

Life-Sciences, Successfully invest during uncertain times

Life-Sciences Investment Series

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Successfully investing in early life science assets, such as medical device projects, diagnostics, digital therapeutics or drug therapies, require conducting thorough scientific due diligence, monitoring the development plan execution, and implementing a development risk identification and mitigation.

Besides the challenging environment, we observed that this era is appropriate to successfully invest in Life Science assets. After interacting with several Biotech founders, we consistently observed that they need the investors' advice and network, as much as the funds.

Life (science) was nice

The general tone of all economic newspapers is no less than worrisome. Except for a few companies; such as electric vehicle manufacturers, the message being spread is negative. One of the economic newspapers which I was reading right before writing this letter, conveyed only negative news, distress, and setbacks for governments and companies.

For several months, we have heard very consistent messages from biotech founders, investors, fund managers and financial analysts that this environment is becoming more and more challenging. And this perception is accurate. It reflects how life science stakeholders struggle every day to conduct their businesses.

But what has changed? Is there an opportunity here?

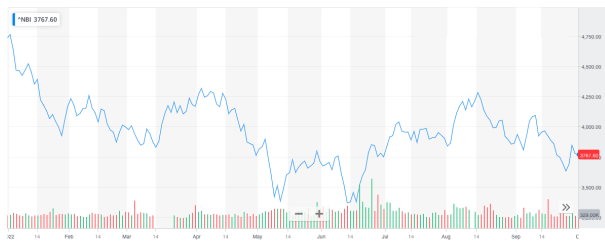
Biotech's valuations, in Covid-19 aftermath, were sky-high for several reasons:

1. The first is that we all realised that we need life-science companies to help us find solutions for health threats, like Covid was. Suddenly, the world understood what clinical trials mean, the related cost, and that all this reattachment did not come from governments, but from collaboration between private organisations and the support of health authorities to conduct development and to approve the vaccines as soon as sufficient evidence was available.
2. The unprecedented financial success of the few companies who managed to develop and commercialise Covid vaccines. All this with the blessing of the governments and the general opinion.
3. In addition to the happy few that successfully developed vaccines, many companies generated substantial sales of new products/solutions during the pandemic period. The need to monitor infections in a large population created a golden era for the diagnostics sector, labs and diagnostic equipment and consumable manufacturers. We wanted or needed to test ourselves before meeting our parents, travelling even going to a restaurant. As a consequence, economic actors cut from the same cloth, benefited from these accelerated approvals/emergency use authorisations and generated revenue. All this in a context of almost free pricing: I remember an antigen test at a wellness "shop" in the US in January 2022, executed by an inexperienced young man, had a cost of 99 USD per person.
4. Several investment funds, which in the past did not consider life science due to its complexity, decided to invest in it.
5. The Central Banks' monetary policies increased the pressure on fund managers to "put their money to work", de facto increasing the available funding for start-ups.

Right time to invest in Life Sciences assets? Yes!

All these factors, one after the other, vanished. The context has changed since early 2022. Some of the main changes were:

1. Inflation pushed Central Banks to increase interest rates
2. The stock market value of several biotechs plummeted, and it did worse than other indexes.
3. Health Regulatory Agencies went back to "normal mode", and continued the review of the data provided during the assessment of emergency authorisations, suspending several initial authorisations. E.g. the FDA announced the end of the EUA era on Sept 27, 2022 [News Release](#).
4. Darwin's principle applied; several companies either disappeared in a consolidating market or were acquired.
5. And most importantly, the demand for Covid vaccines, tests, masks, etc... decreased!
6. A tense environment due to Ukraine's geopolitical situation, supply shortages and inflation.



Nasdaq Biotechnologies Index (NBI), 01 Jan 2022 to 30 Sept 2022

Looking at this context, it might feel that making a good investment in the life-science area now is simply wishful thinking, if not a dream.

We anticipate the opposite! We concluded that it's the right time to develop your assets in Life Sciences, for the following reasons:

1. Even if the Covid epidemic seems under control these days, the emergence of a "nasty mutation" is always possible. Public health will need permanent protection against new mutations, at least for the vulnerable population, similar to flu management.
2. The brains and creative energies that attracted huge investments 9 months ago are still at work.
3. Lower expectations from previous investors will allow you to invest in better conditions than 9 months ago.
4. You can be more selective, and better assess before committing to an asset.
5. Life science companies will be more likely to execute their development programs (execution does not necessarily mean success, whereas "not executing" does mean failure!). During the past 2 years, the combination of increased research and reduced access to clinical search centres delayed most clinical studies and increased the cost of non-clinical studies and manufacturing. A slight reduction of ongoing development projects is desired to rebalance the relationship between biotech and research centres/vendors.
6. Before initiating financing round, life science companies will need to better prepare their business case, it is the end of "easy money".

7. The pandemic accelerated important changes in health care integration of health data, telemedicine etc... This enabled new approaches to tackle public health challenges, and governments to understand the value of new therapeutic solutions.
8. There are still significant unmet medical needs: neurodegenerative diseases and metabolic diseases, among others.

How to succeed?

To successfully invest in the Life Science sector, in addition to the necessary sanity check of the business plan and management team expertise, I observed the following fruitful behaviours

1st set of behaviors: Assess, and continuously re-assess

The due diligence process is adapting. Besides the quality of the team and the market opportunity, additional emphasis is set on the science and the implementation of the development plan.

The science:

How solid is the project's scientific ground? Is the approach validated, or considered a plausible approach to address the medical need?

Have other research groups attempted to use the same solution? If they did not succeed, what are the reasons for this? Is the solution addressing a medical need or just an aspiration?

In case the solution is expected to disrupt the field, what are the efforts needed to win over the resistance (or for slow adoption)?

The likelihood of achieving the development program:

Regardless of how bright the idea is, does the team have the capacity to achieve this development program?

Is there sufficient data generated to initiate the next steps? What is the probability of technical success at the next milestone and what are the measures implemented to increase it?

Anticipating the success of the upcoming milestone, which would be the next steps? If the data is better than expected, does the company benefit from it?

Are the development programs "pressure-tested"? Should any unexpected event (good or bad) take place, what would be the impact on the project costs and timelines?

2nd set of behaviors: Nurture and support

Once you have invested, continue investing!

Your assets need your money of course, and this is the visible part of the deal. However, your assets also need your network and experience, especially since times are as challenging as they are now.

Successful investors permanently support their assets to implement the development plan. And this support is not to address your anxiety as an investor (legitimate) but to increase the overall chances of success.

We observed that successful investors:

1. **Put healthy pressure** on achieving the next development milestone. The ability of the team to achieve the next milestones is directly correlated with asset maturity and the team's ability to mitigate future issues.
2. **Review in detail the risk assessment and mitigation measures.** This is a powerful tool to anticipate issues/good news and to save time, should any of this happen. Risk and mitigation measures are not anxiety management tools. They are an anticipation tool that identifies potential issues, and documents the possible impact, likelihood, and mitigation measures. The best tools are the more specific ones and the most time-consuming as well. This is an investment of time that is not a natural approach for biotech founders. They believe that their project will succeed, and if something happens, they will handle it. You need to help them, not only by being in 'reactive mode', but by anticipating and pre-reviewing the proposed mitigation measures by your technical advisors.
3. **Open your network and the network of your technical advisors** to your assets. You and your advisors are naturally in connection with many other vendors and experts. This will save them a lot of time.

In a nutshell

In the current context, successful funds managers and investors in Life Science assets tend to:

1. Conduct thorough due diligence, exploring the market opportunity, team experience, finances, legal and science.
2. Continuously invest their time, expertise and network.

For all these reasons, at Health Economia, we do believe that this era is an exciting one.

Health Economia Team

About Health Economia

Health Economia is an advisory firm, providing LifeScience investors scientific and technical support. We help our customers to make informed decisions about the development of their assets and act mainly on the buy side.

As your scientific back-office, we support you in:

- Shaping your targets compounds or device development strategy developing the manufacturing and supply framework
- Identifying risks & remediation activities during funding and M&As

Health Economia experts, with 25+ years of experience in regulatory, pre-clinical, CMC and Clinical Development, will support your projects.

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