PINK SHEET
CITELINE REGULATORY

01 Jan 2005 | **News**

Amgen: Portrait Of A Modern Major Pharma Company?

by The Pink Sheet

After reaching several corporate milestones in 2004, Amgen enters the New Year with two goals: preserving its entrepreneurial image as it joins the top tier of the pharma industry and putting the finishing touches on a growth plan that could reinvent the very model of big pharma

After reaching several corporate milestones in 2004, Amgen enters the New Year with two goals: preserving its entrepreneurial image as it joins the top tier of the pharma industry and putting the finishing touches on a growth plan that could reinvent the very model of big pharma.

Amgen has outgrown its role as a biotech bellwether stock and is now firmly ranked in the top 10 U.S. pharma companies. In fact, after a 3.8% gain in 2004, Amgen is valued by Wall Street at approximately $80 bil. That places it number five among pharmaceutical stocks, behind Pfizer, Johnson & Johnson, GlaxoSmithKline and Novartis.

Amgen now faces what may be its most difficult challenge yet: managing expectations for sustainable growth as it matures without surrendering its self-image as a "biotech rebel" taking on big pharma.

Amgen recorded several milestones in 2004 that reflect its new maturity, including crossing the $10 bil. annual sales threshold, joining the top 10 companies in U.S. pharmaceutical sales, and launching its first small molecule drug product - the hyperparathyroidism treatment *Sensipar* .

However, Amgen is not ready to surrender its biotech roots, as a *Forbes* magazine cover story celebrating Amgen's selection as company of the year makes clear. The headline is "The Biotech Rebel with a Blockbuster Future." Ironically, the value of Amgen's "biotech" roots may never be higher, now that the company is becoming less and less distinguishable from its big pharma peers in terms of size and product line.

Amgen's leap to the top tier of pharma market caps reflects its extraordinary underlying growth, from a sales base of $4 bil. in 2001 to over $10 bil. today, but it was helped along by a collapse in valuation for traditional pharma stocks.

In 2004, Amgen passed Lilly, AstraZeneca and Merck in market capitalization, though it remains well behind all three in sales and profits.

Merck is the poster child for why investors are wary of the big pharma model. The company's withdrawal of the COX-2 inhibitor *Vioxx* helped make 2004 a year to forget for the brand name industry. Merck was worth well over $100 bil. when the year began but shed more than 30% of its value to close the year with a market cap of just over $70 bil.

Nevertheless, Merck remains twice as big (and more than twice as profitable) as Amgen. The companies' relative values heading into 2005 suggest the weight given by investors to the downsides of Merck's product liability exposure and the upcoming *Zocor* patent expiration.

Merck was not alone in shedding value in 2004: the "F-D-C" Index of NYSE pharmaceutical stocks closed the year down 8.2% *(see chart: ""*[1] *The Pink Sheet' Index Of NYSE Pharmaceutical Stocks: 2004*"*)*.

Although 2004 may be a year to forget for most big pharma companies and their investors, there were several bright spots amidst the bad news *(see links to "*[2] *Stock Overview" and other Fairer Winds boxes)*.

Amgen's modest 3.8% increase looks strong by comparison to big pharma, but the company actually trailed the "F-D-C" Index of NASDAQ biopharmaceutical stocks, which gained 8.9% for the year.

The performance of most biotech stocks was even stronger, considering Amgen's disproportionate impact on the index. Amgen's market cap now exceeds that of the next nine largest independent biotechs combined (Biogen Idec, Gilead, Genzyme, MedImmune, Chiron, Sepracor, Millennium, Cephalon and Amylin).

The *Forbes* cover is part of a public relations effort by the company that included its first-ever New York City analysts meeting in January. The message: Amgen wants to use its unique background in biotech to define a new model for big pharma.

Amgen's business profile has several elements any pharma company would envy.

First and foremost, its products face no exposure to generics in the conventional sense. The company sells five billion-dollar-plus products and each is regulated as a biologic: *Epogen* , *Aranesp* , *Neupogen* , *Neulasta* and *Enbrel* .

Amgen will be at the forefront of the follow-on biologics debate, but even in the worst case scenario, the company is likely to face competition from non-interchangeable brands rather than the immediate and almost complete generic erosion typical for conventional pharmaceutical products.

During the Jan. 27 analysts meeting, Exec VP-Commercial Operations George Morrow underscored the value of the all-biologic product line when he showed a slide depicting Epogen's performance since it was launched in 1988.

He described Epogen's "beautiful growth curve," essentially a straight line from $0 in 1988 to in excess of $2.6 bil. in 2004. CEO Kevin Sharer "reminds me that we would like to see this for all of our products," Morrow observed. "We will try."

As the launch of Sensipar indicates, Amgen is no longer limited to biotechnology product opportunities. Although Sensipar is a modest-sized opportunity, Sharer believes that the company's investment in small molecule research capacity over the past decade has paid off.

Amgen "can compete with any other company on a project-by-project basis in the small molecule world," Sharer told a medical innovation conference sponsored by the Cleveland Clinic in October. With Amgen's existing base in biotechnology, "we don't have to fit the target to our modality. We fit the modality to the target."

Amgen also has a cost structure that most pharma companies (and their investors) view with envy.

As a relatively young company, Amgen does not have a large portfolio of legacy products (the so-called "tail" drugs) that require most big companies to maintain relatively large, low-margin manufacturing infrastructures.

Amgen has also built its business to the $10 bil. level without investing in a large primary care sales force.

As a result, its SG&A spending consumes a markedly smaller percentage of sales than most pharma companies. In 2004, Amgen's SG&A line was 24% of sales. Most big pharma companies spend closer to a third of sales on SG&A.

Amgen is closer to spending parity between the SG&A function and R&D, with 19% of sales devoted to research. Other big pharma companies typically spend closer to 15% of sales on R&D.

With a total headcount of just 13,000, Amgen's employee base is smaller than the sales organizations of other big pharma companies.

That translates into a significantly more efficient company as measured by sales and profits per employee. Amgen generates about $800,000 in revenue per employee, compared to about $400,000 for Pfizer, Merck and J&J. Looking at net income, Amgen reported about $180,000 per employee, compared to less than $100,000 for the other firms.

Amgen's next big test may be proving that it can move into primary care markets without sacrificing its lean organization.

Amgen has two late-stage development projects that could be its first full-scale entrants into the primary care market.

Amgen's highest profile R&D effort is the bone resorption inhibitor AMG 162, which is undergoing an extensive *Phase III* program. During the January analysts briefing, Morrow noted that the combined patient population for all the indications under study for AMG 162 is nearly 50 mil. people in the U.S.

Morrow, who joined Amgen in 2001 from GlaxoSmithKline, pointedly described the research program "as one that I am more excited about than any other product I've ever been associated with in my career."

Amgen will not follow the conventional approach when launching the product. "We can do it without using the pharma model," Morrow declared. He questioned the "conventional pharma wisdom of 2,000 reps and carpet bombing the GP audience and spending $400-$500 mil." to support a launch.

"We don't have everything totally worked out right now, but I am convinced that we can do that much more effectively and much more efficiently than what you would see in a typical large pharma company," he said.

If AMG 162 does successfully complete development and enters the market in the next two or

PINK SHEET
CITELINE REGULATORY

three years (Amgen is being deliberately vague about potential launch timing), the launch could be a milestone event for the entire pharma industry.

The sustainability of large field forces is one of the big questions facing pharma companies heading into 2005. More and more companies appear to see a quandary: concluding that sales and marketing spending is too high but not wanting to be first to make cuts ([3] (Also see "*Industry Cost Structure Must Change, But Will Not Start At AstraZeneca – CEO*" - Pink Sheet, 31 Jan, 2005.), p. 9).

However, companies like Amgen and Roche (which shed most of its primary care sales force at the start of the decade) are now talking about the absence of a field force as a competitive advantage ([4] (Also see "*Roche Vision Of Rx Future Includes IT And China, But Not Large Sales Force*" - Pink Sheet, 31 Jan, 2005.), p. 10).

Amgen is more quietly moving towards the primary care market from a different direction: the company is conducting clinical trials to demonstrate the value of anemia therapy in chronic kidney disease and congestive heart failure patients.

Successful trials will "take us into the primary care setting" with Aranesp, Morrow said.

If Amgen is successful in implementing a new sales model for Aranesp or AMG 162, it could have a ripple effect on other big pharma companies who are drafting restructuring plans but are wary of being the first to move.

Another unique feature of Amgen's profile that may serve the company well in coming years is its long and deep familiarity with the Medicare system.

During the Cleveland Clinic conference, Sharer noted the increasing pressure on pricing in the pharmaceutical sector, but suggested that "for Amgen, I don't think it will matter an enormous amount."

"For Amgen, we are essentially totally in the price control market now. We are there. We've been there for a long, long time."

During the January analysts meeting, Amgen was less explicit about that element of its business, but fully half of Morrow's presentation - including discussion of individual product performance - focused on the Medicare reimbursement climate.

Amgen's exposure to the Medicare market is one of the near term challenges facing the company as it tries to navigate the payment changes under Part B in 2005. Most manufacturers are more focused on the start-up of the Part D benefit in 2006.

Amgen faces other challenges as well. The company is still overwhelmingly a U.S. business, with over 80% of product sales in the domestic market.

And, despite its rapid growth in the first half of the decade, Amgen remains less than a quarter the size of the number one pharma company (Pfizer) and its favorite rival (J&J).

At $10 bil., Amgen's entire business is smaller than Pfizer's *Lipitor* franchise.

Those numbers suggest the size of the challenges ahead for Amgen - and the potential consequences if the company's attempt to define a new big pharma model fails.

- *Michael McCaughan, Lee Kalowski*

Fairer Winds For Pharma?

[5] *Fairer Winds: J&J Guidant Acquisition Caps Off Strong Year*

[6] *Fairer Winds: Elan Approval Gives 'Product Story' New Meaning*

[7] *Fairer Winds: OSI Banner Year Fueled by Tarceva Approval, Iressa News*

[8] *Fairer Winds: Ventiv Impresses As Sales Contracter*

[9] *Fairer Winds: Wholesalers See Sunnier Skies After Summer Storms*