R&D VALUATION AND STOCK-MARKET REACTIONS TO PRODUCT INNOVATIONS

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EVIDENCE FROM THE PHARMACEUTICAL AND BIOTECH INDUSTRY

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Abstract

R&D investment became an important value driver in modern economies. Yet little is known about the way R&D creates value. The absence of reliable information creates uncertainty and asymmetric information which complicate valuation-procedures. To close this gap, I investigate the relationship between innovation progress and R&D valuation. Event-study and regression analyses are used to examine the stock reaction to R&D progress announcements of German biotech and pharma firms. The results indicate that investors account for non-financial disclosures to reduce the information asymmetry. Additionally, investors perceive an announcement to have a value impact when it marks nearly complete reduction of uncertainty.

JEL-Classification*:* G14; G30; M21

Keywords*:* R&D, valuation, capital markets, information asymmetries, uncertainty, event study, cross-sectional regression, non-financial disclosures, biotechnology, pharmaceutical

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1 Introduction

Modern economies are characterized by a science- and knowledge-orientated shift (e.g., Grossman and Helpman (1995)). Research and technology intensive industries constitute a rising part of total economic activity. Firms depend increasingly on their 'stock of knowledge' to ensure competitiveness and future expected benefits. As a consequence, an increasing proportion of firm value stems from future expected benefits of intangible assets. R&D projects, in particular, constitute a predominant part of these intangibles and represent a key productive input for many firms. The magnitude of R&D grew substantially over time. In 2008, worldwide corporate R&D investments increased at an annual rate of 9 percent.[1] The growth rate continued at high levels compared to 10 percent and 7 percent in previous years. In absolute terms, more than €380 billion was spent on R&D projects in 2008. The towering level of investment underlines the predominance of R&D in modern economies and emphasizes the provision for R&D investments in assessing the company value (e.g., Griliches (1981)).

Despite the growing importance of R&D for companies, we know few about the way R&D projects actually create value. The channels which markets adopt to value R&D investments and incorporate R&D related information are largely unexplored. Especially the question how R&D progress is transmitted into stock prices remains unsolved. Information on the progress of R&D projects provides valuable insights on the feasibility and duration of the project. Therefore, progress announcements are important in assessing the value of R&D investments (e.g., Fama (1991)).

However, R&D progress is a complex procedure and worsened by lacking disposable and reliable information. It creates vast valuation uncertainty and asymmetric information problems (e.g., Aboody and Lev (2000), Oriani and Sobrero (2003)). Thus, the question remains how investors deal with this challenge and how capital markets incorporate information on intangible R&D investments.

To shed light on these puzzling issues, I analyze the stock market reactions to non-financial R&D progress announcements in the biotech and pharma industry. In contrast to the overwhelming part of the existing literature that examines value effects of R&D related financials (e.g., Chan et al., 1990; Chan et al. 2001; Eberhart et al. 2004) I concentrate on the impact of non-financial R&D progress disclosures on the market value of the firm. Focusing on R&D undertaken in the biotechnology and pharmaceutical industry I assess the stock price movements corresponding to sequential drug trial outcomes. The sample comprises related announcements of German biotech and pharma firms for the period between 2000 and 2008. I selected the biotech and pharma sector, first because biotech and pharma companies invest heavily in R&D as their predominant value driver. In 2008, 19.2 per-

[1] The statistical data in this paragraph are drawn from "The 2008 EU industrial R&D Investment SCOREBOARD". It provides information on the 1000 European and 1000 Non-European companies investing the largest sums in R&D. The report is monitored and guided by the European Commission. It can be obtained from the European Commission Joint Research Centre or at http://iri.jrc.ec.europa.eu/research/scoreboard_2008.htm.

cent of total R&D investments are attributable to the biotech and pharma sector making it by far the most R&D-intensive industry. In absolute terms, the sector spent more than €72 billion on R&D projects. Over the past three years the R&D investments grew at a compound annual growth rate of 13.2 percent. Due to the vast R&D dependency we could expect noticeable market reactions to non-financial R&D announcements. Second, R&D in the biotech and pharma industry transfers directly in the drug development process. The drug development process, however, is divided into clearly separated but highly sequential stages (e.g., Schwarz (2005)). The chronological character of R&D in biotech and pharma companies allows for testing how markets react to R&D progress. Third, focusing on only one industry, namely the biotech and pharma sector, prevents my results from being derogated by any inter-industry effects.

The findings indicate that investors incorporate non-financial disclosures in their valuation of R&D investments. Stock prices react significantly when such information is released. Investors seek non-financial disclosures about R&D progress as an additional source for valuing R&D investments.

The results also reveal how investors cope with the complexity of R&D investments when R&D projects are valued. Investors are reluctant to R&D-related uncertainty. Stock reactions are most pronounced for development stages that are characterized be low uncertainty - namely patent granting and receiving marketing approval. Information on interim results is associated with vast uncertainty. Therefore, interim information is marked by a heavy valuation discount and shows the smallest magnitude in price reactions.

The study increases our understanding of how R&D value is created and uncertainty about the firm's future prospects is sequentially transmitted into stock prices. It provides a linkage between R&D progress and market valuation. Implications can be deduced for investment purposes and the communication practices between firm managers and outside investors.

The remaining part of the paper is structured as follows. In section 2, I give an institutional description and a theoretical consideration about valuation problems related to uncertainty and asymmetric information. Then, testable hypotheses about the market reaction to R&D progress announcements are derived. Section 3 describes the empirical research setting. I explain the sample selection and research methodology used. In section 4, the empirical results are presented and discussed. Section 5 sums up and discusses the results. The paper ends with a short summary and conclusive outlook in section 6.

2 Institutional Background

In the next part, I give an overview on R&D in the biotech and pharma industry and explain the drug development process. Then, I point out the vast uncertainty related to R&D investments and heavy information asymmetries between investors and company managers. From this, I derive a priori predictions about how R&D progress announcements are expected to be transmitted into stock prices.

2.1 Drug Development Process

Developing a new drug is a rigorous and highly regulated process. Several *stages* need to be passed before a drug finally reaches the patient (e.g., Schwarz (2005)).

First, the company undertakes in-house R&D to get a better understanding of the targeted disease. New chemical entities are evaluated and analyzed for their interaction with the sickness. This is considered the screening and discovery period.

After a promising substance was identified, the drug candidate enters a preclinical testing period. Here, animal tests are employed to assess the new candidate's safety profile. Experiments are conducted to obtain preliminary data on the substance's efficacy and toxicity. Companies usually file for patent protection during this stage.

Following satisfying preclinical tests, the company applies for human testing with the responsible authorities. In the US, drug manufactures file an investigational new drug application (IND) with the Federal Drug Administration (FDA). In Germany, firms need to obtain permission by the Ethical Commission as well as the responsible governmental departments "Bundesinstitut für Arzneimittel und Medizinprodukte" or "Paul-Ehrlicher-Institut".

The evaluation of new drug candidates within human clinical trials follows to a large extent a standardized procedure.[2] The substance must pass three consecutive phases. Throughout the process, the trials are supervised by the respective governmental bodies.

In *phase 1*, the substance is tested to determine safety, tolerability, and dosage. The candidate's pharmacokinetics are also examined. A non-therapeutic evaluation takes place with a small group of healthy individuals as probands. The sub-categorization in phase 1A and Phase 1B refers to single and multiple dosage assessment.

Phase 2 trials are conducted to evaluate the effectiveness of the substance. A small number of volunteer patients are included. For the first time, the candidate is tested at individuals with the targeted

[2] The International Conference on Harmonization provides an international standard on how clinical studies should be conducted. The "Good Clinical Practice" codex was first proposed in 1996 and tries to synchronize the clinical trial process in USA, Europe, and Japan.

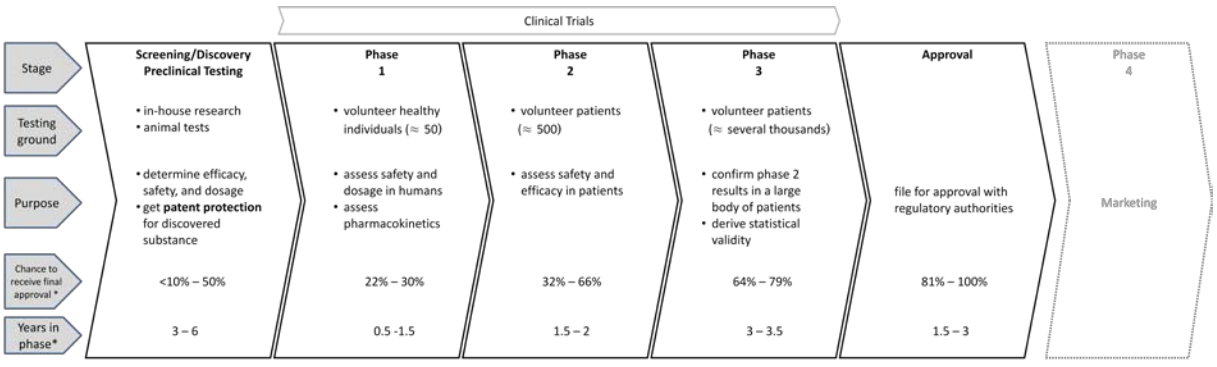
disease. Sometimes phase 2 studies are split into phase 2A and phase 2B. Then the study in phase 2A focuses entirely on dosage where phase 2B trials assess the efficacy.

In *phase 3*, the candidate is tested for safety and efficacy in a large sample of patients for statistical inference. The patients are closely monitored to detect any form of side effects. The results are compared with those obtained by established treatments and placebo-therapies.

When the drug developing company believes that sufficient evidence for its candidate's safety and efficacy was collected, it files for *marketing approval* of the substance. Given the high filing costs, companies most likely choose to do so when they are convinced of a positive outcome. All gathered information is sent to the regulatory authorities. In the US, firms file for licensing at the FDA. In Europe, companies can either file for marketing authorization in each member state or turn to the European Medicines Evaluation Agency (EMEA) for a European-wide application. The governmental bodies review the material and retrace the substance's safety and efficacy. If the results meet the expectations and guidelines, the firm will be granted approval to marketing the new drug. However, the company is still obliged to monitor the drug and report any adverse effects. This is sometimes referred to as phase 4 or the post marketing surveillance phase.[3]

Figure 1 summarizes the drug development process and its major stages.

Figure 1. Drug development process.



* Estimates are based on the analyses of Stewart et al. (2001), Kellog and Charnes (2000), Struck (1994), DiMasi (2001), and PhRMA (2008).

Within the drug development process *patent filing* is an eminent step. The prominence of patents originates from the steady shift towards a more science- and knowledge-based economy. Hall (2007) cites patents as the indispensable necessity to protect the property rights associated with the intangible assets that form a large part of the company value. First, patents securing marketing rights and

[3] I concentrate on the most common way to drug approval. There are special modifications on the process such as orphan drugs, expedited review circumstance, and others. For more information on the development process see Dimasi et al. (2003), Friese et al. (2007), and Volkers et al. (2005).

therewith help pharmaceutical companies to justify immense drug development expenses. Undertaking such efforts would be irrational if the firm cannot prevent free-riders from marketing identical substances at low costs. Patents help to address this issue and allow the drug developer to exclude generic producers from the market. So, patents ensure future monopolistic market power. Patent protection is the essential precondition to extract all future benefits related to a successful drug development and R&D investment. In their inter-industry survey, Cohen et al. (2000) provide empirical evidence that patents have a strong influence in the pharmaceutical industry. A recent survey among senior executives of the 15 largest pharma companies reveals that driving product and flow and managing patent challenges is of major concern to top management.[4]

Besides securing rights in product markets, patents are a major determinant in attracting financial resources (e.g., Hall (2005), Lerner (1994)). Young biotech and pharma companies usually depend on external funding to finance their R&D investments. Despite the inability to generate own profits in early years, biotech firms need to develop a broad R&D portfolio to ensure future revenues. A promising R&D pipeline serves as an indicator for future earnings. Biotech firms, therefore, have an incentive to get their intellectual property legally protected. They can then use their patents in signaling growth potential to external financiers and venture investors.

The drug development process is characterized by a large amount of *uncertainty*. Once a company identified a promising substance it remains unclear whether it will make it through the different development stages all the way to marketing approval. In fact, it is rather unlikely. Based on the 2008 report of the Pharmaceutical Research and Manufactures of America (PhRMA), only one candidate out of about 5,000 to 10,000 evaluated chemical entities will be granted marketing approval.[5]

In tackling this uncertainty, some work has been undertaken to estimate the success rates of a compound to make it from one trial phase to another (e.g., Bienz-Tadmor et al. (1992), Struck (1994), Kellog and Charnes (2000), Steward et al. (2001), and DiMasi (2001),). These studies typically take publicly available information and assess how many candidates pass the phases. The authors come up with historical transition estimates. They find that a candidate is more likely to receive a final approval the more advanced it is in the drug development process. E.g., the probability for a candidate currently examined in phase 3 studies to receive a final approval is higher than for substance in the phase 1 trials. Besides success rate estimates the authors' research also expose the long-winded cha-

[4] The information is derived from the Global Pharmaceutical Industry Report, Part II 2008, published by Ernst & Young Publications

[5] See "Pharmaceutical Industry Profile 2008" published by Pharmaceutical Research and Manufacturers of America (PhRMA), Washington DC, March 2008. These estimates are even lower for genetic compounds as reported in "Good Business Practice & Case Studies on Biodiversity", European Federation of Pharmaceutical Industries and Associations, Brussels, Belgium, September 2007.

racter of a drug development. Development time can range from 12 to 15 years. A drug candidate is likely to remain between one to three years in each human trial phases.

In addition to high uncertainty during the application process, drug development requires vast resources and high costs. DiMasi et al. (2003) estimate the average total R&D expenditures per new drug to be US$ 802 million. They also find that development costs increased over time by an annual rate of 7.4 percent above inflation. Grabowski et al. (2002) also report a steady increase in R&D investments per new drug introduced from 1980 to 1994. In light of such high monetary inputs investors are interested in information on the R&D progress. Successful R&D is necessary for the drug to cause not only high development costs but also to bear future revenue potential.

2.2 Uncertainty and R&D valuation

Almost all of the firms' future profits depend on the outcome of their R&D investments. Following the seminal reasoning of Griliches (1981), R&D investments create intangible capital. Hence, the value of the firm should account for these intangible assets in addition to the firm's conventional tangible assets. The fair market value of biotech and pharma firms has to reflect the heavy R&D dependency and therefore incorporate information on the companies' R&D investments. The question remains how R&D projects create value and how capital market participants are able to transmit the complex progress of R&D into the market value of the firm.

A first idea can be derived from traditional investment theory. Assuming investors apply conventional discounted cash flow valuation (DCF), announcements on R&D progress should translate immediately into the market value of the firm. The present value of a newly-discovered medical substance is weighted by the product of all estimated success-probabilities of passing from one phase to the other. Whenever drug developers report positive information about a candidate passing from one phase to another, the weights are adjusted. In efficient capital markets, this positive information on R&D progress will lead to a positive stock price reaction and an increase in market value. Moreover, these reactions should diminish in magnitude for later phases in the drug development process. Candidates further up in the development process are afflicted with less uncertainty because the probability estimates to receive a final approval increases the further up a candidate is situated in the process.

However, I challenge this simple reasoning because it disregards the peculiarities in valuing R&D investments. The relationship between R&D investments and the market value of the firm is ambiguous as a result of problems associated with the character of R&D investments.

Compared to investments in tangible assets, R&D investments differ in an important dimension. The restricted disposability of information related to R&D projects – especially in the biotech and pharma sector – derogates the investors' ability to assess adequately the value of an R&D investment and

increases valuation uncertainty (e.g., Goel and Ram (2001)). Due to insufficient information sources, investors lack satisfactory parameters to account appropriately for the uncertainty in the valuation process. The information available for R&D investments is more restricted compared to other investments for two key reasons (e.g., Lev (1999), Aboody and Lev (2000), Oriani and Sobrero (2003)). First, corporate accounting information is insufficient for economic analyses, therefore, reducing the source of information from an investor's point of view. Second, the information content of external sources is also of little use to investors due to the unique and inexplicable characteristics of R&D investments.

2.2.1 Inadequate Accounting Rules and Asymmetric Information

Investors need a value-relevant source of information to assess satisfactorily R&D investments. One such source are financial disclosures on R&D expenditures.[6] However, a growing body of literature suggests that there are more sources of information for adequately valuing R&D investments than financial disclosures like R&D expenditures alone.

The fundamental problem of R&D expenditures as an information source in valuing R&D investments is that such disclosures are driven by a *backward-looking* accounting system. R&D investments are usually expensed immediately; therefore, no information on a future change in value of the underlying investment can be retrieved.[7] Consequently, information asymmetries between mangers and outside investors arise (e.g., Aboody and Lev (2000)). Accounting rules require most other investments to be capitalized and marked-to market or impaired in subsequent periods. That treatment provides investors with management beliefs about the change in asset value and therefore adds an additional credible and economically significant information source. However, an immediate expense

[6] A series of empirical studies examines the impact of explicit R&D expenditure announcements on share value. Chan et al. (1990) look at announcements about unexpected R&D expenditure increases and find significant positive stock price reactions. Similar results are reported by Szewczyk et al. (1996) and Chan et al. (2001). All studies report a positive relationship between the firm's research expenses and stock price reactions. Long-run effects after R&D expenditure announcements are explored by Eberhart et al. (2004). The authors find positive abnormal stock returns over a 5-year period following the company's R&D increase. These studies suggest that quantitative and explicit R&D expenditure announcements reveal new information and influence positively share value. Investors tend to regard such announcements as proxies for R&D intensity. From there, future economic growth duration and competitive advantage potential are deduced.

[7] Lev (1999) surveys international disclosure requirements. In the US R&D companies are required to expense R&D. In other countries R&D can be capitalized. However, strong requirements must be fulfilled and strict amortization constraints apply. In Germany, commercial law prohibits the capitalization of self-provided intangibles.[7] Leibfried and Pfanzelt (2004) argue that even under international accounting standards (IAS) an immediate expense of R&D investments is very likely for pharma and biotech companies. IAS 38 allows for a capitalization of intangibles if there is a substantial probability of future benefits. Yet drug development is characterized by a high degree of uncertainty. Biotech and pharma companies, therefore, are unlikely to qualify for that regulation.

of R&D efforts deprives that information from the investors. Therefore, examining financial disclosures alone reveal little about how R&D progress is incorporated in stock prices. R&D projects are usually of a rather long-time, stage-specific character (e.g., Kelm et al. (1995)). This results in a large time lag between the initial R&D investment and the realization of benefits. First, the project is initiated and substantial R&D expenditures are announced. Then, R&D work is undertaken until the project eventually approaches marketability. The period between project initiation and marketing stage is not adequately reflected by a firm's R&D expenditure disclosures. Therefore, financial disclosures are only of limited use in assessing R&D investments.

Gou et al. (2005) also point out a *conceptual disadvantage* of financial disclosures on R&D. They argue that input measures such as R&D expenditures have less significance in explaining the value of intangibles than output-related measures like patent filing or information on the product development stage. There is no causal relationship between spending resources on R&D and discernible future economic benefits.[8]

Given the drawbacks of financial disclosures, many researchers attribute importance to non-financial information sources to value R&D investments. Amir and Lev (1996) point to the value-relevance of non-financial information in fast-changing and technology-based industries. Hirschey et al. (2001) find that R&D expenditures have only limited power to explain the market value of a firm once non-financial R&D disclosures are taken into account. In their analysis, non-financial information on patent quality adds significant power in explaining the market value of the firm. Deng et al. (1999) argue that a firm's periodic R&D expenditures are a scant value indicator given the fast-changing environment of R&D-intensive firms. Healy and Palepu (2001) also suggest that such disclosures in innovative industries are of little use to outside investors. Furthermore, Guo et al. (2005) report empirical evidence that product-related announcements add more explanatory power in the pricing of biotech initial public offerings than pure financial variables.

Due to the inadequate accounting information, I argue that investors turn to measures other than financial disclosures to get a more adequate understanding of the progress of R&D projects and the value of R&D investments. In overcoming the existing information asymmetries created by the accounting standards investors are likely to pay additional attention non-financial disclosures. These announcements enhanced their basis of information and thus will help to assess whether R&D investments will lead to future economic benefits. Non-financial disclosures on the progress of the R&D investment, therefore, carry useful and economically relevant information to outside investors.

[8] The Financial Accounting and Standards Board acts on the same reasoning: "A direct relationship between research and development costs and specific future revenue generally has not been demonstrated, even with the benefit of hindsight, "any sort of cause and effect basis – cannot be applied to research and development costs". See Statement of Financial Accounting Standards No. 2, §41, §49, Norwalk, Connecticut, October 1974.

According to Fama (1991), new and value-relevant information should lead to a stock price reaction. Therefore, I hypothesize that

H 1: Investors incorporate non-financial disclosures on R&D progress in assessing the market value of the firm. Hence, a significant market reaction to non-financial R&D progress announcements is expected.

2.2.2 Uncertainty of R&D Investments

Additional non-financial disclosure can be considered useful and value relevant to outside investors. However, it still is unclear how this extra information is used by investors to actually value the complex R&D process.

The valuation of an R&D investment is complicated considerably by its inherent widespread uncertainty. Two major uncertainty categories become significant during R&D progress (e.g., Encaoua et al. (2000), Foray (2004), Herstatt and Sandau (2006)): Technical uncertainty and legal uncertainty. [9]

Technical uncertainty refers to the fact that a company cannot be sure beforehand that the R&D innovation will receive final marketability. When valuing a R&D investment properly, one has to take into consideration the probability that the product makes it to the final marketing stage. In the case of R&D in the biotech and pharma sector, one has to account for the probability that the drug candidate passes through all phases of the drug development process. Some work has been done to estimate such transition probabilities. But it is questionable how reliable these estimates are and how useful it is to apply them in valuing any drug development project.

Aboody and Lev (2000) point out the *uniqueness* of R&D investment compared to regular capital investments. Technological advances are unparalleled to firm whereas investments in commercial assets share common characteristics across firms in the same industry. Consequently, investors cannot extract any substantial information from the R&D efforts of other companies.[10] The exclusivity of R&D investments is particularly prevalent in the biotech and pharma industry. Developing a new drug is a unique and unprecedented investment. Each drug candidate addresses different diseases. In

[9] Another dimension is market uncertainty. It refers to the uncertainty concerning the potential financial benefit of a particular investment. However, this source of uncertainty exists throughout the entire R&D process and should therefore have been incorporate into the stock prices at the start.

10 Aboody and Lev (2000) also mention the absence of organized markets for R&D as an additional source which worsens considerably the problems of uncertainty and asymmetric information. Because there is no market for R&D investments, investors lack a valuable source to convey information from. Prices of traded assets usually reveal information on the expected productivity and profitability.

addition, the substances' dissimilar chemical structures hinder precise side-effect forecasts. Hence, the benefit of knowing that several other substances made it or made it not to the final approval stage is rather restricted. Drawing conclusions from past incidences in assessing how the new candidate will work in each development phase is not meaningful. Given the uniqueness of the R&D investment, historical transition rate estimates are of limited use in accounting for the technical uncertainty in the drug development process.

Thus, it is hard to draw parallel conclusions from other drug trial outcomes. Moreover, these transition estimates depend on the regulatory environment and vary considerably over time (e.g., DiMasi (2001)) which weakens their information content even more.

In addition, there is a *structural deficiency* in the deviation of the transition estimates. Most estimates are derived from publicly available information. Since firms disclose voluntarily information on their drug candidates passing from one clinical phase to another, any estimate based on such data is subject to a sample selection bias. Kelm et al. (1995) and Dedman et al. (2008) find that drug developers announce significantly more positive news on candidates succeed to another phase than negative news about drugs failing in clinical testing. In light of the vast number of substances that fail during the drug development process, the reporting quality of firms is rather low. Therefore, it is most likely, that estimates based on such information are positively biased and overestimate the true underlying success probabilities. Given the unreliable and noisy character the information content of such estimates is limited.

The *timeline* adds additional uncertainty. Even when a drug passes from phase 1 to phase 2, it remains unclear whether it will pass phase 2 but also whether phase 2 will last two, three, or more years.

I define **Legal uncertainty** as the innovating firm's threat of losing its headstart of knowledge to copying rivals. This danger becomes particularly prevalent in a technology- and science-based economy and is therefore crucial for biotech and pharma companies. When obtaining innovative knowledge is costly and transmitting the information is uncomplicated, competitors have an incentive to annex this invention. Not having incurred the development cost, the rival can offer the final product at a cheaper price compared to the developer. As a consequence, the inventor is crowed out of the market (e.g., Czarnitzki and Tool (2007)).

Given the strong level of uncertainty associated with R&D investments, the question remains how investors account for it when valuing R&D progress. In general, I expect that investors react favorably to any positive R&D progress announcement. However, I argue that price effects will be most pronounced at the cornerstones of the drug development process. These milestones are patent granting and receiving marketing approval.

Zhang (2006) finds empirical evidence that greater information uncertainty leads to less pronounced actions of investors. He concludes that uncertainty delays the flow of information into stock prices. Lev and Sougiannis (1996) affirm this result in their empirical analysis of R&D investments. They presume the existence of an additional risk factor associated with R&D which the market accounts for. Narayanan et al (2000) derive similar results. They condition investor reactions only to credible and economically relevant information. Major milestones like approval or patent granting are of high credibility as well as value relevance. Such announcements are validated externally by regulatory authorities and have a value impact especially in innovative industries. The high information quality of such signals is therefore likely to induce evident market reactions.

I follow this reasoning and expect market reactions to be less pronounced for clinical trial announcements since lots of uncertainty remains in the development process. Investors' reactions are assumed to be most intense at the milestone events where lots of the uncertainty inherent in the R&D process is disbanded.

Patent granting as well as marketing approval reduces significantly the uncertainty during the R&D process. Obtaining a patent signals the quality of an R&D department and reduces lots of legal uncertainty. The company receives legal protection of its intellectual property and can exclude third parties from free-riding.[11] Receiving marketing approval disbands uncertainty as well and should therefore have strong positive effects on stock prices. Although positive announcements from the preclinical phase to phase 3 signal positive interim information, lots of uncertainty remains. The clinical trials represent a black-box where the possibility of failure is omnipresent. But once final approval was received, all technical uncertainty is removed. Then, the drug can be released to generate profits.

Patent granting as well as marketing approval reduces significantly the uncertainty related to the drug R&D investment. In addition, both events describe a distinguishable legal asset. A patent-protected substance and a marketing-approved drug can be divested easier than some self-generated knowledge. The importance of the different clinical phases in valuing the R&D investment is indistinguishable. Lots of the inherent uncertainty in the drug development remains despite the substance's transition from one phase to another. In contrast, patent granting and marketing approval reduce significantly the uncertainty present within the R&D process. Therefore, I hypothesize that

[11] Literature documents the skewed profit distribution of technological innovation (e.g., Scherer and Harhoff (2000)). However, I argue that publically reported innovations – as they are used here – are associated with greater future economic benefits than those that are not publically announced (e.g., Austin (1993)). Therefore, pronounced stock price reactions should be expected.

H 2: The market reacts most strongly to positive announcements at the cornerstones of the drug development process – patent granting and receiving marketing approval.

2.2.3 Related Research

After the development of a conceptual framework for the market reactions to R&D progress, I present overview of related empirical literature.

Several studies report positive market reactions to product approval announcements. Chaney et al. (1991) look at companies that introduce a new product between 1975 and 1984. They pool pharmaceutical and chemical companies and find positive announcement effects for 241 new product introductions. According to their findings, the value of new product announcements is greatest for most technology based industries. Bosch and Lee (1994) document empirical evidence that FDA approvals on new products have considerably large wealth effects. They use a sample of 130 drug approvals between 1962 and 1989 and find significant price reactions at the announcements. Based on their results they argue that a significant amount of uncertainty about final approval decisions is present almost up to the announcement date. Then the market incorporates fully the marketing potential of the new product. Sharma and Lacey (2004) analize a sample of 344 drug approvals by the FDA and 41 outright rejections. They ascertain significant positive market reactions to drug approvals and downturns in stock prices for drug rejections. Sarkar and de Jong (2006) also notice significant positive price reactions to drug approvals in the US.

Only few studies examine stock market reactions over the entire period of R&D progress. Kelm et al. (1995) propose a stage-dependency of market reactions to R&D announcement. They use R&D progress announcements of biotechnology firms between 1977 and 1989. Two stages are defined: The innovation stage includes all progress news of projects; the commercialization stage comprises new product introductions. The authors report non-indistinguishable positive stock price responses to both stages. However, control variables have a stage-dependent effect when regressed against the excess returns on the announcement days. Unfortunately, the authors generalize the innovation stage by merging several dissimilar R&D phases. Therefore, their analysis is limited and does not provide detailed explanation for the entire R&D process.

Ely et al. (2003) employ a sample of 156 announcements by US biotech companies during 1988 and 1998. They analyze the market reaction for each in-process clinical trial status. The authors describe a significant market response only for phase 2 announcements. Dedman et al. (2008) examine a sample of UK biotech and pharma firms and 151 drug trial related announcements during 1990 and

1998. They find that later stage announcements – phase 3 and final approval - are most value-relevant to investors.[12]

So far, a comprehensive study of the entire R&D process and its market valuation is missing. The existing literature is limited on the analysis of selected R&D stages. To close this gap, I conduct a broader analysis by including all major stages of the drug development process.

Moreover, Oriani and Sobrero (2003) stress that most of the studies are based on US data while no comprehensive results are available for European countries, where the market structure is notably different.[13] To overcome this deficiency I examine the biotech and pharma companies in Germany. Germany is the predominant market for innovation in continental Europe. In 2008, the growth rate of R&D investments for EU firms overtook that of US firms for the first time. EU firms account for 30 percent of total R&D investments compared to 38 percent of US firms. Germany by itself accounts for almost 11 percent of worldwide R&D spending. Bräuninger et al. (2008) report further evidence on the importance of biotech and pharma industry in Germany. Patent applications show a stronger growth in Germany than in competitive locations. Also, most of the clinical studies undertaken in Europe are registered in Germany. Given the dominance of R&D undertaken by firms in Germany it is worthwhile to extract closer insights on the German biotech and pharma sector in particular.

[12] They report a negative market reaction to patent granting. However, their sample contains only 6 observations. Due to insufficient observations, they drop this category for their further analysis.

[13] Roll (1992) and Griffin (2002) also point out the necessity to examine country- and industry-specifics when evaluating stock returns.

3 Methodology

3.1 Sample selection

I focus my attention on R&D progress announcements of German biotech and pharma companies. In order to derive a representative sample of firms engaged in this sector, I employ the company survey of "biotechnologie.de" as a starting point. "biotechnologie.de" is a service provider that undertakes a survey of biotechnology and pharmaceutical companies on behalf to the German Federal Ministry of Research and Education. The study is addressed to all companies operating in the German biotech and pharma industry. I retrieved all companies that took part in the 2008 survey. Then, I reduced the sample to all publicly listed firms. For these companies, I looked up their SIC-codes. These sample SIC-codes are used as a guideline. As a final step, I filtered out all companies with such guideline codes from a database containing all companies that were ever publicly listed in Germany. The resulting firms form my company sample for which I looked up drug trial related R&D announcements.

The chosen procedure tackles the problem of survivorship bias. Since I do not limit myself to firms currently active in the targeted industry sector my sample also includes firms that are not traded anymore. The selection process also ensures that my sample comprises the largest number of companies of interest possible. Relying solely on the SIC-classifications for biotech and pharma companies could give rise to a sample selection bias. That is because SIC-classifications assigned to firms are sometimes arbitrary and not very precise. Hence, using only firms that fall into SIC-biotech and SIC-pharma categories cannot prevent the sample from either comprising firms that, in fact, are not heavily engaged in that sector or not including misclassified firms that actually operated in the biotech business. In my case, SIC codes are derived from companies that are known to be engaged in the biotech and pharma sector. Hence, the sample is likely to capture the whole spectrum of targeted firms. The final sample comprises of 33 companies.

Stock price data and company information are retrieved via Thomson Datastream and Worldscope. Table 1 provides descriptive statistics for the included firms over time. The standard deviations of the various accounting measures reflect the broad character of the sample. The selection contains both young firms and well-established drug developers.

Table 1. Descriptive statistics for the company sample.

Position		Y2008	Y2007	Y2006	Y2005	Y2004	Y2003	Y2002	Y2001	Y2000
Total assets	Mean	50.97	3328.39	3124.43	2149.95	2098.92	2125.78	2582.29	2608.47	2704.32
	Std. Dev.	177.91	90833159.38	100454517.72	43335620.32	45412903.79	44851217.48	62062164.98	54078477.48	56402760.65
	Nobs.	2	33	33	33	32	31	28	26	24
Common Equity	Mean	20.62	1296.41	994.55	799.11	791.30	764.21	950.20	1061.61	1085.55
	Std. Dev.	156.34	11706061.54	6532190.71	4480682.49	5295260.29	5158981.93	8623676.60	11141457.27	10915044.65
	Nobs.	2	32	32	33	31	31	28	26	24
R&D Expenses	Mean	6.02	183.89	177.43	150.25	162.18	179.08	222.14	261.56	288.32
	Std. Dev.	156.34	11706061.54	6532190.71	4480682.49	5295260.29	5158981.93	8623676.60	11141457.27	10915044.65
	Nobs.	2	32	32	33	31	31	28	26	24
Market Cap.	Mean	2933.91	3728.92	3077.27	2656.90	2152.79	1805.65	1506.23	2591.92	4282.02
	Std. Dev.	48852553.95	91509915.41	49319458.84	34083935.71	20235812.26	15329883.13	11504527.00	33919773.07	87182119.61
	Nobs.	32	32	31	27	24	24	24	24	20

3.2 R&D progress announcements

For all sample firms I collect drug trial related announcements during the period from 2000 to 2008. The disclosures are retrieved from company websites and news services. The three dominant news providers were screened for corresponding drug trial announcement. DGAP (Deutsche Gesellschaft für Ad-Hoc Publizität), EuroAdhoc, and HUGIN provide both ad-hoc publications and corporate press releases. These three news providers account for more than 95 percent of total market share. Therefore, it can be assumed that nearly all of the information released by companies is accounted for. 576 drug trial related announcements from pre-clinical testing through market approval were found.

The collected announcements fall into different categories. Since several disclosures describe similar stages in the drug development process, related announcements are pooled together. Table 2 describes the announcements and various categories. I apply a comparable grouping scheme as Dedman et al. (2008). Finally, six announcement categories are formed. They comprise “reaching phase-1”, “reaching phase-2”, “reaching phase-3”, “success in phase-3”, “patent and approval”, and “negative announcements”. “Negative announcements” includes adverse notifications on the entire phases of the development process. All drug trial related declarations that could not be assigned to either category were excluded. This leaves us with 350 announcements in total for the subsequent analysis.

Table 2. Description of announcement classification.

Announcement	Number of announcements	Announcement category	Number of observations per category
Pre-clinical success	15	Reaching Phase-1	43
Partial approval to beginn clinical trials	1		
Approval to beginn clinical trials	11		
Preparation of phase-1-study	1		
Start of a phase-1-study	15		
Phase-1 success announcement	23	Reaching Phase-2	52
Phase-1B success announcement	2		
Phase-1/2 success announcement	6		
Phase-1/2A success announcement	1		
FDA approves start of phase-2 study	1		
BfArM approves start of phase-2 study	2		
Start of a phase-2 study	14		
Start of a phase-2A study	3		
Phase-2 success announcement	28	Reaching Phase-3	72
Phase-2A success announcement	6		
Phase-2B success announcement	7		
Approval to beginn phase-2/3 study	1		
Start of a phase-2/3 study	3		
Phase-2/3 success announcement	3		
Approval to start a phase-3 study	2		
Start of a phase-3 study	22		
Phase-3 success announcement	46	Success in Phase-3	48
Phase-3B success announcement	1		
Phase-3 positive interim results	1		
Patent granted	16	Patent and Approval	114
US-patent granted	14		
Non-EU patent granted	2		
Approved by EMEA	19		
Approval in USA	37		
Approval in UK	2		
Approval in China	1		
Approval in Japan	6		
Approval in Canada	3		
Approval in European member states	14		
Pre-clinical failure	1	Negative announcements	21
Phase-1 failure	1		
Phase-1/2 failure	1		
Phase-2 failure	7		
Phase-3 failure	11		
Total number of announcements	350		350

Descriptive statistics of the event sample are provided in table 3. The majority of event announcements occurred in most-recent years. The distribution of events expose that companies are more likely to release favorable R&D progress announcements than adverse notifications. I find only 21 negative notifications whereas 329 positive announcements were communicated for the same period. This result confirms the evidence of Dedman et al. (2008), Ely et al. (2003), Kelm et al. (1995), and Narayanan et al. (2000) who also report relative low levels of negative-toned announcements.

Table 3. Distribution of events over the sample period.

Year	Negativ announcement	Reaching Phase-1	Reaching Phase-2	Reaching Phase-3	Success in Phase-3	Patent and Approval
2008	2	11	17	18	7	18
2007	4	5	8	20	18	24
2006	6	4	15	9	7	13
2005	3	9	4	7	6	10
2004	2	6	3	9	5	11
2003	2	3	3	5	1	13
2002	2	1	2	1	2	15
2001	0	3	0	2	2	6
2000	0	1	0	1	0	4
Total	21	43	52	72	48	114

3.3 Event-study methodology

To examine how investors cope with R&D progress information, an event-study analysis is conducted on the stock reactions after the announcements (e.g., MacKinlay (1997), Narayanan (2000), Kothari and Warner (2004)). The goal is to investigate whether the cross-sectional stock return distribution is influenced by the R&D announcements.

Events of interest are classified as the drug trial related announcements throughout the drug development process.

Abnormal returns are derived via a market model. I use the German composite stock index (CDAX) as a market proxy. It includes all 664 companies in the German prime and general standard. Therefore, the index measures the performance of the entire German stock market and is suited for the subsequent analysis.[14] Following Dedman et al. (2008), I select a 150-trading-day estimation period to calculate return parameters via an OLS regression. To examine the price reactions I choose several event-windows of different length. A ten-day gap is kept between the reported event-windows and the corresponding last day of the estimation period. The break should prevent the regression estimates from being biased by event-induced influences.

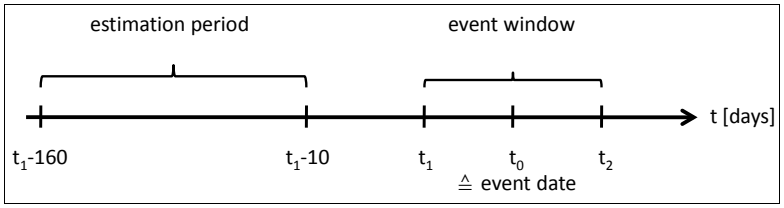
The econometric design is formulated as follows. The market model is specified as:

$$R_{i,t} = \alpha_i + \beta_i R_{M,t} + \varepsilon_{i,t}.$$

Where $R_{i,t}$ is the return of firm i at time t. $R_{M,t}$ is the return of the market index M at time t. The disturbance term $\varepsilon_{i,t}$ is assumed to iid $N(0,\sigma_i^2)$. The regression parameters $\hat{\alpha}_i$ and $\hat{\beta}_i$ are estimated over the 150-trading-day estimation period.

[14] For detailed description and weighting scheme see the website of the Deutsche Börse Group. As a robustness check, event study results are replicated by using the German DAX index as an alternative proxy for the market. The major findings do not change after this adjustment.

Figure 2. Timeline for the event study.



Abnormal returns (AR) are defined as the difference between the actual return and the expected or "normal" return based on the market model:

$$AR_{i,t} = R_{i,t} - (\hat{\alpha}_i + \hat{\beta}_i R_{M,t}).$$

These ARs are then aggregated across observations to form average abnormal returns (AAR). Then, the ARRs are consolidated over time according the chosen event-window length. The cumulative average abnormal returns (CAAR) are defined as:

$$CAAR[t_1, t_2] = \sum_{t=t_1}^{t_2} AAR_t.$$

t_1 and t_2 mark the window's starting and ending point. Both measures are defined with respect to the event date (t_0). The starting point t_1 indicates the number of days prior the event date whereas t_2 reflects the days after the event.

To test the null hypothesis that the examined event has no impact on the stock return I use standard t- and Boehmer-tests (see Boehmer et al. (1991)).

The tests are conducted on whether or not the CAAR over the corresponding event window is statistically different from zero. If the null is neglected, one can conclude that the event has a significant impact on the share prices.

4 Empirical Results

4.1 Announcement Returns

Table 4 describes the market reactions to all positive R&D progress announcements for various event windows.[15] The CAAR [0;+1] accounts for the price movement on the event date and the day after. Stock prices increase on average by 3.99 percent. The increase is statistically significant. Moreover, the CAAR [-10;-1] measures the cumulated average abnormal returns over a ten-day period before to the event. I find a moderate increase of 0.90 percent which is statistically not different from zero. This contradicts any suspicion of information leakage and heavy selling activities prior to the event. The CAAR [+1;+10] measures exclusively price reactions after the announcement. I find a slight and insignificant negative return of -0.71 percent. The result indicates that the positive reactions on the announcement date are persistent and not abolished thereafter. Similarly, the CAAR[-30;+30] of 3.99 percent provides evidence that positive R&D progress announcement create value over an extended time period.

Table 4. Stock market reactions to all positive R&D progress announcements.

All positive R&D progress announcements - Estimation Period: [t-160;-10]

		Boehmer Test	t-Test	
Event window	CAAR	z-score	t-value	Nobs
[-10;+0]	4.93%	3.742***	3.506***	313
[-5;+0]	4.62%	3.621***	3.315***	313
[-1;+0]	4.33%	3.801***	3.385***	313
[0;+1]	3.99%	3.704***	3.481***	313
[0;+5]	3.52%	3.191***	3.163***	313
[0;+10]	3.34%	2.513**	2.637***	312
[-1;+1]	4.28%	3.714***	3.391***	313
[-10;-1]	0.90%	1.304	1.393	313
[+1;+10]	-0.71%	-1.546	-1.146	312
[-30;+30]	3.99%	2.114**	2.332**	307

***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

Table 5 presents results for announcements on patent granting or marketing approval. I find significant positive effects on the event date. The CAAR [0;+1] is positive and highly significant at 8.31 percent. Again, I cannot collect any evidence on information leakage. Looking at the price development preceeding the event, the data does not suggest any run-up phase. The CAAR [-10;-1] is 1.05 percent and statistically not different from zero. Therefore, I can conclude that the market incorporate effi-

[15] Different number of observations for each event window is due to missing stock market data.

ciently these positive information. An analysis of different event windows also reveals that the positive market reactions to announcement can be preserved beyond the initial event date. Both, CAAR [0;+10] with 7.35 percent and CAAR [-30;+30] of 9.48 percent are significantly positive. The endured price effect shows that information on both patent granting and receiving marketing approval has a value-enhancing effect for biotech and pharma companies.

Table 5. Stock market reactions to patent and approval announcements.

Patent and Approval - Estimation Period: [t-160;-10]

		Boehmer Test	t-Test	
Event window	CAAR	z-score	t-value	Nobs
[-10;+0]	9.52%	2.771***	2.612**	111
[-5;+0]	9.17%	2.688***	2.517**	111
[-1;+0]	9.44%	2.912***	2.718***	111
[0;+1]	8.31%	2.816***	2.701***	111
[0;+5]	7.52%	2.709***	2.638***	111
[0;+10]	7.35%	2.394**	2.342**	110
[-1;+1]	9.29%	2.897***	2.732***	111
[-10;-1]	1.05%	0.813	0.834	111
[+1;+10]	-1.19%	-1.106	-1.312	110
[-30;+30]	9.48%	2.664***	2.450**	108

***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

In a second step, I examine the market reactions to announcements for all clinical trials. I grouped together all events in the categories “Reaching Phase-1”, “Reaching Phase-2”, “Reaching Phase-3”, and “Success in Phase-3”. These four events form collectively the new event category “Phase-123”. The idea is to examine how investors cope with trial-related announcements compared to patent and approval announcements. Table 6 displays the market reactions to positive announcements during the entire clinical trial process. I find that the market reacts positive around the announcement. However, the reactions are smaller in magnitude compared to the price reactions of patent and approval granting. The CAAR [0;+1] of 1.61 percent is significantly positive. There is no evidence for any information leakage. The CAAR [-10;-1] of 0.82 percent is not significantly different from zero and indicates no run-up period.

The CAAR [0;+10] of 1.15 percent is also not different from zero. All positive effects on or around the event date fade away within a short period of time. The same conclusion can be drawn by looking at the widest window of thirty days prior and after the events. The CAAR [-30;-30] of 1.01 percent is

statistically not different from zero which implies that the initial positive impact on the event date cannot be sustained.[16]

Table 6. Stock market reactions to clinical trial announcements.

Phase-123 - Estimation Period: [t-160;-10]

		Boehmer Test	t-Test	
Event window	CAAR	z-score	t-value	Nobs
[-10;+0]	2.42%	2.881***	2.922***	202
[-5;+0]	2.12%	2.876***	2.756***	202
[-1;+0]	1.52%	3.509***	3.443***	202
[0;+1]	1.61%	3.319***	3.360***	202
[0;+5]	1.33%	1.786*	1.930*	202
[0;+10]	1.15%	0.925	1.248	202
[-1;+1]	1.53%	3.023***	3.031***	202
[-10;-1]	0.82%	1.028	1.125	202
[+1;+10]	-0.45%	-1.116	-0.544	202
[-30;+30]	1.01%	0.210	0.643	199

***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

Although the negative announcement sample is small, I run an analysis for the market reactions to adverse R&D progress information. The results can be found in table 7. The abnormal price reactions to the adverse news are strongly negative surrounding the event date. The CAAR [0;1] is -12.01 percent. Despite the small sample, the abnormal drops are highly significant. The drastic negative reactions extend over a five and ten day window after the event. The CAAR [0;+5] is -11.04 percent and CAAR [0;+10] is -12.64 percent. Both measures are highly significant and suggest a persistent negative impact of R&D-related adverse information on the market value of the firm. The CAAR [-30;+30] over the entire event window is -14.73 percent and significant. It indicates a heavy negative value impact of adverse R&D progress announcement on the firm.

[16] I also analyze each event category "Reaching Phase-1", "Reaching Phase-2", "Reaching Phase-3", and "Success in Phase-3" separately. The results are ambiguous and produce no clear-cut picture.

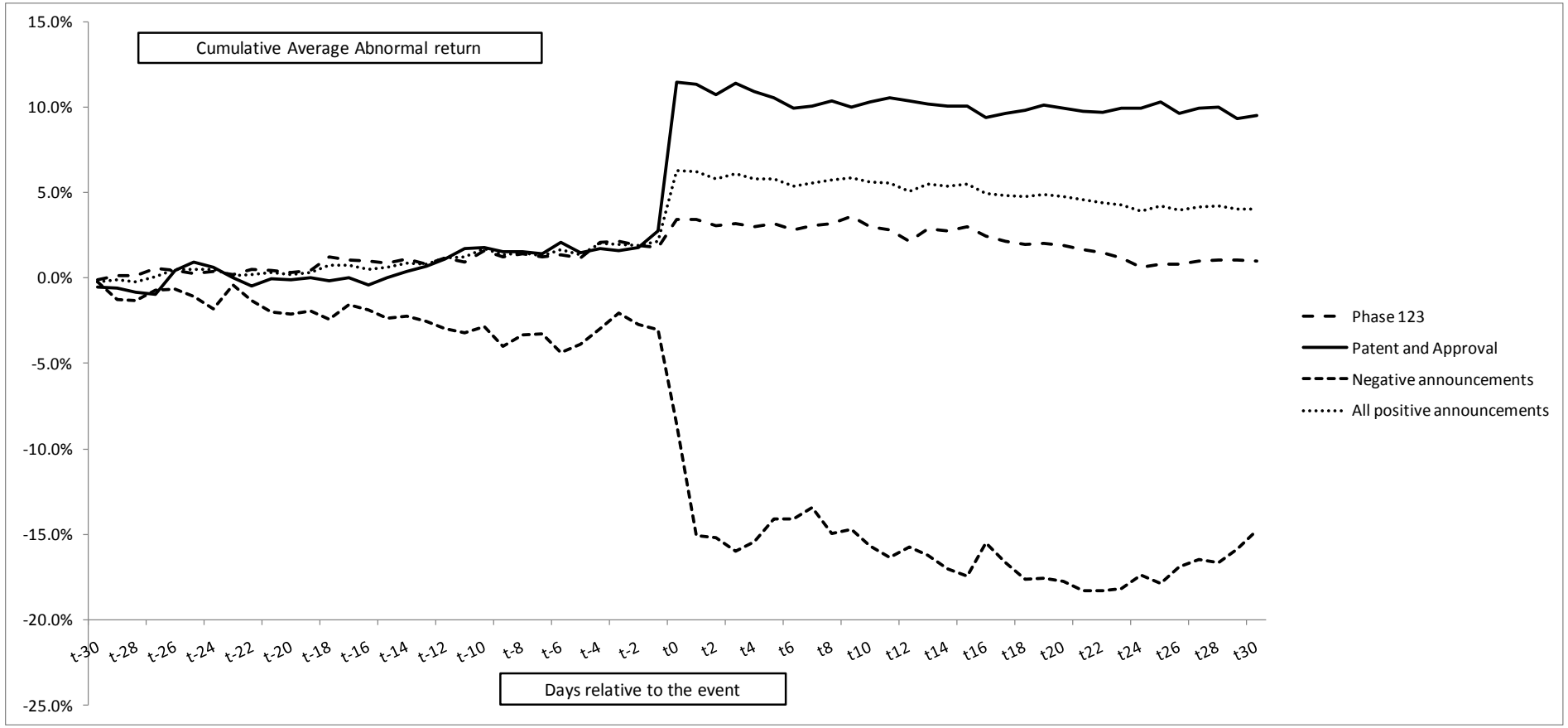
Table 7. Stock market reactions to negative R&D announcements.

Negative announcements - Estimation Period: [t-160;-10]				
		Boehmer Test	t-Test	
Event window	CAAR	z-score	t-value	Nobs
[-10;+0]	-5.35%	-1.557	-1.336	21
[-5;+0]	-4.18%	-1.200	-1.097	21
[-1;+0]	-5.81%	-2.143**	-1.869*	21
[0;+1]	-12.01%	-3.355***	-3.069***	21
[0;+5]	-11.04%	-3.066***	-2.883***	21
[0;+10]	-12.64%	-3.294***	-3.101***	21
[-1;+1]	-12.32%	-3.506***	-3.195***	21
[-10;-1]	0.16%	0.104	0.093	21
[+1;+10]	-7.14%	-1.625	-1.547	21
[-30;+30]	-14.73%	-3.212***	-2.740**	21

***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

Figure 3 plots the CAAR over time to compare the magnitudes of price effects for different groups of events. The graph illustrates once again that the sharpest price reactions in magnitude occur for negative events and patent and approval announcements.

Figure 3. Cumulative average abnormal returns.



4.2 Cross-Sectional Analysis

The previous examination does not control for company characteristics and additional predictors that can influence potentially the stock price reactions to R&D progress announcements. Therefore, I conduct a supplementary cross-sectional regression analysis to test my hypotheses while controlling for confounding effects.[17]

The dependent variable is the AR at the event date t_0. As suggested by McWilliams and Siegel (1997), I rely on the one-day abnormal return to ensure that besides the event of interest no confounding effects bias my results. The regression is run for three event categories. First, ARs for "Phase-123" are regressed against dummy and control variables. Second, a regression on ARs for patent and approval announcements is performed. In a final step, the ARs of all positive announcements (Phase-123 and Patent and Approval are pooled together) are regressed against a set of dummies and control variables.

Table 8 provides a description of the control variables. Given the diverse sample structure of small and large firms I include the market value of equity to control for any size effects. The controls also contain the ratio of market to book value of equity. Fama and French (1992), Chan et al. (2001) and others apply the measure to proxy the firm's growth opportunities. The implied growth options possibly reflect potentially the market's prior expectations and can therefore influence the reactions to R&D progress announcement. In addition, I select a measure of the R&D intensity of the company (see Szewczyk et al. (1996)). Moreover, the set of controls comprises information on the companies' leverage, profitability, and cash flow level.[18]

[17] Due to a small sample size I excluded negative events from the regression analysis and focus exclusively on positive announcements.

[18] I have to ensure that the accounting information used in the regression to explain the AR are known at the time of the event. Therefore, I apply the methodology developed by Fama and French (1992). Following Chan et al. (2001) p. 2438, I assume a minimum gap of 4 months after fiscal yearend before the financials are disclosed. If the event date lies four months after the most recent fiscal yearend, I use the financials of the previous year otherwise I use the information two years before.
Given that most firms have a fiscal yearend identical to calendar yearend, I assume the 31st of December to be the fiscal yearend for all companies that I do not have data on their actual fiscal year end.

Table 8. Description of regressors.

Regression variable	Description
Patent and Approval	Dummy variable that takes the value 1 if either a patent is granted or marketing approval is received, 0 otherwise.
US	Dummy variable that takes the value 1 if FDA approves the drug for prescription in the US, O otherwise.
Approval	Dummy variable that takes the value 1 if a marketing approval is received, 0 otherwise.
Phase 1, 2, and 3	Ordinal variable that takes the value 1 if the substances reaches phase-1, 2 if the substances reaches phase-2, 3 if the substance reaches phase-3, 4 if the substances passes successfully phase-3.
Size	Natural logarithm of the market value of equity at the event date.
Implied growth options	Market to book value of equity.
Research Intensity	Percentage of R&D expenses to total assets.
Leverage	Percentage of total debt to total assets.
Profitablility	Return on equity.
Cash Flow	Cash flow measure.

The regression results are reported in table 9. The dependent variable for model 1 and model 2 is the AR for all four phases “Reaching Phase 1”, “Reaching Phase-2”, “Reaching Phase-3”, and “Success in Phase-3”. Both regressions are conducted to determine whether information on the level of the phase influences the AR on the event date. Model 1 describes the reference case without any phase-related information. In model 2, I add an ordinal variable that assigns numbers to each phase in increasing order. This is an appropriate procedure since it captures the increasing in importance of each phase for the final marketing approval. However, the coefficient of this ordinal variable in model 2 is 0.0056 (t=0.93) and statistically not different from zero.

In model 3 to model 5, the AR for events on patent or approval granting is regressed on a set of dummies and controls. Model 3 refers to the base case without any information on the type of event. In model 4, I append a dummy marketing authorization. I find that the dummy coefficient is 0.0047 (t=0.196) and not significant. This confirms that pooling patent and approval events is actually justified. The abnormal returns on the respective events are indistinguishable. Thus, the market values patent and approval announcement equally favorable. In model 5, I include a dummy accounting for FDA approval in the US. The rational is to determine whether approval decisions in the US are more positive valued than other approvals or patents. The US represents potentially the largest market for drugs and the approval decision for that particular region could have a stronger impact. The dummy coefficient is 0.0338 (t=1.794) and slightly significant at a 10 percent level. Hence, I retrieve minor evidence that US approvals are to some extent considered more value-relevant than approvals for other countries.

For model 6 and model 7, I pooled together all positive R&D progress announcements that is I grouped phase-123 and patent and approval announcements. The goal is to verify whether the hypothesized cornerstones of the drug development process are of more value-relevance than clinical trial related information. I compare directly both types of events to assess the question. The base-

case is set up in model 6. No stage-related information is included. In model 7, I add two predictor variables. The first one marks the effects related to patent and approval events. The second predictor reflects stage-related information for the clinical trial announcements. I find that the patent and approval predictor is 0.0313 (t=1.999) and highly significant whereas the variable capturing clinical trial related information is 0.0074 (t=1.455) and not significant at all.

Table 9. Cross-sectional regression results.

Cross-sectional regression estimates and independent variables from regressing the abnormal return (AR) for different R&D progress announcements on selected independent variables. See table 8 for independent variable definitions.
The White (1980) heteroskedasticity-consistent t-statistics are reported in parentheses. *** denotes significance at the 1% level, ** denotes significance at the 5% level, and * denotes significance at the 10% level.

	Dependent Variable is the AR on the event date for the event clusters						
	Phase 1, 2, and 3 announcements		Patent and Approval announcements			All positive announcements	
Independent Variable	Model 1	Model 2	Model 3	Model 4	Model 5	Model 6	Model 7
Patent and Approval							0.0313
							(1.999)**
US					0.0338		
					(1.794)*		
Approval				0.0047			
				(0.196)			
Phase 1, 2, and 3		0.0056					0.0074
		(0.93)					(1.455)
Size	-0.0098	-0.0114	-0.0123	-0.0125	-0.0127	-0.0115	-0.0119
	(-2.655)***	(-2.67)***	(-2.51)**	(-2.445)**	(-2.781)***	(-3.821)***	(-3.753)***
Implied growth options	-0.0007	-0.0009	-0.0012	-0.0012	-0.0018	-0.0007	-0.0011
	(-0.662)	(-0.839)	(-0.832)	(-0.844)	(-1.249)	(-0.956)	(-1.357)
Research Intensity	-0.0591	-0.0656	-0.1162	-0.1228	-0.131	-0.079	-0.0861
	(-1.072)	(-1.169)	(-1.68)*	(-1.637)	(-1.965)*	(-1.789)*	(-1.991)**
Leverage	-0.0005	-0.0005	-0.0008	-0.0009	-0.001	-0.0006	-0.0007
	(-1.37)	(-1.397)	(-2.349)**	(-2.004)**	(-2.876)***	(-2.173)**	(-2.669)***
Profitablility	-0.0001	-0.0001	-0.0006	-0.0006	-0.0007	-0.0002	-0.0003
	(-0.5)	(-0.585)	(-1.79)*	(-1.863)*	(-2.516)**	(-1.223)	(-1.448)
Cash Flow	>0.0000	>0.0000	>0.0000	>0.0000	>0.0000	>0.0000	>0.0000
	(1.74)*	(1.8)*	(1.403)	(1.453)	(1.54)	(2.534)**	(2.349)**
Constant	0.0953	0.0926	0.1303	0.1302	0.1289	0.1112	0.0947
	(3.33)***	(3.308)***	(4.109)***	(4.111)***	(4.294)***	(5.073)***	(4.354)***
Nobs	192	192	87	87	87	279	279
adj. R^2	0.1196	0.1239	0.1981	0.1882	0.2318	0.1616	0.1745
R^2	0.1473	0.1560	0.2540	0.2543	0.2943	0.1797	0.1983
F	4.564***	4.252***	3.891***	3.368***	4.118***	8.511***	7.419***

Across the different models, R&D intensity is only weakly related to the degree of AR on the event date. This result supports our initial hypothesis (*H 1*) on the limited explanatory power of input orientation financial disclosures when it comes to valuing R&D investments.

Furthermore, I find an inverse relationship between size and the magnitude of the AR at the event date. The size coefficient is highly significant throughout the various settings and stage-independent.

The larger a company is the less impact R&D progress announcements have on its market value. Larger firms can be assumed to have larger drug candidate pipelines. Hence, R&D investments are distributed and diversified. So, if one candidate succeeds the overall impact is likely to be smaller for larger firms compared to smaller firms that might have only very few potential drug candidates. The market value of smaller firms depends on fewer R&D projects and should therefore react more intensely on positive announcements.

The regression analysis also reveals that company leverage has a rather robust impact on the AR. Except for model 1 and model 2, I find that higher leverage is negatively associated with the AR on the event date, ceteribus paribus. The results are highly significant. The potential reward for high-levered companies of receiving a patent or marketing approval could be smaller because such firms lack the financial resources to extract all future benefits. If a high-levered firm is granted a patent, for example, it could be questionable whether it can proceed smoothly through all the remaining, cost-intensive clinical trials. Also, if such a firm receives marketing approval it is not clear whether it possess the funds and the structure to penetrate the market in full. Thus, the firm might not be able to exhaust completely the potential of the drug. Investors seem to recognize the associated drawbacks for high-levered firm and account for them in their market valuation.

5 Discussion

The empirical analysis supports my initial hypotheses on the market reactions to R&D progress announcements.

Event-study results reveal that non-financial disclosures are of value-relevance to investors. Market reactions are significantly different from zero upon the release of non-financial disclosures as shown in table 4. Investors obviously use such information on the advancement of R&D to adjust their value perception. These finding are in line with *H1*.

After splitting the sample into patent and approval announcements as well as clinical trial-related announcement, I find again significant positive price reactions. However, the stock movements are more pronounced for patent and approval information than for clinical phase successes. This result supports *H2*. Investors value that information more favorably that are accompanied by a sensible uncertainty reduction. R&D progress announcements lead to significant market reactions that are stronger to positive corner-stone announcements than to encouraging interim results. The value impact for patent and approval announcements is significantly positive over the entire 60-day-window whereas the price reactions to the clinical-trial related announcements vanish over the same time period.

The findings are in line with Bosch and Lee (1994), Sharma and Nelson (2004) who also report strong positive market reactions to product approvals. Moreover, the sharp reactions to negatively toned announcements also confirm the rationing that investors value those announcements most strongly that are associated with less uncertainty. Adverse news during the drug development process usually indicates the abandonment of the project. Therefore, the investors gain certainty in a negative sense – that is the R&D investment will not create future benefits but only sunk costs.

Regression results provide further support for *H2*. Regression model 2 as well as model 7 indicates that clinical phase-related information is not incorporated by the investors. The market reactions to the R&D progress in clinical trials is not phase-dependent since the phase-variable is statistically not significant. In contrast, patent and approval information is what investors regard as most valuable. The patent and approval dummy variable in model 7 is highly significant. The results indicate that AR returns for patent or approval announcements are circa 3 percent higher than for clinical trial success information, ceteribus paribus. Therefore, one can confirm *H2*. Investors assign greater value-relevance to the cornerstone announcements patent granting and marketing approval than to clinical trial based news. Investors react most strongly to announcements that are associated with less uncertainty compared to interim-announcements. Receiving a patent and being granted marketing approval seem to be the most important stages in the drug development process for outside investors.

6 Summary and Implications

In this study I address the question how R&D investments create value by examining how R&D progress is transmitted into stock prices. I use non-financial disclosures on the drug development process for biotech and pharma companies as an indicator for R&D progress.

Unlike the stereotype one-time R&D information in most other industries about, e.g., a new product launches, R&D in the biotech and pharma sector is described as a clear-cut and highly sequential procedure. The drug development process is characterized by several unique but chronological stages. This structured process allows me to analyze the market impact of R&D announcement along the drug development.

I outline the institutional set-up for R&D valuation. The fundamental challenge in the context of R&D valuation is the limited availability of dependable information. Thus, investors are exposed to vast *uncertainty and asymmetric information*. As a result, I argued that investors use non-financial disclosures as an additional information source in valuing R&D investments. Moreover, I presumed that those information which is associated with the least remaining uncertainty are most relevant to in-

vestors. I divided R&D-related uncertainty into technical and legal uncertainty. For these categories, marketing approval and patent granting mark the ultimate endpoints. Therefore, I assumed that market reactions are most pronounced for these announcement classes.

Based on a sample size of 350 announcements, I conduct an event study and cross-sectional regression analysis. The results support the initial hypotheses. Investors seek non-financial disclosures on the progress of R&D in valuing the firm. I find evidence that stock market reactions are significantly different from zero for such announcements. Moreover, stock prices react heavily once the drug candidate enters a stage with low levels of remaining uncertainty.

Thus, the study contributes to a better understanding of the valuation of R&D investments. It sheds light on the way investors deal with high levels of uncertainty and asymmetric information in assessing the fair market value of R&D investments.

The market takes into account all available information – especially non-financial disclosures on the R&D progress – when valuing R&D investments. Investors consider all accessible information over the entire R&D process to cope with information asymmetry and create a more profound basis for the value estimates. Furthermore, the findings underline the complex structure of the R&D investments. Investor reactions are stage-depended and are sensitive to the uncertainty related to each development stage. I find evidence that price reactions are withheld until a certain amount of uncertainty is extracted from the underlying R&D investment.

The implications of this study are twofold. From an outside-investor perspective, including non-financial disclosures into the valuation process can considerable improve the quality of valuation estimates. Further, company managers themselves can benefit from a comprehensive communication with investors. Providing continuously updated information on the ongoing R&D helps to reduce the existing information asymmetries and decrease potential risk premia. Moreover, this information must provide sufficient uncertainty reduction to be valued accordingly. As indicated above, stock price reactions are most pronounced for announcements related to low levels of uncertainty. In the case of R&D projects, investors perceive an announcement to have a distinct value impact when it marks a nearly complete reduction of uncertainty – patent granting and marketing approval. Managers therefore are challenged to assign greater reliability to their interim announcements. Both, the embedding of detailed, worthwhile management assessments and a long-dated development of reputation can add the necessary trustworthiness to interim announcements.

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