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Taking the measure of small-cap biotech: Bio-Path Holdings, CytoDyn

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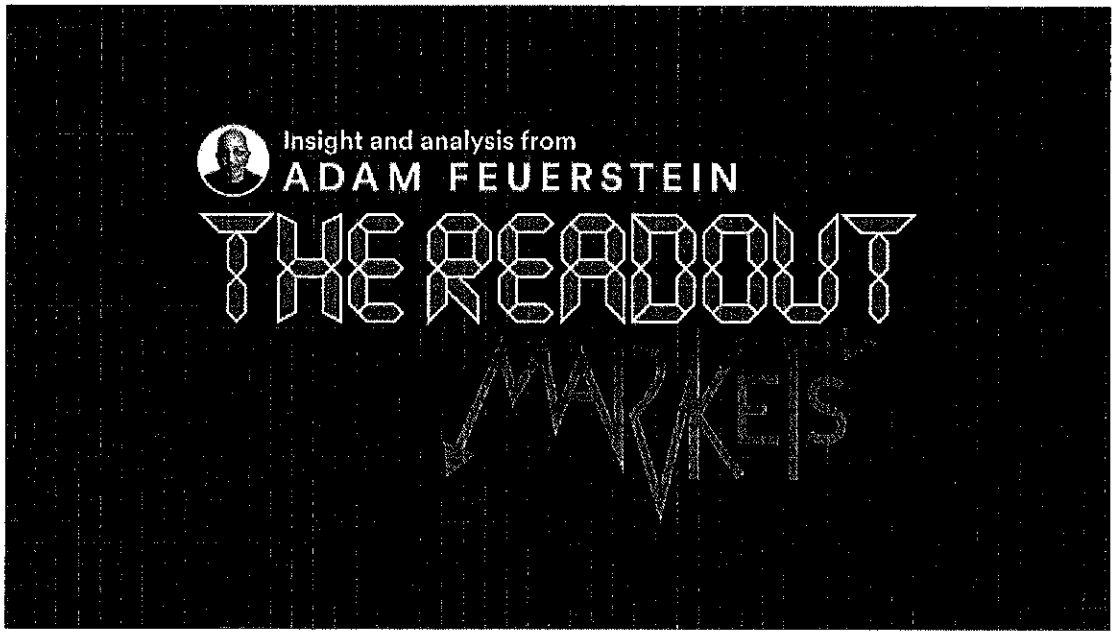

I'm back with another semi-regular column tracking the ups and downs in small-cap biotech. Today, I take a look at Bio-Path Holdings (BPTH[5]) and CytoDyn (CYDY[6]). Hint: Red flags hoisted on both. As a reminder, I'm taking requests for companies to cover, so reach out to me on Twitter[3] (DMs are open), email, or in the comment section of the column.

Shares of Bio-Path Holdings soared an astounding 700 percent over the past two trading sessions. But the company-issued press release that triggered the stock surge omitted some sobering information about its experimental blood cancer drug. Was that misleading? I think it was. Bio-Path's CEO disagrees. I spoke to him by phone on Thursday night.

Let's break down this crazy Bio-Path story, starting with the incredible stock volatility — an eightfold jump in the share price in two trading sessions.

Bio-Path closed Tuesday above $4. On Wednesday, it nearly tripled to $12. On Thursday, Bio-Path shares more than tripled again to $39. Volume was insane — more than 100 million shares were traded in a company with a tradable float of 500,000 shares.

The trigger for the stock-trading mania was a "clinical update" press release issued by Bio-Path on Wednesday morning. In the release, Bio-Path said 65 percent of the 17 patients with acute myeloid leukemia, enrolled in its clinical trial, were now responding to treatment with its blood cancer drug called prexigebersen. Last December, the prexigebersen response rate was 47 percent.

The updated results from the clinical trial were "strong evidence" of prexigebersen's safety and efficacy profile in difficult-to-treat acute myeloid leukemia patients, Bio-Path CEO Peter Nielsen said in the press release.

With that seemingly positive update on a blood cancer drug, biotech stock traders had a grand old time with Bio-Path shares. The company's low float was like dry tinder in a bonfire; the whole thing just exploded.

But the prexigebersen update disclosed by Bio-Path was cleverly worded in a way that, to me, was misleading because it falsely inflated the drug's efficacy. For patients with acute myeloid leukemia (AML for short), the only treatment response that matters is complete remission. These can be full remissions or incomplete/partial, but anything else is considered a treatment failure.

The complete remission rate in the prexigebersen AML clinical trial was 29 percent, per Wednesday's update.

What Bio-Path failed to mention, however, was that the 29 percent complete remission rate has not changed since last year. Bio-Path first announced interim results from the prexigebersen AML clinical trial in April 2018. The complete remission rate was 29 percent. The data were then updated in December and presented at the American Society of Hematology meeting. There, the complete remission rate was 29 percent.

And that 29 percent complete remission rate is derived from just five patients out of the 17 patients treated in the study. These are small numbers that can have an exaggerating effect.

Nothing relevant has changed about the response to prexigebersen treatment among the AML patients treated in Bio-Path's clinical trial since last year. Investors were not particularly impressed by the same prexigebersen data last year, either. Last December, Bio-Path was trading at 25 cents, forcing the company to push through a 20-for-1 reverse stock split and a distressed financing just to remain afloat.

In a phone interview Thursday night, Nielsen acknowledged that the rate of complete remission in the prexigebersen AML clinical trial has not changed. Instead, the company chose to highlight a 65 percent overall response rate (up from 47 percent) that lumps in patients with minor responses and stable disease.

This gives the broadest view of prexigebersen's potential clinical activity in AML, which is what Bio-Path felt was best to share with investors on Wednesday, Nielsen told me.

"We're excited about the potential for prexigebersen," he added.

Biotech traders were excited too, but perhaps for misleading reasons.

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CytoDyn claims to be developing a new drug for HIV that will fundamentally change the way the disease is treated, deliver billions of dollars in revenue, and end the HIV market dominance of Gilead Sciences. It's an enticing investor pitch that's often echoed across biotech investing message boards and DIY investing websites like Seeking Alpha.

Unfortunately, very little of this overly optimistic CytoDyn story is likely to ever come true. CytoDyn might secure FDA approval for its HIV drug, called leronlimab, or PRO 140. And the drug does treat HIV differently than most currently approved HIV drugs, although it's a stretch to call it a medical breakthrough.

After that, the CytoDyn investor pitch veers off the road. Even if approved, leronlimab is a niche therapy that will be used by a tiny number of patients with HIV resistant to current medicines. The drug is an injectable antibody, making it less convenient and more expensive than standard HIV pills. Revenue might be measured in the tens of millions of dollars per year, if all goes right. Is Gilead worried about its HIV business collapsing from CytoDyn competition? No, hardly.

Leronlimab belongs to a class of HIV drugs called entry (or fusion) inhibitors. These drugs work by blocking the virus from entering healthy immune cells. That's different from most HIV drugs, which act against the virus after it infects immune cells. Three entry/fusion inhibitors have reached the market, but none generates significant revenue because doctors reserve their use for the small number of patients with multidrug-resistant HIV. Selzentry was approved in 2007 but generated just $150 million in 2018 sales for GlaxoSmithKline. The FDA approved Trogarzo one year ago; sales were $4.25 million in the last reported quarter ending Nov. 30, 2018, according to Theratechnologies, the drug maker that markets the treatment.

Trogarzo is a good comparable for leronlimab. FDA approval was based on a small study of 40 heavily treatment-experienced HIV patients published in the New England Journal of Medicine[9]. It's also worth reading the accompanying editorial[10] for the concerns raised about interpreting data from such a limited study.

CytoDyn's registration study for leronlimab enrolled 52 HIV patients with multidrug resistance (although patients were not as sick as those in the Trogarzo study). Results were presented at a medical meeting in June 2018. You can download the poster here[11]. There's nothing in these leronlimab data that would worry Gilead. At best, CytoDyn's drug is similar to Trogarzo, with the important caveat that FDA hasn't vetted leronlimab. The company started the FDA submission process but it won't be complete until additional leronlimab safety data are collected. When that happens seems to be a moving target.

Leronlimab is also being developed as an injectable maintenance therapy for HIV patients who might want a break from taking a single pill each day. But this idea is already being explored by GlaxoSmithKline with long-acting, injectable versions of its own HIV medicines[12].

Biotech penny stocks are ignored by most investors and therefore struggle to raise the money necessary to develop drugs. CytoDyn is no exception. The company's shares trade on an over-the-counter exchange and it's perennially short of cash. The balance sheet is a mess, bloated with convertible stock offerings and a mountain of warrants. At 51 cents per share, CytoDyn's market value is just over $150 million. If you count dilution from convertible stock and warrants, the market value already approaches $350 million.

I understand and can even sympathize with CytoDyn's predicament, but that doesn't excuse the outlandish claims made in investor presentations. Leronlimab "revenue potential of greater than $480 million[13]" in 2020? Leronlimab peak HIV sales potential of $11 billion? That figure would make it the most commercially successful HIV drug of all time. Please, that's just not credible, which also explains why CytoDyn is a biotech penny stock.

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