



# **Amgen comes out of the closet**

**Bem 106 Final Paper**

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On March 23<sup>rd</sup>, 2004, Amgen held its first Research and Development day (R&D day) and revealed 24 ongoing programs that were in clinical studies or about to enter clinical studies. Without the accurate knowledge of the consequences, Amgen took a large risk in holding R&D day, which would to some extent “open the secret curtain” to the public and rivals. Amgen pursued such a strategy to attract more investment, build credibility for the new management team, and to play positioning and signaling game with its rivals in the biotechnology industry. A strategy analysis on the past history and current state of Amgen reveals that holding the R&D day was indeed a good decision that could help Amgen sustain its strong growth into the future.

## **THE BIOTECHNOLOGY INDUSTRY**

The race to discover new “biotech” drugs began in 1973 when Stanley Cohen and Herbert Boyer introduced recombinant DNA technology. Thirty years later the industry has a market capitalization of over \$189B with sales of \$24B in the US alone. The structure of the industry is quite unique and largely defined by the nature of its scientific work. Many of the drugs coming out of biotech are truly life changing for their recipients and combined with a patent can provide instant stardom and billions of dollars of sales. Many biotech companies are founded on the hope that their research idea will become the next big blockbuster drug, and investors have proven they are willing to bet on it.

In 2002, there were 1466 firms in the industry with 318 of them publicly traded. The public companies accounted for over 90% of product sales. This reveals two classes of biotech companies. There are those that have products on the market, growth in sales, and strong research and development programs. Yet the majority is in the second class with no products out and is trying to struggle through the clinical setbacks while quickly burning through their remaining cash, driven by the huge rewards that might lie ahead of them. The probabilistic nature of the drug discovery process leads most biotech companies to labor for years without turning a profit, and many never do.

The industry cherishes “blockbuster drugs”, those that have generated over one billion in sales, and the facts are that only 9 biotech drugs have been elevated into this class. The average market cap of the top five companies is over three times that of the

next five. This paints an even more staggered picture of the industry, with a select few firms towering over the rest.

### **THE DIRECTION OF THE INDUSTRY**

The industry has steadily become more and more defragmented with time. Can it sustain this trend? Large companies have some significant advantages and can run more efficiently. They have a centralized research department, which allows for shared knowledge and physical assets. Overhead costs for administration per researcher is somewhat decreased. There are inherent risks in research, and a large company with a lot of capital can afford to try for riskier drugs, and support the setbacks that might occur along the way without busting the bank. In addition, large companies already have set up distribution channels and have the experience to go along with it. With their distribution advantage, small companies can be bought for a profit, although this practice alone is probably not enough to fully support a large company.

Yet small companies do have one crucial advantage. The best and most creative researchers often want to work in a small company where they are given more freedom and have a larger stack in the success of the company. For big companies to survive, they still must produce profitable drugs, and skill is often an important aspect of this process. Without the best researchers, large companies could potentially fizzle out after the patents on the drug that made them rich expire. Thus a likely direction for the industry is that it will continue to be populated both by a few large companies and many small startups that continue to appear at regular intervals.

### **AMGEN**

Amgen is biotech's largest firm. It was started 24 years ago and rose to the top by the success of two blockbuster drugs, Epogen and Neupogen. To many industry experts, Amgen has matured into a role that larger traditional pharmaceutical companies find themselves in. Their strategy is to purchase smaller companies late in the drug development process and use their expertise in marketing and sales to generate more value than was paid for the company. All of Amgen's large-scale products that it is currently selling, except for the original two, have been acquired through purchases.

These purchases have generated headline; most recently they placed a bid for Tularik for \$1.3B, and in 2002 Immunex was purchased for an industry high \$16B to get the drug Enbrel, used to treat rheumatoid arthritis. These actions placed Amgen in the habit of acquiring smaller companies in the industry.

Investors have been wary of Amgen's future profits, because even though the company is making some money on top of the purchase price of its acquisitions, the amount will not be sufficient to replace the lost revenues once the patents expire on their current drugs. The real moneymakers are new drugs taken internally from an early stage to a product. Amgen, like all biotech firms, spends huge sums of money on its R&D programs, in hopes of finding the next blockbuster. The company has traditionally kept its research pipeline secret, instead trying to convince investors of future profits with its current profits and some vague graphs. Investors are worried that a large corporate environment is not the ideal place for the highly creative work of the best scientists, as evidenced by the pharmaceutical industry.

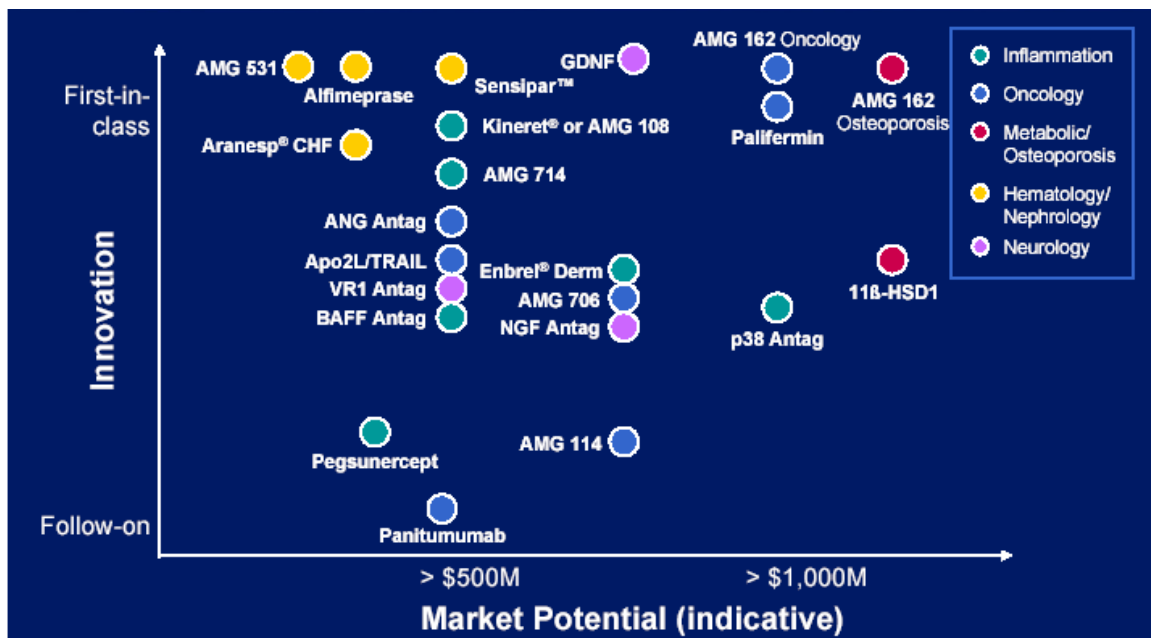
#### **RESEARCH AND DEVELOPMENT DAY - MARCH, 2004**

In order to remove the worries, Amgen announced its first "Research and Development" day. Amgen tried to change people's impression that it lacked creativity and R&D to support future development, and was in fact striving to discover therapies in areas that no effective treatment currently exists. In addition, the company assured investors of a promising compound annual growth rate of 30-32 percent in product sales and a growth rate of 25-27 percent in adjusted earnings per share.

On R&D day, Amgen invited investors to attend meetings to discuss the pipeline. The five principle research fields that Amgen focused on were inflammation, oncology, metabolic disease and osteoporosis, hematology and nephrology, and neurology. The designs of these programs followed four guiding principles: "focus on grievous illness; be modality independent; understand efficacy in patients earlier; and ensure seamless integration from basic research though commercialization." In order to convince the investors that it was able to sustain the strong growth, Amgen gave technical information about its innovative programs and evaluated each drug's commercial potential

individually. For every drug program, Amgen used professional terminologies to explain the basic biological principles, pathways and mechanisms behind the program thoroughly and the effects they expected on patients. Amgen put its emphasis on commercialization; maximizing the profit is its ultimate goal. A successful drug relies heavily on the commercialization process, therefore creating a set of commercialization strategies that fit the organization was crucial and R&D day was the first step to initiate this prolonged process.

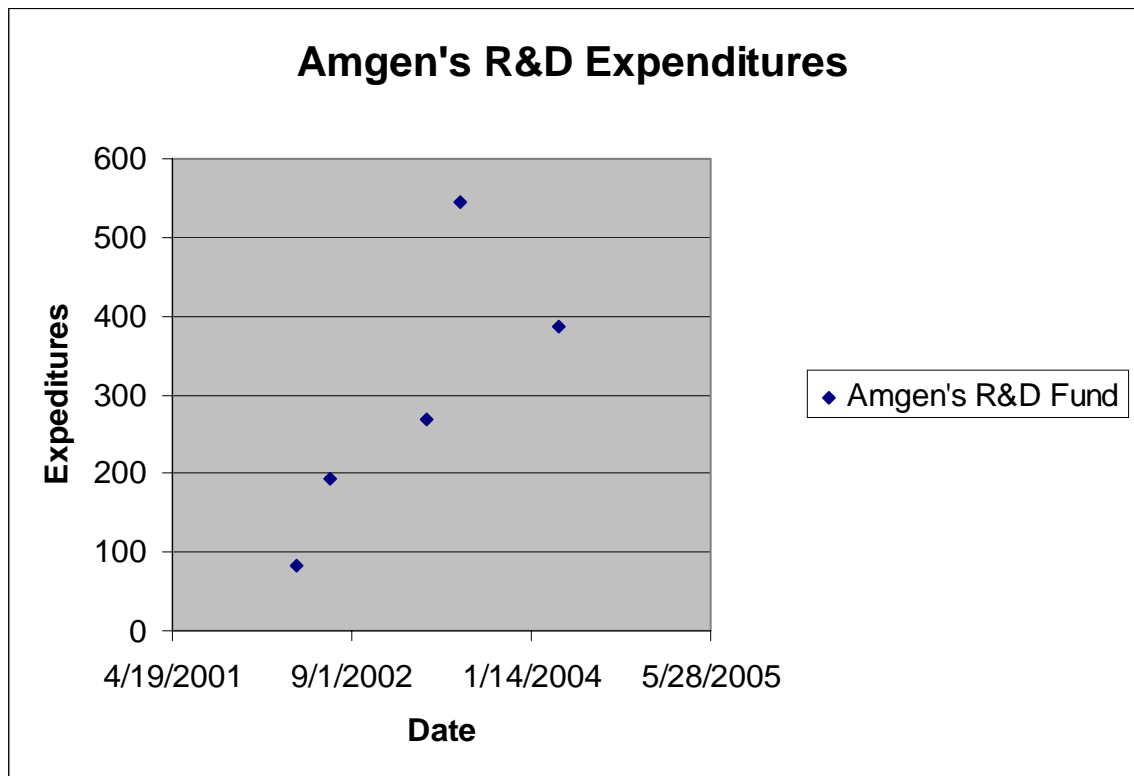
It was estimated that 13 of Amgen’s drug programs could have a market potential greater than 500 million dollars and 5 of them greater than 1 billion. This suggests that most of the Amgen products will become future blockbuster drugs in the market if they were successfully developed. One of the best examples to illustrate the innovation of Amgen was the development of metabolic disease and osteoporosis drugs such as AMG 162. AMG 162, a human monoclonal antibody, is the key to develop an effective osteoporosis drug that has an undeveloped market of 4 billion patients. There are no effective treatments existing at the moment. The clinical studies of AMG 162 had entered phase 3, which hinted a very good probability of successfully developing an effective osteoporosis drug.



*Exhibition 1.* Amgen’s Pipeline reflects their innovation and what they think will be blockbuster drugs

## INCREASED INVESTMENT

The most direct reason Amgen had R&D day was to increase investment. One of the ways it accomplished this was by establishing a strong pipeline, both through product space and through time. Amgen attempted to overcome the fear that it will not be able to produce its own blockbuster again by disclosing information about an impressive number of drugs, 24 the 40 drugs it will heavily invest in. Each one of these 24 drugs has some large probability of failing, but their joint probability is much lower. An ambitious investor can then calculate the expected number of successful drugs and by extension some rough estimate on his expected return and its variance. Before R&D day, less information was available, so the variance in the expected return must have been higher. Amgen is betting that investors will now estimate a higher expected return with lower variance than they did before, which would lead to increased investments.



*Exhibition 2.* Amgen's Research and Development Expenditures

## **DIVERSIFICATION**

Amgen could further signal to investors future success as it revealed that its research programs are spread throughout product space, both in the kinds of drugs used and in their application. Amgen has primarily dealt with large molecules but recently expanded into antibodies and small molecules. (Add slide) These new avenues are used in the pharmaceutical industry, but it was unknown how well Amgen could adopt the technologies. R&D day was a chance for Amgen to show off how well it had proceeded in these endeavors. Also, for some of the powerful molecules, more than one program was designed to develop drugs of different effects that use different mechanisms or pathways of the same molecule. Amgen told investors that it not only tried to develop the best drug with minimum side effects, but also strived to find drugs for diseases with a large number of patients who had suffered from a lack of effective treatments. In this way, Amgen shrewdly told investors that it is spending its research funds in ways that could provide large returns. Another advantage of research diversification is that certain diseases might prove to be too difficult or simply not admit a drug that can pass FDA approval, no matter how lucky researchers are. For this reason, and also to prevent competition among Amgen's own drugs, spending time on diverse research provides optimal chances of future profits.

## **THE PRODUCT DEVELOPMENT TIMELINE**

Amgen released a well-defined schedule for the progress of each program at the meeting. Most of the drugs that Amgen advertised were projected to finish clinical stage in either 2004 or 2005, which would be expected to be available soon once the approval of safety was granted by the FDA. One of the effects was to show investors that profitable drugs could be produced soon and that a steady stream of candidate drugs will mature. This is important because otherwise investors would put their money in other places until it looked like Amgen was going to test more drugs.

## **INCREASED CASH FLOW**

If Amgen did not have a R&D day, the volume of investments would stay approximately the same, if it was not worse due to the lost of faith in the company. Yet lack of increase in investment could be bad news for a large fast growing biotech company like Amgen, which might be hindered from developing innovative programs with great market potential if it ran into problem of funding shortage. Holding a Research and Development day is the next best alternative available to Amgen, and an effective way to attract attentions from the investors. If investors like the drugs that Amgen reveals, more cash flow will be generated for Amgen, further indicating higher confidence. If a drug revealed on R&D day that seemed likely to hit big would raise the stock price immediately and attract investment in that drug right after the seminar. At the time of its actual release, even though the investors might not be surprised, Amgen would already have benefited from the good prospects. Compared to a soar in the stock price in response to the release of a surprising blockbuster drug, revealing a great pipeline in advance would give Amgen a big boost to its value only after a long period of time. Considering the basic principle of getting more pleasure out of spending today rather than tomorrow, it would then be economically wise for Amgen to acquire funds today through R&D day rather than later through profits from a drug.

## **ESTABLISHING CREDABILITY**

Many investors were concerned about recent reforms in the Amgen management team. The Research and Development day was the good opportunity for the new management team to indicate its capabilities and earn trust. To this end, Amgen's management "opened their books" for review to the public. Recent scandals with Enron and WorldCom introduced great amounts of distrust from investors in large companies. In post-Enron thinking, Amgen's traditional secrecy could be viewed as a cover up and suggest that Amgen does not in fact have a strong pipeline. Since Amgen investors had little or no notion of the pipeline drugs that they were investing in, they might now want to redirect funds into a more overt industry where they could determine upfront the



worthiness of their investments. R&D Day was a strong move to suppress these thoughts and secure the investors loyalty.

### **THE CONSERVATIVE NATURE OF R&D DAY**

An interesting point is that Amgen was actually very conservative in releasing its drug information; it was not nearly as secretive or informative as it first appeared to be. The molecular biology and biochemistry claimed as the basis behind the drugs were simple pathways familiar to first year biology students. Amgen did not release much more detailed information than the general area of research in which they were working. The purpose of this move is two fold. First Amgen needed to pick a position between giving away too much information so that a rival could steal the idea and too little information for investors to define each drug and assess it's potential market value. Amgen's goal was to find the optimal spot between the two. It clearly made the released information vague enough to restrict idea theft, and was left with the problem of convincing investors about the worth of the drug. The solution was to devote about half of R&D day to promoting it's own assessment of the potential value of each drug.

Amgen's other purpose in being conservative could have been to use their first R&D day to "test the water" for future R&D days. Most of the drugs that Amgen advertised were projected to finish their clinical stage in either in 2004 or 2005, and Amgen did not mention very much about its R&D beyond next year. Amgen certainly did not know how investors would react to R&D day, and thus releasing a conservative amount of information would decrease the deviation of the investor's response, and allow for a post R&D day analysis without the potential of making a large error.

### **TIME POSITIONING AND SIGNALING**

Besides attracting investment, Amgen's other main goal of R&D day was to play signaling and positioning games with its rivals. Amgen used its announcement of how far away it is from completing each of its drugs to start a chain reaction, which will allow it to gain information from its rivals. The intended situation is for rival companies who

may be working a similar drug. Once investors in the rival see that they will be competing against Amgen, they will probably force the rival to reveal where it is in the development process. Amgen can then respond.

<i>Rival's position</i>	<i>Rival's Responses</i>	<i>Amgen's gain</i>
<b>Behind in Development</b>	<b>Quit</b> - Amgen's resources are larger, and the rival might feel they have no chance	Amgen loses a weak competitor, increases the odds the drug will be finished first in the industry
	<b>Merge</b> - The rival attempts to merge with Amgen	Amgen is not likely to do this unless for a very low price
	<b>Continue</b> - unlikely, but rival may feel it can still beat Amgen	Amgen may gain investors from rival, and will accelerate development to insure they are first
<b>The same point in Development</b>	<b>Quit</b> - Rival does not think it can beat Amgen	Amgen loses a moderate competitor
	<b>Merge</b> - The rival feels like Amgen might overrun them and tries to cut its loses	Amgen may be able to negotiate a good price for important technology
	<b>Continue</b> - The rival thinks it can beat Amgen in a footrace with superior technology or people, not funding	Amgen has the option of increasing funding to try an accelerate development
<b>Ahead in Development</b>	<b>Quit</b> – Unlikely	Amgen loses a strong competitor
	<b>Merge</b> - Perhaps Amgen initiated, the rival will command a large sum	Amgen could gain very valuable intellectual property and use its distribution advantages to make money
	<b>Continue</b> - The rival thinks it will develop the drug first	Amgen will learn that another company is ahead, and then has the option to back down on it's own development if desired

**P38**

P38 is a small molecule that is in big news because of the formidable competition between the two giants, Amgen and Johnson & Johnson, both in search for an effective

drug using this molecule. P38, an enzyme, was believed to be responsible for touching off several inflammatory signals. J&J acquired Scio Inc., a small company that had a P38 drug in Phase 2 of clinical trial, with \$2.4 billion last year, expecting to replace Amgen's next blockbuster Enbrel with a more powerful P38 drug. On the Research and Development day, in order to protect Enbrel, Amgen revealed that its own P38 drug had completed Phase 1 trial. Even though it was well behind J&J, it sent a signal that it was ready to compete, and that Amgen thought it might have a chance to catch up with J&J. In addition, it was possible that Amgen aimed at developing a better P38 drug with fewer side effects and more functions instead of focusing on the progress alone. The strong reaction from Amgen also showed its fighting spirit to maintain the advantages it had earned in certain area.



*Exhibition 3.* Amgen's product strategy teams.

## CONCLUSIONS

Based on this analysis of Amgen R&D day, we can conclude that it was a strong move. If investors like what they see in the pipeline, Amgen will attract more investment. At the very least R&D day will have built credibility for the new management and provided industry signals that Amgen can use for its own advantage.

A brief look that Amgen's relative industry performance around this event showed small changes in the market cap. Although stock prices have dropped slightly for Amgen by 3.8%, the change is not significant taking into account of the overall decrease of the market. The success of Research and Development day was masked by simple fluctuations in the marketplace. Nevertheless, all the reasons Amgen had supported a Research and Development day and now is in fact too close to the event to decisively pinpoint what the results would be. However, if similar situations were to occur, holding a Research and Development day would indeed increase investor's confidence in Amgen and conservative revealing of its position would signal to other investors as well as rivalries the advanced phases the company is currently in.

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