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Hospitalized biotech stocks

Illiquid, unfollowed, undesired and battered, micro-cap biotech stocks tick nearly every contrarian's boxes. We write to present a pair that a longtime subscriber has presented, or should we say pitched, to us. He is long and bullish and asks to go unnamed. We are not long, but persuaded. What follows may be mistaken, but if so, it will be honestly mistaken.

Saying his piece, our subscriber introduced his biotech specialist, who likewise requested anonymity. So be it. We'll call him Anonymous.

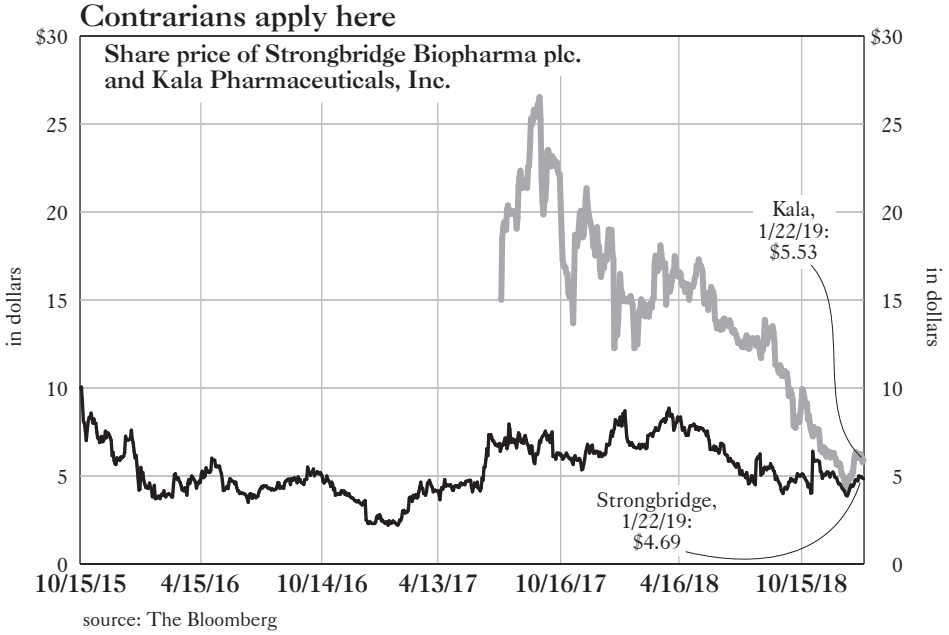
"A couple of caveats," Anonymous led off. "They are long-term, two-to-three-year-plus-type investments. It's arguable whether these are publics [i.e., public equities], because they are illiquid and hard to build positions in. We are not investing in hot, giant gene-editing/gene therapy/immuno-oncology where a lot of people over the last couple of years on the public side have made money largely through momentum. These are not areas that we focus on. What we tend to focus on are clinically de-risked companies or even potentially revenue-stage companies. Furthermore, what we look for are companies that we think are trading at substantial discounts because it is very easy to be wrong even in these clinically de-risked or revenue-stage stories. But what tends to happen, particularly in the micro-cap, illiquid public companies, is that you find yourself getting opportunities because there will be a company that maybe went public too early, had multiple assets and the lead asset fails and when the lead asset fails all the public investors flee that company."

Many have fled in the past three months or so, Anonymous notes. He described a bear market not quite up to the sanguinary quality of 2008 but right up there with 2015-16: "Part of this is that the overall market traded down, and then biotech trades at some beta to the overall market, and then further exacerbating it was tax-loss selling. In an illiquid public biotech company, when there is tax-loss selling, those sellers are basically just price-takers, because there is not sufficient demand on the buy side, and it is not an efficient market in general and so all of that compounded into a significant gap downdraft for the sector. God forbid you had to raise money during that time—you got further crushed. There are examples of companies that announced positive clinical data and then raised money shortly thereafter and are trading at substantial discounts to what they were before the positive clinical data."

Strongbridge Biopharma plc. (SBBP on the Nasdaq; 52.4 million shares outstanding for a $245.9 million market cap) is the first pick to click. "They had clinical data in the midyear time frame," our source said. "Furthermore, they had a financing overhang that they completely solved for, and the stock is actually trading at levels lower, or around, where they were before the clinical data and before they solved for their financing overhang."

It would have been better, Anonymous allowed, if the Strongbridge IPO had not approximately coincided with Hillary Clinton's tweet condemning predatory drug pricing; and if the lead underwriter, Bank of America, had not begged off the

Contrarians apply here



source: The Bloomberg

position of lead underwriter at a pregnant moment in the transaction; and if the company had raised the $60 million it had intended to do and not the $25 million it actually got. Better, too, would have been an IPO price of $15 a share, which management sought, rather than $10, for which it settled. Now the stock is under $5.

"They are focused on rare diseases," Anonymous went on. "As an orphan company [i.e., a company treating rare, so-called "orphan diseases"], you get patent protection of seven years because you are focused on small patient populations. The reality is that, at the end of the day, any of these companies can acquire assets and build a business around them. However, to be successful, you really have to have a strong commercial-execution team. One of the reasons that we got attracted to the company was that the CEO, Matthew Pauls, is a former head of commercial at Shire, and then his chief commercial officer also came from Shire and led the launch of several of these rare-disease franchises."

Strongbridge has three assets: Recorlev (levoketoconazole), a treatment for Cushing's syndrome; Keveyis (dichlorphenamide), a treatment for primary periodic paralysis; and Macrilen (macimorelin), which is used to diagnose adult growth hormone deficiency. Having acquired Macrilen in January 2018, Strongbridge sold it to Novo Nordisk in October for $145 million in cash plus a royalty stream. "More importantly," said Anonymous, "Novo is actually funding the company's endocrine sales force for three years. What this allowed Strongbridge to do is pay off all the debt they had. They had $90 million of debt. They've got this royalty stream. They've got Keveyis, which is being commercialized, and they had $140 million of cash at the end of the third quarter 2018."

Anonymous described the promise of Recorlev, foremost among the three therapies, and offered a sum-of-the parts analysis based on the present value per share of estimated, naturally speculative, future cash flows: "If you assume $2 for Keveyis," he said, "$1 for the royalty stream on Macrilen and then, conservatively, $10 for Recorlev, you get to a $13 per share price versus today's price of a little less than $5." Cash, some of which will be burned, adds $2 a share. The risk that the FDA stays shuttered, throwing a monkey wrench into the timetable for clinical trials, is a clear and present danger, he added.

Kala Pharmaceuticals, Inc. (KALA on the Nasdaq, 33.8 million shares outstanding for a $186.9 million market cap), is value-laden specimen No. 2. Kala develops drugs for the eye. "They went public at $15," Anonymous recounted. "They actually traded as high as $26. They have two drugs. The first one, Inveltys (loteprednol etabonate ophthalmic suspension 1%), for post-surgical inflammation, is approved and thought to be the smaller revenue opportunity."

The second drug, unapproved, has no brand name but goes by its lab tag, KPI-121 0.25%. As its name suggests, it's a 0.25% suspension of loteprednol etabonate using Kala's proprietary formulation. Probably, Anonymous said, the sentiment that propelled KALA into the 20s was the hope for KPI-121's use as dry-eye therapy (a $500 million or $1 billion opportunity as opposed to Inveltys, which might generate $250 million). Subsequent to the Kala IPO, the dry-eye compound hit its two primary endpoints in the first Phase 3 trial and hit one of two primary endpoints in the second Phase 3.

"This second trial was perceived to be a failure and caused a delay in approval for dry eye until, likely, the middle of next year," he ventures. "I believe that, upon announcing they were running a third Phase 3 trial, the market perceived this delay as a failure with the risk that the drug never gets approved. I think the market is ignoring Inveltys.

"They launched the drug a couple of weeks ago," Anonymous went on. "The drug is at least a $200 million peak revenue opportunity, and the reason I say that is there are two steroid eye drops that are currently used for this indication, each of which does $200 million. But both require drops four times a day, and with Inveltys you only have drops twice a day. Compliance is a huge issue with these patients. So, by being able to deliver [drops two times a day rather than four], I think that is a meaningful benefit. Thinking about that drug, which is now launched, and the sales force that is built out already, that in and of itself is worth $12 a share." Make fair allowance for the possibility—even 50-50—that the dry-eye compound delivers meaningful revenue and you can imagine a future share price at a substantial multiple of today's.

If, of course, the FDA reopens, some future progressive Congress does not enact sweeping drug-price controls, and the science most cursorily described by your interest-rate-minded correspondent pans out in the lab and the marketplace. At least you can't say the stocks are overbought.

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