with them). Meeting new people through your network, cold outreach, and events intended for meeting co-founders can also be fruitful. This last approach works best if you have a specific reason and desired skill set when searching for a co-founder.

Benefits of Cofounders

One major reason for looking for co-founders is that there is a major category of tasks listed for either the CEO, CSO, COO, or CBO description that no one on the founding team has any interest in. For example, if you're really interested in continuing to develop the science towards a therapeutic (or other end product), but have no desire to lead fundraising, external conversations, make high level strategic decisions, and generally build the company's infrastructure outside of the science, it may be valuable to recruit a co-founder to serve as CEO (or talk to your early investors about helping you find a CEO).

It can be challenging to determine when your founding team may benefit from an additional co-founder. If there are essential business tasks that must be performed before the company has raised any money and that no one on the founding team is able to do, it's generally necessary to recruit an additional co-founder. Once the company has raised some money, folks who join the company from that point forward are typically considered employees. Although your first funding is a significant milestone which is often used to distinguish between co-founders and employees, that distinction is entirely up to your founding team. There are examples of companies that hire employees before raising any money with solely equity compensation (usually for a specific task that is clearly defined by the founding team) and also examples of companies that bring on new co-founders years into the company's journey.

Another benefit to bringing in co-founders is that they may have a different set of experiences than you. This is especially true if the co-founder literally has more experience. It can be beneficial to work with experienced life sciences executives if you can convince them to join your founding team. Recruiting more

senior executives onto the team can help attract top-caliber talent, but with it comes a disparity between experience levels. To make this relationship work, you generally need to be realistic about your experience, what skills you bring to the company, and make it clear that you're hoping to not only work with the other person but also learn from their experience. It can be challenging to attract these experts to work with you, especially when your company is just an idea with limited proof of concept data. To increase your chances, work on crafting an exciting story to sell them on your science and its potential impact, and make it clear that you're open to feedback and growth.

An important note here is that you may actually have little control over decisions regarding the executive team depending on where you get funding. Larger, more traditional **venture creation firms** will often find experienced life sciences professionals to serve as co-founders and executives to the company. Depending on the specific terms of the investment, you may not be an executive in the company you helped to start! This can be a good

option if you're enthusiastic about the idea and continuing to translate the science (academic scientific founders can often end up in senior scientific roles), but not interested in the entrepreneurial or company building aspects. There are also many VC firms where you can take an investment and keep most or all of your founding team in place (some firms prefer this!), although this is more likely if you or your co-founders have some startup experience. Decisions surrounding your executive team can be discussed and negotiated with your investors and founding team as part of the fundraising process.

Aligning with Your Cofounders

Regardless of how you met your co-founders, it's important that you're aligned on major decisions. In the **table below**, we list some questions that are important to discuss before you commit to going into business together. **It's important to keep discussing these questions because the answers will change!**

Questions to ask and reflect on with potential cofounders

Company Vision

- If they were not involved in coming up with the idea, make sure they have a deep understanding and appreciation of it, and that you have a shared vision
- Discuss a backup plan in case the idea doesn't pan out – are you OK working on other, related ideas?
- Define what success means to each of you: is it a regulatory approval, a certain number of patient lives impacted, an exit where you make a lot of money?
- What exit scenarios (e.g. IPO, acquisition, etc.) are acceptable to you?
- What values will be reflected in the company's culture?

Personal Roles

- What types of work are you interested in doing? What roles are acceptable to you?
- If you start as an executive and begin to feel that your role is unmanageable, are you comfortable stepping into a lower level position (e.g. VP or director)?
- Similarly, if the responsibilities change and you are no longer interested in the role, when would you make the decision to switch roles?
- What roles would you absolutely not want?
- It's very uncommon for the executive team to stay the same throughout the lifetime of a company – running a 10 person company requires very different skills than running a 250 person company
- Why build this company instead of another job? What are your personal goals?
- What aspects of the company (e.g. scientific platform, company culture) are most important to you?

Logistics

- How will we split equity? (Some of our advice is below)
- Where will the company be based? Will we work remote or in-person?
- What needs to happen for us to commit to the company full-time?
- What is your personal financial situation? How long can you work for little to no salary until you need a reasonable salary to help cover living expenses?
- What are your expectations for work hours? What things outside of work are important to make time for? How long will we work these hours? (Getting a company off the ground is a lot of work!)
- What will we do if we have trouble agreeing on an important decision? What will happen if we decide we don't want to work together anymore?

Incorporating

Unless you have a significant reason not to, you should form a **Delaware C-corp**. Most investors will want to invest in C-corps as it helps protect individuals from liability should the company be sued for any reason. There are a few **Limited Liability Corporations (LLCs)** and **Public Benefit Corporations (PBCs)**, but these are exceptions to the rule. You can incorporate once you're sure you want to spinout, have a timeline to join the company full-time, and you have agreed on an initial equity split. With good reason, you can also incorporate sooner, such as if you are applying for SBIR or STTR grants. Keep in mind you may have a bit of corporate clean-up required when you raise your first angel or VC money, as you may need to issue more shares to adjust equity split. Recommended tools to help with the incorporation process are Stripe Atlas and Clerky. You can also work with an attorney; this is often not necessary and will be more expensive.

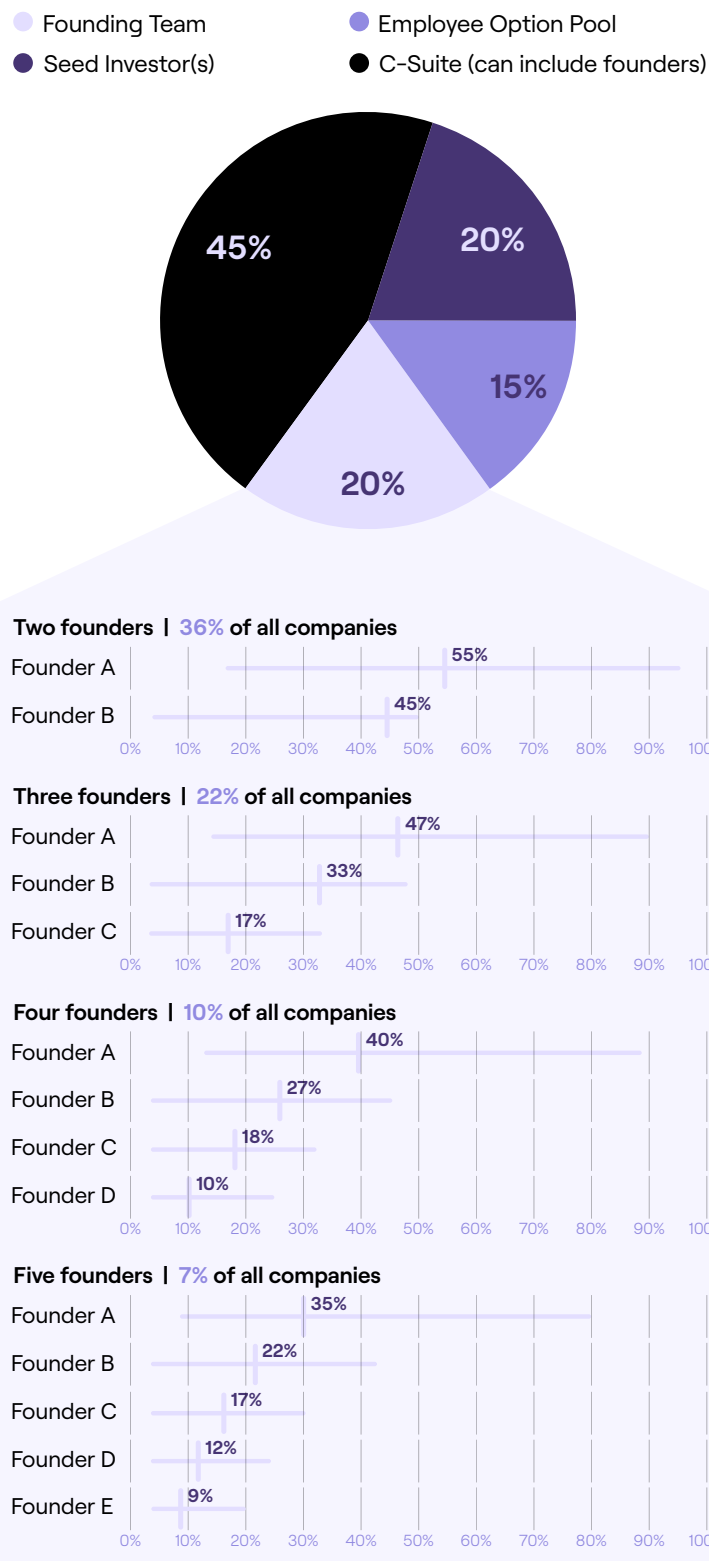
Initial Equity Splits

When you incorporate your company, you will create a certain amount of shares. The number of shares does not matter and will change as you raise money. Those shares need to be issued to a specific person or entity. The best way to think about equity at this stage is in terms of percent ownership of the company. The following are some guidelines that we've seen in the literature and gathered from interviews, but equity splits can vary significantly depending on specific circumstances, so we encourage you to seek out advice from trusted advisors to determine what makes sense for your situation.

80/20 Split for Builders/Founders: A common suggestion is to aim for a 80/20 split between builders (future employees) and creators (the founding team), after accounting for **dilution** from your initial seed investment. If you're spinning out from an academic lab, this will typically involve dividing the 20% pool between all co-founders and your PI. Equity splits may vary, but generally an even split among the number of co-founders and PI *from this 20% pool* is favored. This 20% pool is reserved for founding members only. It's appropriate to give "scientific founder" equity from this 20% pool to academics who have contributed significantly to the idea, but do not plan to be involved in the company moving forward. As you hire employees (and pay yourself!), that equity is taken from the remaining 80% pool based on projected contributions to the company. Initial investors, founders that will continue to be involved, and future employees will receive equity from this 80% pool, of which ~15% should be reserved for non-C-suite hires as an option pool. In practice, equity is not always equal among co-founders; some data on equity split is shown below in [Figure 5](#).

You and other founders who will remain involved in the company should also receive additional equity for the 80% reserved for builders. We now discuss one potential way of dividing this equity, though please note it can vary significantly by company.

Figure 5: Equity splits by founding team sizes



Source: <https://info.carta.com/rs/214-BTD-103/images/Cofounder%20Equity%20Report.pdf>

Founding Executives: 30–50%

If there are multiple co-founders with positions of similar responsibility, this should be split roughly equally. Founder equity split is difficult to change later, and can lead to resentment among the founding team if not done fairly; if you decide to use anything except equal splits tread carefully—remember, most of the hard work is ahead! That being said, as you can see in the Carta data, many companies do have unequal equity splits among founders. These discrepancies may be because someone has been working on the idea for significantly longer, some of the founders have different experience levels, the scope of responsibility / commitment will vary between the founders' roles, or differentials in cash compensation (among other reasons).

Other C-level management: 0.5–10%

Generally, 0.5%–10% per C-level executive depending on skills, experience, and when they join the company (e.g. they should get more equity if they join before the company can afford fair cash compensation, and even more if they have significant experience).

Early Employees: 10–20%

Allocate 10–20% of equity for early employees. Consider this in tiers, where the first 10 employees receive a total of X% equity, the subsequent 10 are awarded a total of Y% equity, and so on.

Part-time academics: 3–6%

Around 3–6% is reasonable for each part-time PI founder that will remain involved (e.g. spend 1 day/week with the company). This should not be more than 10–15% total based on expected contribution.

Early Advisors / Board of Directors: 0.1–3%

The time commitment and value of these people varies considerably, so there is a broad range of what is acceptable (between 0.1% and 3%). A collaborator who is willing to chat once or twice a month should be on the lower end of the spectrum. A big name PI who is willing to lead your scientific advisory board should be on the higher end, maybe even more. Similarly, an experienced biotech exec willing to serve as an executive chairman of your board should also be on the higher end, and possibly more than 3%.

University: <10%

University equity and royalties can be complicated; please see our "Licensing from Your University's Tech Transfer Office" playbook for additional details.

Typically, all company equity, including founder shares, should **vest** over four years, meaning ownership of the equity is gradually earned over this period. There's also a **one-year cliff**, meaning no equity is vested in the first year, but a quarter of it vests after one year, with the rest vesting monthly or quarterly over the next three years. This approach ensures commitment

to the company's growth. Deviating from this norm, especially in ways that let early employees or founders leave early with much equity, can be seen negatively by investors, as it may indicate a lack of long-term commitment

Equity Details

Disclaimer: This playbook is for informational purposes only, you should not construe any information or other material as legal, tax, investment, financial, or other advice. We are not attorneys, accountants, or financial advisors, nor are we representing ourselves as such, and the information contained in this playbook is not a substitute for financial advice from a professional who is aware of the facts and circumstances of your individual situation. Regardless of anything to the contrary, nothing available on or through this playbook should be understood as a recommendation that you should not consult with a financial professional to address your particular information. We expressly recommend that you seek advice from a professional.

At early stage companies, equity-based compensation is most commonly in the form of **incentive stock options (ISOs)**. This means that the person has the option to pay money to buy the stock at some set price. Often, the cash is not very meaningful to the company, but can sometimes be a significant investment for the individual. Many companies have options that expire 90 days after a person leaves the company. This can leave a sour taste in the mouth of early employees who work at the company for a few years and decide to move on, and then need to decide if they want to spend thousands of dollars (or more!) to take a risk on the startup's success, or let their options expire. However, you can give the right for people to exercise incentive stock options up to 10 years after issuance. This is an employee friendly thing to do; another employee friendly thing to do is allow **early exercise**. This means that the employee can buy all the equity immediately, but does not actually receive it unless they stay and it vests.

If the employee files an **83(b) election** following early exercise, it can provide tax benefits to the employee in the future. An 83(b) election is a decision made by the employee to be taxed on the total fair market value of restricted stock at the time of granting, rather than as it vests. Filing an 83(b) election can be financially beneficial in several ways. First, you can avoid the **alternative minimum tax (AMT)** as your equity vests. Due to AMT, you may be subject to paying taxes on income that doesn't exist, with money you may not have! By filing an 83(b) election, you're exempt from these AMT implications. Second, by filing this election, the IRS treats you as owning your equity from the moment you exercise your options. Consequently, you become eligible to pay long-term capital gains tax rates (which are typically lower than regular income tax rates) much earlier. It's crucial to remember that 83(b) elections must be filed within

30 days of an equity grant, so be prepared! There is significant complexity involved, so it's advisable to consult with a trustworthy financial advisor. Keep in mind that this information pertains specifically to U.S. tax regulations.

Hiring

Your First Hires

The founding team handles every function in the early days of the company, from business development to IP licensing. It's crucial for your first hires to be adaptable to a startup's dynamic nature, where roles are fluid and demands are intense. As we've discussed, your ideal first hires are people you or your co-founders have worked with in the past, but there is also value in pursuing talent outside of your immediate network. Cold outreach may be necessary and surprisingly effective, and a LinkedIn recruiter lite account can help identify potential candidates. If you see mutual connections, ask your mutual connection for a warm introduction. If not, send a personalized message clearly stating the purpose of your company, the role, and why you think the candidate would be a good fit.

Your first 10–15 hires set the tone of the company, and with each additional employee, roles become more specialized. As these employees form the foundation of the company's culture, the founder's involvement in the hiring process is critical. You should hire employees gradually rather than all at once to avoid abrupt culture shifts. If you're an operational founder, you're likely the final decision-maker. Other scientists on your team will likely focus their interviews on assessing technical competency; you need to ensure that you are recruiting and hiring scientists and engineers that have the ability and interest to develop your pipeline or platform towards drug candidates, rather than solely on advancing scientific knowledge.

"Academia is me, biotech is we."

It's crucial to appreciate that technical skills alone won't suffice. Unlike academia, success in a startup is measured differently. Startups have a distinct culture emphasizing teamwork, shared responsibility, and a faster work pace with regular deliverables.

Business considerations play a major role in determining what science to progress and how to progress it. Look for individuals who can work with a multidisciplinary team to turn scientific concepts into tangible products and don't carry an oversized ego.

Although important, be cautious when assessing for "culture fit" in an interview; lack of a clear framework can inadvertently let personal biases influence hiring decisions. It's beneficial to first articulate the values central to your company's culture. Consider whether your company prefers quick or measured decision-making. Do you lean towards inductive or deductive reasoning? Is it essential for decisions to be backed by experimental data, or is theoretical reasoning sufficient? How does the company communicate: through real-time discussions or asynchronous, written methods? These preferences are often shaped by the founder's own working style. Defining your company culture using such criteria helps in objectively evaluating cultural fit during interviews. (*For more information, see our Company Culture section.*)

Interviewing

To make the clearest hiring decisions from interviewing, defining the behaviors and traits you value in your company is key. Structuring behavioral questions around these values can uncover whether candidates possess attributes necessary to succeed and contribute positively to company culture. Questions should ask for demonstrations of collaborations, ability to work through ambiguity, and adaptability to execute tasks outside of their skillset. Before making a final hiring decision, request references from previous employers/collaborators to learn what it's like to work with the candidate.

Structured interviews and work samples are helpful yet often inherently biased; a coding challenge in R will not pick up a brilliant computational biologist experienced in Python. As much as possible, try to design your interview questions and any requests for work samples to align with the candidate's strengths. In addition to interviewing the candidate yourself, conversations and interviews with other team members can bring important complementary perspectives to gauge candidates' compatibility with your team's dynamics.

If possible with a candidate's current employment, it's helpful to hire them as a consultant or intern and provide small projects at first to build rapport. This allows you to assess the candidate's fit with the company prior to bringing them on full-time. They should perform tasks and be evaluated as they would if they were a real employee, such as experimental design, running experiments, and communicating results (both internally and externally). Set up frequent meetings with potential hires to discuss common interests and be upfront about "scoping them out" for a potential full time hire.

Before the Interview

- **PRELIMINARY MEETING:** Organize a meeting with all interviewers to align on the role's expectations and necessary competencies as determined by the hiring manager or team.
- **ASSIGN INTERVIEWER COMPETENCIES:** Ensure that each interviewer focuses on different aspects of the candidate's profile to gather diverse insights without repeating questions. For example, one interviewer may focus on scientific technical skills while another may assess leadership ability.
- **REVIEW RESUME AND JOB DESCRIPTION:** Each interviewer should review the candidate's resume and the job description thoroughly to understand their background and tailor the interview questions accordingly. If a specific bullet or experience sticks out you can reference it: "I saw you've done X on your resume at Y company, tell me more about your experience."
- **PREPARE YOUR QUESTIONS:** Develop specific questions based on your assigned competency. Avoid asking controversial or legally sensitive questions.

- **WRAPPING UP:** Share your contact information (email), discuss the hiring timeline, and encourage the candidate to reach out if they have further questions.
- **LEAVE A GOOD IMPRESSION:** Keep in mind that the candidate is also interviewing you, likely amongst multiple other interviews and pending offers. If the candidate likes you, then they may refer their network to you even if they do not ultimately accept the role.

After the Interview

- **DEBRIEF:** Have a quick huddle to discuss candidates at the end of the interview day to nominate top candidates.
- **ASSESS THEIR +1S:** Ask yourself if this person will bring an aspect of diversity that will positively contribute to the team and company. Will they bring something unique? That something could include a technical skillset, non-traditional career experience, or a new mindset for innovation.
- **PROVIDE FEEDBACK TO THE HIRING MANAGER:** As soon as possible, or while interviewing, write your thoughts with examples (e.g. "I like them because they demonstrated a collaborative approach in their answer to X question from their experience at Y.") By attaching details from your conversation, you can help avoid interview bias.

During the Interview

- **INTRODUCTIONS:** Introduce yourself briefly (education, experience, role, position in company, and a brief note on company experience). Allow the candidate to introduce themselves. Be sure to share your interview plan and if you are taking notes. Provide context on your role and how it is related to theirs.
- **ASK YOUR PREPARED QUESTIONS:** Start with your competency-based questions to make sure they are covered. Questions can be asked fluidly in a conversational flow, or more Q&A style. We provide some examples in the next subsection.
- **LISTEN FOR "I", "ME", AND "WE":** If you notice a pattern of "we" within an interview or answer to a specific question, follow up by asking "Who is 'we'? You should distinguish what the individual accomplished and what their role was in the team.
- **SAVE TIME FOR CANDIDATE QUESTIONS:** Dedicate at least five minutes for candidates to ask their questions. Remember that after multiple rounds of interviews they may not have further questions, but don't hold this against their candidacy!

STAR Questions

Look for the candidate to explain the Situation, specify the Task and their role in it, the Actions they took, and the Result.

- **SITUATION:** What was the business problem or goal? Who was involved? What were the time constraints?
- **TASK:** What did you hope to achieve? How did you come to that conclusion? Who did you consult with?
- **ACTION:** What did you do? What tools or resources did you use? Who did you work with? What obstacles did you encounter?
- **RESULT:** What were the results? What feedback did you receive? What did you learn?

Core Competencies and Interview Questions

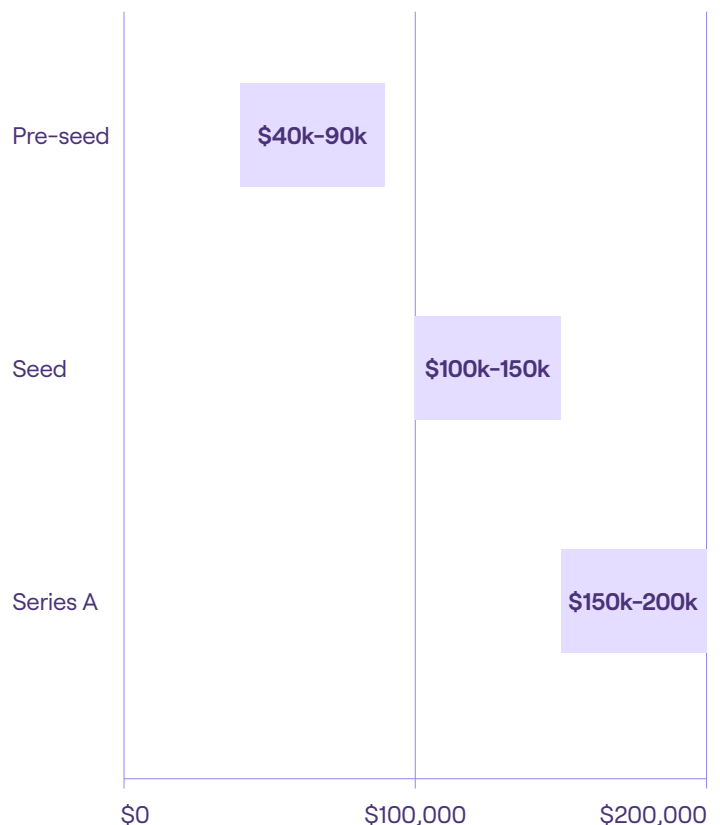
- **TEAMWORK:**
 - Describe a project where leading a collaboration with others led to more successful results.
 - How did you communicate and deliver project results to your team?
- **PROBLEM-SOLVING**
 - Describe how you solved a challenging problem with limited resources.
 - Can you walk me through a system that you either invented or significantly improved?
- **ADAPTABILITY**
 - Describe a situation where you faced significant changes outside your control and how you adapted.
 - Talk about a time when you had to quickly pivot from an ongoing project due to an urgent matter.
- **INITIATIVE & SELF-AWARENESS**
 - How have you set and monitored your progress towards goals in your previous position?
 - Describe a situation where you had to complete a project with minimal direction.
- **PERSONAL VALUES**
 - If you were to start a company tomorrow, what would its top three core values be?
 - How would your friends and family describe you?

“When conducting interviews, the key question you are trying to figure out is “What is it like to work with this person?””

Compensation

Compensation is an essential part of recruiting employees after you have made the decision to make them a job offer. The first compensation decision you will make is how much to pay yourself. We have already discussed equity above, but figuring out the correct cash compensation can be tricky. Paying yourself too much can be a red flag for investors, who may fear that you’re not prioritizing the financial health of the company. At the same time, you need to pay yourself enough to take care of your expenses. When your company has only raised small amounts of grant money or pre-seed capital, you should generally pay yourself as little as possible to comfortably cover your living expenses, which can vary depending on cost of living in your area and personal circumstance. Pay will generally increase as you raise more money; ensure you increase your employees’ pay alongside your own, especially if you are not yet paying market rate. **Figure 6** shows reasonable ranges based on funding stage, but it’s acceptable to go outside these ranges depending on the situation (e.g. if necessary to recruit an experienced executive, etc.).

Figure 6: Reasonable salary ranges for startup CEO pay



Compensating early hires fairly is crucial for retention and growth. Create an equity structure upfront—define how much equity you will give to the first hires, the next 5, the next 10, etc. Be transparent about your equity structure. For an employee to fairly assess the value of their equity, they need to know details like share price, total outstanding shares, and future fundraising plans; be sure to have these details on hand while making job offers.

Some companies intentionally make a cultural decision to flatten salary ranges between roles (e.g. paying lab techs more and executives less). An abundance of studies suggest that women don't negotiate around salaries and lowballing potential employees with the expectation of negotiation is unfair as an employer. Pre-negotiate offers to avoid perpetuating these biases (i.e. offer as much as you are willing to pay). If you end up paying a new employee more than you pay your existing employees, then raise comparable existing position salaries to match or beat it. Otherwise, you risk losing employees and their morale—there's nothing more demotivating than not rewarding the team that helps you grow.

Compete for talent through compensation, but stay within budget constraints. One useful strategy is to determine a compensation formula in advance, including some flexibility between equity and salary (within limits). This involves educating employees about practical equity results, with resources like RACap⁴. Be optimistic about the future of the company to excite potential employees, but don't mislead your employees into planning their lives based on becoming millionaires from unrealistic equity expectations. Besides salary and equity, consider health insurance coverage, 401k matching, and additional benefits like a fitness/gym membership. With a balanced equity and salary structure in place early on, you can recruit the team you need.

Navigating Employment:

Contracts, Compliance, and Human Resources

Ensure a smooth transition into the company by addressing key employment policies and documentation. Employment contracts, Confidentiality and Intellectual Property Assignment (CIIA) agreements, payroll management, and Human Resources (HR) policies should be clearly outlined. Additionally, navigating tax ID and compliance across multiple states can be complex; consider outsourcing these functions to streamline your operations. Outsourcing early-stage compliance, payroll, and logistics can be facilitated through consultants. Your investors will likely have their own recommendations vetted by other portfolio companies.

As your startup matures and the workforce expands, contemplate developing a comprehensive benefits strategy. Think about introducing a dedicated HR professional around the 25-employee mark to oversee vital functions like onboarding, performance management, retention strategies, and refining your recruiting processes.

Employment Agreements

An employment agreement should contain an invention assignment clause, stipulating that any inventions, ideas, or intellectual property created by an employee or contractor during their employment or engagement with the company will be owned by the company—not the individual. Key elements include: scope of work, duration, disclosure, assignment of rights, and assistance in patent procedures. This is especially important for anyone still employed part-time by the university as universities often claim the IP of any work done by the student / postdoc / professor unless it is explicitly not done for the university (and does not use any university resources). If you are working with academics who have facilities or equipment that they need to use as part of the work they are doing for the company, it's important to draw up a formal agreement describing how their university's resources will be used, and who is going to own the subsequent IP. This can help avoid sticky situations down the road.

How to Fire Someone

Letting someone go is the hardest part of building a team, but occasionally it's necessary. Most of the time, people are working in good faith to do their best work. Sometimes, it's possible to fix particular issues without needing to fire someone. When performance issues come up, communicate them and provide a chance to improve over a set period of time to accomplish a concrete set of objectives. Oftentimes, these issues can arise from misaligned expectations around what deliverables are required from the employee, and how to best communicate with you about their work. One mechanism to help your employees understand that their work is not meeting your standards is called a performance improvement plan (or PIP). These plans are short documents that outline your concerns about their performance, the standard you expect them to meet, and a plan to get their work up to that standard.

However, not everyone will be a fit no matter how hard you try. If possible, you can try to shift responsibilities and reposition an employee to where they may be better suited, but ultimately you may need to let someone go.

Never fire someone alone (for liability reasons!). Have a trusted third party present and always loop in legal counsel and HR to cover your bases. Document everything thoroughly. When the time comes, be compassionate yet direct. One of the challenges with firing someone, especially at a small company, is the morale impact on your team. In practice, you will commonly encounter one of two situations.

The first reaction you may see is your team being completely supportive of the decision. At a small company, teams work closely together. If someone's work is poor quality or they are difficult to work with, the rest of their team will be the first to know. When the person is fired, the team will understand and sometimes even be thankful they don't need to work with that person anymore.

⁴<https://racap.thinkific.com/courses/understanding-the-value-of-your-equity>

The second reaction is that people will be surprised and uneasy. The unease usually comes from concern about whether their own job is safe. In situations like this, it's helpful to reiterate the processes you have in place to address poor work performance, or other issues that may lead to someone's firing. While that person's firing may have been a surprise to the rest of the team, make it clear that it wasn't a surprise to that person due to these processes. You can further reiterate mechanisms you have to allow people to safely voice their concerns and have a constructive discussion.

Consultants

There are many functions needed to keep a company operational. When a company is first getting started, there isn't enough work to justify full time hires for many of these roles; however, these functions are essential. You should first evaluate whether a new hire is needed, distinguishing business operations that can be outsourced to a contractor or consultant, and if the role requires part-time or full-time effort to fulfill a role's obligations. For example, most HR and legal positions can be outsourced to part-time consultants (or companies that provide consulting services) until the company hits 30-50 employees. Consultants often cost more per hour than a full time hire, but you save money in the long run if you only have 10 hours of work per week for a person to do. In addition, consultants are usually experts for their responsibilities, alleviating worry about the quality or reliability of their work.

How do I know if I need a Consultant?

In general, you should start with a description of the role. What are the primary responsibilities of the role you need to fill? How many hours per week will be required? As a starting point, you can reference and modify descriptions from job postings currently online. From this description, you can determine if the person should be a full time hire, part-time in-house hire, or external consultant. Generally, if you expect a role to take 40+ hrs/week and the need is long-term, it's best to hire someone full time. If the role will require significantly less than 40 hours, you need to decide if you should hire someone in-house or engage a consultant. If you have a particular task that is somewhat unique to the company or your technology (e.g. reviewing the results of experiments and updating an internal database with summarized metrics), it can be beneficial to hire a part-time, in-house person so that you can set the expectation of a longer-term relationship and train the person. If you have a fairly standard set of tasks (e.g. reviewing legal documents and handling HR compliance), it's often best to hire an external consultant.

Common Consulting Roles

Consultants in early-stage companies primarily manage tasks like payroll, benefits, HR compliance, hiring logistics, accounting, insurance, equity management, and invoicing (if applicable). You have the option of engaging comprehensive service providers or selecting individual consultants for specific tasks, with the possibility of handling some aspects yourself. Opting for comprehensive

services, while generally more costly, can significantly reduce your mental load. On the other hand, choosing individual consultants is more budget-friendly but requires you to oversee multiple operational processes. These processes might not be central to your company's success, but neglecting them can lead to failure.

Although a seamless HR process alone doesn't guarantee company success, ignoring legal compliance can result in serious issues. For example, lawsuits from disgruntled former employees can arise if employment laws are not properly followed, potentially leading to a company's collapse. For this reason, it's important to have a good HR consultant as soon as you hire your first employees.

Another good consultant to hire early is a data management specialist. When your company's technology heavily relies on data, bringing in an in-house expert early to establish a strong data management infrastructure can be highly beneficial. If you are an AI-first biotech or rely on a computational platform, you should consider an early full time hire. If funding is limited or you are a less computational-centric biotech, you can temporarily use consultants to bridge the gap—keep in mind that an inadequate data management system can be expensive, particularly if it results in loss of experimental data. If you are working with health data, make sure that your data infrastructure is compliant with all laws and regulations, including HIPAA in the US.

In addition to operational consultants, scientific consultants can form an important part of a company's strategy. If you are a first-time founder, you should not assume you know which experiments to conduct to derisk your therapeutics spinout efficiently without pharma veteran expertise. If you're developing a platform that is ultimately going to be used as part of the drug development process, an experienced drug developer can provide invaluable insights into your scientific planning. If you're validating a target or developing a single therapeutic, drug development expertise is also essential. Experienced drug developers can be expensive and you may have difficulty convincing them to join your company, so you may need to hire them as consultants until you get some exciting data and to entice someone to join full time.

Finding the Right Person

Having a consultant perform poor quality work can cause problems, and take up a lot of mental energy that you should be spending elsewhere. References from people you know and trust can be hugely valuable when hiring consultants. If you have concerns about the quality of the work done by the consultant, don't be afraid to find someone else. Parting ways with a consultant is much easier than firing an employee.

Transitioning to Full Time

If you have a good relationship with a consultant and the amount of work you have for them is growing, consider trying to recruit them to your team. Remember, one of the best ways to know if someone will be good is to have worked with them in the past. If your consultant is excited about your company and idea, it's not uncommon for

them to seriously consider joining your team full time and winding down other consulting work. In fact, some people cycle between consulting for a few companies simultaneously, joining their favorite, and repeating. As the workload ramps up, if the person is not interested in joining your team full time, then it is not uncommon to stop working with them due to lack of availability. It is worth asking if they can recommend talented people for a full-time hire.

Advisors

No one person can be an expert in everything required to run and grow a successful life sciences startup. You can and should informally engage with personal and professional mentors who can help provide guidance on important decisions. You can also formalize advisory relationships by giving someone equity in the company (or pay advisors on an hourly basis, or for your most valuable advisors, both!). This is typically done through either the scientific advisory board or board of directors, discussed in Chapter 4. It is also possible to hire someone as a special advisor for equity and/or cash independent of these entities.

Company Culture

As a founder, your vision and principles are the foundation of your company's culture. It's crucial to consciously embed these values from the outset. Hiring should prioritize technical expertise and alignment with your company's ethos, ensuring that new hires integrate into and promote the culture you want to build.

Mission, Vision, and Values

Your mission, vision, and values define the form of your culture. At the early stages, clearly defining your company's culture is less important than derisking your technology as fast as possible. Once you start hiring full-time employees, however, it is worth having a serious and intentional discussion about the culture you want to create.

Mission

Your startup's fundamental purpose and reason for existence, guiding the "why" behind your endeavors and decision-making.

Vision

A vivid portrayal of your startup's future aspirations and achievements, inspiring your team to collaborate passionately and innovate towards a shared goal.

Values

The moral code shaping behaviors and interactions within your startup, uniting team members around shared beliefs and principles to create a cohesive work environment.

To build a sustainable company, long-term vision and strategic planning are essential. Although therapeutics spinouts are frequently acquired, focusing solely on the short-term can attract people with transient ambitions. From the onset, articulate the mission and motivation guiding your company's creation, the vision of the impact you want to make, the values that guide you towards that vision, and how they manifest in your organization.

Team members aren't going to spend their time browsing your company's website to figure out what's expected of them. Instead, they turn to their peer colleagues to discern the cultural norms and values that influence their behavior. When someone joins your team, they're not motivated solely by perks like free lunches. They want an environment where personal and professional growth is encouraged. Core values should enhance, align, and motivate your team's strengths towards your vision. Your company's values should be reflected in your scorecard for evaluating current employees, future hires, and, most importantly, **you**. If it's just words, nobody will take you seriously.

A helpful exercise is to define around 3–5 core values, their descriptions, and tangible examples of employee actions that exhibit them. After iterating and refining these with your founding team, you should clearly display and communicate these values to your employees. Some examples are shown in **table below**.

Examples of Company Values, Descriptions, and Employee Actions Demonstrating Them

Value	Description	Employee Actions that Exhibit Value
Integrity	Upholding honesty, transparency, and ethical conduct; doing the right thing, even when unseen.	1. Admitting and correcting mistakes in a timely manner. 2. Upholding commitments and ethical standards in decision-making.
Collaboration	Emphasizing teamwork, respect, and sharing ideas to achieve common goals.	1. Actively participating and highlighting others' inputs in team meetings. 2. Offering help and support to colleagues.
Innovation	Embracing change, thinking creatively, and seeking continuous improvement.	1. Actively seeking new knowledge and embracing constructive risks. 2. Encouraging and participating in creative brainstorming sessions.

Company culture is created by the collective behaviors that you foster within your team, underpinned by your company's values. To assess the current state of your company culture, ask yourself about individual actions in the context of your values. Does everyone contribute in group meetings, or is there a silent minority? When mistakes inevitably happen, how fast do employees report them and to whom? Do employees spend time together outside of the workplace? When an individual achieves a milestone, how is this celebrated and rewarded by yourself and other employees? Reflecting on these questions can provide insight into the tangible expression of your company's culture and how it aligns with your intended values.

An important aspect of company culture is building a set of workplace rules that your employees can follow. As a founder / executive, it's important that you're getting the information you need from employees to make key decisions. The employees doing the work in a specific area are usually more knowledgeable about their functional area than you are, especially once the company is more than just a few people. However, building a culture where employees understand their role in this process and feel empowered to tell you what they think you need to know can be challenging. One way to make it easier is to explicitly set rules.

These rules come from an understanding of the culture you're trying to build, especially clearly defined values around communication and debate. Once you have defined these values, create explicit rules for employees. How should they update you on their work? How are key decisions made and communicated within the company? How should they bring up disagreements with your decisions? For example, one executive might prefer disagreements be settled through written memos outlining clear theory and rationale, while another executive might prefer to see a demonstrable prototype and experimental results.

Clearly defining these rules will help your employees feel more comfortable and confident. An important aspect of defining these rules is to both communicate them to new employees (and reiterating them to existing ones) and playing by the rules yourself. By doing so, your employees won't be concerned with inconsistent backlash or consequences for acting in good faith to help you make the best decision for the company.

Being consistent and predictable with clear criteria for success is the best thing you can do to make your employees feel comfortable doing their jobs.

Diversity, Equity, and Inclusion

Having set clear, consistent rules that apply to all employees equally, the next step is to ensure that these guidelines reflect principles of diversity, equity, and inclusion.

Diversity is typically thought about in terms of ethnic or gender composition, but at its core, operationalizing diversity is a mindset appreciating the value diversity brings at every level of a company's function. By cultivating a diverse workforce, you create an environment where innovative thinking flourishes due to unique perspectives, leading to enhanced problem-solving and creativity. You can adopt non-discrimination and diversity policies, and bring on board members with a diversity of backgrounds and experiences. (For more information and actionable pledges, we recommend reviewing The Gaingels Letter⁵ and associated resources.)

Equity is the cornerstone of a just and inclusive startup culture. It entails providing equal access to resources, opportunities, and support, regardless of background or identity. Strive to eliminate barriers that hinder any team member from reaching their full potential. To reduce bias in hiring, consider implementing practices that focus on skills and potential rather than pedigree or traditional qualifications. Provide and communicate clear pathways and promotions for employees to grow into. By promoting equity, you empower your employees to thrive based on their skills, contributions, and efforts to foster trust and loyalty.

Inclusion goes beyond diversity, encompassing the practice of creating an environment where every team member feels welcomed, respected, and valued. The profound impact of a strong sense of inclusion cannot be understated, as it results in a remarkable 56% surge in job performance, slashes turnover risk by 50%, and reduces sick days by a staggering 75%⁶. Actively seek out and amplify diverse voices, perspectives, and ideas. Inclusive startups prioritize collaboration, open communication, and shared decision-making.

⁵<https://gaingels.com/gaingels-letter>

⁶<https://hbr.org/2019/12/the-value-of-belonging-at-work>

Strategies to Foster Belonging

- Establish open communication channels for team members to express thoughts, concerns, and ideas freely.
- Implement regular feedback sessions and anonymous suggestion systems to encourage contributions from all team members.
- Initiate mentorship and buddy programs with more senior members for mentorship, including scientific advisors.
- Cultivate a culture of recognition and appreciation, celebrating individual achievements to boost morale.
- Form cross-functional teams and collaborative projects to encourage innovation through diverse perspectives.
- Host team retreats, holiday parties, and regular social events to build comradery outside of the workplace.
- Place a high value on open communication. Give people as much information as you can to promote autonomous decision-making aligned with the goals of the company. The people best equipped to make decisions are those on the ground.

Onboarding

Onboarding is a critical phase for employee retention and productivity. The Society for Human Resources (SHRM) research points out that 69% of employees are more likely to stay with a company for three years if they experienced great onboarding and organizations who commit to a structured onboarding program experience 50% greater new hire productivity⁷. As a company grows beyond 10 employees, personalized interaction with founders and executives may decrease, making structured onboarding even more vital. Once you have hired a new team member, ensuring that every aspect of their onboarding acknowledges who they are and what they will bring to their work each day will substantially impact their sense of belonging and ability to adapt to their role. The first 90 days of onboarding is critical to transition a new employee, and we've provided a table of outcomes and how to accomplish them in **the table on page 36**.

First 30 Days: Learn Culture, Business, and Product

In the first month, new hires familiarize themselves with key job functions, company policies, and specific procedures. Training is emphasized to help them understand their role and settle into their responsibilities. Cultural immersion is a priority, with introductions to the company's values, mission, and team dynamics. Strategies are implemented to integrate the new hire into the team, including weekly check-ins to address any concerns as swiftly as possible. New hires can meet colleagues through department presentations, non-traditional surveys revealing personality/hobbies, and lunch meetings with staff and executives. A "buddy system" with a senior employee can also aid their acclimation.

30-60 Days: Align Vision

This phase focuses on aligning new hires with the company's vision and improving role proficiency. It's crucial for them to

understand how their work contributes to overall organizational goals. They should also deepen their knowledge of available resources and support systems. Regular, clear communication with managers and team members helps outline responsibilities and goals, fostering a sense of empowerment and clarity. Executives or an equivalent supervisor should meet new employees weekly throughout this period. It can also be helpful to have skip-level meetings, where senior employees meet new employees that they do not directly work with. After 60 days, new hires should feel increasingly integrated, understand their role's impact, and growth opportunities.

60-90 Days: Establish Execution Efficiency and Impact

In this final phase of initial onboarding, new hires should be fully integrated and actively engaged. The focus is on enhancing task execution efficiency and their impact on team projects. Clearly outlining communication channels and providing continuous feedback helps employees develop their skills, and identify areas for improvement. New hires should have and be able to explain concrete projects, milestones, and evaluation criteria for success. This period is also key for building team relationships and trust as new hires assume more responsibilities.

One-Year Milestone: Recognize Achievement and Determine Long-Term Fit

The one-year mark signifies a significant milestone in a new hire's journey. By now, they should be considered a fully integrated team member. Managers can gauge their productivity, skills, and alignment with the company's culture and values. It's a good time to discuss the employee's long-term role in the organization, exploring career development options and future goals. Be sure to recognize their achievements over the year to celebrate their contributions and reinforce their value to the company.

⁷<https://www.shrm.org/executive/resources/pages/0523-onboarding.aspx>

Goals for the First 90 Days and Strategies to Accomplish Them

Goal	How to Accomplish
I understand <company> goals, values and culture	• Share information about <company> values • Share corporate goals and milestones for the year • Encourage asking as many questions as possible • 1:1 Meeting with CEO (or similar)
I know my team	• Schedule 1:1s with team members and key stakeholders • Schedule recurring 1:1s with Manager • Include in ongoing and spontaneous discussions that will impact their responsibilities
I know my role	• Share team goals and ensure they are clear on which specific goals they will be responsible for • Clearly communicate deliverables, milestones, and timeline expectations of initial projects • Articulate responsibilities with respect to company values

Questions to Ask for Employee Onboarding at 30/60/90 Days

Overall Onboarding Experience:	Role Expectations and Support:
1. How was your onboarding experience? What is going well and what could be better? 2. Is the job what you expected it to be? 3. Do you feel you have the information, tools and resources you need to do your job successfully? What would improve your experience? 4. Do you have any feedback for me? How can I better support you?	1. Are the goals we've discussed clear? 2. Do you feel like you have a good understanding of your role within the organization? 3. Are you feeling appropriately challenged by the position and growing in your role? 4. Do you feel you are able to be productive and effective in your position? If not, why? 5. Is there any additional specific training that you feel you need to be more successful? 6. Are you receiving enough feedback, assistance, and clarity from me?

Culture and Team:

1. Are you feeling welcomed by the rest of your team and the broader organization?
2. Who have you met with in your team? Is there anyone you haven't met but would like to?
3. Have you spent time with your team outside of the office?
4. Are you experiencing any challenges in particular that I can assist you with?
5. Is the organization what you thought it would be?
6. Is there anything outside of your role that you would like to contribute to?
7. What recommendations do you have for us to help support your onboarding?

It's inevitable that the company will run into growing pains. When this happens, it can be helpful to have a direct and open discussion with your team. If you're no longer getting the information or deliverables you need, schedule a meeting with the relevant people and explain why you feel you have a problem, ask if they have any ideas for how to resolve those issues, and suggest your own solutions. It's important to approach these conversations with openness and curiosity to create a comfortable environment for your employees to work with you to find a solution.

As your company scales to 30 employees, another inflection point emerges, requiring even more deliberate efforts to sustain the established culture. With a larger and more diverse team, maintaining consistent practices and values becomes increasingly challenging. At this point, you are bringing in more commercial and business development people, which can be a source of conflict with scientists. These individuals may have different perspectives, priorities, and intrinsic motivations from the research-oriented team. Founders must navigate this transition by fostering open communication, emphasizing shared objectives, and creating opportunities for cross-functional collaboration to bridge gaps and promote a cohesive culture that accommodates both research and business needs.

Evolving Culture as the Company Grows

As a startup undergoes growth and transformation, the culture will inevitably evolve as well. Maintaining a core culture involves clarifying your stance on remote, hybrid, or in-person work, promoting open communication through shared tools, and anticipating culture shifts at different employee milestones.

Amongst your cofounders, complete transparency is key. It's important that everyone is able to contribute to key decisions as you define your company and chart its path with your initial funding. However, as the company grows, complete transparency can hinder your employee's ability to work productively. For example, it is likely not beneficial for new employees to be made aware of every time an investor passes on your company while fundraising. It's important you openly communicate details that your employees need to know to do their job. However, this open communication should not extend to areas not relevant to your employees and outside their locus of control. People outside of HR should not be privy to personal issues about specific employees. People outside the legal team don't need to know details around any legal issues the company may have. You should think carefully about what information is necessary, helpful, and distracting, and set clear boundaries where needed.

A notable inflection point necessitating a change in communication strategy is at 10-15 employees, where the founder's ability to directly influence and oversee every aspect of the company becomes limited. This shift necessitates the establishment of more structured communication channels, onboarding protocols, clear processes, and shared values to ensure that the company's culture remains intact as new team members join.



04

Chapter

Organizational Management and Running a Biotech

Organizational management is paramount for the success of early-stage biotech companies; effective strategies change drastically as the team expands from cofounders to a team of 10+ individuals. With an initial handful of employees, it's feasible to maintain close relationships and monitor individual contributions. However, company growth requires a shift in operational and organizational strategies as team structures and company roles become more specialized. This is done with the support of a founder/CEO's Scientific Advisory Board and Board of Directors, which come with their own considerations to build, manage, and leverage support from effectively. In this chapter, we cover organizational strategies for founders, their associated Scientific Advisory Board and Board of Directors, and executive leadership strategies for success.

Transitioning from a Flat to Hierarchical Organizational Structure

One of the major challenges with a growing organization is ensuring effective communication. A good organizational structure can make communication easier. Most companies start with a relatively flat structure, where everyone reports to the CEO (or other relevant executive) and interacts with each other regularly. These frequent meetings across all functional areas help everyone stay informed on matters relevant to their responsibilities. However, as your company grows to 10–15 people, a flat reporting structure and constant communication can become increasingly challenging.

At that inflection point, it's beneficial to think about the key functions of the company to group people into teams and start to form a more hierarchical structure. You will generally have a group focused on company operations (HR, finance, operations, etc.), which could start as one team and break up into separate teams once the company is of sufficient size. Depending on the nature of your company and corporate strategy, you may have a business team dedicated to partnerships, but it's less common at the very early stages (pre-seed, seed) of therapeutics spinouts. The last major functional group at therapeutics spinouts is the scientific team. The nature of the work performed by scientific teams varies significantly among companies, so the structure can be quite varied.

Your company may have a group of scientists working on platform development, another working on in-vitro work for a specific drug program, and another working on in-vivo work for that drug program. You may have a computational team, which itself may consist of groups performing different functions. You may only have platform scientists, or only have in-vitro work, or something else entirely. It's worth discussing with your scientific advisors how to best divide the scientific efforts.

As your scientific team grows closer to 10 people, it may be beneficial to assign leads to different key scientific areas to serve as scientific managers. Depending on workload, these employees can also spend some of their time in the lab executing experiments. If your company does not have a dedicated CSO, or the CSO has limited bandwidth, it can be helpful to pair each lead scientist with an operator that functions as a project-specific CSO/COO combination. This ensures a duo that can envision, assess, and execute scientific workflows.

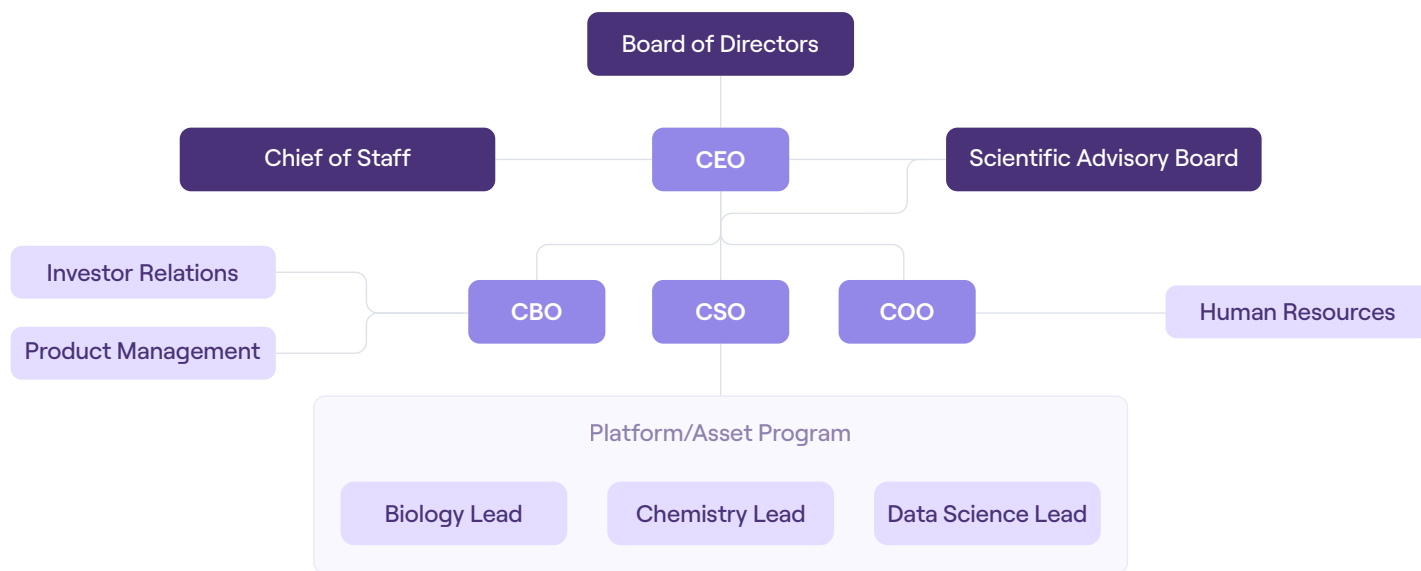
Scientific teams left to their own devices without a business / operational partner may spend disproportionate time on intriguing scientific questions, at the expense of slowing down core product development. This is especially true if your scientific team has limited industry experience. Ideally, you have an experienced drug developer playing a major role in leading your scientific team, but this may be a challenging hire without strong data or a large network. In these situations, you can try bringing on a pharma veteran as a fractional advisor, and explore hiring them full time if you have exciting milestone data as you transition from seed into Series A. An example organizational chart is shown in [Figure 7](#).

Alongside the development of this hierarchical structure, a dichotomy will emerge between those doing the science and those managing the science. Those who end up in management level roles will spend most or all of their time managing other scientists, interpreting data, determining experimental plans and scientific direction, and communicating results. However, it can be helpful for these employees to spend 5–10% of their time in the lab. If you have a C-level role in the company, you will be mostly interacting with other managers. As your team grows from your first few employees to 15–20 people and you start promoting or hiring managers, it's important to get an employee's input as to how they want to spend their time. Not everyone

has aspirations to be a manager or executive, and it's important you don't force your early scientific hires into these roles if they prefer to stay at the bench. Regardless, your organizational

structure should have clearly defined career advancement mechanisms (at the very least with regular salary increases, if not also increases in scope / responsibility).

Figure 7: Example of spinout organizational structure



This structure may vary across companies. Note that auxiliary functions such as investor relations, product management, and HR are typically managed by the C-suite until the team expands enough to warrant independent full-time hires. Chief of Staff roles vary in scope and can sometimes work primarily with one C-suite executive and other times can move across the entire company.

Board of Directors

A board of directors is a governing body of a company that oversees both the strategic direction of the company and the company's executives. Directors have legal and fiduciary duties to the shareholders of the company, so it's a significant commitment that should be considered carefully. When you start your company, the board of directors may just be you. As the company gains funding, lead investors will often request board seats as terms of their investment so they have closer insights into the progress of the company. It's important to balance the composition of your board with people who are not investors to get alternative perspectives and motivations.

Fiduciary Duties

By law, every Delaware C Corp needs to have a board of directors. Every member of the board of directors is subject to the fiduciary duties of care and loyalty. **Duty of care** means that the board member needs to exercise reasonable care in the management of the corporation; they must stay informed about the operations of the company and its progress. **Duty of loyalty** means that the director needs to act in the best interest of the company and its shareholders.

You are generally required to consult the board on major decisions affecting the overall strategy and finances of the company (including executive compensation). Your board members should be people who you trust and are aligned with you on the overall goal and direction of the company. The board also has the authority to fire the CEO should it be deemed necessary.

Value of Board Members

Members of the board can serve as a valuable resource, especially to an academic founder who may be less experienced in the business world. It's generally a good idea to find board members who can help provide expertise in an area where you're less experienced. That expertise should continue to be useful as the company grows, as the person will usually be on the board for a number of years. Experienced executives can be useful board members, especially those who have worked in small companies. As mentioned previously, investors also generally negotiate board seats as terms of their investment. The board directs the company, and may vote on large strategic decisions. As a result, you want to be cautious about offering board seats to minor investors in the seed round. Board positions give

significant control over the company, which may not reflect the contribution of their seed investment, especially as you raise larger rounds in the future. It is likely that the lead investor in larger Series fundraises (and perhaps others who significantly participate in a fundraiser as well) will have a board seat.

Here are some concrete examples of how a board member can add value. Board members can help with financing strategy, including working with you to determine how to best frame the company to investors. Board members can make introductions to potential partners. Board members can also help with hiring strategy and organization structure, which includes interviewing candidates for important and executive level positions. They can also help set the strategic road map for the company, providing guidance on which projects to prioritize, and contribute to your development as a budding founder.

Remember that the board is generally responsible for oversight of the company and the executive team's performance. Without a board in place, this oversight doesn't exist, which can be harmful for a first time founder that may benefit from the boards' feedback and advice. To update and inform the board, there are generally quarterly board meetings. Executives will often meet one on one with board members regularly and ad hoc.

Board Compensation

Board members are typically compensated with equity that vests over time, and can also receive cash compensation. Good board members will understand that an early stage company needs to be conscious of their capital **burn rate** and may accept the position for only equity (and/or relatively small cash compensation) until the company matures. A normal amount of equity is between 0.1-3%, vesting over a 1-3 year term.

Scientific Management

Once you've set your initial organizational structure (it will evolve as the company grows), you need to put mechanisms in place to monitor what is happening across all company functions. This section focuses on scientific management, geared towards founders who end up as CSOs.

As a scientific executive, your primary job will be to set clear, focused, and practical goals. This includes making sure the scientific team does not get distracted by arbitrary experiments exploring unimportant tangents (although, there does need to be a balance - exploring the unexpected questions can lead to some useful discoveries!). The primary job of your scientific team leads is to execute on those goals. You should set priorities and deadlines, assisting scientific team leads to come up with the experimental plans. You should establish a regular meeting cadence with scientific management based on when important experimental decisions are made and the speed at which your teams make tangible progress.

It is helpful to leverage a project management tool to keep track of the projects within each scientific team. ClickUp and Kaleidoscope.bio are examples of tools you can use. Sometimes, an Excel Spreadsheet is the best solution. Experiment with different tools until you find what works best for you and your company. Be sure to track and harmonize experimental data as well, using tools such as Benchling. It can also help to write (or have your team leads write) executive summaries of major experimental results so you can quickly review progress and remind yourself of past discoveries.

As a CSO, you need to keep track of the progress across different scientific functions and ensure teams are making meaningful strides towards the company goals. You may be the only person with all the relevant context to make decisions around scientific directions. In addition to understanding the science, you must also be aware of investor expectations, company **runway**, business development conversations, and the competitive landscape. When you make major decisions, help explain this greater business context to your scientific team leads, especially when your decisions may be counterintuitive based on the science alone.

Scientific Advisory Board

While a Board of Directors and Scientific Advisory Board are formal entities, the SAB is more casual with less direct influence over company direction. A scientific advisory board consists of scientists who you believe can meaningfully contribute to the R&D efforts at the company. SAB members can provide value in a number of ways. The CSO (and sometimes senior scientists) can call your SAB members to discuss scientific questions and ask for technical advice. **Key opinion leaders** (KOLs) for your therapeutic area of interest also make great SAB members. They can provide a detailed understanding of the current medical thought-leadership, and also have the ability to influence opinion more broadly on the products your company is developing. SAB members can help with recruiting key scientists, and assist with fundraising by sharing their excitement about your technology with investors. Unlike the board of directors, there are no formal or legal requirements associated with the scientific advisory board. As such, when someone joins your SAB, their role can be flexible. The founding PI is generally a member of the SAB.

Because the commitment of an SAB member is flexible, you can be generous with adding people to your SAB as long as they have some relevant expertise. You can view your SAB as a network of experts to turn to when you (or your CSO) need scientific advice. If you're developing a therapeutic, it's a good idea to have experienced drug developers on your SAB. It's also helpful to have indication-relevant expertise if you have identified an indication of interest for your therapeutic or platform technology.

For SAB members who will be more involved (e.g. a weekly meeting), a larger amount of equity (0.25-0.5% over 4 years) and cash compensation is reasonable. For scientists who you expect to call on a few times a year for ad hoc meetings or referrals, you can give substantially less (0.1-0.2% over 4 years) and no

cash compensation. These numbers can increase significantly with big name scientists (e.g. Nobel prize winners). In general, it's better to start building your SAB with people who have the expertise **and** the time to actually engage with your business and help when you need them. As you make progress, you can entice bigger names that might help with fundraising as you look to raise larger Series B/C rounds. A big name scientist that believes in your science and company vision can serve as a strong positive signal to potential investors and partners.

Communication Strategies

One of the most important characteristics in founders building successful companies is clear and effective communication. It's important for your team to understand what to do, why they're doing it, and how it helps achieve the overall vision of the company. As discussed at the beginning of this chapter, corporate structure can help streamline communication but is less important when your company is very small. As the company grows, it becomes more challenging to understand individual contributions, provide feedback, and ensure everyone's efforts are aligned towards the company's goals.

One way to help manage communication as your company grows is with a daily standup meeting. At this type of meeting, everyone in the group can take 5 minutes to outline what they accomplished yesterday, and what they plan to work on that day. These meetings are best if they are low pressure so employees do not feel micromanaged. It should be a space for everyone to openly share their work plans to ensure that their work is aligned with the company's goals and makes sense in the context of everyone else's work – including what you're working on! You can schedule more in depth one on one meetings with each employee to get more detailed updates about their work, provide feedback, set goals for the following week (or month), etc. These standups can occur within each company function (operations, science, and business) with the respective executives in each area. It's important that executives meet regularly amongst themselves as well.

Once the company's operations become expansive and complex enough where you cannot possibly keep tabs on everything, it's valuable to develop a culture of ownership. When you define a new project or task, clearly identify who is responsible for which tasks. Specify any necessary deadlines. If you want someone to actively communicate with you, indicate when and how they should update you. If you've built a team of people you trust, this can be a great way to free up mental bandwidth to focus on the company's top priorities while ensuring other important work gets done. With a culture of ownership, it's important for employees to hear from the company's management regularly so they have context on the activities of other teams. This will enable your employees to make minor decisions on their own given what they know about the rest of the company's work and

priorities. At minimum, you should schedule a quarterly all-hands meeting where you walk through important updates across all areas of the company. Last, be sure to commensurately acknowledge and reward successful ownership and completion of company projects to promote a positive work culture.

Administrative Strategies

Organization is an essential skill for a startup executive; you need to make sure what's important is getting done and nothing important is falling through the cracks. Gleb Kuznetsov, CEO and co-founder of Manifold Bio, has shared some templates that are useful examples of administrative strategies that have worked for him. [Here](#) is a template used during weekly management team meetings to track progress across different company functions. It's also helpful to set objectives and key results that you want to keep tabs on. [Here](#) is a template to list out objectives across different company functions and track their progress at a high level. There are a few other resources shared [here](#) that may be useful.

As a founder, you will talk to a lot of people. Some days, your calendar may consist of 16 back-to-back 30 minute meetings. Using a CRM such as Affinity to track who you're talking to, why, and a brief summary of your conversation linked to more detailed notes can help keep you accountable for following up on key conversations—and monitor that you're talking with the right people. A well organized company drive (something like Google Suite works) is essential so you can easily find the documents, data, or slides you need. Make sure to set expectations with your team so that everything stays organized. This should include a well defined onboarding process so new hires are familiar with how your company operates.

Leadership Strategies

Last, as a new executive, it's important to think about ways to develop yourself as a leader. The most useful advice we can give is to stay humble, surround yourself with experienced mentors, and ask for help when you need it (and when you think you don't). That being said, there are a few major skills that an industry leader needs to learn that are often not discussed in academia.

One of the most important skills is storytelling. As academic researchers, we often contextualize science by discussing prior, related work. We then present our own work and discuss how it will advance the field. Storytelling in industry is much different. You need to make your science attractive to a wider audience. Investors, potential pharma partners, and employees across all functions will need to buy into a vision that's formed around the product or platform you are developing. Contextualize why the problem your company is solving is important in the world. For some audiences, this also includes why the problem you're

solving is economically valuable, and how solving it will lead to a profitable company. You should be able to tailor your pitch about your company to a leading university professor in the field, and your grandmother in less than five minutes.

In academia, it's also common for trainees to inherit partially developed projects. As a result, you may end up working on a project without a complete understanding of how your project fits into the field. Consequently, you may end up trying to craft a story after you've already invested significant time into the project. With a startup, it's important to take a step back and think about the problem you're trying to tackle, understand the context, and identify the best solution for the problem. This could include leaning heavily on existing solutions instead of investing time and resources into significant scientific development, which is more common in academia where higher value is placed on novelty. As a startup executive, it's also important to take ownership over all the work your team does and speak up if you feel the company is moving in the wrong direction.

Another important skill of an industry leader is to emphasize collaboration and teamwork. In academia, the end goal of most work is papers or funding; people are happy with collaborations if impactful papers are published with their name as an author. In industry, the most important goal is getting the science to work. Each individual's contribution is far less important. As part of this more collaborative nature, it's important to be more communicative and more reliable with deadlines, which are often seen as suggestions in academic projects.

Running a company entails a high degree of technical and emotional intelligence, and you will quickly find that micromanaging employees is impossible at scale. Instead, you should seek to delegate responsibilities to colleagues, empower them to take ownership, and recognize and reward their successes. This entails cultivating the leadership skills of employees from the onset, ensuring their development into managerial positions as the company expands, and empowering them to train new team members independently.

By building a transparent company culture, your early employees can help support you in your growth as a leader, and provide accountability in areas where you may need improvement. Having a strong network of mentors and advisors is essential for this growth. As a company leader, you not only need to manage a growing team, but you also need to manage the company's budget. Our next chapter will discuss just that.

Transitioning from academia to industry is hard enough, but doing so as an executive at your own company is even harder. Be patient with yourself, and understand that you will make mistakes.



Sale Performance

05

Chapter

Money

Fundraising

Fundraising is one of your primary functions as a founder, especially if you act as CEO. This generally means selling the story and vision of your company, supported by proof of concept data, to a variety of investment sources. As a therapeutics company, it is likely you will need to raise from VC funds, which will give your company funding in exchange for equity and/or board seats. A crucial component to consider when signing a **term sheet** with a VC firm is that they can support you beyond funding. VC firms lie on a spectrum in terms of the operational support they provide, such as introductions to potential SAB members, hands-on help with company creation, assistance with future fundraising, etc. There is significant complexity to fundraising, and it will be the primary topic of a future playbook.

Budgeting

One of the most important factors in determining how much to raise is the cost of generating key data to support your hypothesis around the core technology of the company. Figuring out that number can be challenging; in this chapter we will provide a few approaches to help put together a realistic estimate. There are three main categories for which you need to budget:

- i. Science
- ii. People
- iii. Space

A budget template kindly provided by Manifold Bio can be found [here](#).

Budgeting for Science

First, it's helpful to outline your anticipated scientific milestones. If you've discovered a new target, your first steps will likely be to validate that target in human cell lines, followed by in-vivo experiments and validation with primary patient disease tissue. If you've developed a novel therapeutic modality, your first experiments may be to demonstrate activity against a well validated target. If you're developing a platform technology, then your primary focus might be on developing the platform, then validating it for a specific use case.

As an academic scientist, it can be helpful to think about the development of your product like a grant proposal. The primary difference is that with a grant proposal you are often advancing a scientific hypothesis, whereas in a startup you need to advance a translational hypothesis. With each major experiment, you need to be generating evidence that your technology can ultimately lead to a product that can be commercialized: a drug, diagnostic, or service that other companies developing drugs or diagnostics will use. Take a minute, and think about the development of your science into a product over the next 12-24 months.

Now, write up a GANTT chart with the major scientific milestones. For each scientific milestone, ask yourself what specific experiments need to be done. Be specific and outline in as much detail as possible. This exercise will help you arrive at a more accurate estimate, and also help provide an outline for your first scientific hires (as with most science, it's very likely to change in the future). For each major milestone, ask yourself what this set of experiments proves about your technology, and how investors are likely to view it. Your next investors are going to be funding those experiments so you need to be able to convince them of their value. Your subsequent investors will need to be sufficiently convinced by those experiments to give you more money at a higher valuation. You may have difficulty raising money if you don't have an experimental plan that can generate data supportive of your core hypothesis in 12-18 months.

For each experiment, estimate what reagents you will need, what animal / cell models you will need, what staff you will need, and how long it will take. Get quotes from vendors for reagents and cell/animal models. Get quotes for any equipment you will need (budget for new, but try to buy used or at an auction). Remember that in addition to core scientific staff (likely full time hires), you will benefit from regulatory consultants, and consultants with drug development expertise.

There may be some experiments you wish to outsource to a CRO. In general, it's best to outsource standard experiments to CROs to provide secondary or tertiary validation. Any science with novel assays or novel technology is best performed by your own team in-house. Similarly, any time-sensitive experiments are best performed in-house. Get quotes from CROs for any work you want to outsource.

After you've estimated the cost of reagents, mice/cell lines, equipment, you can budget some savings from any relevant tax incentives (e.g. new R&D tax credits from the CHIPS act).

Budgeting for People

After budgeting for science, you can put together a budget for people. This includes scientists, your executive team, any consultants necessary to keep the lights on (HR, legal, etc.), and business development hires. It's generally best to grow the team slowly and carefully in the early stages. You don't want to hire a large team of people, blast through a bunch of experiments in 6 months, and then get stuck figuring out next steps with 20 scientists on your payroll. This approach risks depleting resources and leaving you with a sizable team of scientists without clear direction for future research. A more prudent strategy involves securing a modest funding round, assembling a compact team, and dedicating 6-18 months to conduct critical experiments that substantiate your initial hypothesis. Following this period of focused research and validation, you will be in a stronger position to acquire additional funding and thoughtfully grow your team.

In addition to salary, you need to budget for payroll taxes, benefits, and miscellaneous expenses (e.g. if you need to buy every new employee a laptop). It's helpful to spend some time doing market research to identify a fair, realistic compensation package. Offering equitable pay not only fosters employee satisfaction but also aids in retention. Attempting to save money by paying staff 10-20% less than market rates can prove more expensive over time. Undercompensation may lead employees to feel undervalued, increasing the likelihood of them departing unexpectedly. Prior to finalizing your budget, it's wise to add an additional 20-50% to your estimated timeline and adjust your financial projections accordingly. It is more advantageous to slightly overestimate your budget, leaving a reserve in your account for the next funding round, than to find yourself in a financial shortfall, leading to unnecessary stress and hasty decision-making.

Budgeting for Space

Lastly, you can budget for space. Consider the number of workstations or benches required for the scientific team detailed in your experimental plans. Seeking input from investors and real estate agents will provide you with average rates for laboratory space in your locality. It's essential to clearly understand your specific space requirements, such as Biosafety Level (BSL) compliance, backup power, and core services. As a precaution, inflate these estimates slightly for a safety margin.

With these calculations, you now have an initial estimate of the funds required to achieve your milestones. This figure will guide your initial fundraising endeavors. Keep in mind that as your experiments progress and yield results, it's common for both the scientific plan and budget to evolve. This is why we recommended including a buffer in both your timeline and cost

estimates. As you progress, continuously monitor your financial runway, particularly if you hire additional staff or encounter significant unforeseen expenses. Generally, positive experimental data is necessary to secure a subsequent funding round at a higher valuation. However, in certain situations, existing investors might offer a bridge round if your capital dwindles mid-way through your experimental plan. Such scenarios can place your company in a less favorable negotiating position, potentially leading to raising money at suboptimal valuations or conceding control aspects like board seats.



Chapter

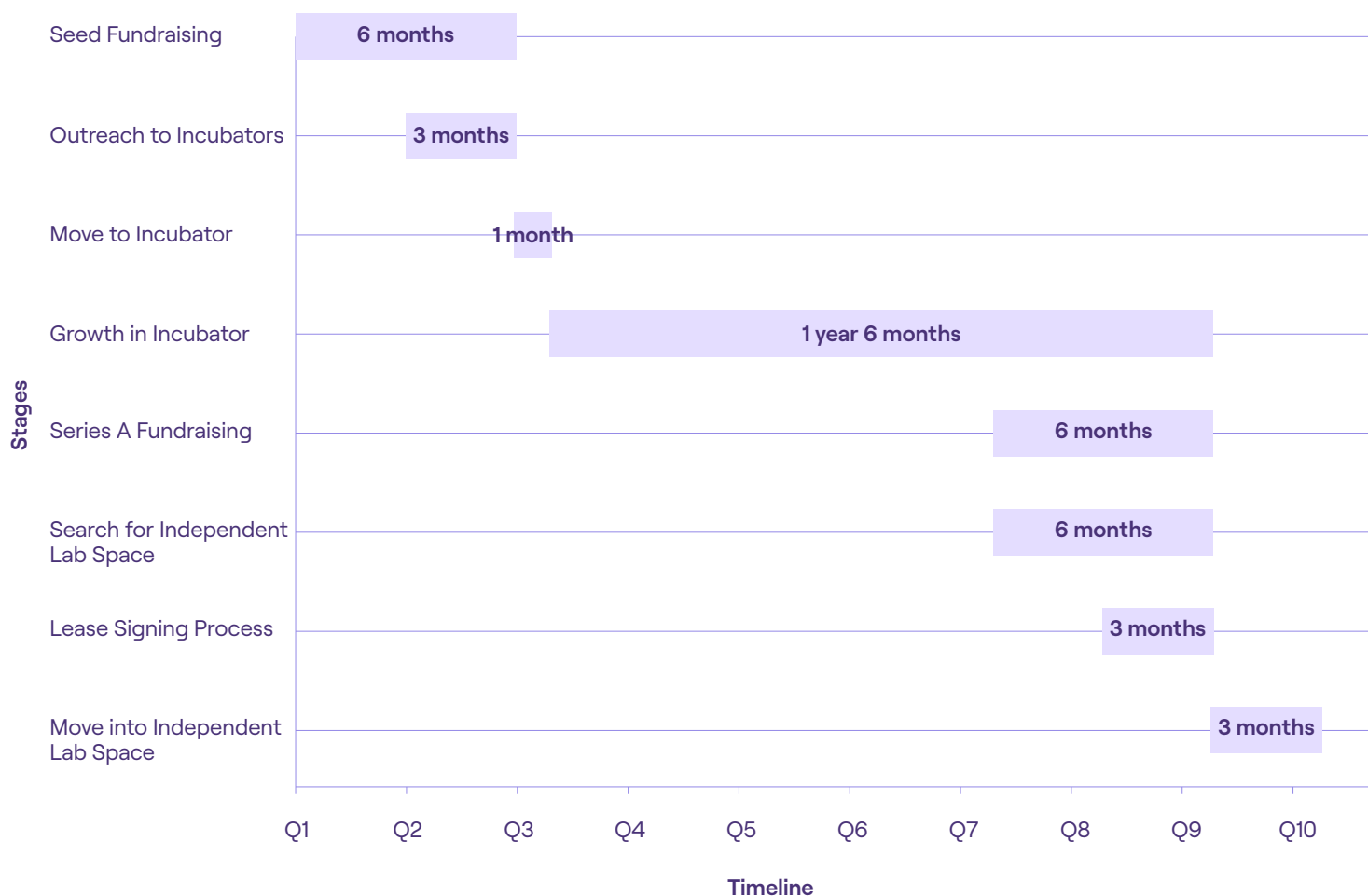
Lab Space and Real Estate

Introduction to Incubators, Accelerators, and Leasing Independent Lab Space

As your biotech startup transitions from an academic lab to a commercial enterprise, securing the right lab space is critical. This journey often begins when you raise seed funding and/or enter an incubator. Incubators allow startups to further derisk

technology and accelerate growth. This chapter covers both the transition into incubators and eventually out of incubators into independent space. We will discuss key considerations for choosing the right lab space to support your startup's growth.

Figure 8: Biotech startup journey from seed fundraising to independently leased lab space



Timelines are highly variable and company-dependent. Timelines partly adapted from Pillar VC in addition to expert interviews.^{8,9}

⁸ Lab Space Vendors from Pillar VC https://www.pillar.vc/playlist/category/starting-a-company/real-estate/lab-space/?post_type=vendor

⁹ Timelines and lab space considerations partly adapted from Pillar VC <https://www.pillar.vc/playlist/article/the-bio-lab-faq/>

Incubators

Incubators play a significant role in supporting early-stage startups before they are prepared to operate independently in their own lab space. Incubators, which may be run by academic institutions, venture capital firms, or other corporate entities, typically provide shared lab and office facilities to fledgling startups until they have the resources to support their own independent lab space.

The incubator model for biotechs gained momentum in Boston around 2015, offering various benefits to startups. Most incubators will provide shared equipment and core facilities like biosafety cabinets, fume hoods, common space cleaning, and liquid nitrogen. In addition, companies have access to a broader community of other startups and often specialized equipment which may be prohibitively expensive at the seed stage. This equipment is often essential for derisking technologies and advancing proof-of-concept work. In this way, they serve as a transitional platform between academia and owning a dedicated space. The business of incubators differs from permanent lab spaces. Incubators typically operate under a license model, which provides more flexibility compared to leases associated with independent spaces. Startups can more easily transition from an incubator by cutting ties with a license (and vice versa), whereas permanent spaces require adherence to lease terms.

As a starting point, Pillar VC provides a list of incubator and real estate services^{8,9} along with their Lab Space FAQ.

Why incubators first?

Incubators offer several advantages over independent lab spaces for early-stage startups. They provide an environment for companies to develop without the financial overhead of acquiring and operating an independent lab facility.

Additionally, incubators place significant emphasis on fostering community which includes facilitating talent recruitment and retention through intentional design of collaborative and well-equipped spaces. Participating in an incubator can also provide additional benefits through networking and operational support. This is especially relevant when a startup is fundraising for a Series A round, as affiliation with a top incubator serves as a seal of approval and positive signal for investors. Companies that graduate from prestigious incubators may access preferred venture capital opportunities and receive priority access to space within the incubator's broader real estate portfolio.

What should you consider before entering an incubator?

When evaluating incubator options, startups should carefully weigh trade-offs between available equipment, cost structure, aesthetics, and location accessibility. It is prudent to explore

"second tier" incubator spaces, as the most popular and in-demand locations may not provide the ideal scientific environment or equipment needed. Proximity to core facilities and on-site amenities should be considered, along with office-to-lab ratios, presence of any specialized lab facilities like vivariums, availability of specialized equipment, and overall facility layout. If the incubator lacks certain needed equipment, determine if outside equipment can be brought in, and ensure the space is properly fitted to support it. Incubators frequently lack specialized equipment such as mass spectrometry, high-performance liquid chromatography, and cell sorting. Incubators may partner with academic institutions and service providers to help you access core lab facilities for more specialized equipment and facilities.

Incubators vary in the number of resident companies they will accommodate, but most forecast demand at least one year in advance to provide for the growth of incoming startups and ensure sufficient tenant runway. Because most of the resources are shared, you should be looking out for the number of benches and desks available now, and in the next 1-2 years. Plan for the eventuality that as your team expands to around 10 people, you might outgrow the incubator's capacity. Be careful to align your expansion objectives, fiscal runway, and scientific operations with the space and facilities the incubator offers.

Incubators typically structure pricing as a fee-for-service model. However, some incubators have affiliated seed funds that will invest in resident companies in exchange for equity. Startups should aim to minimize equity dilution where possible, and apply to a variety of shared lab space options to maximize choices. It is unlikely that an incubator will accept a startup without some evidence of ability to pay (or agreement on payment via equity), and venture capital or angel investment is generally viewed more favorably than capital raised through SBIR/STTR grants or bootstrapping. Incubators want to ensure resident companies are sufficiently funded to carry out experiments and fulfill financial obligations.

To improve chances of securing incubator space, initiate conversations when you begin fundraising for a seed round. This provides helpful insight into market availability in the desired timeframe, and allows relationships to form in advance of finalizing seed funding. Without proactively reaching out, it can be challenging to ascertain what particular spaces and equipment may be accessible during the intended residency period. Generally, companies will begin formally evaluating options at least 2-3 months prior to desired move-in timing. In addition, contacting current incubator tenants to get reviews and insights, especially those who recently joined or departed, can help inform your decision-making.

⁸ Lab Space Vendors from Pillar VC https://www.pillar.vc/playlist/category/starting-a-company/real-estate/lab-space/?post_type=vendor

⁹ Timelines and lab space considerations partly adapted from Pillar VC <https://www.pillar.vc/playlist/article/the-bio-lab-faq/>

Outgrowing Incubators

Although incubators can provide a great starting place, your company will eventually outgrow the shared incubator space. The primary signal that your company is ready to consider renting independent lab space is when the incubator lacks capacity for your continued expansion. This often stems from insufficient bench space to accommodate your growing scientific team, but it can also occur if you need specialized equipment the incubator cannot offer, or provide adequate space for.

It's important to do your scientific planning 6-12 months in advance so you're not caught off guard and forced to slow your experimental work. This planning should cover both staffing needs, and required equipment (including if you need to house animals for in-vivo studies). Maintain regular communication with your incubator's management team to ensure they can support your growth trajectory. Begin scoping potential lab spaces at least 6 months prior to your expected need for increased capacity. For markets with high demand or if construction is needed for specialized build-outs, initiate the search process 1-1.5 years in advance (yes, this may mean you may need to start looking as soon as you move into an incubator!).

To provide a general benchmark, the median tenure for companies in a typical incubator is around 14 months. However, overall incubator stay duration varies; first-time founders often stay in incubators longer (2-3 years) up to a maximum team size of ~10. Graduating from an incubator often aligns with closing a Series A funding round, commonly \$10M+, although companies without extensive space or equipment needs (e.g. computational platforms) may stay longer. Remember that moving into your own space requires managing additional compliance and operations like EH&S, permitting, lab management, so it is important to have sufficient funding to bring on the necessary staff as employees and/or consultants.

Independent Space: Leasing & Subleasing

As your startup scales, you'll likely want more space to expand your team, build out facilities, and establish a company culture. Navigating permanent lab spaces comes with more complexity versus incubators. You must manage all infrastructure and services from power to waste handling, address permitting for biosafety and chemical storage, acquire lab equipment, and build/retrofit facilities.

Permanent spaces often involve multi-year leases and may require upfront capital for maintenance or updates. Landlords of permanent spaces typically provide tenant improvement allowances to update facilities, which can expedite the process of getting up and running. Equipment, basic and specialized, must be purchased if it does not already come with the space.

One advantage of permanent space is that, in contrast to incubators, the space can be sublet. Subleases for independent lab space are popular at the time of writing this playbook, and there is an excess of space on the market. During and immediately post-COVID, capacity was increased as biotech startups raised large rounds and sought out lab space. Now, lean market conditions are making companies more conservative, leading them to downsize and sublease space while reducing their burn rate. For new startups, this means an ample variety of selection is available, enabling faster setup with existing facilities and equipment through subleasing.

Starting the Leasing Process

Engage a broker and real estate attorney to identify options and negotiate lease terms to secure space. Incubators are often well connected to the real estate market, and may even own lab space outside of their primary incubators that you can lease. But mostly, you'll need an experienced broker to search beyond incubators. Brokers may represent landlords in addition to tenants, and will typically ask that you work with them exclusively as they are paid by landlords once a deal is closed. You should seek referrals for a real estate broker and attorney from other founders, investors, or staff at your incubator.

Expect to review and tour 5 to 20 options with your broker before making a final decision. When you find a good location, the next step is to form a Letter of Intent (LOI) between yourself and the landlord, outlining proposed lease terms and conditions. Signed LOIs indicate both parties will continue negotiating, without seeking other offers until a lease is finalized. Unsigned LOIs are non-binding, and it's wise to continue exploring alternative options until a lease is finalized (landlords will also consider alternative tenants!). Negotiations can take several months and you should review final leases closely with your attorney so you can fully comprehend your liabilities.

What types of leases are there?

The two main lease types for startups are **Triple Net (NNN)** and **Full Service Gross (FSG)**, calculated **per square foot (PSF)**. In a Triple Net lease, the "Nets" refer to aspects of building operations that tenants pay on top of rent: real estate taxes, maintenance, and insurance. These costs are shared across tenants proportional to space occupied—if you take 10% of space, you pay 10% of building expenses. This means each Net fluctuates yearly based on usage, creating more risk if shared costs rise. Triple net leases may also come with capital improvements to be made to the property by the landlord (not passed on to the tenant), and leasehold improvements to upgrade the space for specific needs such as specialized equipment.

NNN means that building expenses are shared among tenants, and the landlord is still responsible for performing maintenance and upkeep of the property.

Triple Net (NNN) = Rent + Utilities + ((% share) * (Maintenance + Insurance + Taxes))

A Full Service Gross (FSG) lease bundles base rent per square foot with additional preset operating expenses per square foot from the base year when signed. A gross lease has less variability than NNN; you'll know exactly how much you'll pay each month, avoiding fluctuating payments due to usage, repairs, or other factors. This provides a predictable monthly cost for the tenant and simplifies the process of managing property expenses for the landlord. As a consequence, however, you will have less flexibility to keep operating costs down with a flat maintenance fee. FSG base rent is typically higher than in NNN leases as the landlord assumes responsibility for building maintenance expenses.

When agreeing upon a FSG, you may encounter additional items such as tenant improvements, outlining property changes to meet specific needs like a vivarium. Landlords may provide a tenant improvement allowance (e.g. \$50 / sq ft) to update facilities that remain after the lease period.

Gross Rent PSF = Net Rent PSF + Utilities + (Insurance + Maintenance + Taxes PSF)

You can compare prices on a per square foot basis to assess costs between incubators and independent lab space facilities, factoring in specialized equipment and other resources. Incubators may charge on a per bench basis, providing a cost advantage for early-stage companies with smaller teams. In either case, you will encounter an escalation clause that allows for the landlord to increase the base rent over time to account for proportional increases in operating expenses.

Compare prices per square foot between incubators and independent spaces, factoring equipment and resources. Incubators can charge per bench, benefiting smaller teams.

An example: Kendall Square NNN is \$115/sq ft, plus \$35 for FSG operating/tax expenses, totaling \$150 gross. Add \$60 for lab space permits and EH&S, and total independent lab space cost is ~\$210/sq ft. An incubator may offer the same for \$200/sq ft., and have the added advantage of not having to coordinate logistics of permits, EH&S, etc. Over company expansion, incubators become less financially and operationally advantageous as companies outgrow capacity limits.

How do I find equipment?

Equipping a new leased lab space can be a major expense. With some persistence and creativity, you can build out a cost-efficient lab without breaking the bank on brand new equipment. There are several strategies to find quality used equipment at more affordable prices.

First, check if any equipment comes with the lab space, especially if you are subleasing from another company. Oftentimes benchtop equipment like incubators, fume hoods, and cabinets are left available.

Search online marketplaces like eBay, Craigslist, and LabX for common lab equipment like centrifuges, microscopes, and pipettes. Companies like Cambridge Scientific sell high-quality refurbished and reconditioned equipment such as microscopes and centrifuges at discounted prices compared to new instruments.

Reach out through your network of academics, advisors, and other startups in the area to find out if any labs are selling or giving away old equipment. Academic labs often upgrade instruments after a few years and may offer deals on functional older models.

Consider leasing or financing options to acquire large, specialized equipment like DNA sequencers or mass spectrometers. This spreads out upfront costs over time rather than a major one-time capital purchase. Consider outsourcing experiments requiring expensive experiments to CROs that already own and operate the equipment.

Sponsored Research Agreements

It is possible to gain access to specialized university lab equipment and core facilities through sponsored research agreements with an academic institution. Under a **sponsored research agreement (SRA)**, the startup provides funding to support continued research in the academic lab on an area of interest. This could involve leveraging the academic insights to optimize the startup's core technology or explore novel applications.

In exchange, the agreement grants the startup certain rights negotiated with the institution, such as exclusive license to resulting IP or an option to license IP. The institution and researchers often retain rights to publish findings, with reasonable review by the company to protect confidential information. Sponsored research agreements allow startups early access to emerging innovations at universities before patents get filed. The startup can then further develop the technology with the support of the academic lab. The institution benefits through additional research funding and translating discoveries.

What infrastructure, and services will I need to consider?

The infrastructure and services needed to build your lab space will depend on your type of company; we've included a non-exhaustive list of considerations below. To help ease the transition from incubator to independent lab space, it is recommended to hire a project manager with specific expertise in overseeing new lab space buildouts to help develop your timeline and oversee the transition.

A key decision is whether to establish your own lab space for research or outsource work to contract research organizations. While building your own lab provides more control and intellectual property protection, it demands significant investments in real estate, equipment, and staffing. On the other hand, CROs offer specialized expertise and project management with less upfront capital requirement. Often, the best approach is a

combination of both models: perform core research in-house to focus on your novel technology and outsource supplementary research or occasional experiments to CROs. This strategy not only offers flexibility and avoids major equipment expenses but also balances IP protection, costs, and access to advanced tools. We further discuss effective management of CROs in [Chapter 7: Contract Research Organizations](#).

Wet Lab Considerations

Properly addressing biosecurity, environmental health and safety (EHS), and compliance from the start is crucial, but can also seem daunting. Bringing in outside experts is advisable to implement best practices suited to your research focus and scale. Hiring an experienced consultant on a project basis can provide an initial assessment of biosafety levels, identify key risks, and outline an action plan for training, facilities safeguards, protective equipment, and regulatory compliance.

For ongoing support, larger CROs often have dedicated EHS and compliance teams who can essentially function as an outsourced safety department. They develop comprehensive protocols around access controls, inventory management, waste disposal, exposure response, and continuous staff education. The expertise and infrastructure needed to fully support biosecurity and compliance can be costly to establish internally for an early stage company. By leveraging consultants or partnering with CROs, startups can build a strong culture of safety and responsibility from day one in an efficient, affordable manner. An extended list of wet lab considerations is shown below in **the table**.

Dry Lab Considerations

If your biotech startup has a significant dry lab component, it's wise to bring on an IT consultant early when transitioning into independent space (or before). AI-first companies will have IT and data science among the first hires; more traditional biotechs should consider hiring a full-time hire for IT within the first 50 employees. In the beginning, you likely don't need a full corporate IT team, but you do need expertise in managing data infrastructure. Investing early in centralizing data storage, implementing backup systems, and cataloging data assets can help you prevent data loss and have your ducks in row in case you are audited.

Bioinformatics pipelines can be outsourced, while in-house data analysis is important for safeguarding company trade secrets. A cloud-native approach will help you scale your dry lab operations more efficiently, and platforms like Amazon Warehouse Services offer health and life sciences blueprints to help structure your data workflow and administration. In addition, multi-cloud platforms are also popular and can provide additional flexibility.

Even for biotechs with a wet lab component, it's essential to centralize experimental data on a server, complemented by a robust backup system, to mitigate data loss from inevitable instrument failures. It's also valuable to have detailed documentation of your experiments; electronic lab notebooks are recommended as it

makes sharing and collaboration easier. You should consult with a data management expert once you reach the Investigational New Drug (IND) application stage. At this point, data management becomes more complex due to increased regulatory scrutiny and the necessity for thorough audits and regulatory submissions. Startups should also implement stringent controls, including role-based access, data encryption, multi-factor authentication, and regular audits to safeguard their proprietary research data.

Wet Lab Considerations

- Lab Layout and Workflow Design
- HVAC, Fume Hoods
- Plumbing and Gas Lines
- Storage for Reagents, Samples, Chemicals
- Temperature/Humidity Monitoring
- Autoclave, Glasswasher
- Hazardous Materials Handling
- Safety Equipment – Eyewash, Showers
- Waste Removal – Chemical, Biological
- Facilities Maintenance and Cleaning
- EHS Policies and Training
- Access Control and Video Surveillance

A **Laboratory Information Management System (LIMS)** centralizes storage and tracking of data assets, but a formal LIMS system may not be necessary for your use case depending on your needs. When engaging external labs, cloud providers, or bioinformatics services, sign Business Associate Agreements (BAAs) to ensure confidentiality. Stay current on data integrity best practices for electronic records and digital signatures. For IND submissions, have Standard Operating Procedures (SOPs) for data archiving and disaster recovery. Train personnel on proper data collection, reporting, and change control. A consultant can advise cost-effective security measures scaled to company growth and risk tolerance, enabling innovation without compromising data protection. An extended list of dry lab considerations is shown below in **the table**.

Dry Lab Considerations

- Data Infrastructure and Storage
- Cloud Platforms
- Data Backup Systems
- Data Security Controls
- HIPAA Incorporation and Other Regulatory Compliance
- Role-Based Access Permissions
- Lab Information Management System
- Bioinformatics Pipelines
- Data Governance Policies
- SOPs for Data Management
- Personnel Training on Data Practices
- Business Associate Agreements

General Lab Considerations

Whether you have a wet lab or dry lab, there are other factors to consider related to logistics, employee satisfaction, and general support, shown in **the table below**.

General Lab Considerations

- Location
 - Proximity to Academic Institutions
 - Nearness to Potential Partners/Acquirors
 - Access to Gym Facilities
 - Availability of Childcare Facilities
 - Logistics including Nearby Highways and Delivery Access Points
- Staffing
 - Headcount needed for lab operations
 - Define roles and hire personnel like principal scientists, technicians, quality staff, and facilities/equipment maintenance.
- In-house Compute or Cloud-based Solutions
- Insurance
- Desk Space, Chairs, Office Supplies Storage
- Conference Rooms, Call Pods
- Transportation and Parking Space
- Lunch Space, Cafeteria

Venture Creation Firms

Venture creation firms offer an alternative path to VC funding that may complement accelerators, incubators, and bootstrapping for creating a biotech. While incubators and accelerators support external startups short-term, venture creation firms like Atlas Venture and Flagship Pioneering actively build new startups (such as Moderna¹⁰) internally with major capital commitments. A venture creation firm scientifically and commercially validates a biotech concept before recruiting an experienced management team to found startup companies. Ideas often come from within the venture creation firm, but can occasionally be brought in from external scientists.

The venture creation firm takes an active role in establishing lab operations, hiring scientists, acquiring technology, and guiding strategy. They provide significant capital investment for the startup to develop over several years, retaining majority ownership. With this model, founding academics should not expect to be CEO as serial entrepreneurs and pharma veterans are favored to scale the company fast. However, reaching out to a venture creation firm can be an appealing option if you're interested in continuing to develop your technology outside of academia, but don't have any significant interest in remaining on the management team of the company in the long term (scientific founders can often take on mid-level scientific management roles within their companies). Venture creation firms may own their own lab space and/or partner with incubators to build companies.

Future of Lab Real Estate

The future of lab real estate is shaped by macroeconomic factors, as companies and operators exercise caution making long-term commitments. Incubators are exploring extended stay options as startups incubate longer amid economic conservatism. Market-specific needs are emerging, especially for cell and gene therapy companies that require space and equipment for manufacturing and process optimization. Additionally, a growing presence of AI/ML companies have specific computational infrastructure and data needs, alongside lab in the loop approaches combining wet lab and dry lab experimentation.

Real estate players must work creatively with startups to provide affordable, right-sized lab space on flexible timelines. Virtual lab and distributed models may also emerge to complement physical infrastructure. The future lab ecosystem will likely involve fluid partnerships between incubators, academic labs, CROs, and startups to share spaces and equipment. Companies will seek targeted solutions that balance control, costs, and access to specialized resources.

¹⁰ <https://www.flagshipioneering.com/companies/moderna>



Chapter

Contract Research Organizations

As you start your company, it is fiscally and organizationally important to strategically outsource functions to external service providers like CROs that do not warrant a full-time hire or in-house team. This can both prevent unnecessary overhead costs (e.g. specialized equipment like a mass spec) and advance R&D efforts faster (e.g. by outsourcing in-vitro/vivo disease models and IND-enabling studies). In this chapter, we will discuss how to effectively manage successful relationships with contract research organizations.

Cultivating Relationships Between Founders and CROs

When working with external scientific consultants, active management is crucial. CROs often don't have the same resource constraints and time crunch of a startup. This can result in slower progress and scientific decision-making without considering the role an experiment plays in the context of your company's scientific plan. To avoid these issues, request frequent progress and follow up if the CRO is non-responsive or experiments are falling behind schedule. Additionally, consider arranging a visit to the CRO facility. This allows for direct engagement with the scientific team and provides an opportunity to firsthand observe their facility operations and capabilities.

Founders often face significant challenges in identifying which company functions to outsource and selecting high-quality vendors¹². The exact functions best suited for outsourcing to CROs will differ depending on the specific needs of your biotech, but generally all bespoke experiments, or those essential to your core product should be done in house. Standardized experiments can more easily be outsourced to CROs. Assistance from VC investors, advisory board members, peer founders, and copilot organizations like **Curie.Bio** can be invaluable in selecting top contractors. After identifying a CRO, there are several key steps in establishing and nurturing a successful relationship with a CRO. These relationships are generally contractual and dictated by a few key documents.

Key Documents

Your collaboration with a CRO is operationalized through the following key documents.

Request For Proposal

A **Request for Proposal (RFP)** is a formal business document that Sponsors (e.g. your biotech) provide to vendors outlining specific project requirements, timelines, deliverables, key milestones, and terms of the associated bidding process¹³.

- **Invitation to Bid:** An RFP invites CROs who feel confident that they can fulfill the project requirements to bid for and potentially acquire the contract. It also provides a functional framework of expectations so that CROs can create appropriate proposals that address the Sponsor's needs.
- **Pitfalls to Avoid:** Issuing RFPs without a comprehensive understanding of project requirements can lead to CROs making assumptions or prioritizing their preferences, potentially skewing the proposal. Incomplete and inaccurate information can result in more limited, cost-effective solutions in an attempt to win the contract; if budget assumptions and timelines are inaccurate, this can lead to costly delays and discontent for all parties.
- **Strategies for Success:** You can improve the RFP experience by only sending RFPs to CROs you have vetted through your personal and professional network. Working with a disreputable CRO that inflates its capabilities can lead to significant downstream risk. If you send out multiple RFPs, include a parsimonious and common bid grid, limiting the number of line items for quick comparison during the review process.

¹²For further information on evaluating CROs, please see <https://www.nature.com/articles/nrd4057>

¹³ <https://vial.com/blog/articles/optimizing-the-rfp-process/>

Master Service Agreement

The **Master Service Agreement (MSA)** is a legal contract that sets the overarching terms and conditions between two or more parties that will govern an ongoing services relationship. It allows for simplified and efficient SOW execution, incorporating a few key components¹⁴:

- **Legal Essentials:** Most MSAs will include language around confidentiality, IP rights, drug target exclusivity, warranties, liabilities, and termination. It's important to read the IP rights section closely as some CROs may want to own certain IP developed from the work you ask them to do.
- **Subcontractors:** Notably, the CRO is responsible for subcontracted services without the need for a separate MSA.
- **Business Model:** The MSA should outline the model for your contract, which is typically a fee-for-service agreement for early stage companies. Less frequently, you will see a "full-time equivalent" model which pays for full-time employees based on the time spent on your experiments. Other models, like risk-sharing (which reduces service fees in exchange for equity), are more appropriate for later stage in-vivo efficacy and IND-enabling studies. Be mindful that terms can be flexible with negotiation. For example, a CRO may do 500k worth of experiments for free if paid within a year, otherwise they receive 25% equity.
- **Data Handling:** The MSA should outline systems that are in place for data management and security.

Statement of Work

A **Statement of Work (SOW)** is a mutually agreed upon legal document that describes details around the scope, timeline, and cost of a specific project. It ensures a shared understanding of a project's requirements, including all tasks and deliverables, pricing and invoicing, communication schedules, reporting requirements, and any specific clauses not already stated in the MSA. Exact terms and conditions will vary; you can find an example of an SOW from the NIH [here](#). If the project is narrow in scope and you don't anticipate an extended relationship, sometimes the MSA and SOW can be combined into one document.

Guidelines for Successful CRO Management

Hold an Introductory Meeting

- Describe the overall scientific project and how CRO capabilities integrate into it.
- Reference examples of published work that exemplifies what you'd like the vendor to accomplish.
- Propose an ideal protocol you've selected (if you know) for the work and identify open questions.
- Provide a contact list of members on the founder's team who the vendor would be interacting with, their company roles, and their responsibilities for this project.
- Ideas on budget and timeline for completion.
- With mutual interest and alignment from the vendor on your proposed work, clearly define next steps together to reach a proposal, and an expected timeline.
- Set up a second meeting if you need more time to discuss with the CRO before an RFP.

Structure the Relationship

- Establish RFP, MSA, SOW documentation. If you are satisfied with a CRO proposal following an RFP, you typically move into an MSA followed immediately by the SOW. The MSA and SOW can also be done in parallel.
- Establish invoicing process and content.
- Agree on governance as early as possible by establishing a governance document, a standalone document that aligns teams on rules and responsibilities. For an example of a governance doc, please see [here](#).
- Establish how and when decisions are to be made and how those decisions are to be communicated.
- Establish a "point person" from each side who will be the primary contact for communication and scheduling.
- Establish an Issue Escalation process. This should be put in place at the start of the project, if not already agreed upon in the MSA or the SOW.

¹⁴ <https://s3.amazonaws.com/scienceexchange-assets/addf/Managing+CRO+Relationships+FINAL.pdf>

Execute the Science

- Communicate with the “point person” as defined in the governance for all activities.
- Share the context for the requested experiments.
- Share a detailed example procedure for key experiments or go over their plans in detail before they start key activities.
- Review and approve all protocols and procedures prior to the work starting.
- Determine the format, method and timing for all results to be delivered.
- Confirm which templates will be used for data reporting and annotation.
- Specifics of the data transfer can be spelled out in a Data Transfer Agreement ideally outlined in the SOW if not already in the MSA.

Monitor Progress and Data

- Schedule a kick-off meeting at the beginning of the engagement reiterating goals of the project, including reporting, quality expectations, and timelines.
- It’s important for your point person(s) to check-in on progress weekly along with (at least) large group quarterly progress calls.
- Create well-defined agendas.
- Disseminate accurate summary updates and meeting notes to all team members in a timely manner.
- Both parties should be expected to respond to emails or phone calls the same day if possible, no longer than 24 hours after the question is received.

Resolve Conflicts

- Do not let conflicts go unresolved.
- Checklist for when a conflict arises.
- Draft an email that clearly describes the conflict and its genesis, focusing on the facts and send to the CRO scientific lead, project manager, and business development representative.
- Discuss the issue until both sides agree on a resolution.
- Send a follow-up email to the CRO with the agreed upon resolution.
- Put a process in place so that such a conflict does not arise again.

Close Out

- End an engagement on a positive note to help ensure future successful engagements.
- Identify with whom you would have the business terms and financial discussions and use them to close out the engagement.
- Ensure all deliverables have been received and nothing is outstanding.



Chapter

Final Advice

Translate and commercialize science for impact

Academia is not always the ideal environment for translating scientific discoveries into therapeutics that reach patients; commercializing your research through company creation can help you overcome the valley of death. Forming a corporate entity around your IP allows you to work with incubators, accelerators, and Nucleate, alongside funding sources like angel investors and venture capital, to transform a proof of concept into tangible product for patients.

Spinout for why, not when

Macroeconomic conditions are always changing, and your decision to spinout a company should be primarily based on intrinsic value, personal circumstances, and a burning passion.

Distinguish if you are a platform or single asset company at the start

Platform companies can discover and produce multiple therapeutic assets. Single asset companies focus on advancing a single therapeutic for a specific indication. Understanding which archetype you are can inform which investment sources and commercialization pathways to pursue.

Start a Target Product Profile early

With a single asset in development, you should outline how your therapeutic will improve upon the standard of care and provide value to patients and clinical workflows. This will grow and evolve over time as you advance a candidate.

Co-founders and first hires are crucial

Your choice of co-founders can make or break your early-stage company—ideally you have worked with them before! It is critical to align on company vision, ownership of responsibilities, and logistics like equity splits to get your company off to a good start.

Plan for shifts in organizational structure and company culture

As your company and team grows beyond the founding team, proactively plan for and implement organizational, communication, and administrative strategies that monitor the company's expanding functions. In addition to your employees, your Board of Directors, Scientific Advisory Board, and personal mentors can be instrumental for handling inflection points in your company's development.

Budget conservatively

Expect everything to take longer than you expect and go over budget – plan accordingly!

Set a well-resourced, cost-effective lab

Give your scientists access to the tools and equipment they need to be successful. Incubators, subleases, and buying used equipment can be a cost-effective way to set your team up for success until you're ready to move into independent lab space.

Utilize CROs intelligently

CROs can be fantastic partners to help advance your science, but it's worth doing bespoke experiments that involve your core technology in house. When working with CROs, be sure to actively manage your relationship to set yourself up for success.

Glossary

Chapter 01

Therapeutic

A treatment to prevent or cure a disease or its symptoms.

Small molecules

One of the major categories of therapeutics, an organic compound with a low molecular weight.

Biologics

The other major category of therapeutics, isolated or manufactured from living organisms.

Accelerators

Programs that support teams with a well-defined business concept or technology towards further development and commercialization.

Incubators

Programs that support teams in the early stages of ideation and technology development towards a more refined technology or business idea.

Nucleate's Activator

The Activator represents a new class of entrepreneurial resources, and functions as an equity-free educational program upstream of traditional accelerators and incubators, aimed at lowering the activation energy for aspiring entrepreneurs to explore the commercial potential of their technologies or research in human health (Bio) or planetary health (Eco).

Druggability

The ability of a drug target to be modulated by a small molecule or biologic, usually by binding directly to the drug target.

Drug-like properties

A set of properties that are usually necessary for a drug to be safe and effective in humans (e.g. solubility, potency, toxicity, etc.).

Valley of Death

The critical phase in translating innovations where promising projects fail to survive due to lack of funding and resources, preventing commercialization towards a tangible product. This gap typically occurs between academic research and pharmaceutical development.

Intellectual Property

Any creation or invention; usually discussed in the context of patents, copyrights, trademarks, or trade secrets.

SBIR/STTR Grant

Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) grants are non-dilutive funding opportunities that support research collaborations between small businesses and academia. NSF and NIH both have SBIR/STTR grant programs, as do other entities.

Non-dilutive funding

Funding that allows existing shareholders to maintain their equity (i.e. keep the same portion of the company after the funding) – most commonly grants (SBIR/STTR) or loans.

Corporate entity

A legal business unit formed to conduct specific activities, usually the business unit has certain rights and responsibilities.

Seed-stage venture capital fund

A venture capital fund which invests in companies at the earliest stages, usually when they are still generating proof of concept data and haven't received other venture capital money.

Angel investor

Investors who provide initial capital for startups at the earliest stages, usually before or alongside investment from seed-stage venture capital funds. Angel investors are often wealthy individuals investing their own money so they can make decisions more quickly than venture capital firms. They also have more freedom to invest in ideas that may not have figured out a business model if they believe in the idea or founding team.

Equity

Ownership of part of a corporate entity.

Board of directors

The governing body of a company which oversees the activities of a business, they are considered representatives of the shareholders who own equity.

Valuation

The perceived economic value of the company and its encompassing assets.

Chapter 02

Drug target

A molecule (usually a protein) that a drug aims to modulate in order to treat a disease or alleviate symptoms.

Biological risk

The risk that modulating the drug target does not meaningfully affect the disease or its symptoms.

Chemical risk

The risk that the drug target may not be successfully modulated by a drug.

Hit identification

A process in drug development where one identifies initial compounds that have activity against a specific drug target.

Absorption, distribution, metabolism, excretion, toxicity (ADMET)

Key pharmacokinetic and safety properties that are often measured during the drug development process.

Lead program

The most advanced and promising drug development project within a company, usually receiving the most resources and attention.

Investigational new drug (IND) (and -enabling studies)

A request to the FDA for permission to begin clinical trials for a new drug; IND-enabling studies are a set of pre-clinical studies required by the FDA as part of the IND application.

Good lab practice (GLP) standards

A set of principles from the FDA that ensures that quality and reliability of lab studies.

Good manufacturing practice (GMP)

A system to ensure that drug products are consistently manufactured to meet high quality control standards acceptable for human use.

Phase 1 trial

Initial human clinical trial generally focused on safety of the drug in a small group of volunteers.

Phase 2 trial

Subsequent clinical trial generally focused on safety and efficacy of the drug in a larger group of patients with the disease of interest.

Phase 3 trial

Often the final clinical trial focused on comparing the safety and efficacy profile of the drug to the clinical standard of care in a large population.

New drug application (NDA)

An application submitted to the FDA requesting exclusive permission to market a new small molecule drug in the US for a limited period of time.

Biologics license application (BLA)

An application submitted to the FDA requesting exclusive permission to market a new biologic drug in the US for a limited period of time.

Contract research organizations (CRO)

A company that provides outsourced research services (from lab work to clinical trials).

Single asset company

A company focused on developing a single drug candidate (or a few related drug candidates).

Platform company

A company focused on developing novel technology that can be applied to multiple drugs or diseases.

Target product profile (TPP)

A document outlining the desired characteristics and goals for a drug candidate.

Key opinion leaders (KOLs)

Experts in a particular field whose opinions can influence the field, clinical KOLs are especially important to engage with during drug development as they can significantly influence adoption of your drug if approved.

Standard of care

The current accepted treatment and clinical adoption for a specific disease.

New chemical entity (NCE)

A drug with novel chemical structure that has not been approved for human use for any indication.

Chapter 03

Scientific founder

A person significantly involved in the development of the company's main technological innovation.

Venture creation firms

An entity that founds and builds new startups, usually providing initial management and capital.

Delaware C Corp

A type of corporation commonly chosen due to favorable laws and regulations.

Limited liability corporations (LLCs)

An alternative business structure.

Public benefit corporations (PBCs)

A for-profit corporation but with certain legally defined goals related to positive impacts on society, the community, and/or the environment.

Dilution

The phenomenon by which the percent ownership of existing shareholders decreases when new equity is issued (e.g. in exchange for venture capital investment).

Vest

The process through which an employee earns the right to keep their granted stock options, usually occurs in monthly or quarter intervals as a fraction of the total grant.

One year cliff

A one year time period during which no vesting occurs; usually a large amount of stock options vest at the end of this time period equivalent to the length of the time period divided by the total length of the grant (typically four years).

Incentive stock options (ISOs)

A form of stock compensation where the employee is given the option to purchase stock at specific price (strike price) set at the time of the grant; ISO grants usually vest over a four year period with a one year cliff.

Early exercise

The right to exercise stock options early, usually before they have vested; most commonly used to potentially minimize tax liability. NOTE: There can be significant tax liabilities associated with early exercise, this playbook is not legal, tax, or financial advice and we recommend you consult an expert.

83(b) election

A tax filing often done in conjunction with early exercise that allows individuals to pay taxes on the fair market value at the time of exercise instead of time of vesting. NOTE: There can be significant tax liabilities associated with filing (or not filing) 83(b) elections, this playbook is not legal, tax, or financial advice and we recommend you consult an expert.

Alternative minimum tax (AMT)

A supplemental income tax that can be triggered upon exercise or vesting of ISOs.

Diversity

The presence of differences in an environment, encompassing attributes such as race, gender, age, sexual orientation, socioeconomic status, and more. It recognizes and values the unique perspectives that diverse backgrounds bring.

Equity

Equal access to resources, opportunities, and support, regardless of background or identity. It addresses systemic inequalities and aims to provide tailored support to the specific needs of individuals to achieve fair outcomes.

Inclusion

The practice of creating an environment where every team member feels welcomed, respected, and valued to create a sense of belonging for everyone.

Chapter 04

Duty of Care

A legal obligation for the board member to exercise reasonable care in the management of the corporation; they must stay informed about the operations of the company and its progress.

Duty of Loyalty

A duty to act in the best interest of the company and its shareholders.

Burn Rate

The amount of cash a company spends over a certain period of time (usually discussed as monthly or annual operating expenses).

Runway

The amount of time a company can support its expenses given its current revenues and the amount of cash it has available.

Scientific Advisory Board

A scientific advisory board consists of scientists who you believe can meaningfully contribute to the R&D efforts at the company. SAB members can provide value in a number of ways and are compensated through payment and/or equity. The CSO (and sometimes senior scientists) can call your SAB members to discuss scientific questions and ask for technical advice.

Key opinion leaders (KOLs)

Clinicians or scientists who have a detailed understanding of the current standard of care and cutting edge treatment options for your indication of interest; they generally also have the ability to influence opinion more broadly with respect to the drugs your company is developing.

Chapter 05

Full Service Gross (FSG)

A Full Service Gross (FSG) lease bundles base rent per square foot with additional preset operating expenses per square foot from the base year when signed.

Triple Net (NNN)

“Nets” refer to aspects of building operations that tenants pay on top of rent: real estate taxes, maintenance, and insurance.

Sponsored research agreement (SRA)

An agreement where the startup provides funding to support research in the academic lab for a particular project of interest. This could involve leveraging academic insights to optimize the startup’s core technology or explore novel applications.

Laboratory Information Management System (LIMS)

Software that helps manage and track data, samples, and workflows.

Chapter 06

Request for Proposal (RFP)

A formal business document that Sponsors (e.g., your biotech) provide to vendors outlining specific project requirements, timelines, deliverables, key milestones, and terms of the associated bidding process. In response, vendors will provide proposals.

Master Service Agreement (MSA)

A legal contract that sets the overarching terms and conditions between two or more parties that will govern an ongoing services relationship.

Statement of Work (SOW)

A Statement of Work (SOW) is a mutually agreed upon legal document that describes details around the scope, timeline, and cost of a specific project; these can be standalone documents or can be written under an existing MSA.



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Schmidt futures

LHP



Nucleate Mission & History

Non-profit, trainee-led, educationally focused

Our programming is fully organized and executed by our student leaders, and supported by corporate and philanthropic sponsors. Our unique trainee-led structure allows us to execute on our educational mission without charging fees or requiring teams to give up equity in their companies to participate in our programs.

01 Mission

To empower academic trainees through open-access educational resources.

02 Vision

To solve the world's most pressing biomedical and ecological challenges by enabling the next generation of bio- and eco-entrepreneurs.

03 Origins

Nucleate, formerly Activate Bio, was founded in Boston in 2018 within the GSAS Harvard Biotech Club. We have a 501(c)(3) status and operate under a franchise model wherein our organization supports and organizes regional chapters. Nucleate currently operates 39 chapters across 20 countries world wide.

04 Leadership

Our leadership team is composed of 600+ diverse and exceptional academic trainees in PhD, MBA, MD, JD, MS, and undergraduate degree-granting programs. Our leadership is passionate about bridging the gap between innovation and translation by helping to educate future founders and biotech leaders and build support systems to encourage the translation of groundbreaking scientific work. Our leadership team aspires to become future leaders in biotech through VC, BD, and entrepreneurship.

Nucleate Team

Playbooks Team

Committed to developing free and publicly playbook resources for the life science entrepreneurial community, addressing key knowledge gaps experienced by scientific trainees.

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Nucleate is a non-profit fueled by academic trainees, and we have them to thank for their tireless and creative efforts towards enabling the next generation of life science talent. Thank you to all members of Nucleate, past and present.

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