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Anna-Marie MacDonald , Editor

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# Investors Must Ask Tough Questions When Deciding on Investments in Pharmaceutical Startups

Hettie Stroebel, Founder & CEO

According to a recent report, startups developed 65% of the total drug development pipeline. And 42% of the products filed with the FDA. That creates huge opportunities for investors but also has the potential for enormous risk. Research and development of a new drug can take years and, in some cases decades. In the end, there is no guarantee the product gains FDA approval and makes it to market.

*When considering an investment in a startup pharmaceutical company, investors have a lot to consider. Pharmaceutical science and the FDA approval process are complicated. Investors need to ask tough questions and evaluate the value proposition of the proposed drug. Does the drug meet an unmet need in the market? What truly differentiates the proposed pharmaceutical from others in the marketplace? What are the expected patient populations and the payment methods? Will insurance companies cover and reimburse the expense?*

Here are a few areas where investors need answers before putting money on the table. With this information, investors can triangulate the opportunity.

### Who is the team and what are their experiences?

The development of a drug from research to approval is a complicated process, and a startup must have a team with diverse backgrounds. While the research team is important, the startup must have experts in finance and fundraising, FDA regulations, science and manufacturing.

A product launch is a highly complex endeavor and requires competencies beyond research and development. Investors must have the confidence that the team can not only develop the product but also bring the product to market at scale. Failure results in a complete loss of the investment. Investors need to know who on the team has been through the

entire lifecycle of a product previously. How well does the team fit together? Do skills overlap or does each team member bring a unique set of skills and experiences to the team? What is the track record of the executive team members individually and collectively?

### How strong is the value proposition?

Most often, startup-developed drugs were similar to standard of care or only a slight improvement, representing a more challenging launch position than those with more dramatic clinical advantages.

An MVP (minimal viable product) is not sufficient at all to start a journey in drug discovery and development. Medical innovation, today, needs to stand head-and-shoulders above competitors and deliver a compelling (attention demanding), relevant (purpose driven), and meaningful (significant) value (be useful/worth) proposition across all decision-makers regarding use by patients.

## What are the investments in people and dollars?

The launching of a new pharmaceutical takes years and requires a huge amount of capital before any revenue is generated. The average time to market is almost 12 years, and there are sure to be pitfalls along the way. Chief executive officers must make sure the startup is well funded and understand the fundraising benchmarks.

The startup needs a clear plan for how long the product will take to develop and the timing of the anticipated launch to best estimate funding required during each phase. Otherwise, the startup could get halfway into the approval phase and run out of capital. A startup needs to be on a solid financial footing and have the funds to pay for the people necessary to bring the product to market. Talent costs money, but in the end, paying for talent gives investors the best opportunity for a solid return on investment.

### What is the probability of success?

When evaluating an investment in a pharmaceutical company, investors need to calculate the expected return on investment. That starts with the type of drug. A recent study showed that drugs in oncology, rare diseases and with multiple indications return the highest for investors.

As well, investors need to understand the startup's plan to get the product out of the research and development phase and through trials. A recent report related to startups found that only 4.3% of new drugs developed by startups leave Phase 1 development and have a successful clinical trial. That is a small number and should give investors pause. What makes a particular startup different? Has it completed any preliminary studies on the viability of the product? What is the plan for commercialization? Have other companies tried and failed to develop similar drugs? These questions need to be answered.

### What is the new product planning strategy for launch?

Only 4% of primary care and 6% of specialty launches are achieving launch excellence.

It is a complicated and time-consuming process to take a drug from concept to generating revenue. An investor must pressure test the process that the startup has developed to lead the team through the entire cycle. What resources is the team given? What are the constraints put on the team? What risks should be mitigated?

Solid goals and timelines need to be

established to take the team through the various stages in the process. Everyone cannot work in a silo. They must be a cohesive unit that works well together and have established processes and goals. That requires a strong team and a complex understanding of the drug discovery and approval process. How is the team able to balance the multiple stakeholders when meeting goals? What are the timelines set for the various phases in the development process? Are the resources in place to help the team succeed?

## Conclusion

After all the questions are asked, very few companies pass the test. Investors must be picky. That increases the chance of success and can create a huge return on investment. There are an extraordinary number of doctors and researchers who have formed pharmaceutical companies in the last few years but very few will succeed. Investors need to take the time to examine the startup and decide whether the organization has a reasonable chance of success.