BUSINESS

Anaemic outlook for Amgen

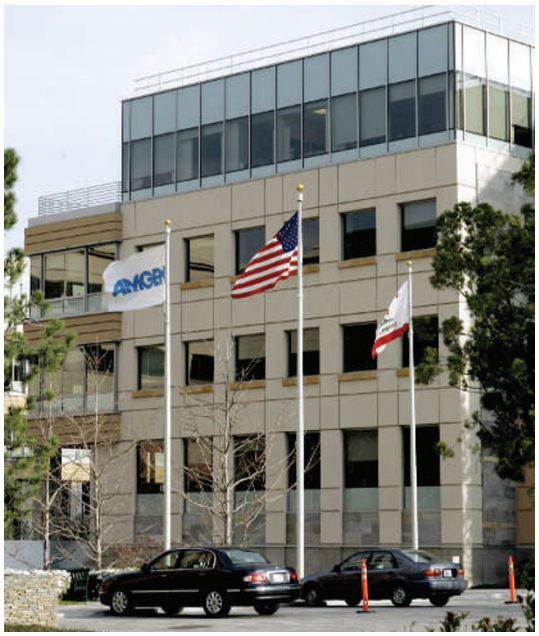
A rash of problems has knocked some of the shine off one of the world's top biotechnology companies, as **Meredith Wadman** reports.

April may have been T. S. Eliot's cruellest month, but for Amgen, it was nothing to May. Last month, the company whose name is synonymous with biotechnology success took an unprecedented battering.

The setbacks centred on safety and pricing concerns about Epogen and Aranesp, Amgen's prized pair of anti-anaemia drugs. And they had analysts predicting that the glory days of the Thousand Oaks, California, company in that lucrative market could be gone for good.

"Amgen is a company that's facing significant hurdles at the moment," says Peter Knight, an analyst with Wood Mackenzie, a life-sciences consulting firm based in Edinburgh, UK. However, he adds: "It's easy to paint a very bleak picture and that's probably not very accurate," arguing that Amgen will continue to dominate anaemia drug treatment in the United States.

Others are less sanguine. "They can't even think about the anti-anaemia market coming back," says William Tanner, an analyst at Leerink Swann, an investment bank based in Boston, Massachusetts. "It's going to be a ghost of its former self."



R. SAXON/AP

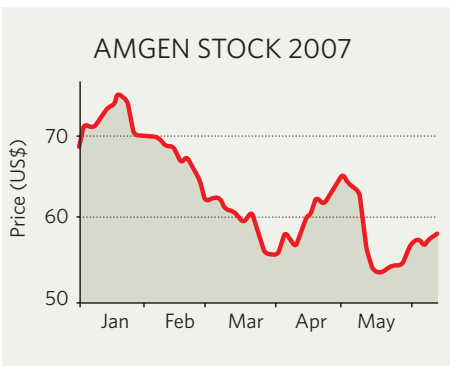
Under siege: problems mount at Thousand Oaks.

Epogen and Aranesp generated $6.6 billion of Amgen's $14.3-billion global revenue last year, while the company's drug pipeline is somewhat anaemic itself, with only one potential blockbuster, osteoporosis medication denosumab, in late-stage trials. "The great thing about denosumab is that it is arguably the best asset in the collective biotechnology–pharmaceutical pipeline," says Mark Schoenebaum of Bear Stearns, a New York broker. "The bad thing is it's all that Amgen has in its late-stage pipeline right now of commercial significance."

Amgen is seeking to rectify that. Earlier this month, it paid $300 million to buy Alantos Pharmaceuticals, a diabetes-drug company based in Cambridge, Massachusetts, and $420 million for Ilypsa, a kidney-drug company in Santa Clara, California, whose leading drug candidate would complement Amgen's anaemia remedies in patients with kidney failure.

The two anaemia drugs have all but defined Amgen — and the anaemia market — since Epogen became the company's first marketed drug in 1989. Aranesp, a longer-lasting version of the same genetically engineered, blood-boosting protein, went on sale in 2001, aimed at anaemia caused by cancer chemotherapy. Its sales in particular have driven Amgen's growth since, leaping by 26% in 2006, when total company sales grew by 15%.

But in January, the company announced that cancer patients receiving Aranesp in a clinical trial were more likely to die than those on placebo. Then in February, it emerged that a Danish trial of Aranesp in people receiving radiation for head and neck cancer had been stopped after more deaths and cancer recurrences occurred in the Aranesp-treated group. Amgen had not publicized this news, and the matter is now being investigated by the Securities and Exchange Commission.



The US Food and Drug Administration (FDA) took action in March, slapping a 'black box' warning on both drugs, urging that they be prescribed at the lowest possible doses. On 10 May, a committee of FDA advisors went further, recommending limits on Aranesp's use in cancer patients. The FDA is not bound to follow the advice of its external advisors, but it usually does.

Last month's troubles worsened on 14 May, when Medicare, the US government health programme for the elderly, proposed severely limiting reimbursement for the anaemia drugs when used in cancer. This proposal — which may still be modified — provoked loud complaints from oncologists and Amgen's retort that it is "not supported by scientific evidence". The company has a huge amount riding on the final Medicare ruling, which is expected by September — especially since private insurers often follow Medicare's lead.

Then it emerged that the New York state attorney-general had subpoenaed the company, demanding documents on its activities in drug marketing, pricing and promotion. Amgen received the subpoena the day after *The New York Times* reported that some physicians have profited richly by prescribing Amgen's drugs to Medicare patients.

The damage to sales of Amgen's two blockbuster anaemia drugs cannot be gauged until July, when the company will release its second-quarter results. Analysts have downgraded the stock, however, and the company lost $9 billion in market value during May, on top of similar losses earlier in the year (see graph).

Company officials declined to comment in detail, instead reiterating public statements emphasizing Amgen's commitment to safety and defending the current use and pricing of its drugs. Chief executive Kevin Sharer, for example, has asserted that many hundreds of thousands of patients who could benefit from Amgen's anaemia drugs are not receiving them — and pointed out that the price of Aranesp has fallen by one-third since it was introduced.

The company's travails have also served to remind the markets of the inherently high risks of the biotech sector, analysts say. "We're not talking about Pfizer, with 50 products in its portfolio," says Knight. "Biotechnology companies are vulnerable to disastrous events in one or a small number of their drugs." ■