Why M&A Flurry Has Top MKM Analyst Smiling All the Way to the Bank

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COMPANIES MENTIONED

- Abbott Laboratories
- Acorda Therapeutics Inc.
- AstraZeneca Plc
- Bristol-Myers Squibb Co.
- Gilead Sciences Inc.
- GlaxoSmithKline
- Nektar Therapeutics
- Neurocrine Biosciences
- Pfizer Inc.

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THE ENERGY REPORT
THE GOLD REPORT
THE LIFE SCIENCES REPORT
THE CRITICAL METALS REPORT

Sometimes bigger is better. In this exclusive interview with *The Life Sciences Report*, Senior Analyst and Managing Director Dr. Jon LeCroy of MKM Partners points to mergers and acquisitions that have bolstered stock prices and singles out biotech and specialty pharma companies of all sizes that could generate significant returns for investors by addressing unmet medical needs with innovative solutions.

Source: George S. Mack of *The Life Sciences Report*

The Life Sciences Report: Since the end of November, biotech, healthcare and broader markets have been trending upward. But you couldn't make biotech stocks move for any reason prior to late last year. Why do you think this upward trend is occurring?

Jon LeCroy: I think two things are at work here. First, the market overall has been up since November. Part of biotech's outperformance is expected because the biotech index has a higher beta than the broader market. Second, if you look at the broader market from April to June, it was trending downward relative to biotech, which held in place. That period created the biggest disparity in biotech versus the broader market.

TLSR: Why has biotech been stronger than the broader market?

JL: The primary reason has been merger and acquisition (M&A) activity. We have seen a lot over the past nine months, especially between April and June. We saw the acquisition of Amylin Pharmaceuticals Inc. by Bristol-Myers Squibb Co. (BMY:NYSE), which was completed Aug. 8. We heard the first rumors of that deal in April, and got official confirmation a month or two later. We also saw other high-profile acquisitions, including Human Genome Sciences, which was bought by GlaxoSmithKline (GSK:NYSE). AstraZeneca Plc (AZN:NYSE) bought Ardea Biosciences Inc., and Bristol acquired a hepatitis C-focused company, Inhibitex Inc. Looking back to November 2011, when the solid performance of biotech really started, Gilead Sciences Inc. (GILD:NASDAQ) announced acquisition of Pharmasset Inc., which also develops hepatitis C (HCV) drugs. All of that activity helped the space.

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Catalysts at the U.S. Food and Drug Administration (FDA) helped the space as well. We also saw a couple of significant drug approvals this summer, including weight-loss drugs from Vivus Inc. (VVUS:NASDAQ) and Arena Pharmaceuticals Inc. (ARNA:NASDAQ) and more recently Amarin Corp.'s (AMRN:NASDAQ) Vascepa, for heart disease.

TLSR: Is biotech now in a sustained upturn?

JL: I think biotech needs catalysts to sustain its outperformance. Clearly, the primary catalyst is M&A activity. How biotech performs going forward is mostly based on whether there is continued M&A interest out of big pharma.

TLSR: Jon, you follow four fully integrated big pharmas, Pfizer Inc. (PFE:NYSE), Merck & Co. Inc. (MRK:NYSE), Eli Lilly and Co. (LLY:NYSE) and Bristol-Myers Squibb Co. It is rather unusual for a growth-oriented analyst to follow large caps. What is your general investment theory on these companies?

JL: The large-cap pharma names have done well over the past two years. They have been a safe haven in a turbulent market. As an analyst who covers a broad-cap range, and also as an analyst at a mid-size shop, I have to pick my battles. My background is as a physician, and I try to play to my strength, which is to focus on drugs and drug data. When I look at large-cap pharma names, I consider how the pipelines look relative to each other, and what the patent exposure is on drugs that will face generics over the next five years or so. I compare companies based on those two metrics primarily. I also try to stay in front of the hot topic of the moment, whether it's Alzheimer's disease or HCV, and to anticipate what the big drugs are going to be over the next five years. When I compare these things, I look for value.

TLSR: Do you have a favorite big pharma name right now? Can you offer investors an edge?

JL: Our top pick in big pharma is Pfizer, primarily because Pfizer is undervalued relative to its U.S. peers. The four pharmaceutical companies that I follow actually look quite similar, and they are even more similar now, in our view, than they have been historically. They are facing similar pressures, and within the individual companies, are facing the same issues at the same time.

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For one thing, we are seeing the top lines show negative growth for each of the companies, while the bottom lines are staying relatively flat due to cost-cutting. The companies also face austerity measures in Europe, and now face Patient Protection and Affordable Care Act (ACA) measures in the U.S. They also have historically weak pipelines, which is due in part to the cyclical nature of advancements in technology and science. Innovation tends to occur in steps, and the weak pipelines we see today are due in large part to a gap in advancement that occurred 10 or even 15 years ago.

Companies are also facing heavy patent exposure, which is part of a similar cycle, due to the fact that there were multiple blockbuster drug approvals in the 1990s. The four companies are tethered to each other more than they have been before. Our macro view is that they don't look very different, so we tend to be value investors. That leads us to Pfizer as our top pick.

On the other hand there is Bristol, which has a huge premium relative to its peers. Other than being smaller, Bristol doesn't look a lot different from Pfizer in terms of the issues it faces and the amount of new sales it will be able to produce over the next five or six years.

TLSR: Which of these companies has the most patent exposure?

JL: Bristol. It does have the best pipeline, but it also has the worst patent exposure. On the other end, Pfizer has the least patent exposure. It lost Lipitor (atorvastatin) late last year, so that drug is out of the model at this point. Looking forward, Pfizer actually has the least number of drugs going generic, in terms of its sales base

relative to its size.

TLSR: You mentioned the ACA in reference to some of the headwinds facing the large pharmas. What will be its effect?

JL: Overall, we view the effects as mildly negative for the industry. There are four primary issues drug companies face with regard to the ACA. Some have already kicked in. One of the two already in place requires companies to fill half of the Medicare "donut hole," which is the portion of the drug benefit that Medicare recipients must pay themselves. The second is a hefty, nondeductible federal fee that drug companies must pay. These two changes have already impacted the industry.

Drug companies are also going to have to give higher drug rebates to Medicaid. In addition, they must give broader discounts to hospitals.

TLSR: Do these provisions neutralize the (former congressman) Billy Tauzin amendment to the Medicare Part D program, which stipulates that the government can't negotiate fees with pharmaceutical companies?

JL: They are separate issues, but it seems that new payments are more than offsetting the amendment. The drug companies and, potentially more so, the medical device companies, are footing the bill for a fairly big portion of the ACA. The advantage companies received by the exclusion of negotiations over drug pricing is offset by the act.

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Pharma companies could see one advantage: They could potentially get more volume from the ACA. We don't think that will necessarily be true, because it looks like the states are going to have the option to expand Medicaid. Additionally, the bulk of new coverage, from what we can tell, is going to be for a relatively young population that is either covered by parents' insurance plans or is going to be forced into the healthcare market. These younger groups tend to not use brand-name drugs. Younger people tend to be healthier and aren't typically on prescription medications.

While we don't see much benefit in terms of volume coming from ACA, drug companies are paying fees and taking cuts on price. If you are a pharma company, pricing is the one power you want to keep. If you have to choose, pricing is always preferable, in our view, to volume.

TLSR: Would you talk about some of the small- and mid-cap companies that you like?

JL: Let me start with Nektar Therapeutics (NKTR:NASDAQ). Nektar is close to a $1 billion market-cap company. It focuses on pegylation technology, which the company uses to attach a polyethylene glycol (PEG) molecule to an existing drug to improve the pharmacokinetics of that product. The process is applicable to almost any drug that has ever been developed, and the company has developed one of the deepest pipelines in biotech.

Its lead program is called NKTR-118 (naloxegol), for opioid-induced constipation (OIC). OIC is a huge problem for patients who chronically take opioids for pain control. Right now, opioids are the most prescribed set of drugs in pharma, with 250 million (M) prescriptions written every year in the U.S. On top of that, about 40–50% of patients taking opioids chronically end up with OIC. We view it as a huge market

opportunity.

NKTR-118 is currently in phase 3 trials and is partnered with AstraZeneca in what's called the KODIAC program, scheduled to be completed at the end of 2012. We expect the company to present top-line data from the program either in Q4/12 or Q1/13, and we think that offers significant upside potential over the next six months or so. We also think that because of the huge incidence of OIC, it's a billion-dollar opportunity for Nektar and AstraZeneca.

TLSR: Nektar has given away a lot of points on this drug. One billion dollars in revenue works out to be about $200M/year for Nektar. Is that the way you see it?

JL: Yes. We model an average 20% royalty for it.

TLSR: Does that move the needle on Nektar's share price?

JL: It certainly does. We expect revenues this year to be around $77M, so stepping up to $200M/year in revenue is a big deal for Nektar. Beyond that, the company has additional pipeline programs that present significant market opportunities. To touch briefly on one, NKTR-102 (etirinotecan pegol) is a pegylated version of an older chemotherapy drug, Camptosar (irinotecan), which was a billion-dollar seller for Pfizer. Nektar has improved that product and given it about a three-week half-life instead of a multihour half-life. It is currently enrolling phase 3 trials in breast cancer. This is another billion-dollar opportunity for the company.

TLSR: Does Nektar own all of NKTR-102?

JL: Yes, it owns NKTR-102 outright. We would expect it to partner the drug once it gets phase 3 data. Nektar is also working on new pain drugs, inhalable antibiotics and a long-acting hemophilia drug. The company has a very diverse pipeline, and a lot of shots on goal. We are excited about it, especially with the OIC data coming later this year or early next year.

TLSR: What company would you like to talk about next?

JL: I mentioned Amarin earlier. The company is in the cardiovascular space, and is one of the few specialty pharma or biotech companies with an approved cardiovascular asset. That's part of what makes it extremely exciting.

The product is Vascepa (icosapent ethyl), and it was approved by the FDA on July 26. It is indicated to lower triglycerides in patients. Right now, most physicians focus on lowering bad cholesterol, or low-density lipoprotein (LDL). Vascepa targets another lipid, triglycerides, which are a huge problem. High triglycerides affect about 44M people in the U.S., so we are talking about a significant market opportunity.

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The only other approved drug in this class is Glaxo's Lovaza (omega-3-acid ethyl esters), in the omega-3 class of drugs and based on fish oil. Lovaza contains a combination of two omega-3s called DHA (docosahexaenoic acid) and EPA (eicosapentaenoic acid). The downside of having DHA in a drug is that while it does lower triglycerides, it can actually raise LDL cholesterol (LDL-C). In our view, that turns a lot of physicians, especially primary care physicians, away from using the product. They have been using statins for about 20 years, and they have been indoctrinated in the idea that LDL-C is the target of choice, because that's where all

the marketing dollars have been spent. Because Lovaza can raise LDL-C, a lot of primary care doctors haven't been using it.

Amarin's Vascepa is pure EPA, which lowers triglycerides but does not raise bad cholesterol. That will be a huge advantage in the market.

TLSR: Being pure EPA, why didn't Vascepa get new chemical entity (NCE) status from the FDA? That would give it more years of exclusivity.

JL: We are waiting on that decision now. We expect the designation by Aug. 17. The company has made arguments to the FDA explaining why it deserves NCE status. It's not cut-and-dry because Vascepa's active ingredient, EPA, is also one of the ingredients in Lovaza. But we expect it to end up with NCE status.

TLSR: What company would you like to speak about next?

JL: I'll touch on Acorda Therapeutics Inc. (ACOR:NASDAQ), a specialty pharma company with a market cap of nearly $900M. It markets one primary product, Ampyra (dalfampridine), which is approved to help patients with multiple sclerosis (MS) walk better. The product is on track to sell more than $250M in its second full year on the market. The drug is sold by Biogen Idec Inc. (BIIB:NASDAQ) in Europe, and it is doing extremely well there, picking up a lot of steam.

We view MS as an underserved market. One of the company's biggest advantages is that it can charge high prices for its drugs, due to the severity of that disease and because there is no cure for it. Anything that can help MS patients is in demand by both physicians and patients.

Acorda stock has had an overhang due to a post-approval trial that the company just reported. The trial compared the approved 10 milligram (mg) dose and a 5 mg dose, which previously had not been studied in a big trial. With that data now behind them, we think the stock could have a significant run in H2/12.

"Catalysts at the FDA have helped the biotech space perform well in recent months."

The company hopes to expand the Ampyra market out of MS, targeting several other diseases. In the near term the company is looking at the drug in stroke and cerebral palsy. That could multiply potential market penetration. We expect the cerebral palsy data at the end of 2012, and that indication could potentially double the market opportunity. We could see results from a stroke trial in early 2013. This, too, would be a huge indication for the drug. There will be a decent amount of data and a really good opportunity for Acorda's value to grow over the next 6–12 months.

TLSR: Jon, the cerebral palsy and post-stroke deficit indications are in phase 2 now. If the data are good, will the product still have to go through phase 3 trials for those indications, since it already has an approval for MS?

JL: Yes, the company will have to do larger trials for those indications. But in terms of value for Acorda, phase 2 is the big inflection point. Once it sees positive data, the market will give the company credit for a big portion of that. The phase 2 data is where big-value creation happens in biotech.

TLSR: Did you have one more company you could talk about?

JL: Neurocrine Biocciences (NBIX:NASDAQ) is another company that targets underserved diseases with huge potential markets. Its market cap is close to $500M, and it develops oral therapies. Its lead product is elagolix, which is

partnered with Abbott Laboratories (ABT:NYSE). The company has recently started a phase 3 trial for elagolix as a treatment for endometriosis, which is exciting because there are not any good, chronic, oral medications for this disease. Most drug treatments have lots of side effects, and the primary treatment is surgery. The unmet medical need affects almost 6M women in the U.S. If we look overseas, probably another 9M women in Europe and Eastern Europe also suffer from the disease. We think elagolix represents a $500M revenue opportunity at the least, and potentially more if the company can expand the therapy into uterine fibroids. It is currently running a phase 2 trial on that application, which is likely to be completed in the spring of 2013. Uterine fibroids are potentially an even bigger market than endometriosis. It's a huge, huge market.

TLSR: There is some indication that Neurocrine and partner Abbott may not release top-line results on the phase 2 trial for uterine fibroids. Are we going to miss an inflection point here?

JL: It is common practice that unless something out of the ordinary is seen, big pharma companies like Abbott do not release phase 2 data, even when trials are successful. This is partly for competitive reasons, but also because large-cap companies rarely consider phase 2 results material. We would get an indication that the phase 2 results are positive if a registrational trial starts immediately. That information would be available on the clinicaltrials.gov site.

Neurocrine's next product, NBI-98854, is a vesicular monoamine transporter 2 (VMAT2) inhibitor, and the company is starting a phase 2 trial for tardive dyskinesia, a permanent motor disorder caused by taking antipsychotic drugs. This is another completely underserved market. We think more than 400,000 people in the U.S. have some form of this disorder. It has been increasing in frequency as antipsychotic drugs are used more to treat depression, not just schizophrenia. We could have phase 2 data in Q1/13, a near-term catalyst for the stock. If those data are positive, it could move the stock fairly significantly. The product is currently not partnered.

TLSR: Is this a proof-of-concept trial?

JL: This will be the third trial with NBI-98854. The company did a phase 2 trial that had a hiccup when one of the trial sites didn't produce valid data because a lot of the patients enrolled shouldn't have qualified. Yes, it's still in that proof-of-concept phase.

TLSR: I presume that hiccup is the reason for Neurocrine's weak performance? The stock is down 24% over the last six months.

JL: Yes, recent underperformance was due to that glitch.

TLSR: Jon, I've enjoyed this very much.

JL: Good talking to you.

Jon LeCroy joined MKM Partners, based in Stamford, Conn., in June 2011 as an analyst covering the biotechnology/specialty pharmaceuticals sector. Dr. LeCroy previously covered the same sector at Hapoalim Securities USA, Natixis Bleichroeder and Goldman Sachs. He ranked #5 in this year's Wall Street Journal *"Best on the Street" poll in biotechnology. He holds a master's degree in business administration from Boston University's Graduate School of Management, a medical doctorate from the University of South Florida College of Medicine and a bachelor's degree in biology from Wake Forest University.*

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