WHITE PAPER

LIFE SCIENCE

Managing Risks at Every Life Cycle Stage

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Think about your company. What could go wrong? Who would be impacted? To what extent? What type of remedy would they seek? What would happen to your company as a result?

AS YOUR COMPANY MATURES, YOUR RISKS CHANGE.

Now consider this: The answers to these questions likely will change as your company matures. As a result of working with a variety of life science, clinical research and medical device firms of all sizes, we have seen firsthand what can go wrong when risk is not managed properly.

This white paper highlights some of the risk management considerations for each stage of your life science company's growth.

Starting Up

You've developed a great idea that will change the standard of care, dramatically alter the way doctors treat a frustrating disease, or improve the quality of life for people undergoing treatment. So, you've launched a startup, leased space, and you're hiring people as you spend long days proving your concept and catching the industry's attention. There just aren't enough hours in the day to accomplish everything you need to do and to make all the decisions that must be made.

As you're moving forward with enthusiasm and confidence, you're probably not focused on protecting yourself from what could go wrong. Your business may be moving ahead according to plan when something unexpected happens. It might be an employee theft issue, a supplier that goes belly up, or a serious traffic accident that takes a key person out of action for months.

Compared to a more mature company, your startup's risks are not as challenging, but that doesn't remove the need to start planning today for how those risks will change in the future. By addressing four key issues early, you can protect the future of your company and your investment of time and money from being disrupted.

The first key issue is to protect your intellectual property. Your life science startup is built around a new idea. You want to make sure it doesn't fall into the wrong hands or walk off with a disgruntled employee. Your future investors will want to be confident that a competitor won't be able to duplicate or undercut what you're doing before they provide the financing you'll need. We frequently get asked about insurance for intellectual property. However, at this stage we recommend investing in the services of a top intellectual property attorney. You'll thank yourself down the road for making that investment today.

The second key issue is to hire the right people. Companies usually start with a handful of employees, and early hires tend to come from your personal networks. You may know and like those people, but do they have the skills and contacts you need? Will they be 1099 independent contractors? If they are contracted persons, do you want to extend your insurance to cover their activities? Decide upfront how you want to handle this issue.

For example, if you're creating what will be an FDA-regulated product, you need someone who has experience working with regulatory matters and can help you navigate through the gauntlet of regulations and agencies. You also need an attorney with solid experience in helping life science startups, because that attorney will become one of your most trusted advisers as your

company grows. They've been down this road before and know how to protect you.

Overall, human capital will become increasingly important. As the company moves through its early steps, you'll soon need an operations person, a financial person and a host of others. You can't do everything as CEO or president, so you'll need to have people you can trust to take those areas off your plate and bring your strategies and vision to fruition.

The third key issue is to think ahead about funding. It's easy to get focused on finding the money you need right now, but if you're going to get through the coming stages of your business, you need a sense of where you'll turn for the funding you'll need down the road. The key is developing strategic relationships with the people and organizations that can introduce you to the right sources when the time comes. Start nurturing those relationships long before you're ready to make the ask.

Significant funding resources are available, including family offices, individual investors and private equity firms that are entering the venture capital world. The key is to know how to leverage these sources. Rather than try to go it alone, hire people who posses significant contacts with deployable capital to help you raise funding. You'll pay fees for their work, but it will be a small price to pay for quicker, meaningful results.

The fourth key issue is to connect with the right professionals. As with funding, you may not need the services of additional, specialized professionals who know your industry right now. However, building connections with them now gives you access to their expertise and advice when you need it. "Capital" comes in many forms—financial, influence, networking, referrals and ideas.

Professionals have extensive networks you can use. For example, someone introduced me to a startup medical device CEO who mentioned he was negotiating an agreement with a Japanese company and was looking for guidance. I was able to connect him with a Japanese attorney I knew and another CEO who had sold his company to a Japanese concern.

Taking the steps outlined here will not only help you avoid some early potential pitfalls, but will also enhance your ability to obtain funding as you grow and obtain the highest valuation for your company when you're ready to exit.

Growing in Complexity

Two things occupy the leaders of growing life science companies during every waking minute (and frequently keep them from getting sound sleep): *how can we find our next round of funding, and just what will go wrong next?* Money for growth is the shiny object that gets most of their attention but taking the right steps to head off potential pitfalls is every bit as important.

As life science companies expand and mature, the potential risks to their continued viability change constantly. That's why it is critical for company leaders to continually adjust their risk management strategies and associated insurance coverage.

In the past, growing life science companies typically staffed up as their needs increased. They would hire people to design their products, develop prototypes, and deal with regulatory matters and every other step. Today, more companies are instead opting to outsource many of those areas to a variety of third parties. From contract manufacturers, to subcontractors for parts and assemblies, to the logistics of bringing everything together and delivering it to the end users, each additional business partner supports the company's growth efforts, but also creates new risks—particularly to the supply chain.

Contracts will change, especially since the COVID-19 outbreak. Be aware that your upstream and downstream "partners" will be forcing risk to you more than ever. Do not assume all contracts will remain the same when they are up for review or renewal. For example, contractors may ask you to take on

4 KEY ISSUES FOR STARTING UP

1. Protect your intellectual property.
2. Hire the right people.
3. Think ahead about funding.
4. Connect with the right professionals.

the risk of loss for your property, even if it is in the possession of others, or you may find new requirements for not only higher limits of insurance, but also for new types of insurance, as well. Don't be surprised if you are asked to provide insurance for "cyber" or "privacy" breaches or events, "crime" or employee dishonesty coverage, or "any and all liability" with no regard for your contractual partner's obligation to cover their sole negligence. Watch out for onerous, unreasonable requirements for proof of automobile or worker's compensation insurance if the exposure is non-existent.

COMPANIES ARE OUTSOURCING MORE ASPECTS OF THEIR BUSINESS TODAY, CREATING NEW RISKS.

Consider another example. A fast-growing West Coast biotech company needed to expand their operations, so they opened a Chinese office at the end of 2019. The location they chose was Wuhan, which almost immediately became known worldwide as the center of the coronavirus crisis. Could they have forecast that their strategic multimillion-dollar investment would be at risk because of a virus?

In the insurance industry, as in others, we call unpredictable events like the coronavirus "black swans." However, there are any number of events that can be far more common and every bit as disruptive. A contract manufacturer's plant can burn down, or political activity in its region might lead to prolonged delays. A container full of product can fall off a ship and plunge into the ocean. A major storm can destroy power lines, interrupting production of much-needed components for weeks.

Changes in the global economy also present risks. The imposition of tariffs on many products from China have led life science companies to shift manufacturing and logistics out of that country to places such as Korea, Vietnam, Malaysia and Latin America. While many of those locations offer cost advantages, they may also create other risks..

Even if you intend to keep your operations in-house, your risks can change. Consider a company that in its beginning stages is essentially a distributor of products made by someone else. If they decide to begin their own production, their risk profile changes profoundly. Instead of just being responsible for the loss of someone else's product, they'll take on greater liability and losses that can have a more significant impact on their finances.

Life science CEOs often ask a seemingly simple question: *Am I covered for everything?* The answer is that your insurance policies may be 150 pages long. The first five pages tell you what's covered. The next 145 address all the conditions that may modify that coverage. When you're dealing with issues and policies of that complexity and sophistication, you need to be confident that you can trust the professional who is designing that coverage for you.

Growing companies are often loyal to the people who were there at the beginning. But the attorney or accountant who helped when you were a two-person business may not have the expertise to advise you effectively when you're interacting with the FDA or negotiating a mezzanine round of financing. Similarly, the local insurance agent who's been a great golf buddy may lack the savvy to protect you through these stages. Are you willing to bet your company's future on his or her limited knowledge?

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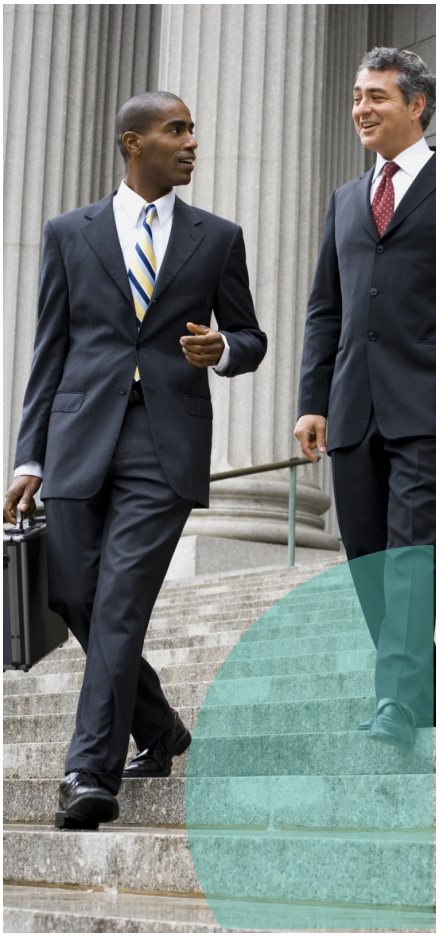
In other words, insurance is no longer a transactional matter. COVID-19 proved it's not a commodity. It's no longer an issue of simply renewing a policy and paying whatever the new premiums are. The bigger your company gets and the more complicated your operations become, the greater the potential risks you'll face and the more complex your coverage becomes.

Protecting your company demands understanding those risks and having the experience to prioritize them. You may face 100 different risks, but you can't obsess about all of them. You need to sort through them and focus your attention on those that warrant your time. That's where outside expertise becomes invaluable. By working with experts and consultants who have guided other life science companies through issues as they grew, you'll be better able to address the inevitable challenges before they crop up, so you can move forward with greater confidence.



Preparing to Exit Successfully

When you started your life science company, you likely had two primary goals. The first was to develop the product, the drug, the technology or whatever idea led you to start your own company. The second was to capture the financial rewards you and the investors who have confidence in your idea deserve for taking the risk.

Whether your eventual exit strategy involves an initial public offering (IPO) of stock or being acquired by a global life science giant, you should take steps today to help you achieve the highest valuation possible when you're ready to make your move. In other words, it's important to anticipate risk management expectations.

Life science startups typically sell to large public companies that are always looking for new technologies that will allow them to capture more market share. Under constant pressure to increase revenue and keep shareholders happy, the leaders of those companies are always watching for the newest innovators. They draw upon a network of experts who report on what's happening and call their attention to promising new developments. Whether the source is someone in the venture capital universe, a researcher or a law firm, they know which companies are likely targets.

In the same way, the leaders of startups should have a good sense of which companies are likely acquirers, based on their current activities, how well the innovations complement what those companies are already doing, and any previous acquisitions. If you can surmise who will eventually make that offer you've hoped for, you should also understand their expectations.

Take steps to show them that you've properly aligned every aspect of your operations and that you've identified and addressed your risks. The more well-prepared your company is, the better the valuation you're likely to see. If your goal is an IPO, count on Wall Street to have similar expectations. When analysts can check all the right boxes, they won't hesitate to give you a green light.

ALIGN YOUR RISK MANAGEMENT ACTIVITIES WITH POTENTIAL BUYERS' EXPECTATIONS.

If this kind of risk management sounds intrusive, it isn't. It's a normal element of due diligence, and the right partners can guide you through it.

Selecting the Right Partner for All Life Cycle Stages

Hylant has a wealth of experience with life science risk management. Having worked with other companies in the sector, we know who buys companies and what they expect to see. We develop risk management plans targeted at a company's desired outcome. If your goal is to be purchased by Company X in a three-year time frame, we'll develop understandable concepts and realistic strategies for your consideration and help you manage every step of the process.

Starting any business involves plenty of uncertainty as it is. Take control wherever you can to reduce those uncertainties and significantly increase the potential for achieving the exit you've dreamed about since day one.

To learn more about managing your risks at any life cycle stage, visit https://hylant-lifescience.com/.