

## ONE PERCENT *by Douglas Friedman*

### Summary

What if one percent (1%) of early-stage investment in biotechnology companies was earmarked for biosecurity? Founders and investors today have much to consider when starting or investing in companies and this includes many security-related topics that are important for a business to survive and thrive. Biosecurity, however, is not typically among these topics. As the bioeconomy grows, biosecurity issues are becoming ever more important for investors to consider. A dedicated percentage, one percent in this case, would encourage all companies to build-in ways to address potential biosecurity issues from the start and inculcate a security mindset while undergoing rapid growth. At seed stage, the one percent may only be a few thousand dollars - enough time for a few hours with a consultant. As a company grows, the one percent will represent tens or hundreds of thousands of dollars dedicated to insuring biosecurity consideration scales with the company. At this level, it may mean dedicated people or systems, and perhaps most importantly, a culture of (bio)security awareness within the company from the start. Companies that start a focus on biosecurity early will be well placed to decide how to best incorporate biosecurity in the long term.

### Background

Biotechnology innovation now affects nearly every sector of the global economy. The ability to harness biology to achieve useful human objectives has skyrocketed in the last two decades. With investment in biotechnology companies at an all-time high, new companies are launching on an almost weekly basis. Even with the excitement and availability of money, starting a new biotech company is challenging and resource intensive. To successfully fundraise, founders must convince investors of a sound idea that has market potential. It is not uncommon for founders to be a group of scientists or engineers that developed an idea in an academic research environment; and while founders often excel as innovative scientists trying to solve a unique problem, they can lack experience in starting and operating biotechnology businesses.

Investor expectations in business plans vary, but questions related to the security implications of the products or services being proposed by the founders are uncommon. That's not to say that security issues aren't of interest to investors or founders. For example, it's a nearly universal requirement for every company to have a cybersecurity plan. Many investors go beyond that and have off-the-shelf cybersecurity plans that they

can provide new companies to get them going. From the investor's perspective, having such plans reduces the overall "cybersecurity spend" by streamlining some of the planning. That begs the question, why isn't biosecurity considered similarly?

Biosecurity is not typically something in the base of investor's experience and many scientists and engineers think more about biosafety than biosecurity. Most academic training is focused on biosafety, with biosecurity being included in only limited cases. If biosecurity is covered, it is typically considered primarily around the use of pathogens and often in a biomedical research context. A broader definition, however, includes considering what a nefarious actor could do with your work. It's not enough to say that the work isn't focused on one thing or another. Serious biosecurity consideration requires scientists and engineers to think critically about how the work could be used if one was to *try* to do something nefarious. How might a new company think about their technology in this way?

### **What if?**

What if one percent (1%) of early-stage investor funding was specifically designated for biosecurity considerations in companies?

Investor expectations or demands could be a potentially strong driving force for biosecurity innovation at new companies. It's common for investors to require new companies to take certain actions when starting their businesses and including biosecurity in the funding requisites for new biotechnology companies would be in keeping with current practice in other areas.

### *What are "biosecurity considerations?"*

The phrase "biosecurity considerations" is intentionally broad. Synthetic biology has the potential to touch every sector and market of the economy; and even to create new markets for its own development. A company's thinking in terms of its own biosecurity strategy and actions should be highly specific to the company. In some cases, it might be that companies partially incorporate this into their biosafety plans, but it is important to emphasize that *biosecurity* and *biosafety* are different, with this concept paper focusing on the former. To that end, every company needs the flexibility to develop and implement a plan that will work for them. A DNA synthesis company has very different considerations than would an organism engineering company. And both have very different considerations from an agricultural biotechnology company. For any plan to be successful, it must be in line with investors' goals of creating a thriving company.

### *Why a percentage? Why one percent?*

Early on, the costs associated with assessing and addressing biosecurity issues for a company will (roughly) scale with the financial growth of a company. Dedicating a percentage of investment funding will help ensure that initial investments in biosecurity development are maintained as a company grows. The right percentage is difficult to determine. For for a company at early-stage investment, consider the following at one percent dedication to biosecurity:

#### Very early investment (\$250,000) - \$2,500 for biosecurity

Although a new company doesn't typically have a lot of money to do anything, it's not too early to think about biosecurity as it relates to the growth for which a founder is aiming. At this early stage, founders might use the dedicated funding to develop a high-level plan for how to incorporate the relevant biosecurity concepts into the the business plan and a few hours of a biosecurity consultant's time to help ensure that all relevant questions are asked.

#### Early investment (\$2.5M) - \$25K for biosecurity

At this phase, a company might start to think about how to build considerations of business-specific biosecurity issues into their policies and plans. This could involve more consultant time to expand the high-level plans to more specifically address their business interests or to dedicate internal staff's time to accomplish the same. There may also be internal development projects that can be started early with dedicated investment (e.g. for product screening).

#### Growth phase (\$20-50M) - \$200K-500K for biosecurity

As a company grows, funding dedicated to biosecurity investment will grow with it. At this stage, founders might consider using the funding for a dedicated staff person focused on biosecurity plan development and implementation. Depending on the nature of the business, funding might also be used to buy out a small portion of all staff's time to ensure implementation of a developed biosecurity plan (e.g. all research and development staff asked to spend five percent (5%) of their time on plan implementation). For businesses that identify highly specific biosecurity implications to their work, a portion of this funding might be directed towards (biosecurity-specific) regulatory issues or requirements that arise or are expected to arise.

Continued growth (\$100M+) - \$1M+ for biosecurity

Once a company reaches this scale (“later-stage”), biosecurity engagement needs will likely diverge depending on the specifics of the company. Some companies entering late-series funding will reduce the percentage of funding dedicated to biosecurity. In other cases, companies may need to increase the percentage of funding for biosecurity issues if there are specific issues that require significant, on-going investment. In other cases, maintenance at one percent may be adequate. In other cases, a smaller overall percentage may be warranted. A company that starts considering potential biosecurity implications for their business early will be well-placed to make this decision at the right time.

*To what end?*

More than one billion dollars was invested in synthetic biology companies in 2017 and this year (2018) is on pace to double that amount. Roughly \$480M went into 38 early stage deals in 2017 and, if the one percent investment guidance in biosecurity was adopted, would represent almost five million dollars and dozens of companies considering the biosecurity implications of their business. Moreover, inculcating a biosecurity mindset into companies early will position them well to consider how best to carry that forward as they grow and develop.<sup>1</sup>

Perhaps the most important outcome will be a culture of (bio)security awareness expected to develop within the companies implementing such an approach.

**Now what?**

It remains an open question as to whether this concept could be successful on a broad scale. For it to work, engagement and dedication by the investor community is a required element to create the norms outlined above. The first step is to socialize and discuss this concept with the investment community, and some of the leaders in biotech today.

A concrete path forward would be the development of a pilot program that has buy-in from one or more leading investors and/or companies. A pilot could take many forms but dedicated engagement from both biosecurity professionals and employees from companies with a history of considering biosecurity engagement is essential. Further, the development of a framework to help founders address biosecurity for their growing businesses, while being flexible to form a program that works with companies in diverse

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<sup>1</sup> “Synthetic Biology Annual Investment Report,” Synbiobeta & Silicon Valley Bank (9/20/2018)

sectors and markets, will require a knowledgeable working group to engage with stakeholders.

Questions that such a working group will likely need to answer include:

- How does the investment community currently view biosecurity?
- What is the best strategy to engage with the investor community to bring the need to them?
- How does this model fit into the business case for investors' decision making?
- How do we convince investors that this concept is worth their money?
- How do established biotechnology companies handle biosecurity? What lessons-learned can and should be implemented into a model focused on early stage companies?
- How, if at all, should academic researchers be engaged? Framing this question is the reality that many startups stem from academic labs and "*there's no such thing as too early.*"