

NEW BIOMEDICINE

RESEARCH

biotechnology research report

Big Troubles for Biotech and Big Pharma

Not just a Fat Issue.

Tickers	DNDN, GSK, VVUS, CELG	Updated:	07/19/2010
		By:	Michael Engmann

In the midst of the bearish direction of the market, the dark clouds continue to hover over equities in the biotech and pharma space. The past few weeks have produced a trifecta of major events, raising concerns greater than the traditional ones, and more than those surrounding intellectual property, improving the health of US citizens, and safety issues. It also appears to be about (guess what) money and politics.

The three recent developments surround **Dendreon (NASDAQ:DNDN)**, **GlaxoSmithKline (NYSE: GSK)** and **Vivus (NASDAQ: VVUS)**. The three have little in common, not size, intellectual property or target markets. But investors interested in long term wins in the sector need to evaluate more than ever whether the capital risk is worth the potential reward, We need to learn from what has happened to these three, and use the lesson as a guide to future investment actions.

The cases are:

1) **Dendreon (NASDAQ:DNDN)** won approval from the FDA in late May of this year for its first in class cancer vaccine, Provenge, for treatment of hormonally refractory metastatic prostate cancer. The stock had rallied to over \$50 per share in anticipation of the event, and then sold off. While investors and analysts considered the impact of the \$93,000 treatment and the ability of the company to ramp up production to achieve the predicted billion dollar drug it predicted, DNDN was blindsided by the U.S. Department of Health and Human Services Centers for Medicare and Medicaid Services (CMS) announced that it would undertake a prolonged review of the drug and its costs before approving payment for the treatment. Analysts and pundits hurriedly announced that this meant at least a year delay in approval for payment. The facts are that there will be a 30 day period for public comment, then perhaps a 60 day period for analysis, and then *as long as one year* before approving payment. The cynical might say that a few million letters, lobbying or a few afflicted members of Congress might make the CMS review period and approval for payment shorter; CMS did not seem to question the FDA decision. Just the costs. That is its job, and increasingly so as the budget deficit balloons.

Conclusion One: New and truly novel drugs that are expensive face an increasing barrier for successful adoption in to routine practice. Companies will need to not only prove safety and efficacy, but also in the ObamaCare environment, more rigorously establish that the cost-benefit analysis of the drug merits payment. To succeed, it will be more important to reduce costs of treatment than fulfill an unmet need, heretofore the Holy Grail and one of the beacons of medical research. Cost will count more than extending lives or lessening pain and suffering. It will be a form of rationing that has not been seen before in the US, more akin to Canada, the UK and other countries.

2) **GlaxoSmithKline (NYSE: GSK)** won and lost all the same day, when its billion-dollar diabetes drug, Avandia, was the subject of the FDA's peculiar announcement that it was reviewing the adverse effects of the previously approved drug, notably the incidence of adverse cardiac events and deaths. The FDA, former commissioners, the previous company CEO and others had all addressed this issue repeatedly since the drug was submitted for approval. The company announced simultaneously that it was settling the class action law suit brought against it related to the cardiac complications for almost half a billion dollars. (10,000 suits at \$46,000 per case).

NEW BIOMEDICINE RESEARCH

biotechnology research report

Conclusion Two: When is an FDA approval not an approval? When ObamaCare “reforms” sweep the country and all political appointees and others scurry to cut costs, and the litigation cloud is over corporations and physicians. Tort reform, no, but rationing, yes. Is this a question of safety, delayed scientific review and justice, or hastened backside covering and cost containment? The latter, it seems.

3) **Vivus (NASDAQ:VVUS)** shareholders jumped for joy (the stock rising from \$7 per share to over \$12 per share) when the news appeared to suggest that its obesity drug Qnexa would be approved based on its superior performance against other competitive drugs and placebos. The FDA Advisory Panel (not the FDA itself) voted 10-6 against recommending approval, citing potential side effects for the drug, not unlike those seen with the infamous fen-phen. One panelist cited birth defects as a potential risk. In the past, this might be a labeling issue, not necessarily grounds for disapproval, as with GSK’s Avandia. There were no actual birth defects in the pregnant women in the study group going to term, but the population appeared deemed too small to overcome the objections. Safety or nervousness over liability? Depression and suicide were also listed as risks, but again, there did not appear to be any suicides in the study group, despite the fact that there were patients in the trial with depression. The panelists are visible, named and they and the agency are at some degree of professional and political risk. Remember thalidomide? No obesity drug has been approved for over ten years.

On the other hand, Secretary of Health and Human Services Kathleen Sebelius stated on CBS Sunday morning on July 18th that combating obesity is a major emphasis of the administration; First Lady Obama is in the fight against childhood obesity. It is the second largest preventable cause of death in the US.

Does the panel’s vote mean Qnexa will not be approved by the FDA? Not necessarily. And VVUS has two or more years of cash on hand to continue the process. Longer studies, and more patients are likely needed. However, when the FDA reconvenes this fall they may approve Qnexa despite the panel’s recommendations. There is precedent for that. If approved will CMS and insurers pay for it? That is another story.

Conclusion Three: Social, political, economic and liability issues all are increasingly at play when a new drug is fortunate enough to make its way through Phase 3 trials, proving safety and efficacy on a limited basis. Then comes the advisory panel and the FDA approval. If the drug gets through those hurdles, can the company be certain CMS and private insurers will pay for it? This process will likely lengthen.

Biotech investing will become more treacherous, especially for those with a strategy of flash or momentum trading. Investors with a longer perspective, in the current environment, need to recognize and expect that the approval process will be extended. Achieving clinical acceptance and payment for the new drugs will be more costly, longer and even more arduous for companies than in the past. And it has never been fast or expeditious.

What companies can win? We believe in small and midcaps with unique, proprietary and game changing intellectual property, especially those with solid cash positions, realistic game plans, strong pharma partners, proven scientists and experienced management. These companies will be attractive acquisition candidates for Big Pharma.

Big Pharma? A bear case can be made for virtually all companies in the sector, especially those with expiring patents or shrinking pipelines. In the current environment, very few seem capable of increasing profits, and they will need to spend their cash acquiring the smaller companies developing the innovative products needed to fill out their pipelines. Internally developed product developments have

NEW BIOMEDICINE

R E S E A R C H

biotechnology research report

been disappointing in Big Pharma in recent years. They will overpay, and many have already, to acquire the new drugs they need. Celgene (NASDAQ: CELG) comes to mind.

Being anything but short Big Pharma seems unwise right now.

We will continue to carefully watch the events that unfold for the small and midcap biotech companies, and when they appear to be positioned to win FDA approvals and launch their new drugs, Big Pharma will be there to buy and partner with them. But the odds are increasingly stacked against them, even when they seem to do everything right, witness DNDN. It does, however, still seem worthy of a long-term buy position.

Financial Ratio for Companies Mentioned in this Report:

Dendreon Corporation (DNDN)	
Current price	\$31.29
52 wk range	\$21.25 - \$57.67
Market Cap (\$MM)	\$4,230.00
EPS (FY09)	-\$2.04
Revenue (\$MM) FY09	\$0.10
Cash per Share	\$5.34
P/E Ratio	N/A

VIVUS, Inc. (VVUS)	
Current price	\$5.41
52 wk range	\$4.90 - \$13.68
Market Cap (\$MM)	\$437.43
EPS (FY09)	-\$0.75
Revenue (\$MM) FY09	\$50.00
Cash per Share	\$2.84
P/E Ratio	N/A

Source: Revere Research.

GlaxoSmithKline plc (GSK)	
Current price	\$36.42
52 wk range	\$32.15 - \$43.47
Market Cap (\$MM)	\$94,560.00
EPS (FY09)	\$1.86
Revenue (\$MM) FY09	\$45,184.60
Cash per Share	N/A
P/E Ratio	11.00

Celgene Corporation (CELG)	
Current price	\$52.04
52 wk range	\$45.27 - \$65.79
Market Cap (\$MM)	\$23,980.00
EPS (FY09)	\$1.66
Revenue (\$MM) FY09	\$2,689.90
Cash per Share	\$6.41
P/E Ratio	28.27

Data as of July 16, 2010



NEW BIOMEDICINE

R E S E A R C H

biotechnology research report

Disclosures And Legal

New BioMedicine, LLC, is not a market maker and does not perform underwriting or manager services.

The information contained in this research is produced and copyrighted by New BioMedicine, LLC (New BioMedicine), and any unauthorized use, duplication, redistribution or disclosure is prohibited by law and can result in prosecution. New BioMedicine is not a registered broker dealer. The New BioMedicine trademark, service mark, and logo are the intellectual property of New BioMedicine. The opinions and information contained herein have been obtained or derived from sources believed to be reliable, but New BioMedicine makes no representation as to their timeliness, accuracy, or completeness. New BioMedicine shall accept no liability for any loss arising from the use of this report, nor shall New BioMedicine treat all recipients of this report as customers simply by virtue of their receipt of this material. Nothing in this report constitutes individual investment, tax, or legal advice. This report is not an offer to sell or a solicitation of an offer to buy any security.

The research provided herein should not be considered a complete analysis of every material fact regarding the companies, industries, or securities named above. New BioMedicine may issue or may have issued other reports that are inconsistent with or may reach different conclusions than those represented in this report, and all opinions are reflective of judgments made on the original date of publication. New BioMedicine is under no obligation to ensure that other reports are brought to the attention of any recipient of this report. New BioMedicine assumes no responsibility to update the information contained in this report.

This report is intended for investment professionals, others should seek competent professional investment advice in conjunction with this report before making any investment decision. The information and material presented in this report are for general information only and do not specifically address individual investment objectives, financial situations, or the particular needs of any specific person or entity who may receive this report. Investing in any security or investment strategies discussed may not be suitable for you and it is recommended that you consult an independent investment advisor. Investments involve risk and an investor may incur either profits or losses. Past performance should not be taken as an indication or guarantee of future performance. This report and supporting materials do not constitute an offer to sell or a solicitation of an offer to buy the securities of the companies mentioned in this report.

The analyst hereby certifies that the research conclusions, recommendations, and views contained herein accurately reflect his personal views about the industry, company, and securities that are the subject of this report and also hereby certifies that no part of his research compensation was, is, or will be directly or indirectly related to the specific recommendations or views contained in this report.



NEW BIOMEDICINE

R E S E A R C H

biotechnology research report

Specific disclosures for this report

Applicable to this Report	Potential Disclosure
N	New BioMedicine, LLC (New BioMedicine) makes markets in any securities and has managed or co-managed a public offering of securities for the subject company within the past 12 months.
N	New BioMedicine received compensation for investment banking services from the subject company within the past 12 months.
N	New BioMedicine expects to receive or intends to seek compensation for investment banking services from the subject company within the next 3 months.
Y	The research analyst or member of the research analyst's household has a financial interest in the securities of the subject company in the form of a (i) long position, (ii) short position, (iii) right, (iv) warrant, (v) future or, (vi) call option in such securities.
Y	New BioMedicine and or its officers or affiliates has a financial interest in the securities of the subject company in the form of a (i) long position, (ii) short position, (iii) right, (iv) warrant, (v) future or, (vi) call option in such securities.
N	The research analyst principally responsible for preparing the report received compensation based upon various factors, including New BioMedicine total revenue, a portion of which was generated by New BioMedicine's investment banking services.
N	The research analyst or a member of the analyst's household serves as an officer, director, or advisory board member of the subject company.
N	An affiliate of New BioMedicine may have a different view from the views expressed herein.
N	New BioMedicine and/or its affiliates beneficially own 1% or more of the subject company.
N	The subject company is a client of New BioMedicine or one of its affiliates.