

ADVANCES IN DRUG DEVELOPMENT

Current Developments in Oncology Drug Research

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Investing in Oncology Biotech Stocks

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H&O How should the oncology community interpret your reporting on oncology biotech stocks?

AF My column in TheStreet.com covers the investing side of the biotech sector. The primary focus is on stocks and what moves the prices of the stocks up or down. My job is to take the science behind the drugs under development and translate it into a judgment of value, of what the science is worth to a company's business as reflected in its stock price. I may not write about every aspect of the medicine that would interest a clinician. For example, at the annual meeting of the American Society of Clinical Oncology, there are hundreds of abstracts and presentations for a clinician or researcher to review, but I focus on a smaller slice because a clinician and an investor have different priorities. I review the new data presented in terms of its effects on stock prices because research and development constitutes a large chunk of the value of biotech companies.

H&O What is an example of a drug that is useful to clinicians but not very good from an investment standpoint?

AF An example of the difference between an investor's perspective and a clinician's perspective would be differing views of the radioimmunotherapies, such as iodine-131 tositumomab (Bexxar, GlaxoSmithKline) and yttrium-90 ibritumomab tiuxetan (Zevalin, Biogen Idec). When these drugs were under development, I wrote about them. At the time, it appeared that there was a great potential for these agents to change the way patients with non-Hodgkin lymphoma would be treated. However, from a commer-

cial standpoint, these agents have been a disappointment, with sales not as high as expected. I have spent little time writing about these drugs in recent years, as the lack of commercial success has become apparent and they no longer factor into their manufacturers' marketing priorities, even though the drugs remain important to clinicians who routinely administer them. If sales increase as a result of new data and these drugs again become a priority for their manufacturers, there would be good reason for me to write about them again for investors.

Furthermore, there may be generic drugs that are popular among clinicians and highly useful, but without a significant commercial presence, such drugs do not fall into the purview of my coverage.

H&O Do you think the industry is overvalued given low success rates and future price pressures?

AF I do not think there is a single correct answer to this question. Overall, it is true there is a high failure rate of investigational compounds for the treatment of cancer. This consideration is part of the risk of investing in the biotech sector. Looking back to the development of the monoclonal antibody rituximab (Rituxan, Genentech/Biogen Idec) and the commercial projections before its launch, few expected it to be as successful as it has turned out to be. Therefore, it was not overvalued at the time and was likely undervalued. Bevacizumab (Avastin, Genentech) is another drug that has turned out to be more valuable than expected. Conversely, it is possible the radioimmunotherapies were overvalued when they were launched. Thus, I try to evaluate each agent individually.

If a layman looks at the marketplace, it may seem surprising that a presentation at a plenary session at a conference touts a median 1-month improvement in overall survival. The layman's response might be that only 1 month does not seem like an important improvement.

But from a patient's perspective, an additional month shared with family may be priceless. It is possible to measure benefit in small units, and that does not diminish the benefit. Anticancer drugs almost never improve survival by 4 years, for example. Does that mean that the effect of drugs is not worth their price? I think this is a difficult argument to make.

The oncology marketplace is becoming more competitive; there is an increasing number of drugs competing for the attention of both clinicians and patients. There are many drugs in the pipeline for the same indications. Pricing pressure also exists. There is more and more discussion in the public realm of the pricing of oncology therapies, particularly antibodies. I am not sure the effects of this conversation are predictable or whether we will begin to see price cuts or insurers refusing payment. The effects remain to be seen, but investors should be aware of these issues.

H&O What factors do you consider in trying to evaluate a drug's worth from an investment standpoint?

AF It is important to start with a fundamental perspective of the available data and determine whether the drug is effective and safe and in what patient populations it will be used. Any analyst who researches drugs professionally, just like any company planning its own commercial prospects, must begin with the data. Furthermore, it is valuable for me to talk to clinicians because they are the ones who will judge the utility of a given agent. I am interested to know whether there are other factors like dosing, administration, or side effects that will affect the decision-making process clinicians enter when considering whether to use a given agent? These factors are combined in the evaluation and must be balanced with one another; if a drug is highly effective but has dosing difficulties or even a high financial burden, these considerations must be weighed against its efficacy.

H&O As the marketplace grows more crowded, how is the value of a drug affected by competitors?

AF Investors are seeing a more crowded marketplace these days. We will almost never see head-to-head studies between two drugs for the same indication no matter how desirable such a comparison may be to clinicians because there would be little commercial support for such an endeavor. Therefore, investors must look at comparisons across different studies with the knowledge of the inherent limitations of this method. Here again, feedback from

clinicians is valuable. I may ask a clinician who has 5 years of experience with drug X if the new drug Y entering the marketplace will change how he or she treats patients. Does drug X remain the drug of choice due to a clinician's comfort with it? What is the decision-making process? These type of questions are becoming more common with the availability of multiple effective drugs for similar indications.

H&O How do you distinguish hype from reality in the evaluation of new anticancer agents?

AF There is always going to be more hype on the investment side than on the clinical side of the oncology world. Wall Street is forward-thinking. The price of a stock is inherently the value of the company's future performance. Investors tend not to look back, which can lead to hype and excitement that is disconnected from history or from reality. There is always the risk of overhyping drugs, and examples are available of it happening in the past. I try to acknowledge that hype does exist because investors, clinicians, and patients alike are always seeking advances, but the enthusiasm must be grounded in the data. Ultimately, the data on the drug constitute the final arbiter of its value. It behooves investors to be well educated about their investments, and clinicians can provide the grounding perspective due to their institutional memory and knowledge. Clinicians have the knowledge to say confidently, "There is a lot of excitement about a new targeted agent, but here are the problems that have occurred with trying to hit that target in the past."

H&O How does the possibility of future healthcare reform initiated by a new president affect the way investors look at the industry?

AF I would say that the possibility of healthcare reform absolutely affects the way investors think. The specifics of the effects on stock prices are impossible to describe at this point because what structural changes will occur are unknown. Still, I believe investors should be thinking about the effect of reforms on the industry. We discussed pricing pressures, and I think ultimately there will be a change because of political momentum in response to the price of healthcare and the price of drugs. Generally speaking, politics and discussions in Washington certainly do affect the way investors look at healthcare and the biotech industry, particularly as election years approach.

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