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New Drugs, Deals Put Pharma Under Insider Trading Microscope

By **Liz Hoffman**

Law360, New York (November 20, 2012, 10:23 PM ET) -- Insider trading indictments this week involving Sanofi-Aventis, Stryker Corp. and Wyeth LLC underscore the need for tighter control of information in the pharmaceutical industry, where companies can live or die on a single clinical trial or drug approval and where a new wave of consolidation is driving high-stakes mergers.

On Tuesday, a former hedge fund portfolio manager was accused in New York federal court of earning a record $276 million by trading on unpublished results from a new Alzheimer's drug trial, gleaned from a doctor involved in the study.

On Monday, former executives from Sanofi-Aventis, Stryker and Celgene Corp. were among six people charged with using confidential information about potential acquisition targets to reap $1.4 million in illegal profits.

Attorneys say the two indictments, which follow similar troubles at Bristol-Myers Squibb Co. in August and Abbott Laboratories Inc. in September, highlight the perils of compliance in the life sciences field, where perhaps more than in any other, success is driven by discrete, closely held pieces of information.

Companies thrive or fail based on U.S. Food and Drug Administration approvals. A positive result in early experiments can generate takeover buzz, while a negative one is often a fatal hit. As the stakes get higher for clinical trials and regulatory approvals, the temptation to misuse information grows, said Jeff Kern, a white-collar expert at Sheppard Mullin Richter & Hampton LLP.

Since 2007, at least 72 people have been charged by prosecutors or sued by the SEC for pharmaceutical-related insider trading. That's more than in the technology industry, even accounting for the two dozen individuals pulled in by the Galleon Group case, according to a review of enforcement actions and FBI statistics.

“When you're looking for the next big miracle drug, there all these questions — does it work? Is it going to get approved?” Kern said. “The answers to those questions are worth millions and millions of dollars.”

And the process is prone to leaks. Clinical tests can drag on for years and involve several iterations as companies tweak formulas. Hundreds of people are involved in a trial, including scientists and lab staff, doctors and patients, vendor services, project managers, lawyers, marketers, lobbyists, lenders and business development staff.

“By necessity, a lot of people are privy to this information,” Kern said. “It's a wider circle than in other industries, and it's hard to keep information with that much buildup from leaking.”

Attorneys said watchdogs like the U.S. Securities and Exchange Commission and the Financial Industry Regulatory Authority will be looking closely at companies with drugs up for FDA approval in the coming weeks. Those include Dynavax Technologies Corp., a one-drug company looking to market a hepatitis vaccine; Theravance Inc., maker of a new pneumonia drug; and Biogen Idec Inc., which is awaiting approval for a multiple sclerosis drug.

“The SEC will be watching, FINRA will be watching and you have to think compliance departments at these companies will be watching,” Kern said.

Another factor that could be driving insider trades is the spike in pharmaceutical mergers and acquisitions activity. As patents on blockbuster drugs expire, pressures to keep growing have led companies like Novartis AG, Pfizer Inc. and GlaxoSmithKline PLC to sell off less profitable divisions like generics and nutrition and focus on acquiring late-stage research pipelines.

This summer, biotech deals hit their highest level in four years with a string of megadeals: GlaxoSmithKline PLC's $3 billion bid for Human Genome Sciences Inc., Bristol-Myers Squibb’s $5.3 billion offer for Amylin Pharmaceuticals Inc., AstraZeneca PLC's $1.26 billion purchase of Ardea Biosciences Inc., and a bidding war for ISTA Pharmaceuticals Inc.

And where transactions flourish, so do the opportunities to profit from nonpublic information, said Joanna Hendon, a partner at Spears & Imes LLP. A heads-up about an acquisition — and the per-share price, which creates an effective floor for the stock — is far more valuable than leaked information about a company’s earnings.

“The more M&A activity there is in an industry or sector, the more opportunities for insider trading will exist,” she said.

Acquisition information was at the heart of the New Jersey bust Monday, as well as the August indictment of a Bristol-Myers Squibb executive who allegedly used information he gleaned from a position on the company's internal M&A committee to bet on the shares of three potential takeover targets.

And recent revelations about insider trading related to Abbott’s $1.4 billion acquisition of Advanced Medical Optics, which closed in 2009, has come back to haunt the company. The SEC now says Advanced Medical CEO James Mazzo, who stayed on to run the business at Abbott, leaked information in advance of the merger that eventually made its way to investors, including baseball Hall of Famer Eddie Murray.

According to Kern, compliance staff at pharmaceutical companies face the same problem as their peers in other industries: Insider trading is almost impossible to prevent and tough to catch without law enforcement measures like subpoenas and, increasingly, technology like wiretaps.

“You can tell your employees what material nonpublic information is, but you can't keep them from sharing it,” he said.

--Editing by Kat Laskowski and Richard McVay.