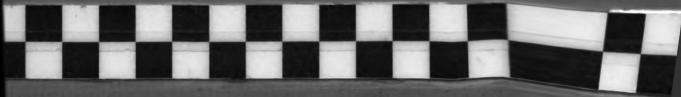




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INTANGIBLE ASSETS: A STUDY OF R&D SUCCESSES
IN THE PHARMACEUTICAL INDUSTRY

presented by
Rebecca Toppe Shortridge

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Ph. D. degree in Accounting

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USING NON-FINANCIALS AS MEASURES OF
INTANGIBLE ASSETS: A STUDY OF R&D SUCCESSES
IN THE PHARMACEUTICAL INDUSTRY

By

Rebecca Toppe Shortridge

A DISSERTATION

Submitted to
Michigan State University
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1999

ABSTRACT

USING NON-FINANCIALS AS MEASURES OF INTANGIBLE ASSETS: A STUDY OF R&D SUCCESSES IN THE PHARMACEUTICAL INDUSTRY

By

Rebecca Toppe Shortridge

This paper examines the valuation implications of a non-financial measure of intangible assets in the pharmaceutical industry. Specifically, I hypothesize that the number of new drugs approved (NDAs) by the Food and Drug Administration provides incremental information to financial variables when assessing a pharmaceutical company's future operating earnings and when predicting its current market values. Further, the paper hypothesizes that the R&D expenditures of successful product developers are more valuable than the expenditures of less successful product developers. The mean number of NDAs obtained by a firm during the sample period is used to distinguish successful from non-successful product developers.

Tests of the hypotheses are conducted utilizing a sample of 23 traditional pharmaceutical firms and 16 generic pharmaceutical firms. The financial and price data was collected from archival databases. The FDA data detailing the drug approvals was obtained from the Food and Drug Administration.

Overall, the results from pooled, cross-sectional regression analyses of the traditional pharmaceutical firms provide support for the hypotheses. In particular, the number of approved new drug applications is positively associated with future sales and with future operating earnings. In addition, the number of NDAs received by a

traditional pharmaceutical firm is correlated with the firm's stock price three months after the fiscal year end. Despite the association with stock price, NDAs are not associated with stock returns. Finally, the results indicate that investors value the R&D of successful product developers more than that of non-successful developers. These results suggest that NDAs can be used as a proxy for the knowledge created with investments in R&D.

The results for the generic pharmaceutical firms are not as strong as those obtained for the traditional firms. First, NDAs are not associated with sales for the generic firms although they are marginally associated with operating earnings. However, NDAs are useful in assessing firm value. These conflicting results might be attributed to the nature of generic firms. Specifically, generic firms generate revenues by offering lower prices than branded products. Thus, my tests may not be sensitive enough to detect the incremental benefit to annual sales and earnings from one additional drug product. The results fail to document a relationship between NDAs and stock market returns. Further, the R&D of successful firms is not valued more positively than the R&D of non-successful firms in either the price or returns model.

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I would also like to thank a few other Michigan State faculty members who have provided me with encouragement and guidance through my tenure at Michigan State. In particular, Dr. Al Arens and Dr. Matt Anderson have served and will continue to serve as role models for me during my career as an academic.

My fellow doctoral students have been a source of strength throughout my studies at Michigan State. Norman Godwin class of 1996, provided invaluable guidance and support during my first two years as a student. Donna Booker was always there to listen to my troubles and joys. Lydia Whitt Rosencrants was a constant companion and friend who provided a shoulder to cry on, a hug for support, and a cheer for my successes.

Finally, I would like to thank my family. My parents, Ron and Judy Toppe, provided me with the desire to learn, the determination to persevere, and the strength to know that I could accomplish whatever I wanted to achieve. Brad, my husband, has made this dream possible. I could not have asked for a more supportive, loving man to help me through these five years. Finally, thank you, Jackson, for helping me to understand what matters most in life.

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Chapter One

INTRODUCTION AND OVERVIEW

Recently, the usefulness of Generally Accepted Accounting Principles, GAAP, has been questioned in the popular press, accounting circles, and academia. Many of the criticisms focus on the fact that most intangible assets are not measured in financial statements.¹ There is little doubt that a large portion of a company's value is derived from its intangible assets. As an indication of this, in 1996 the stock price of firms on the S&P 500 was four times their asset base (Myers 1996). Numerous research papers have documented a relationship between intangible asset proxies and stock price (Hirschey 1982, Hirschey and Weygandt 1985, Sougiannis 1994, Amir and Lev 1996, Barth, Clement, Foster, and Kasznik 1998, Chambers, Jennings and Thompson 1998). However, U.S. accounting regulations assert that most intangible assets should not be recognized on a firm's balance sheet because their values cannot be reliably estimated.² The International Accounting Standards Committee (IASC) has taken strides to recognize some intangible assets by issuing a statement that would permit the capitalization of developed intangibles with identifiable benefits (IASC 1998).

¹For a discussion of some of the weaknesses of GAAP see Fox (1996), Davidow (1996), Wallman (1996, 1995), Bouwman, Frishkoff, and Frishkoff (1995), AICPA (1994) and Elliott (1992).

²Statement of Financial Accounting Standards 2 requires firms to expense all costs associated with research and development activities in the period they are incurred (FASB 1974). This rule was established because the FASB believed it was too difficult to determine the future value of R&D expenditures that might never result in future sales, let alone a profitable product.

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1.1 Motivation

The purpose of this paper is to examine the valuation implications of a non-financial measure of intangible assets in the pharmaceutical industry. Specifically, I consider if new drug applications approved by the Food and Drug Administration provide incremental information to financial variables when assessing a pharmaceutical company's future operating earnings and when predicting its current market value.

The pharmaceutical industry provides an ideal setting to investigate intangible assets as firms in this industry are dependent on their ability to continually develop new products for their drug pipelines. To keep the drug pipelines full of new products, pharmaceutical firms spend millions of dollars on research and development (R&D) every year. These expenditures are presumably incurred to create an asset that will increase the firm's operating performance. However, under U.S. GAAP, no asset is recorded for these expenditures.

Numerous accounting papers examine the relationship between R&D expenditures and market value (Hirschey 1982, Hirschey and Weygandt 1985, Sougiannis 1994, Aboody and Lev 1998). This research stems from the belief that R&D creates an intangible asset and thus should be reflected in stock price. However, R&D expenditures may not be the ideal measure of intangible assets. First, most R&D expenditures never result in a new marketable product. Further, even if the R&D is successful, considerable time generally lapses between the occurrence of R&D and the related product sales. The current paper adds to this literature by examining if the value of the intangible asset created with R&D might be better assessed with a measure of R&D success (i.e. new drug applications) rather than with R&D expenditures.

1.2 Overview of hypotheses

In order for a firm to market any pharmaceutical product, it must file a new drug application with the Food and Drug Administration (FDA). The number of New Drug Approvals (NDAs) granted to a firm represents the number of products the firm can sell on the market. R&D expenditures, available to investors in annual reports, only provide measures of input to the development process. However, much of the investment in R&D may never result in future products. NDAs, meanwhile, are obtained immediately before a product will be marketed; and, therefore, NDAs should be a more reliable measure of future firm profitability than R&D expenditures. Hence, the hypotheses assert that NDAs are a proxy for the intangible asset created with R&D expenditures and should be positively associated with future operating performance even after controlling for R&D expenditures.

Further, if NDAs are associated with future operating performance, they should also be positively associated with contemporaneous market valuation measures. To test the market hypotheses, I regress stock price and stock returns on traditional financial variables, on R&D expenditures, and on the number of NDAs obtained during the fiscal year.

This paper also examines if the R&D expenditures of successful product developers are more valuable than the expenditures of less successful product developers. It is likely that some firms are more efficient at generating new drug products than other firms. A potential measure of a firm's level of achievement is the number of new drug approvals received. Thus, using NDAs, I distinguish successful product producers from non-successful product producers. If the division between firms is appropriate, the R&D

of successful firms should be valued more highly by the market than the R&D of non-successful firms.

1.3 Overview of research design

Tests of the hypotheses are conducted utilizing a sample of 23 traditional pharmaceutical firms and 16 generic pharmaceutical firms. The financial and price data was collected from archival databases. The data detailing the new drug approvals was obtained from the Food and Drug Administration.³ Regression analysis is used to examine the hypotheses outlined in the previous section. Several alternate tests are conducted to ensure the robustness of the results.

1.4 Overview of results

Overall, the empirical results provide support for the hypotheses and imply that NDAs are a proxy for the intangible asset created with investments in R&D. In particular, for traditional pharmaceutical firms, the number of approved new drug applications is positively associated with future sales and future earnings even after controlling for R&D expenditures. Sensitivity analyses further confirm the importance of R&D success for the traditional firms by showing that NDAs remain positively associated with future sales and with future earnings even after including five years of R&D and patent data.

³Investors and other interested parties may obtain information about product approvals from annual reports, 10-Ks, or news releases. I chose to obtain the product approvals from the FDA because it is a complete list of all approvals granted by the Food and Drug Administration.

In addition, the results support the idea that NDAs are important predictors of market value. For the traditional pharmaceutical firms, NDAs are positively associated with current stock price, adding \$0.34, or just under one percent, to the average share price of \$41.27. Once again, sensitivity analyses confirm the importance of NDAs by establishing that the coefficient on NDAs is still positive and significant in the price model after including five years of R&D and patent data.

Despite the positive association between NDAs and stock price, there is no apparent relationship between NDAs and stock market returns for traditional pharmaceutical firms. This is similar to results found in Hirschey, Richardson, and Scholz (1998) in which patent data is reflected in stock price but is not associated with firm returns. The lack of significance in the returns model is likely due to the use of a long window to measure the impact of an event, the receipt of a new drug approval.

The results from the tests of the successful developer hypotheses for traditional firms are also insightful. Firms are classified as successful or non-successful developers based on the mean number of NDAs obtained over the sample period. Firms classified as successful producers have, on average, higher stock prices than those classified as non-successful producers. This result supports the conclusion made earlier that NDAs are a proxy for intangible assets that are not reported on the balance sheets of pharmaceutical firms. In addition, the R&D of successful firms is positively valued by the stock market while the R&D of non-successful firms is not. This suggests that investors are sophisticated as they can distinguish successful from non-successful firms and value firm R&D investments accordingly. Once again, the returns model does not reveal a

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relationship between the proxy for successful drug development and a firm's stock market return.

The results for the generic pharmaceutical firms are mixed. First, NDAs are not associated with sales and are only marginally associated with earnings. This result is most likely due to the fact that generic firms compete by offering reduced prices on branded products whose patents have expired. This strategy means that each additional NDA produced by a generic firm results in a smaller increase in sales revenue and operating profits than an NDA produced by a traditional firm. Therefore, it is likely that the incremental benefits obtained from an NDA of a generic firm are too small to be detected in the annual sales and earnings models.

Even though there is not a strong relationship between operating performance and NDAs for the generic pharmaceutical firms, NDAs are positively associated with stock price. More specifically, each NDA increases stock price by approximately four percent of the average share price of \$12.86, or \$0.47. Thus, even though the incremental benefit from an additional NDA cannot be detected in the sales or earnings models, investors know that NDAs improve the long-range operating performance of the generic companies and value them accordingly. As with the traditional firms, NDAs are not associated with market returns.

Finally, generic firms that are classified as successful producers have, on average, higher stock prices than those classified as non-successful producers. Contrary to predictions, however, the R&D of successful firms is not valued more positively than the R&D of non-successful firms. Surprisingly, the R&D of non-successful companies is positively associated with stock price while the R&D of successful companies is not.

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Once again, there is no relationship between proxy measures of successful R&D and stock market returns.

1.5 Summary

Taken together, the empirical analyses suggest that NDAs can be used as a measure of successful R&D efforts. These results are similar to those found in Amir and Lev (1996), Fornell, Ittner and Larcker (1996), Barth, Clement, Foster and Kasznik (1998) and Hirschey, Richardson, and Scholz (1998) in which non-financial data provides supplemental information to financial data in predicting future sales, earnings, and current stock price.

The remaining chapters are organized as follows. Chapter 2 discusses the pharmaceutical industry and its drug approval process. A review of relevant literature and the development of the hypotheses are contained in Chapters 3 and 4 respectively. Chapter 5 describes the sample used for the study. A case study of a new drug approval for Schering Plough Corporation is discussed in Chapter 6. Chapter 7 presents the empirical results. I summarize the paper in Chapter 8.

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Chapter Two

THE PHARMACEUTICAL INDUSTRY

Before making reasonable assumptions about the important intangible assets in an industry, it is first necessary to have a thorough understanding of how the industry operates. This chapter provides an overview of the pharmaceutical industry and the Food and Drug Administration approval process.

2.1 Overview of the industry

The U.S. pharmaceutical industry is a thriving business. Statistics indicate that during the last two decades it has been the world's leading innovator in drug products. In fact, American pharmaceutical firms hold patent rights to 92 of the 100 most prescribed drugs in the U.S. (Schweitzer 1997). Despite its successful innovations, the industry is frequently criticized for earning excess returns. However, the Pharmaceutical Researchers and Manufacturers Association, an organization that follows developments in the industry, points out that few drugs ever recover their development costs (PhRMA 1997). The association goes on to argue that without reasonable returns on R&D investments, the industry would not be able to obtain the capital needed to invest in innovative medicines that can greatly enhance the lives of many people. To understand the need for large returns on successful products, the next section discusses the uncertainties and time involved in the drug development and approval process.

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2.2 Drug development and approval

Prosperity in the pharmaceutical industry is dependent upon a thriving pipeline of new pharmaceutical products that are created with research and development activities. As an indication of the significance of R&D activities, in 1995, research-based pharmaceutical companies spent 19.4% of sales, more than \$15 billion, on research and development (PhRMA 1997). Meanwhile, the average U.S. industry spent less than 4% of sales on R&D (PhRMA 1997).

Developing new products to fill the drug pipeline is expensive and involves a great deal of uncertainty. In fact, statistics show that only one of 5,000 new compounds ever reaches human testing (Beary 1997). Figure 1, a diagram adapted from Schweitzer (1997), illustrates the process and length of drug development and testing. The process begins with a market analysis to determine if a proposed project has economic potential. This analysis includes an assessment of the pervasiveness of the condition to be treated as well as the market potential for the new drug. After a project passes this initial market analysis, the next phase involves research and testing to determine what causes the condition. This research, frequently called basic research, is the longest and most expensive part of drug development. The focus of this phase of research is to discover a new chemical that will enhance the treatment of the condition. A new chemical in the pharmaceutical industry is referred to as a new molecular entity (NME).

Once basic research has discovered a new molecular entity, testing begins with the assistance of computer models and cell cultures. If this step is successful, testing continues on animals. These initial development and testing procedures take an average of 42.6 months to complete (Schweitzer 1997). Many firms, upon discovering an NME,

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apply for patent protection. A patent grants the filing firm the exclusive right to market the NME for seventeen years from the date the patent is approved.⁴

After completing pre-clinical testing, the NME must pass the rigorous testing requirements of the FDA. First, a firm files an application for an investigational new drug which allows the company to begin testing on human subjects. Human testing proceeds in a series of three phases. Phase I trials typically include a small number of healthy volunteers. Phase II trials are performed on individuals who are suffering from the ailment the drug was developed to cure. These tests are conducted using double-blind placebo testing. Finally, Phase III involves testing in hospitals and outpatient settings. These tests establish the drug's safety and effectiveness. If the proposed product passes all three phases, the firm then files a new drug application with the FDA.⁵ This entire process, from the time early research begins until the time a new drug is approved, averages approximately 12 years (Schweitzer 1997).⁶

Although measures of innovative input, R&D expenditures, are available early in the product development cycle, they may have little meaning in determining the value of a company because of the time and risk of getting a product to market. Therefore, output

⁴In 1995, the international World Trade Organization enacted a treaty extending the patent period for all member countries to 20 years from the date of filing. However, it is unclear if this treaty actually extends the period of exclusive marketing as the clock starts at the date of filing instead of the date of patent approval. (Schweitzer 1997)

⁵It is not unusual for a firm to seek product approval in a foreign country before seeking approval in the United States. This occurs because U.S. regulations are much more stringent than those in many foreign countries. Hence, a drug may be marketed for several years in a foreign country before it is available in the United States.

⁶The process described is frequently abbreviated for drug products that copy existing chemicals. For example, generic pharmaceutical firms copy off-patented drugs. Because the generic firms are duplicating already marketed drugs, these firms merely must establish that the copied product is chemically identical to a drug that has already been approved.

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measures, such as successful product developments, may be more useful to investors when assessing the value of a firm.

2.3 Summary

This chapter provides a brief overview of the pharmaceutical industry as well as a description of the drug approval process. One of the most important ideas established in the chapter is the risk and time involved in the drug development and approval process. The remaining chapters of the paper rely on the industry knowledge to develop and test the hypotheses outlined in Chapter 4.

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Chapter Three

THEORY DEVELOPMENT

There are three different research streams that are relevant to the current project: economics literature that examines the relationship between R&D efforts and R&D productivity, accounting literature that examines the relationship between R&D expenditures and stock prices, and accounting literature that examines non-financial proxies for intangible assets. These three streams of literature will be discussed independently in Sections 3.1, 3.2, and 3.3.

3. 1 Economics Literature

Relevant economic papers have focused on the relationship between R&D efforts and measures of R&D productivity. Bound et al (1984) is one of the first economics papers to evaluate the relationship between R&D and patents. Using a sample of all manufacturing firms listed on the 1976 Compustat Tapes that report both R&D and patents, Bound et al plot the log of patents against the log of R&D expenditures, both scaled by assets. The plot indicates that there is a strong correlation between the number of patent applications and R&D expenditures. Particularly relevant to the current study, a regression of patents on R&D that controls for industries indicates that the drug industry has a significantly higher than average propensity to patent.

Pakes and Griliches (1984) confirms the relationship between patents and R&D in a more comprehensive study that uses patents as a measure of economically significant knowledge. Using the data from Bound et al (1984), Pakes and Griliches show that when

a firm changes its R&D expenditures, parallel changes occur in its level of patenting. In addition, they attempt to estimate the lag structure of R&D. Although the lag effects are significant, the contemporaneous relationship between R&D and patents appears to be most dominant.

Hall, Griliches, and Hausman (1986) expands the sample used in Pakes and Griliches (1984) and focuses on establishing the lag structure between patents and R&D. Their model, like that of Pakes and Griliches', assumes that patents are an indicator of R&D successes. Their results again confirm that there is a strong contemporaneous relationship between R&D expenditures and patents even after controlling for firm size and the lag structure of R&D. They also show that the R&D history included in their model (they include as many as eight years of lagged data) seems to add little to the explanation of the current year's patent applications. However, Hall, Griliches, and Hausman point out that it is difficult to correctly estimate the lag structures because the R&D expenditures across time are highly multicollinear.

These three economic papers all reach the same basic conclusion—there is a strong contemporaneous relationship between patenting and current R&D expenditures. While the authors of all three of these papers acknowledge that they believe R&D history should be important to the prediction of patents, they cannot establish a strong relationship between the R&D lag structure and patents because of multicollinearity. The results from these three papers do suggest that patents are an indicator of the success of R&D activities.

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3.2 Returns to R&D

Some accounting papers attempt to measure the benefits of R&D investments by testing if the expenditures create an intangible asset. To establish the presence of the asset, R&D expenditures are shown to be associated with operating profits and firm value. For example, Hirschey (1982) examined the impact of intangible assets on the market value of a sample of 390 firms listed on the 1977 Fortune 500. Hirschey first analyzed the issue from a theoretical perspective by creating a model that showed that, with a constant rate of amortization and expenditure growth, the relationship between the capital created by intangibles and current levels of expenditures is proportional. Relying on this proportional relationship, Hirschey developed a model to establish the market value of a firm by relying on indicators of future profit, including: current profit, book value of tangible assets, R&D expenditures, and advertising expenditures. Using the sample from Hirschey (1982), Hirschey and Weygandt (1985) altered the above model slightly by using Tobins' Q as the dependent variable. This measure of the dependent variable accounts for the replacement costs of tangible assets, thus more directly isolating the market value of intangibles. The empirical results of both papers indicate that R&D is a significant predictor of the current market value of the firm.

More recently, Sougiannis (1994) and Lev and Sougiannis (1996) examine the value of corporate R&D and its capitalization. Sougiannis (1994), using a sample of 573 firms listed on the National Bureau of Economic Research's RND-Panel, first shows that R&D is positively associated with earnings by regressing earnings on R&D expenditures lagged up to seven years with various control variables. The R&D coefficients vary from positively to negatively significant. This suggests that in some years, the cost of R&D

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outweigh the benefits. He then includes R&D in a valuation model. The results show that a one-dollar increase in R&D results in a total increase in market value of five dollars.

Lev and Sougiannis (1996) further extends prior work by including industry-wide estimates of the value of R&D. Particularly relevant to the current project, Lev and Sougiannis' results suggest that for firms in the chemical and pharmaceutical industry, a one dollar investment in R&D increases future earnings by \$2.63. Overall, the results of both papers imply that R&D is important to investors and that investors appear to restate financial statements when determining stock price to include a measure of capitalized R&D.

All four of these papers, Hirschey (1982), Hirschey and Weygandt (1985), Sougiannis (1994) and Lev and Sougiannis (1996), rely on financial statement measures of R&D expenditures to assess the value of intangible assets to the market. However, because of the length of time required to produce a new product and the uncertainty involved in the development process, R&D expenditures may not be the best measure of the intangible asset. Some recent accounting researchers have begun to address the problem of using expenditures as a measure of intangible assets by using non-financial variables as measures of the intangible assets. Several of these accounting papers are discussed in the next section.

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3.3 Non-financials as measures of intangible assets

3.3.1 Using non-financials to assess market performance

Amir and Lev (1996) is the one of the first papers in a new line of research that attempts to use non-financial information as an indicator of intangible assets. Their sample is comprised of firms in the wireless communications industry. Most of the firms in their sample are start-up companies that have never had positive earnings. Because of this, Amir and Lev believe that their sample firms' financial information is not likely to be useful in predicting stock price or stock returns. Indeed, their research shows that financial information alone is of little use in predicting stock prices and returns in the cellular communications industry. Meanwhile, POPS, a measure of the population in geographic areas where the firm is licensed, is a significant predictor of price. The authors explain this result because POPS is a measure of the future growth potential of the company. In addition, when POPS is included in the valuation model, book value per share and earnings per share are positively associated with stock price. These results suggest that financial and non-financial information provide complimentary information to each other.

Barth, Clement, Foster, and Kasznik (1998) examines the importance of brand values to the capital market. Barth et al rely on estimates of the dollar value of various brands from an annual survey published in *FinancialWorld*.⁷ These estimates make their study of non-financial measures unique because the authors have an estimate of the dollar

⁷The estimates include an assessment of brand-related profits (operating income from a brand minus operating income from a similar generic product), leadership in the market, stability in the market, and others. This process produces a dollar amount estimate of the value of the brand. For example, the Gillette name was estimated to be worth \$10.3 billion.

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value of the intangible instead of a count variable as used in most papers. The authors regress market value on book value per share, earnings per share, and the total brand value per share. Using a fixed-effects pooled regression, they demonstrate that brand values are positively associated with stock price, even after controlling for net income and the book value of equity. Thus, the results are counter to arguments asserted by SFAS 2 which does not allow recognition of intangible assets because they cannot be reliably estimated. This study may be biased, however, because the brand value assigned to the firms might be partially determined by market prices. If this is true, brand value and stock price are associated by construction.

Hirschey, Richardson and Scholz (1998) considers the valuation implications of non-financial measures as proxies for the intangible asset created with R&D expenditures using a sample of high-technology firms.⁸ In particular, the authors posit that patents are indicators of the intangible asset created by inventive activities. However, patents are not a perfect measure as they vary in economic value and scope. Patent scope determines the ability of competitors to manufacture sister products that can take away market share from the original developer. Thus, the authors argue that measures of the quality of patents obtained may provide additional incremental information to the market when predicting stock price. To test the theory, they obtain three measures of patent quality from the *TECH-LINE* database: frequency of patent citations, number of scholarly citations on the patent application, and the median age in years of earlier U.S. patents

⁸The sample is comprised of firms listed in the *TECH-LINE* database. Non-manufacturing firms and those which are in low-tech industries are eliminated from the sample. Thus, the final sample is comprised of firms in the following industries: chemicals and allied products; petroleum refining; industrial and commercial machinery and computer equipment; electronic and other electrical equipment; transportation equipment; measuring, analyzing and controlling instruments; and communications.

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referenced in the patent application. Relying on the Ohlson model (1995), Hirschey, Richardson, and Scholz run a pooled time-series, cross-sectional regression using stock price as the dependent variable. The independent variables are the number of patents granted to firms, the three measures of the quality of patents, book value, earnings, R&D expenditures, and advertising expenditures. Their regression results show that, individually, the number of patents as well as the three measures of patent quality provide incremental information to financial data when assessing stock price. When jointly included in the valuation model, the number of patents and two of three measures of patent quality are significantly positive.

3.3.2 Using non-financials to predict operating performance

In a somewhat different framework, Fornell, Ittner, and Larcker (1996) investigate the valuation consequences of customer satisfaction indexes. Using the American Customer Satisfaction Index (ACSI), they first evaluate if customer satisfaction is reflected in contemporaneous financial statements. To examine the relationship between customer satisfaction and financial statements, the authors provide Pearson correlations between ACSI scores and financial ratios that reflect operating performance. The correlations show that the ACSI scores have a statistically positive association with return on assets, implying that the ACSI scores are at least partially reflected in accounting returns. After concluding that ACSI scores are reflected in accounting numbers, the authors continue the analyses to assess if customer satisfaction is economically relevant to the stock market. Correlations between the ACSI scores and stock valuations (price earnings and market-to-book) are also significantly positive. To strengthen the results, the authors perform regression analyses of the two stock valuation

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measures on the ACSI scores, risk (beta), *Value Line*'s estimates of dividends per common share, and either forecasted earnings per share or forecasted book value. In both cases, the estimated coefficient on the customer satisfaction scores is positive and significant.

In a paper similar to that of Fornell, Ittner, and Larcker (1996), Behn and Riley (1997) examine the usefulness of non-financial indicators to decision makers. In particular, the authors examine the association between non-financial indicators of intangible assets and financial performance measures. Using data from the U.S. domestic airline industry, Behn and Riley use an instrumental variables approach to establish that on-time performance, mishandled baggage, and in-flight service are significantly associated with customer satisfaction. They then use regression analysis to document a positive relationship between the intangible asset, customer satisfaction, and operating earnings and revenues. To reduce the possibility of correlated omitted variables, the authors are careful to include additional key industry variables in the model: load factor, market share, and available miles scheduled. Their results, similar to those found in Fornell, Ittner, and Larcker (1996), establish that non-financial performance information, in particular customer satisfaction, can be useful in predicting financial performance in the airline industry.

3.3.3 Synopsis of papers examining non-financial measures of intangible assets

The results from Amir and Lev (1996), Barth, Clement, Foster, and Kasznik (1998), and Hirschey, Richardson, and Scholz (1998) indicate that non-financial measures of intangible assets are positively associated with market value. Fornell, Ittner, and Larcker (1996), and Behn and Riley (1997) provide evidence that suggests that non-

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financial information can be used to predict future operating performance. Overall, both groups of papers imply that financial and non-financial measures are complimentary to each other and that both should be utilized by decision makers when assessing a firm's market value and when predicting a firm's future operating performance.

3.4 Summary

There is little doubt that the research and development activities of firms create knowledge that can be used to create a competitive advantage. What is questionable is the best way to measure the value of that knowledge. In this regard, numerous research papers have examined the relationship between R&D expenditures and various performance indicators. The disadvantage of this methodology is that much R&D may be wasted and that fruitful R&D may be incurred years before the benefits of the R&D are realized. Thus, using non-financial measures of the knowledge obtained through R&D efforts in conjunction with the financial measures of R&D expense may enhance the prediction of operating and market performance measures.

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Chapter 4

DEVELOPMENT OF HYPOTHESES

Pakes and Griliches (1984) lends insight into the problem of valuing the intangible asset created by R&D expenditures. Their insight is used to unite the three diverse streams of literature presented in Chapter 3 and to develop the hypotheses.

4.1 Economic value of knowledge

Pakes and Griliches (1984), argues that R&D is used to create economically valuable intellectual knowledge, K (See Figure 2). A problem arises because K , a measure of the productivity of R&D activities, is not observable. Thus, in Figure 2, K is shown as k , the net accretion of valuable knowledge. As discussed in Chapter 3, economists working in this area have generally tried to measure k with the number of patents applied for or granted to firms. However, there are numerous problems with using patent counts as a measure of economically significant knowledge in the pharmaceutical industry. First, pharmaceutical firms typically apply for patents very early in the drug development process. DiMasi et al (1991) and Dranove and Meltzer (1994) suggest that a twelve to fourteen year delay between patenting and FDA approval is not unusual. Further, in order for a pharmaceutical firm to market a new drug, it must pass the rigorous testing requirements of the Food and Drug Administration. A patent provides no information about the ability of a new chemical to pass FDA testing; it merely indicates the existence of a new compound and grants production rights to the developer. Toole (1997) argues that patents provide no indication as to the therapeutic

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value of a chemical. In addition, some firms choose not to patent. Generic pharmaceutical companies have few, if any, patents because their business tactic is to recreate and produce off-patented products at low prices. And, as discussed in Toole (1997), many innovations are not patented because firms rely on the old adage: “patent that which you cannot keep secret.” Finally, it is difficult to relate the number of patents to firm performance as the economic significance of individual patents varies immensely.

To alleviate some of the problems associated with using patents as a measure of R&D success, I rely on a proxy that is unique to the pharmaceutical industry. Specifically, the number of new drug applications approved by the FDA will be used as a measure of successful R&D activities.⁹ NDAs are obtained by a pharmaceutical firm very near the time that a new drug product is introduced on the market. Therefore, a count of NDAs should be more reliable than patent counts because much of the uncertainty with product viability and all of the uncertainty of FDA approval has been eliminated. Further, all firms, including generics, must obtain NDAs before their products can be introduced on the market. Thus, the number of NDAs can be used to measure the productivity of R&D, regardless of firm type.

⁹Another potential measure of a successful product is New Chemical Entities (NCEs). This measure is used in Toole (1997) to assess the impact of federally funded basic research on innovation in the pharmaceutical industry. NCEs are granted to completely new molecular entities and not to those that replicate existing entities. Thus, drugs that slightly improve or that copy an existing chemical would not be included as a new product. Further, generic drug companies would appear to have no marketable products as they do not create new chemical entities. Thus, using NCEs as a measure of successful products would greatly limit the measure of a successful product. Therefore, I do not rely on NCEs as a measure of new product developments. The relationship between NCEs and NDAs might be interesting to examine in future research.

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4.2 Hypotheses

The top part of Figure 2 shows that the knowledge created by R&D activities is an important predictor of a firm's future economic success; it helps to create future earnings and increases the market value of the firm. These economic successes, the Zs in Figure 2, are ultimately the variables that are interesting to predict. If NDAs are measures of economically valuable knowledge created by successful R&D projects, then NDAs should contribute to the future operating performance of pharmaceutical firms.¹⁰ Hypotheses 1 and 2 state the predicted relationships between NDAs and future operating benefits:

H₁: *The number of new drug applications approved by the Food and Drug Administration during fiscal year t-1 will be positively associated with the sales revenue of pharmaceutical firms during year t.*

H₂: *The number of new drug applications approved by the Food and Drug Administration during fiscal year t-1 will be positively associated with the operating earnings of pharmaceutical firms during year t.*

If NDAs are available to decision makers and if NDAs are associated with future operating earnings, they should also be associated with current stock prices and market

¹⁰ Perhaps the ideal measure of the knowledge created with R&D activities would be a measure of the value of each new drug application. It is likely that some new products generate much higher sales than others and thus result in higher earnings. For example, Claritin is a widely prescribed product as many people suffer from allergies. However, Pitocin, a drug that is used to induce labor in pregnant women, would not be broadly prescribed. This type of data is difficult, if not impossible, to obtain. Therefore, I simply rely on a count of NDAs as a rough proxy for the value of knowledge obtained through R&D expenditures.

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returns. Hypotheses 3 and 4 state the expected relationship between NDAs and market variables:

H₃: *The number of new drug applications approved by the Food and Drug Administration during fiscal year t will be positively related to the firm's contemporaneous stock price.*

H₄: *The number of new drug applications approved by the Food and Drug Administration during fiscal year t will be positively related to the firm's contemporaneous market return.*

Finally, the X's in Figure 2 represent other observed variables that influence firm benefits. They can be thought of as control variables in the relationship and might consist of things such as tangible assets and firm size. The v's are other variables which impact firm profitability but that cannot be directly observed. These might be comprised of other intangible assets such as customer satisfaction or name recognition.

It is possible that the number of NDAs can be used to identify firms which are relatively more successful at creating new products for their drug pipeline. More precisely, it is likely that some pharmaceutical firms obtain more NDAs per dollar of R&D than other pharmaceutical firms. Conversations with market analysts confirm this idea. In fact, the analysts suggest that some pharmaceutical firms are more methodical at targeting their research efforts and thus are more successful at creating new products. If

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this is true, the R&D of successful firms should be more highly valued by the stock market than the R&D of non-successful firms.¹¹ Hypotheses 5 and 6 explore this idea:

H₅: *The research and development expenditures of successful firms will have a greater positive association with stock price than the research and development expenditures of non-successful firms.*

H₆: *The research and development expenditures of successful firms will have a greater positive association with market returns than the research and development expenditures of non-successful firms.*

4.3 Summary

Pharmaceutical firms spend millions of dollars on research and development in an effort to create knowledge that is economically valuable to the firm. It is not possible to directly observe knowledge or the value it creates. This chapter asserts that the number of new drug approvals received by pharmaceutical firms can be used as a proxy for economically valuable knowledge. Alternatively, the number of new drug approvals can be used to distinguish successful product developers from non-successful product developers. The R&D of successful developers should be more valuable than that of the non-successful developers. These hypotheses will be tested in the forthcoming chapters.

¹¹Based on results obtained in prior research (Hirschey (1982), Hirschey and Weygandt (1985), Sougiannis (1994) and Lev and Sougiannis (1996)), I assume that R&D expenditures are positively associated with stock price for all firms. If this is true, the R&D of successful firms should have a larger positive association with stock price than the R&D of non-successful firms.

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Chapter Five

SAMPLE SELECTION AND DESCRIPTIVE STATISTICS

The pharmaceutical industry provides a good arena to examine non-financial measures of intangible assets as this industry spends a relatively large amount of money on R&D compared to that spent by other industries. Further, the regulation of the industry makes it possible to find a publicly available proxy, the number of new drug approvals obtained from the Food and Drug Administration, to represent successful product development. This chapter includes a detailed description of the sample selection process and descriptive statistics for the final sample of firms.

5.1 Sample selection

The initial sample is comprised of 186 firms in the pharmaceutical industry, SIC code of 2834, included on the 1997 PC version of Compustat. From this sample, 19 foreign firms were eliminated.¹² Additionally, 31 firms were eliminated because their primary business activity is not consistent with the pharmaceutical industry.¹³ Finally, 17 firms were excluded because of data availability.¹⁴ These elimination procedures resulted in a sample of 119 firms.

¹²Two of the 19 firms are based in the U.S. but only sell products in foreign countries.

¹³For example, Jones Medical Industries was eliminated because it is exclusively a distributor of pharmaceutical products. Polymedica Industries was eliminated because it is primarily involved in manufacturing medical equipment.

¹⁴The large majority of these omissions (14) occurred because the firm was not included in the CRSP database. Three of the exclusions were for firms that had only one year of data on Compustat. For several models, lagged variables are used. Thus, each firm was required to have at least two years of data to be included in the sample.

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I collected all financial statement data for the sample firms from Compustat for the twelve year period from 1985 through 1996. Price and return data was obtained from CRSP. The number of NDAs was obtained from the Food and Drug Administration. From 1985 to 1996, 4,997 New Drug Applications were approved by the FDA. Many of the NDAs are granted to subsidiaries of the sample firms. In order to match the NDA with the parent firm, I used the cross-listing of parent and subsidiaries contained in Standard and Poor's Corporation Records. In addition, several of the NDAs are granted to foreign or private firms; these were identified using Standard and Poor's Corporation Records and Wards' Business Directory of U.S. Private and Public Companies. These procedures allowed me to match 3,739 of the 4,997 NDAs. Approximately 45% (or 1,667) of the identified NDAs relate to the 119 pharmaceutical firms included in the sample.

5.2 Descriptive statistics for full sample

Table 1, Panel A, provides descriptive statistics for the 695 firm-years for which all of the relevant data was available.¹⁵ The descriptive statistics show that the sample firms are very diverse. Assets range from a low of \$0.4 million to a high of over \$24 billion. The sample is skewed as the median assets are \$47 million while the mean is \$1.4 billion. Total sales, which consists of sales as well as fees from licensing arrangements and royalties, ranges from \$0 to \$21.6 billion with an average of \$1.2 billion. The firms with no sales are generally small, start-up companies that are spending

¹⁵The sample is comprised of 119 firms during the 12 year period from 1985 to 1996 for a possible testable sample of 1,428 firm-years. However, numerous firms, especially the small, development firms, did not have data for all of the years. Therefore, the final sample is comprised of 695 firm-years.

large amounts of money to develop their pharmaceutical pipelines but have yet to produce a successful product. R&D expenditures range from \$0 to \$1.9 billion with a mean of \$124 million. Thus, on average, the firms in this sample are spending 10 percent of their total revenues on research and development. Finally, these firms, on average, obtain between two and three NDAs per year. Again, this figure is highly variable with most firms obtaining no NDAs in a given year and one firm obtaining a high of 64 NDAs in one year.

5.3 Segregated sample

After examining the business descriptions and financial data of the firms, it was apparent that the sample is actually comprised of three distinct groups: traditional firms, development firms, and generic firms. Traditional firms tend to be large, well-established firms with numerous well-known products. All firms that are members of PhRMA were classified as traditional companies.¹⁶ Several additional firms whose business descriptions indicated that they manufacture original drug products were added to this group. None of the traditional firms incur R&D expenditures greater than their revenues. Twenty-three of the sample firms were classified as traditional firms.¹⁷

¹⁶PhRMA states that member firms are comprised of companies “significantly engaged in the manufacture and marketing of finished dosage form ethical pharmaceutical or biological products under [its] own brand names ... and significantly engaged in pharmaceutical, biopharmaceutical or biological research and development of new molecular entities or new therapies ... and who will continue to conduct such research and development.” (PhRMA 1997) Merck and Eli Lilly are examples of firms assigned to this group.

¹⁷Twenty of the twenty-three traditional firms obtained at least one NDA during the sample period. Two firm’s annual reports indicate that it has at least one drug on the market with FDA approval. However, I was unable to identify the NDA. This could occur if the NDA was obtained prior to 1985 or if the company has a subsidiary or corporate partner that was not identified. The final company markets several products that were purchased from other firms. Further, it has applied for additional NDAs but none were granted between 1985 and 1996.

In contrast to the traditional pharmaceutical firms, development firms tend to be small firms with little or no revenues but very large R&D expenditures. Development firms usually focus on creating cutting-edge products. These firms frequently identify themselves as biotechnology companies. Many of these companies have less than 20 employees, most of whom are scientists. Few of these firms have the capability to manufacture the products they develop and usually license any developed products to traditional firms. This strategy allows them to focus on their expertise—research and development of new drug products. Most of the firms assigned to this group are listed in the North American BioTechnology Directory.¹⁸ The development group is comprised of eighty firms, nearly two-thirds of the sample.

Finally, generic pharmaceutical firms differ from both traditional and development firms because they do not conduct original research. Instead, generic companies copy successful off-patent products originally created by traditional or development firms. The 16 firms included in this class specifically indicated in their company annual reports that their primary operating focus is the production of generic pharmaceutical products.

5.4 Descriptive statistics for segregated sample

Descriptive statistics for these three different categories of firms are included in Table 1, Panels B, C and D. As expected, traditional firms, on average, are much larger than either the development or generic firms with mean assets of \$4.3 billion compared to

¹⁸Several traditional pharmaceutical firms are also listed in the North American BioTechnology Directory (1995) as they conduct biotechnology research. However, they have much more in common with traditional firms than with development firms and thus were only included as traditional firms.

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\$34 million and \$127 million respectively. Both traditional firms and generic firms are usually profitable with average earnings of \$559 million and \$7 million respectively. Meanwhile, most development firms incur losses. It is insightful to compare R&D as a percentage of revenues across the three classes of firms. Specifically, traditional firms spend, on average, 10 percent of their revenues on R&D. Meanwhile, development firms incur research and development expenditures that are twice as large as their revenues. Finally, generic firms only spend 7 percent of their revenues on R&D. This statistic is consistent with expectations. Traditional pharmaceutical firms commit a large amount of resources to R&D but are usually profitable. The development firms, however, are working to establish new products. Thus, they spend most of their capital on R&D but have little or no revenues to cover the cost of their investments. The generic firms spend less on R&D as they are focused on copying existing successful products. Hence, their R&D as a percentage of sales is lower than both the traditional and development firms.

All of the hypotheses focus on the number of new drug applications approved by the FDA. However, less than 1% of the observations for the development firms have acquired one or more NDAs. Therefore, I do not test the hypotheses on the 80 development firms.

5.5 Summary

The sample selection procedures resulted in a group of 119 pharmaceutical firms. I chose to separate these firms into three distinct classifications: traditional firms (23), development firms (80), and generic firms (16). Descriptive statistics presented in the chapter highlight the differences between the three classes of firms. Because the

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development firms have very few new drug approvals, the hypotheses are tested in Chapter 7 using only the traditional and generic pharmaceutical groups.

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Chapter Six

CASE STUDY: SCHERING PLOUGH CORPORATION

Before presenting the results from an industry-wide test of the hypotheses, it is useful to examine the impact of an NDA on one company's operating and market performance. This in-depth review of one company provides institutional detail for the pharmaceutical industry, presents an example of the time-line from a new drug approval to sales, and furnishes anecdotal support for the hypotheses to be tested.

6.1 Schering Plough Corporation

Schering-Plough Corporation is a traditional pharmaceutical firm with 1996 sales of \$5.7 billion and total assets of \$5.4 billion. The company concentrates on developing products in the allergy/respiratory, anti-infective/anti-cancer, dermatological, and cardiovascular lines. Claritin, a non-sedating antihistamine, is a premier product in the allergy/respiratory line as it is the world's largest-selling antihistamine. Claritin received marketing clearance in the U.S. from the Food and Drug Administration in April of 1993. Figure 3 provides a graphic presentation of the impact of Claritin's U.S. approval on Schering Plough Corporation in terms of sales, net income, and stock price.

6.2 Impact of Claritin on operating performance

Before the 1993 U.S. approval, Claritin was marketed in foreign countries. However, the U.S. approval had a tremendous impact on the operating performance of Schering Plough. In 1991 and 1992, world-wide sales of Claritin (all outside of the U.S.)

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hovered around \$100 million. After FDA approval in April of 1993, Claritin generated \$130 million in U.S. sales over an eight month period. In 1994, the first full year of U.S. marketing, Claritin achieved world-wide sales of \$505 million and pushed total company sales to \$4.7 billion. Further, as can be seen from Figure 3A, the increase in Claritin sales comprised approximately 25%, 33%, and 30% of the increase in total company sales for 1992-1993, 1993-1994, and 1994-1995 respectively.

Schering Plough also experienced a large jump in net income in 1994, the first full year of U.S. sales. Specifically, net income from 1991 through 1993 ranged from \$646 million to \$731 million. However, in 1994, net income increased by almost \$200 million to \$922 million (See Figure 3B). While it is impossible to attribute this increase entirely to Claritin, it does correlate with the substantial increase in Claritin sales during the same time period.

In addition to demonstrating the impact of a U.S. drug approval on the operating performance of a firm, Schering Plough's experience with Claritin provides insight into the marketing lag between drug approval and product sales. Conversations with industry analysts and pharmaceutical sales representatives indicate that most pharmaceutical companies are able to market a drug that obtains an approved new drug application within two months. The in-depth analysis of Schering Plough supports the belief that sales of a new product commence almost immediately after the FDA approval of the new product.

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6.3 Impact of Claritin on market value

Finally, descriptive data suggests that U.S. Claritin approval also had a substantial impact on the stock price of Schering Plough Corporation. Figure 3C shows that during the months of January through March of 1993, Schering Plough's stock price ranged from \$55 to \$60 per share. However, in April, the month Claritin was approved, the stock price jumped \$5 per share, or more than 8%. The stock price continued to rise in May and June with a June closing price of nearly \$70, an increase of more than 15% from the pre-approval price.

6.4 Summary

The experiences of Schering Plough Corporation, a traditional pharmaceutical firm, provide an example of the magnitude and speed with which a new drug approval can impact a pharmaceutical firm. Schering Plough Corporation's receipt of an NDA for Claritin clearly provides anecdotal support for all of the hypotheses: NDAs are positively associated with sales, earnings, stock price, and returns.

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Chapter Seven

EMPIRICAL RESULTS

This chapter provides empirical evidence that supports most of the hypotheses presented in Chapter 5. The first section of the chapter demonstrates that NDAs are a reasonable proxy for the economic value created through R&D expenditures. The remaining sections provide the empirical results from the tests of the hypotheses.

7.1 NDAs: A proxy for knowledge

The hypotheses assume that NDAs are a measure of intangible assets created through successful R&D activities. Therefore, before testing the hypotheses, it is important to establish that NDAs are associated with R&D expenditures. Correlation analysis (table not provided) shows a positive relationship between R&D expenditures and NDAs. In order to provide a stronger test of the relationship between NDAs and R&D and to allow for control variables, I perform a regression analysis between the variables. Pakes and Griliches (1984) provides a model that relates the accumulation of knowledge to R&D.

$$k_{j,t} = R\&D_{j,t} + \varepsilon_{j,t} \quad (1)$$

Where:

$k_{j,t}$: the accretion of knowledge for firm j during year t ;

$R\&D_{j,t}$: R&D expenditures by firm j during year t .

However, because k is an unobservable output measure for knowledge gained through R&D endeavors, Pakes and Griliches use the number of patents granted each year as a proxy variable for knowledge. Although the number of patents obtained by a firm are

available to investors fairly early in the development process, they do not eliminate many of the uncertainties of assessing R&D success. NDAs, although available later, are a less uncertain measure of R&D success than patents because they give a company the right to market a new product. Thus, NDAs are used as a proxy for the accumulation of knowledge acquired from successful R&D activities.

In addition, it is likely that larger firms have larger R&D budgets. Thus, R&D could appear to be positively associated with NDAs when, in fact, it is merely a proxy for firm size. To control for this possibility and to provide assurance that the positive relationship between R&D and NDAs is not spurious, total assets are added to the Pakes and Griliches model. This results in the following testable model:

$$NDA_{j,t} = \alpha_t + \beta_1 R\&D_{j,t} + \beta_2 Assets_{j,t} + \epsilon_{j,t} \quad (2)$$

Where:

- $NDA_{j,t}$: the number of New Drug Applications approved by the Food and Drug Administration for firm j during fiscal year t;
- α_t : year specific intercepts (untabulated);
- $R\&D_{j,t}$: research and development expenditures incurred by firm j during fiscal year t;
- $Assets_{j,t}$: total assets for firm j at fiscal year end t.

Because the dependent variable, NDAs, is a count variable, ordinary least squares regression is not appropriate. Therefore, I test this model using a Poisson regression with a log-linear link which ensures that the predicted value of NDAs will always be positive.¹⁹ Table 2 shows that for both the traditional and generic pharmaceutical

¹⁹For a discussion of regression analysis for count data see Cameron and Trivedi (1998) and Greene (1993).

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² According to the variance of the standard error of the mean, the standard error of the mean is 0.001. There is no significant difference between the two groups. The results of the evaluation were clearly presented in Table 1.

companies, R&D has a positive association with NDAs after controlling for firm size.^{20 21}

For traditional firms the coefficient on R&D is positive and significant at 0.01; and for generic firms the coefficient on R&D is positive and significant at 0.05. In addition, assets are not associated with NDAs for the traditional firms but are positively associated with NDAs for the generic firms. The lack of significance of assets for the traditional firms is unexpected as it seems that larger firms would tend to have more NDAs than smaller firms. Despite this, the results provide evidence that there is a positive relationship between R&D expenditures and the number of NDAs obtained. Thus, it is plausible to believe that NDAs can be used as a measure of the knowledge obtained as a result of R&D expenditures.

7.2 Operating models

7.2.1 Tests of hypothesis 1

The real value of the creation of knowledge is the economic benefit it provides to firms; the Z's in Figure 2. I test two different models of operating benefits; a sales model and an earnings model. Relying on models from Behn and Riley (1997) and Lev and

²⁰According to Cameron and Trivedi (1998), the data for this regression is overdispersed because the variance of the dependent variable is more than twice as large as the mean of the dependent variable. This causes problems similar to heteroscedasticity in ordinary least squares regression. Therefore, the reported standard errors are corrected using the method suggested in McCullagh and Nelder (1989).

²¹There is no well-established method for deleting influential observations in a Poisson regression other than evaluating raw residual values. Three of the raw residuals for the traditional pharmaceutical firms were clearly larger than the other residuals; those three observations were omitted from the results presented in Table 2. None of the observations for the generic firms were omitted.

Sougiannis (1996), I developed the following sales model:

$$\text{Sales}_{j,t} = \alpha_t + \beta_1 \text{NDA}_{j,t-1} + \beta_2 \text{R\&D}_{j,t-1} + \beta_3 \text{Assets}_{j,t-1} + \epsilon_{j,t} \quad (3)$$

Where:

$\text{Sales}_{j,t}$	revenues, including royalties and licensing fees and excluding non-operating revenues such as interest, for firm j during year t;
α_t :	year specific intercepts (untabulated);
$\text{NDA}_{j,t-1}$:	the number of New Drug Applications approved by the Food and Drug Administration for firm j during fiscal year t-1;
$\text{R\&D}_{j,t-1}$:	research and development expenditures incurred by firm j during fiscal year t-1;
$\text{Assets}_{j,t-1}$:	total assets for firm j at fiscal year end t-1.

According to Hypothesis 1, the coefficient on NDA should be positive, indicating that the number of approved new drug applications in a year increases the amount of firm sales in the following year. As discussed in the Schering Plough case study, drugs obtaining FDA approval are marketed almost immediately. Therefore, it is possible that no lag is needed in assessing the relationship between operating performance and drug approvals. However, I perform the regression analyses with a one year lag of NDAs to ensure that the new product is on the market for a full year when assessing its impact on sales. R&D and Assets, both lagged one period, are also expected to be positively associated with sales. All financial variables, Sales, R&D, and Assets, are included in the model in logarithmic form to reduce their variance. I do not make any predictions on the year-specific intercepts but merely include them as additional control variables.

The results for the sales model are shown in Table 3. For traditional pharmaceutical firms, reported in Panel A, the coefficient on NDAs in the pooled

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estimation is positive and significant at 0.01 even though R&D expenditures are also included in the model.²² This result supports H_1 and suggests that new drug approvals proxy for intangible assets that help to generate future sales. The year-by-year results, also provided in Table 3 Panel A, provide additional support for H_1 as the coefficient on NDA is positive in nine of the eleven years.²³ Z1 and Z2 statistics are provided to test the significance of the annual t-statistics. Z1 may be overstated when the t-statistics are not independent; Z2 corrects for cross-sectional and serial correlation (Barth 1994). Both Z1 and Z2 indicate that the annual, cross-sectional t-statistics are significant. The lack of significance in the annual results is most likely caused by a lack of power as a result of small sample sizes.

Counter to results found in prior research, the coefficient on R&D for the traditional firms is negative in the pooled regression. The annual cross-sectional results are consistent with the pooled results as the coefficient is negative in 10 of the 11 years, and significantly so in 5 years. The negative coefficient may be driven by the fact that research and development expenditures in the pharmaceutical industry do not generate future sales or earnings for several years. Hence, a one-year lag may be insufficient for capturing any benefit that is directly attributable to R&D. As expected, the coefficient on the log of Assets is positive and significant in the pooled regression and in all of the annual regressions indicating that larger firms have more sales. The adjusted R^2 for the pooled traditional model is 0.95.

²²Following Amir and Benartzi (1998), observations with an R-student value greater than $|3|$ are omitted from the regression results as these observations are assumed to have a significant influence on the results. This methodology is followed throughout the paper for the pooled models. In most of the regressions, 1% to 2% of the observations are omitted. In one case, approximately 6% of the observations are omitted. For additional discussions of influential observations, see Belsley, Kuh, and Welsch (1980).

²³Throughout the paper, annual results are reported when at least ten observations are available.

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Rather unexpectedly, the coefficient on NDA for the generic firms, reported in Table 3 Panel B, is negative, although not significant. This result does not support H_1 . One potential explanation for this result is that a one-year time difference between receipt of an NDA and sales is not sufficient for the generic firms. It is probable that it takes longer for a generic product to generate new sales as the branded product is already entrenched in the market place. This is especially true as physicians tend to prescribe products that they are familiar with. To examine this possibility, I ran the sales model for the generic firms after substituting NDA_{t-3} for NDA_{t-1} . The coefficient on NDA_{t-3} is not significant. Alternatively, the lack of significance may be due to the nature of generic firms. Generic firms earn profits by charging low prices but selling high volumes over several years. Thus, it is likely that the incremental benefit of one NDA cannot be detected in the annual sales variable.

Table 3 Panel B also shows that the coefficient on R&D for the generic firms is negative and significant while the coefficient on Assets is, once again, positive and significant. The annual results are consistent with the pooled results as the coefficients on all three variables have the same sign in the four years for which annual data is presented. In addition, the Z1 and Z2 statistics show virtually the same significance levels for all three coefficients.

In summary, for the traditional pharmaceutical companies, the results from the sales model show that NDAs at $t-1$ are positively associated with sales at t . This supports H_1 and implies that NDAs can be used as an intangible asset proxy that is useful for assessing future revenues. H_1 is not supported by the results obtained for the generic pharmaceutical firms as the coefficient on NDA is negative, although not significant, in

the pooled regression as well as in the annual regressions. As discussed, this is likely due to the fact that the incremental benefit of one NDA cannot be detected in the sales variable.

7.2.2 Tests of hypothesis 2

The earnings model, adapted from Lev and Sougiannis (1996), is:

$$\text{NIBRD}_{j,t} = \alpha_t + \beta_1 \text{NDA}_{j,t-1} + \beta_2 \text{R\&D}_{j,t-1} + \beta_3 \text{Assets}_{j,t-1} + \epsilon_{j,t} \quad (4)$$

Where:

$\text{NIBRD}_{j,t}$:	income before discontinued operations, extraordinary items, changes in accounting methods, depreciation and amortization, and research and development expenditures;
α_t :	year specific intercepts (untabulated);
$\text{NDA}_{j,t-1}$:	the number of New Drug Applications approved by the Food and Drug Administration for firm j during fiscal year t-1;
$\text{R\&D}_{j,t-1}$:	research and development expenditures incurred by firm j during fiscal year t-1;
$\text{Assets}_{j,t-1}$:	total assets of firm j at fiscal year end t-1.

The model predicts that future earnings are a function of tangible and intangible assets. Depreciation and R&D are added back to operating income since they are write-offs of the independent variables—tangible and intangible assets. This model differs from the Lev and Sougiannis model in two ways. First, Lev and Sougiannis do not include non-financial measures of intangible assets in their model. However, because I am interested in examining non-financial measures of successful R&D activities, NDAs are added to the model. Also, Lev and Sougiannis include advertising expenditures as an intangible asset. Advertising expenditures are definitely important to firms in the pharmaceutical industry. In fact, according to PhRMA, many firms spend almost as much on advertising

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and promotion as they spend on R&D. While it would be ideal to measure this intangible asset, Compustat only reports advertising expenditures for a few of the sample firms and this number is rarely reported in the firms' 10-Ks and annual reports. Thus, in the price model, advertising expenditures are potentially a correlated omitted variable. As in the sales model, one lag of NDAs is included in the earnings model as firms generally are able to market a new drug relatively quickly after obtaining approval from the FDA.

The results, presented in Table 4 Panel A, support Hypothesis 2 for the traditional pharmaceutical companies. The earnings model for the traditional firms shows that the number of new drug applications approved by the FDA in year $t-1$ increases net income in year t . This is true even though the input measure for knowledge, R&D expenditures, is included in the model. R&D expenditures and assets are also positively associated with future earnings. Contrary to the sales model, the coefficient on R&D is positive and significant in the earnings model. It is possible that this reversal occurs because R&D is subtracted from net income. More specifically, firms with large R&D budgets may appear to have larger net income simply because R&D is added back to the dependent variable. Similar to the sales model and consistent with predictions, assets are positively associated with NIBRD. The pooled model produces an adjusted R^2 of 0.98 with a sample of 169 observations.^{24, 25}

²⁴The large decrease in N from the sales model to the earnings model occurs because negative earnings observations are dropped when the log is taken.

²⁵An adjusted R^2 of 0.98 is relatively high for an accounting research paper. However, this high value is consistent with the results reported in Lev and Sougiannis (1996).

Overall, the annual cross-sectional results, reported for years with at least 10 observations, are consistent with the pooled results. In particular, the coefficient on NDA is positive in all eleven years and both the Z1 and Z2 statistic indicate significance at 0.01. Furthermore, the coefficient on R&D is positive in 8 of 11 years and the coefficient on Assets is positive and significant in all 11 years.

The results of the earnings model for the generic firms, reported in Table 4 Panel B, provide weak support for Hypothesis 2 as the coefficient on NDA in the pooled model is positive and significant at 0.10. The year-by-year results are similar as the coefficient on NDA is positive and significant in two of the three reported years. However, the mean coefficient for the annual results is positive but neither the Z1 or Z2 statistics are significant. Again, the weak association between the operating measure and NDA is likely due to the nature of generic pharmaceutical firms. These firms rely on large volumes with relatively low profit margins. Thus, it is likely that the dependent variable is not sensitive enough to detect the incremental benefit of one NDA. Meanwhile, R&D and Assets are both positively associated with future earnings. The model for the generic firms generates an adjusted R^2 of 0.86.

7.2.3 Summary of operating models

The two operating hypotheses, H_1 and H_2 , are supported by the regression results from the traditional pharmaceutical firms: NDAs are positively associated with both future sales and future earnings. This implies that NDAs can be used as a proxy for intangible assets in the pharmaceutical industry. These results support the conclusions made in Behn and Riley (1997) in which the authors found that non-financial

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performance measures were useful in predicting operating performance in the airline industry.

The results from the generic pharmaceutical companies do not support H_1 as NDAs are not associated with future sales. Weak support is obtained for H_2 as NDAs are positively associated with earnings in the pooled model at the 0.10 level. The lack of results is likely attributed to the fact that generic pharmaceutical firms rely on low-price, high volume strategies; and, thus the incremental impact of one NDA cannot be detected in annual operating results.

7.3 Market models

In addition to examining the relationship between NDAs and operating performance, I test both a stock price model and a market return model. These are conducted to determine if the number of NDAs, a non-financial measure of R&D successes, are reflected in investor valuation decisions.

7.3.1 Tests of hypothesis 3

Amir and Lev (1996) examine the usefulness of various GAAP and non-GAAP measures in predicting the stock price of firms in the wireless communications industry. They begin their analysis with the following basic model:

$$\text{Price}_{j,t} = \beta_0 + \beta_1 \text{BVPS}_{j,t} + \beta_2 \text{EPS}_{j,t} + \varepsilon_{j,t} \quad (5)$$

Where:

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| $\text{Price}_{j,t}$: | stock price of firm j at the end of the third month following the firm's fiscal year end; |
| $\text{BVPS}_{j,t}$: | (total assets – total liabilities)/shares outstanding for firm j at the fiscal year end t ; |

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EPS_{j,t}: earnings per share before extraordinary items, discontinued operations, and changes in accounting methods, and after adding back depreciation and amortization and research and development expenditures for firm j during year t.

To this model, Amir and Lev add two non-financial measures of intangible assets in the wireless communications industry; POPS, a measure of the population in licensed metropolitan and rural areas, and PEN, the number of subscribers divided by POPS.²⁶

Likewise, I start with this basic model and add one financial measure and one non-financial measure of the intangible asset created through R&D expenditures.

Specifically, I include R&D expenditures and the number of NDAs approved each year.

R&D expenditures are included in the model because I am interested in assessing if NDAs provide incremental information to decision makers when determining the stock price of pharmaceutical firms. This results in the following model:

$$\text{Price}_{j,t} = \alpha_t + \beta_1 \text{NDA}_{j,t} + \beta_2 \text{R\&DPS}_{j,t} + \beta_3 \text{EPS}_{j,t} + \beta_4 \text{BVPS}_{j,t} + \varepsilon_{j,t} \quad (6)$$

Where:

Price_{j,t}: stock price of firm j at the end of the third month following the firm's fiscal year end;

α_t: year specific intercepts (untabulated);

NDA_{j,t}: the number of New Drug Applications approved by the Food and Drug Administration for firm j during fiscal year t;

R&DPS_{j,t}: research and development expenditures per share incurred by firm j during year t;

²⁶Barth, Clement, Foster, and Kasznik (1998) also tests intangible assets in a valuation model that is on a per share basis. Hirschey, Richardson, and Scholz (1998) examines the valuation implication of patents using the market value of equity scaled by book value of assets as the dependent variable. There is no clear justification for either method. I chose to use the per share model because the impact of NDAs on a per share basis is easier to interpret.

EPS_{j,t}: earnings per share before extraordinary items, discontinued operations, and changes in accounting methods, and after adding back depreciation and amortization and research and development expenditures for firm j during year t;

BVPS_{j,t}: (total assets – total liabilities)/shares outstanding for firm j at fiscal year end t.

Because a price model examines total firm value at a point in time, it would be ideal to include the accumulated NDAs across time in the model rather than the approvals in one particular year. However, it is not clear how long the accumulation period should be as drugs differ in the amount of time they are used. For example, a truly creative product is likely to be valuable to a firm for a long period of time. Meanwhile, some products become obsolete in a few years as more effective and safe replacements are developed. This same type of issue is present when patent counts are included as independent variables in a valuation model. I follow the methodology used in Hirschey, Richardson, and Scholz's 1998 paper in which the authors include annual patent counts as an independent variable in the valuation model versus the sum of patents over several years.

The results, presented in Table 5, provide support for Hypothesis 3 as NDAs are positively associated with stock price for both traditional and generic pharmaceutical firms in the pooled models. For traditional firms, reported in Panel A, the price model has an adjusted R² of 0.62 with a sample size of 212.²⁷ NDAs are significant and add thirty-three cents, or nearly one percent, to the average firm stock price of \$41.27. The annual cross-sectional models are consistent with the pooled results as the coefficient on NDA is positive in eleven of the twelve years and significantly so in 1985, 1987 and

²⁷The sample size for the price model is larger than that used for the operating models because no lagged variables are required.

1991. Further, the mean coefficient for the annual data is positive and significant. These results suggest that the number of NDAs obtained by traditional pharmaceutical companies is viewed as an intangible asset by the stock market and provide support for Hypothesis 3.

Interestingly, for the traditional pharmaceutical firms, the coefficient on R&DPS is negative and significant in the pooled model. Also, the annual regressions produce a negative coefficient in 8 of 12 years as well as a negative mean coefficient. Further, the Z1 statistic is negative and significant while the Z2 is negative but not significant. This result is note worthy because most related literature predicts that R&D and other similar expenditures (i.e. advertising) will result in an increase in stock price as this type of investment is actually creating an intangible asset. In fact, Sougiannis (1994) shows that a one dollar increase in R&D generates, on average, a five dollar increase in total market value.

There are two possible explanations for the conflicting results found between pharmaceutical firms and prior research. First, it is possible that R&D expenditures are incurred relatively early in the pharmaceutical industry in relationship to product releases. This might cause the market to place little value on the intangible created by the expenditures. Alternatively, R&D in the earlier research papers might be correlated with an alternate measure of intangible assets that is omitted from the model. I examined this possibility for the sample of pharmaceutical firms by running the price regression with NDAs omitted. The coefficient on R&DPS for the traditional firms remains marginally negative while the coefficient for the generics is still insignificant. Thus, the first explanation is more plausible. In general, in the pharmaceutical industry, the number of

NDA appears to be a better measure of the potential marketable products owned by a firm; hence, R&D is viewed as an expenditure that reduces investors' equity.

Finally, for the traditional firms, the coefficient on EPS is positive and significant but the coefficient on BVPS is not significant. This result is surprising but might be an indicator of the amount of intangible assets that are not included on the balance sheets of pharmaceutical firms. Amir and Lev (1997) reports findings that are somewhat similar to the one noted above. In particular, in the wireless communications industry, Amir and Lev find that BVPS is not significantly related to stock price until non-financial measures of intangible assets are added to the model. They explain this result by saying that the financial and non-financial measures compliment each other when assessing a firm's value. It is likely that my model still omits several measures of intangible assets, especially brand loyalty generated by large expenditures on advertising and promotions. Perhaps if additional non-financial measures of the unreported intangible assets were included, the results would be consistent with those found by Amir and Lev.

The results from the price model for the generic firms also support H_3 as the coefficient on NDA for the generic firms is positive and significant at 0.01. All six of the yearly NDA coefficients are positive and three of them are significant. In addition, the Z-statistics, which summarize the t-value of the annual coefficients, are both significant. Although this result is consistent with H_3 , it is somewhat unexpected given that NDAs were not positively associated with future sales and were only modestly associated with future earnings. This suggests that, while the incremental benefit of an NDA cannot be detected in operating performance measures, the market understands the importance of new drug approvals to the long-run health of generic firms. Thus, for both the traditional

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and generic firms, NDAs can be used as a proxy for intangible assets that are not recognized.

Similar to the results obtained for the traditional firms, the coefficients on R&DPS and BVPS are not significant while the coefficient on EPS is positively significant. The pooled model produces an adjusted R^2 for the generic firms of 0.39 with a sample of 120 firms.

7.3.2 Tests of hypothesis 4

I also develop and test a market return model. Similar to Amir and Lev (1996), I start with the following market return model:

$$\text{Return}_{j,t} = \beta_0 + \beta_1 \text{EPS}_{j,t} + \beta_2 \Delta \text{EPS}_{j,t} + \varepsilon_{j,t} \quad (7)$$

Where:

$\text{Return}_{j,t}$: market return for firm j from the end of the first quarter for year t to the end of the first quarter for year t+1;

$\text{EPS}_{j,t}$: net income from continuing operations for firm j during year t, divided by the number of shares outstanding;

$\Delta \text{EPS}_{j,t}$: the change in net income per share for firm j from year t-1 to year t, divided by the number of shares outstanding.

To this model, I add a measure for the intangible asset created with R&D expenditures. Specifically, I include the number of approved new drug applications obtained in a year, the unexpected new drug applications obtained in a year, a measure of research and development expenditures, and the change in research and development expenditures. In addition, time specific intercepts are included in the model. This results in the following model:

$$\begin{aligned} \text{Return}_{j,t} = & \alpha_t + \beta_1 \text{NDA}_{j,t} + \beta_2 \Delta \text{NDA}_{j,t} + \beta_3 \text{R\&DPS}_{j,t} + \beta_4 \Delta \text{R\&DPS}_{j,t} \\ & + \beta_5 \text{EPS}_{j,t} + \beta_6 \Delta \text{EPS}_{j,t} + \varepsilon_{j,t} \end{aligned} \quad (8)$$

Where:

$\text{Return}_{j,t}$:	market return for firm j from the end of the first quarter for year t to the end of the first quarter for year $t+1$;
α_t :	year specific intercepts (untabulated);
$\text{NDA}_{j,t}$:	the number of New Drug Applications approved by the Food and Drug Administration for firm j during fiscal year t ;
$\Delta\text{NDA}_{j,t}$:	the change in the New Drug Applications approved by the Food and Drug Administration for firm j from fiscal year $t-1$ to fiscal year t ;
$\text{R\&DPS}_{j,t}$:	research and development expenditures incurred by firm j during year t divided by the number of shares outstanding;
$\Delta\text{R\&DPS}_{j,t}$:	the change in research and development expenditures per share for firm j from year $t-1$ to year t ;
$\text{EPS}_{j,t}$:	net income from continuing operations before depreciation and amortization and before research and development expenditures for firm j during year t , divided by the number of shares outstanding;
$\Delta\text{EPS}_{j,t}$:	the change in net income per share (from continuing operations before depreciation and amortization and before research and development expenditures) for firm j from year $t-1$ to year t , divided by the number of shares outstanding.

The pooled results for the traditional firms, reported in Table 6 Panel A, do not support Hypothesis 4. Specifically, neither NDA nor ΔNDA are significantly associated with stock returns for the traditional firms. However, the coefficient on ΔNDA is positive, although not significant in nine of the eleven reported years and both the Z1 and Z2 statistics for ΔNDA are positive and significant. Thus, while the pooled model does not produce significant results, the annual results do provide some support for the idea that ΔNDA , the unexpected NDAs, are positively associated with returns.

Table 6 Panel A also shows that R&DPS is not associated with firm stock returns but Δ R&DPS is negatively associated with stock returns. This result is consistent with the results reported for the price model and implies that an increase in R&D expenditures causes the value of the traditional pharmaceutical firms to decrease. Similar to results documented in prior research, unexpected earnings are positively associated with stock market returns. Utilizing a sample of 193 firms, the returns model for the traditional firms produces an adjusted R^2 of 0.17.²⁸

For the generic firms, the coefficient on NDA is negatively significant in the pooled regression. Meanwhile, the results from the yearly analysis show that the coefficient on NDA is positive in three of the four reported years and that the mean coefficient is positive although not significant. The lack of significance in the yearly results is likely due to low power as a result of the small sample sizes. Further, the negative coefficient on NDA in the pooled model appears to be driven by 1996 as the coefficient in all other years is positive. The results indicate that there is not a consistent relationship between Δ NDA and returns. As in the returns model for the traditional firms, Δ R&DPS is negatively associated with stock returns while Δ EPS is positively associated with stock returns for the generic firms.

The negative coefficient on Δ R&DPS for both the traditional and the generic pharmaceutical firms is counter to the results obtained in prior research which, in general, show that R&D is positively associated with market performance. As discussed earlier, one explanation for this result is that R&D is incurred so early in the development cycle

²⁸The large negative adjusted R^2 s reported in the annual regressions are caused by having a small sample size in relation to the number of independent variables.

of pharmaceutical firms that the market assigns little value to the information provided by the expense.

The absence of a significant positive relationship between NDAs and returns for both groups of firms is somewhat surprising given the positive relationship found between NDAs and stock price in the previous section. The presence of multicollinearity between NDAs and Δ NDA could produce inefficiencies in the model and cause NDAs to be insignificant. However, correlation analysis shows that NDA and Δ NDA are only weakly correlated. Therefore, inefficiency as a result of multicollinearity does not appear to be the cause of the insignificance.

An alternate reason for the insignificance of NDA in the return model is that the release of product approval information and the return data are not properly matched. The results reported in Table 6 use fiscal year NDAs and financial data while the returns start with the first quarter of year t and are calculated through the first quarter of year $t+1$. Most prior research uses first quarter returns to ensure that all of the firms have released their financial data and that the market has had time to incorporate the data. However, the NDAs are available immediately upon approval by the FDA. Thus, it might be more reasonable to match returns with the fiscal year to investigate the impact of NDAs on market returns. Hence, I calculated market returns during the fiscal year and ran the regression analysis again. The results are not materially different from those reported in Table 6. Specifically, the coefficients on NDA and Δ NDA are not associated with returns for the traditional firms. For the generic firms, the coefficient on NDA is negative and significant while the coefficient on Δ NDA is also negative, although not significant. The sign and significance of the other coefficients are virtually unchanged.

The results from the returns model do not support Hypothesis 4. In particular, while NDAs are positively associated with stock price for the both traditional and generic pharmaceutical firms, they are not positively associated with stock returns. Most surprising is the fact that the coefficient on Δ NDA is negatively associated with returns for the generic firms, albeit at 0.10. Hirschey, Richardson, and Scholz (1998) reports similar results for patent data. In their paper, the number of patents is positively associated with stock price but is not significantly associated with stock returns. Perhaps both of the results have the same problem--using a relatively long window for predicting returns for a specific event. It is likely that numerous other factors affect stock returns over a one-year time period and may overshadow the impact of new drug approvals.

7.3.3 Summary of market models

The results for the market models are mixed. The results from the price model for both the traditional and generic pharmaceutical firms support Hypothesis 3 and indicate that the number of new drug approvals, a non-financial measure of R&D success, is helpful in assessing firm value. In addition, the insignificance of BVPS suggests that current balance sheets provide little information when assessing the value of firms in the pharmaceutical industry. I expect that these results would also hold in other industries that are highly dependent on intangible assets that are not measured on a firm's balance sheet. In fact, Amir and Lev (1997) shows that neither BVPS nor EPS are associated with stock price in the wireless communications industry when solely included in a price model. Therefore, finding alternate measures of key intangible assets may be critical for assessing value in industries which are dependent on these unrecognized assets.

Despite the fact that NDAs are positively associated with stock price, they are not positively associated with stock returns. Hirschey, Richardson, and Scholz (1998) finds similar results for patent data. These results can most likely be attributed to the fact that a relatively long window, one year, is used for evaluating a market reaction to an event. Future research that examines a short-window surrounding the receipt of an NDA might prove fruitful.

7.4 Sensitivity analysis: H_1 - H_3

As discussed earlier, an alternate measure of the knowledge created through R&D expenditures is the number of new patents obtained by a firm. I discussed several reasons why this measure might not be the ideal choice for economically valuable knowledge in the pharmaceutical industry. However, to provide additional support for the results obtained previously, I ran the regression models for the traditional firms including patent counts as an independent variable.^{29, 30} The first column of Tables 7, 8, and 9 provides the results for the sales, earnings, and price models after including one year of patent data.

In the Sales model, the coefficient on NDA is positive and significant even though patents at t-1 are also included in the model. As in the original sales model, R&D is

²⁹ I collected the patent data from the U.S. Patent Office (1999). Because of the way the database works, the patent data is gathered on an annual basis (i.e. it is not based on a firm's fiscal year end). Thus, the reported results using patent data contain noise to the extent that firms have fiscal year ends.

³⁰ Patent counts are only added to the models for traditional firms as generic firms, in general, do not apply for patents. To make sure that this assumption is valid, I searched the U.S. patent database for 6 of the 16 largest generic pharmaceutical companies. For the twelve year period from 1985 to 1996, the 6 firms (72 firm-years) obtained a total of 3 patents between them. Meanwhile, the mean number of patents for the traditional pharmaceutical companies is 51 and the mode is 38.

negatively associated with sales while assets at t-1 are positively associated with sales.

Utilizing 185 observations, the model generates an adjusted R^2 of 0.96.

It is also possible that because of the length of time involved in the development process that additional lagged variables should be included for R&D expenditures and patent data. Therefore, I add five years of data for both patent counts and R&D expenditures in the sales model. The results are essentially the same as those with one year of R&D and patent data. The only notable change is that the coefficient on patents at t-1 changes from positive and significant to negative and insignificant. This result is likely caused by the high multi-collinearity in the model. Specifically, the five years of patent data are correlated between 0.86 and 0.96, causing the model to be inefficient.

The results for the earnings model including the patent data continue to support H₂. The coefficient on NDA remains positive and significant even though the number of patents received during year t-1 is included in the model. The coefficients on patents, R&D, and Assets at t-1 are also positive and significant. When five years of patent and R&D data are included in the model, the coefficient on NDA is still positively associated with earnings. As in the sales model, none of the patent variables are significant. Similar to results found in Sougiannis (1996) the R&D coefficients vary from positively to negatively significant. This implies that in some years the cost of R&D outweighs its benefits.

The results for both the sales and earnings models that include patent data support the conclusions made previously. Specifically, each NDA received in year t-1 increases sales and earnings in year t. And, while patents at t-1 are positively associated with both sales and earnings, they do not provide the same information as that provided by NDAs.

Thus, NDA information is useful above and beyond that of R&D and patent data in assessing future sales and earnings.

The results for the price model, including patents, are also consistent with the original price model. The coefficient on NDAs is 0.28 and is significant at 0.01. In addition, the coefficient on patents is positively associated with price. Similar to the results provided in Table 5, the coefficient on R&DPS is negatively associated with price. EPS is positively associated with stock price at 0.01 while BVPS is marginally associated with stock price.

Including five years of patent and R&D data in the model generates somewhat different results. First, as in the model with one year of patent data, NDAs remain positively associated with stock price at 0.01. Meanwhile, the significance level for BVPS increases from 0.10 when one year of patent data is included to 0.01 when five years of patent and R&D data are included. The BVPS result is interesting because BVPS was not associated with price in the original model and was only marginally associated with price when one year of R&D and patent data are included. Meanwhile, the significance level of EPS decreases from 0.01, when only one year of patent and R&D data are included, to 0.10 when five years of data are included. These shifts in levels of significance are difficult to explain.

Another interesting result occurs as the coefficient on patents at time t is negative and significant when 5 years of R&D and patent data are included in the model. This result is likely due to multi-collinearity in the patent data. One final change is that EPS is no longer positively associated with price when the model is expanded to include five years of R&D and patent data. I have no explanation for this result.

Overall, the results shown in Tables 7, 8, and 9 suggest that NDAs provide information to investors that is not provided by patent counts. Perhaps NDAs and patents provide two pieces of information in a puzzle. For example, the patent data provides early information on R&D progress while the NDAs provide data about products that will be marketed in the near future.³¹

7.5 Successful developer models

As discussed in the hypothesis development section, it is likely that some firms are better at developing new drugs for their pipelines than other firms. The R&D of the efficient developers should result in larger increases in sales and earnings and therefore should be valued more highly by the stock market. This idea is tested by partitioning the firms into successful and non-successful groups based on the number of NDAs obtained. To make the division, I first computed the mean number of NDAs obtained in a year by each firm. I then calculated the median of the firm means for both the traditional and generic group of firms. Any firm in which the mean NDAs is greater than the respective median is classified as a successful firm. Both the price and return model are adjusted using the following methodology. First, NDA is replaced with a dichotomous variable that is set to 1 if the firm is deemed to be successful and 0 otherwise. Then, an interaction between successful firms and R&D expenditures is included. Hypotheses 5 and 6 predict that the coefficient on the interaction term will be positive.

³¹ I did not run the patent sensitivity analysis on the return model since Hypothesis 4 is not supported.

7.5.1 Tests of hypothesis 5

To test H_5 , I modified the price model to include the successful firm dichotomous variable and the interaction between success and R&D expenditures. The results from this model are reported in Table 10. For the traditional pharmaceutical companies, the Success coefficient is positive and significant. This result provides further support for H_3 and suggests that there are intangible assets that are not being recorded on the balance sheets of pharmaceutical companies. The coefficient on R&DPS is negative although not significant.

H_5 asserts that the coefficient on the interaction between Success and R&DPS will be positive as the R&D of successful firms should be valued more highly than the R&D of non-successful firms. The pooled results for the traditional firms support this assertion, as the coefficient on the interaction is positive and significant. In fact, the results indicate that the R&D of non-successful firms is not valued by the stock market at all as the coefficient on R&DPS is not significant. As expected, EPS and BVPS are both positively associated with stock price.

The annual regression results reveal an interesting phenomenon. In particular, there seems to be a change in the way the stock market values pharmaceutical firms after 1991. From 1985 to 1990, the coefficient on Success is positive in each of the six years with a mean coefficient for this period of 27.38. During the last six years, however, the magnitude of the coefficients decreases generating a mean of only 11.96.

The coefficients on R&DPS also change from the first six years to the last six years. From 1985 to 1990, the coefficients on R&DPS are always positive and generate a mean coefficient of 20.53. Beginning in 1991, five of the six coefficients are negative

and produce a mean coefficient of -4.97 . Thus, from 1985 to 1990, the summarized annual coefficients on R&DPS are positive and significant with a Z2 statistic of 3.20 while from 1991 to 1996, the summarized annual coefficients on R&DPS are negative and significant with a Z2 statistic of -2.21 .

Finally, the annual coefficients on the interaction between Success and R&DPS also change from the first six years to the last six years. From 1985 to 1990, the coefficient is negative in all six years and significantly so in 3 of those years. The annual data produces a mean coefficient of -19.29 and a Z2 statistic of -3.36 , which is significant at 0.01. However, from 1991 to 1996, the coefficient on the interaction is positive in five of the six years with a mean coefficient of 4.94 that is significant at 0.01.

These dramatic shifts in coefficient values from the first six years to the second six years are very intriguing. During the first six years, the magnitude of the coefficient on Success is very large. However, from 1991 to 1996, the magnitude on this coefficient starts to decline and the significance level begins to drop. In particular, during the first six years, three of the annual coefficients are positively associated with stock price while only one is positively associated with stock price during the second six years.

At the same time, the ability to value R&D expenditures seems to become more refined. From 1985 to 1990, R&D, on average, is positively valued by the market. However, the R&D of successful firms appears to be negatively associated with price. Counter to the early results, from 1991 to 1996, the R&D of successful firms is valued more positively by the market than the R&D of non-successful firms. In particular, the results show that the coefficient on the interaction between Success and R&DPS is positive in five of the six years and significant in three of those five years. During this

same time period, the R&D of non-successful firms is negatively valued by the market. These results seem to suggest either that investors learn which firms are successful as time passes or that investors become better at interpreting the data that is available to them. It is likely that both of these explanations contribute to the change in the relationship between the dependent and independent variables.

It is possible that the change in results is caused by the method used to segregate the successful and non-successful firms. In particular, I separate the firms into successful and non-successful groups based on the mean number of NDAs obtained over the entire sample period. Investors do not have access to all of this data when they are valuing the firms. For example, I use information available in 1996 to classify firms in 1985. Investors only have access to data that is available in 1985. Thus, it is possible that as investors gain more knowledge, their distinction between successful and non-successful firms more closely matches mine and drives the results.

For the generic pharmaceutical firms, Success is positively associated with stock price. This provides additional support for the results reported in Table 5 and suggests that NDAs are a measure of intangible assets. Contrary to the results found for the traditional firms, R&DPS is positively associated with stock price while the interaction variable is negatively associated with stock price. This result is difficult to interpret. As before, EPS is positively associated with price while BVPS is not. The results from the five reported annual regressions are consistent with the pooled results.

Overall, the results from the successful price model provide mixed support for H_5 . For the traditional firms, the coefficient on R&DPS for non-successful firms is not significant. However, the interaction between R&DPS and Success is positively

associated with price. This implies that the R&D of successful firms is valued by the market and that the R&D of non-successful firms is not. The results from the generic firms, meanwhile, do not support H_5 as the coefficient on the interaction variable is negative and significant. This result is surprising.

The results from the successful price model also provide additional support for H_3 as the success intercept is positive and significant for both the traditional and generic firms. The magnitude of the coefficient on Success suggests that successful firms have significant intangible assets that are not currently being reported on their balance sheets.

7.5.2 Tests of hypothesis 6

The results from the successful returns model are reported in Table 11. The pooled results for the traditional and generic firms do not support H_6 . In particular, the coefficient on the interaction between Success and R&DPS is not significant for either group of firms. The year-by-year analyses provide similar results. For the traditional firms, the coefficient on Success*R&DPS is positive in six of the eleven years and significantly so in one of those six. The coefficient is significantly negative in four of the remaining five years. These conflicting results make it difficult to draw conclusions about the model. Further, for the generic firms, the coefficient is not associated with returns in any of the four reported years. The coefficient on Success* Δ R&DPS is not significant for either the traditional or generic firms. Similar to the results reported in Table 6, the change in EPS is positively associated with returns for both the traditional and generic firms.

The results reported in Table 11 do not support H_6 as the R&D of successful firms is not more positively associated with market returns than the R&D of non-successful

firms. This result is not surprising given the results reported for the returns model in Table 6.

7.6 Summary

This chapter presents the empirical results from the tests of the six hypotheses. In support of the operating models, NDAs are positively associated with one-year ahead sales for the traditional firms and with one-year ahead earnings for both the traditional and generic firms. In addition, NDAs are positively associated with stock price for both groups of firms. These results suggest that NDAs can be used as a proxy for intangible assets not recorded on the balance sheets of pharmaceutical firms. Neither NDAs nor the unexpected NDAs is associated with market returns for either group of firms. As discussed, this result is likely due to the fact that a relatively long return window was used, one year, to assess the market response to an event. Future research might benefit by an event study that assesses market reaction around the date the NDA is received.

The results from the successful product developer hypotheses are mixed. The empirical results for the traditional pharmaceutical firms support the price model, H_5 , as the R&D of successful firms is positively associated with firm market value while the R&D of non-successful firm is not. In addition, being classified as a successful firm increases stock price; this provides additional support for H_3 and suggests that there are intangible assets that are not recorded on the balance sheet of pharmaceutical firms. The results for the generic firms do not support H_5 as the R&D of successful firms is negatively associated with stock price. However, similar to the traditional firms, additional support is provided for H_3 as the dichotomous success variable is positively

associated with price indicating that the non-recognized intangible assets of successful firms are valued more than the intangible assets of non-successful firms. Finally, the regression results do not support H_6 for either group of firms as the R&D of successful firms does not generate larger returns than the R&D of non-successful firms.

Chapter Eight

CONCLUSION

This paper examines a non-financial measure for the intangible asset created with R&D expenditures in the pharmaceutical industry, namely the drug pipeline. After confirming that NDAs are a valid measure of the accumulation of knowledge, I examined if NDAs are associated with the following measures of economic performance: future sales, future earnings, current stock price, and market returns.

8.1 Review of results

8.1.1 Summary of the results for traditional pharmaceutical companies

To summarize, I will first highlight the results from the traditional pharmaceutical companies. Hypothesis 1 asserts that the number of approved new drug applications will be positively associated with future sales. This hypothesis is supported by the empirical results as the coefficient on NDAs is positive and significant in the sales model.

Further, the regression analysis for the earnings model shows that each NDA obtained by the traditional companies has a positive impact on one period ahead operating earnings. Thus, H_2 is supported. The anecdotal evidence discussed in the case study provides additional support for H_2 . In fact, Schering Plough's net income increased by almost \$200 million the year after the FDA approval of Claritin. These results are consistent with those found in Fornell, Ittner, and Larcker (1996) and Behn and Riley (1996) which found that non-financial indicators can provide information that is useful in assessing future operating performance.

Because the number of NDAs is positively associated with future sales and earnings, they should also be valued by the stock market. Hypothesis 3 predicts that the number of NDAs will be positively associated with the current stock price. The empirical results for the traditional pharmaceutical companies are consistent with this hypothesis. In particular, each NDA obtained during year t increases the three month out stock price by approximately one percent. The U.S. approval of Claritin by Schering Plough further demonstrates how large the impact on price can be. In the month that Claritin was approved, the stock price of Schering Plough increased from approximately \$60 per share to approximately \$65 per share, or more than 8%. This result suggests that there are substantial intangible assets that are not recognized on the balance sheets of traditional pharmaceutical companies. It is therefore important that investors consider alternate measures of the assets that are not recorded.

Although there is a relationship between NDAs and stock price, there is no apparent relationship between NDAs and market returns. The lack of an association between NDAs and returns is likely a result of using a long window to evaluate investor reaction to a particular event. Hirschey, Richardson, and Scholz (1998) obtained similar results when assessing the relationship between patent data and market performance measures. In particular, they found that patent information was positively associated with stock price but not with annual stock returns. In the future, it would be beneficial to conduct an event study surrounding the release of drug approval information.

To check the robustness of the NDA results, I included the number of patents obtained by the traditional firms in the sales, earnings, and price models to ensure that NDAs provide information that is not available in patent counts. In all three models,

NDAAs are positively associated with the dependent variables after controlling for patents and R&D. As a final verification of the models, I included five years of R&D and patent data in the models. Once again, NDAAs are positively associated with future sales, future earnings, and current stock price. This implies that approved new drug applications provide information useful for assessing future operating performance and current stock price that is not available in R&D and patent data.

Finally, analyses were conducted to determine if the research and development expenditures of successful firms are more highly valued than the research and development of non-successful firms. Successful firms are identified as those with a relatively higher level of NDAAs per year. The coefficient on Success is positive. This result supports the earlier conclusions that NDAAs are an indicator of unrecognized intangible assets. In addition, the interaction between Success and R&DPS is positively associated with stock price indicating that the R&D of successful product developers is valued more by investors than the R&D of non-successful producers. The return model exhibits no differences between successful and non-successful firms.

Overall, the results for the traditional pharmaceutical companies provide support for the hypotheses. NDAAs are positively associated with future earnings, future sales, and current stock price. In addition, a dichotomous variable that distinguishes successful from non-successful product developers is positively associated with stock price as is the interaction between the dichotomous variable and R&D. These results imply that NDAAs are a proxy for economically valuable knowledge in the pharmaceutical industry. The results also suggests that investors value the R&D of successful firms more than the R&D of non-successful firms.

8.1.2 Summary of the results for generic pharmaceutical companies

The results for the generic pharmaceutical firms are mixed. First, Hypotheses 1 is not supported as NDAs are not positively associated with future sales. This result might be attributed to the fact that generic firms rely on low-price, high volume market tactics. Therefore, it is possible that the incremental benefit to receiving an NDA cannot be detected in sales for a single period. NDAs are marginally associated with future operating earnings.

Despite the weak operating results, NDAs are positively associated with stock price for the generic firms. This suggests that NDAs can be used as a proxy for the intangible asset created with investments in R&D. As with the traditional firms, there is no relationship between NDAs and returns.

Finally, the results from the generic pharmaceutical firms do not support the successful product producer hypotheses. While being classified as a successful product producer is positively associated with stock price, the R&D of successful firms is not positively associated with price. More surprising, the R&D of successful firms is negatively associated with stock price. This result is difficult to interpret. As with the traditional firms, there is no relationship between successful firms and stock market returns.

8.2 Summary

The analyses confirm the results found in other research (Amir and Lev 1996; Fornell, Ittner, and Larcker 1996; Behn and Riley 1997; Barth, Clement, Foster, and Kasznik 1998; and Hirschey, Richardson, and Scholz 1998). In particular, non-financial

measures of economic value can be used to provide additional information in firm valuation decisions. More specifically, non-financial measures of R&D success provide information not contained in R&D expenditures. This documents that providing non-financial information (i.e. NDAs) to investors and analysts enhances their ability to predict operating and market performance of firms in the pharmaceutical industry.

Measuring intangible assets will continue to be an important focus of standard setters, decision makers, and investors. In this light, several streams of future research might prove beneficial. First, it is interesting that the results for the traditional and generic pharmaceutical companies are not the same. Future research could strive to identify an alternate measure of intangible assets for the generic firms. In addition, advertising and direct promotion to physicians and hospitals creates another important intangible asset to pharmaceutical firms. A study that incorporated a value for this intangible would enhance the understanding of this industry. Further, an event study focusing on the time surrounding the release of new drug approvals by the Food and Drug Administration might provide additional insight into the valuation of successful R&D endeavors. Also, research that investigates methodologies for assigning value to new products would make strides toward valuing intangible assets.

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FIGURES AND TABLES

Figure 1

Pharmaceutical R&D Timeline

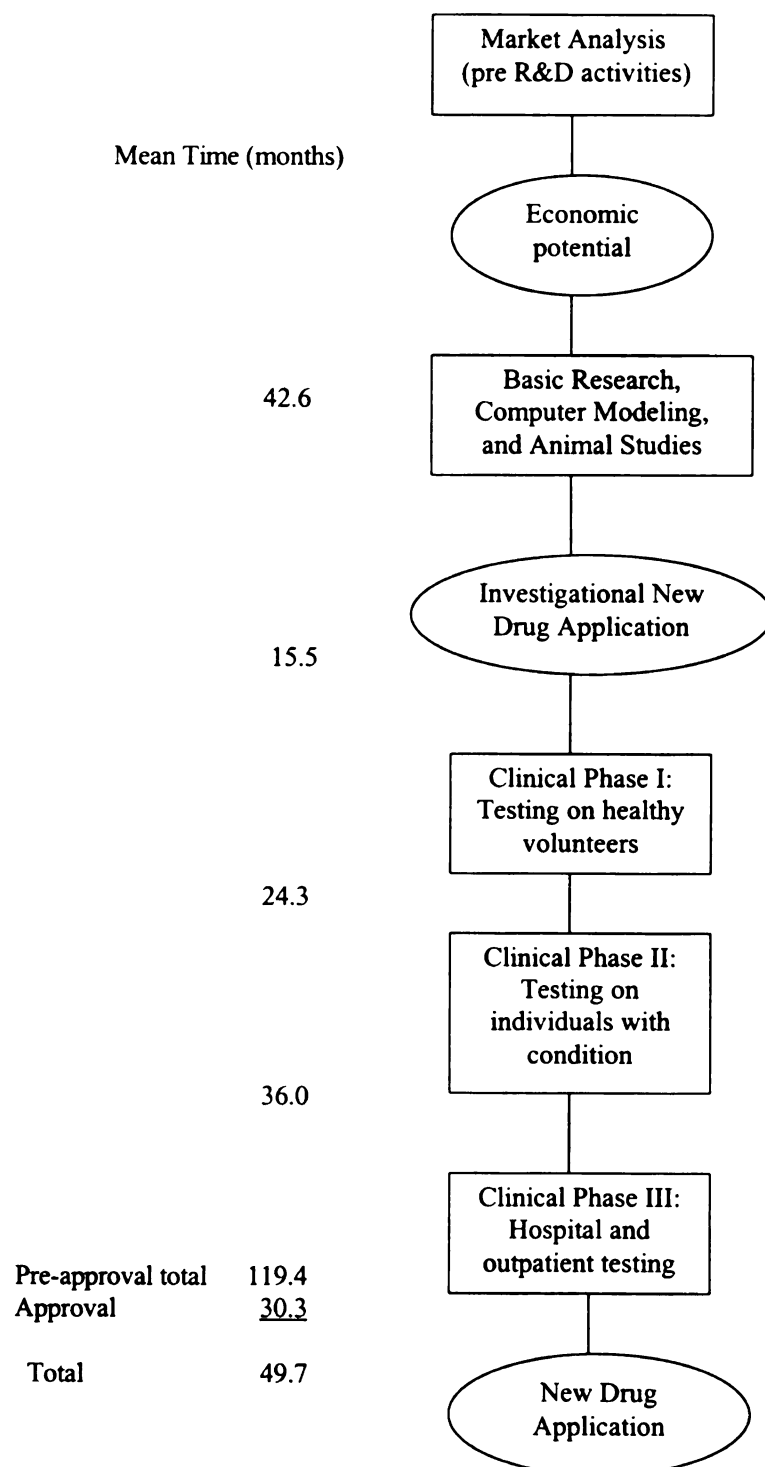
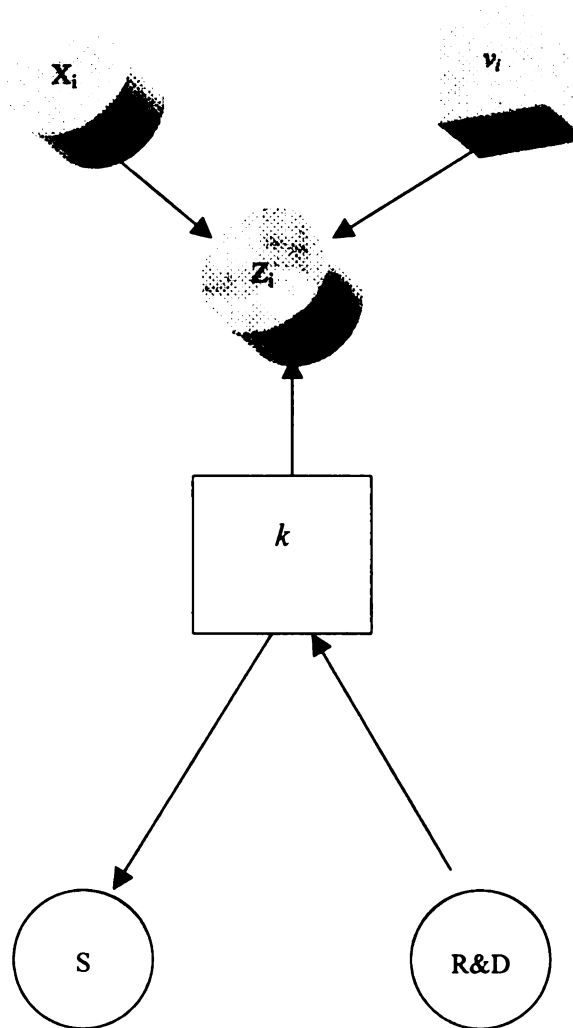


Diagram adopted from Schweitzer (1997), Figure 1.3.

Figure 2

The Knowledge Production Function



Where:

- R&D: research and development expenditures
- S: measure of R&D success, economics papers usually use patents granted
- k : additions to economically valuable knowledge
- Z 's: indicators of expected or realized benefits from invention
- X 's: other observed variables influencing the Z 's

Diagram adopted from Pakes and Griliches (1984), Figure 4.

Figure 3

Schering Plough Corporation

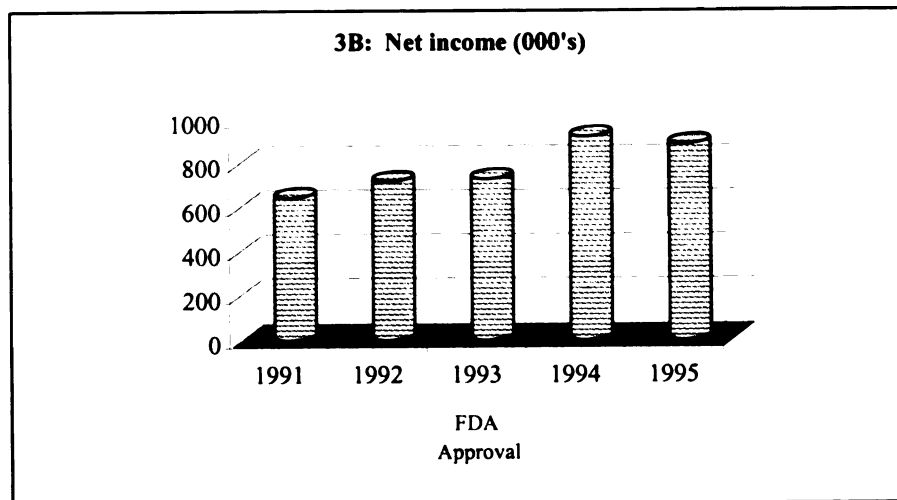
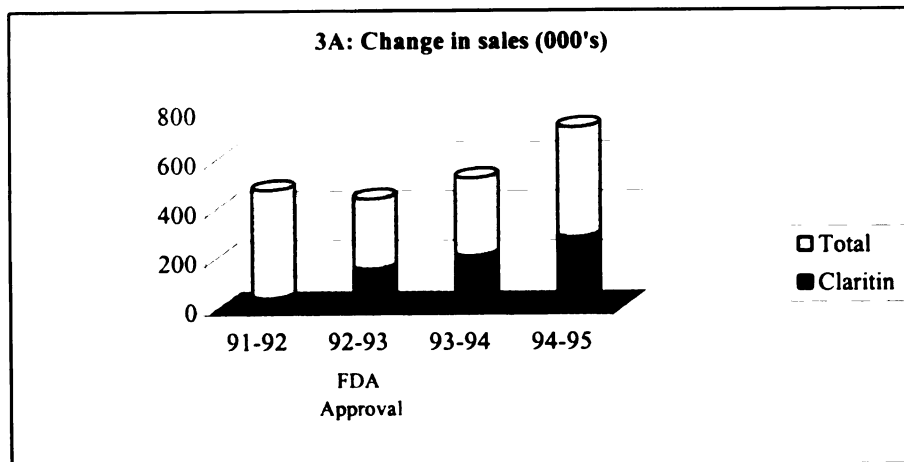


Figure 3 (continued)

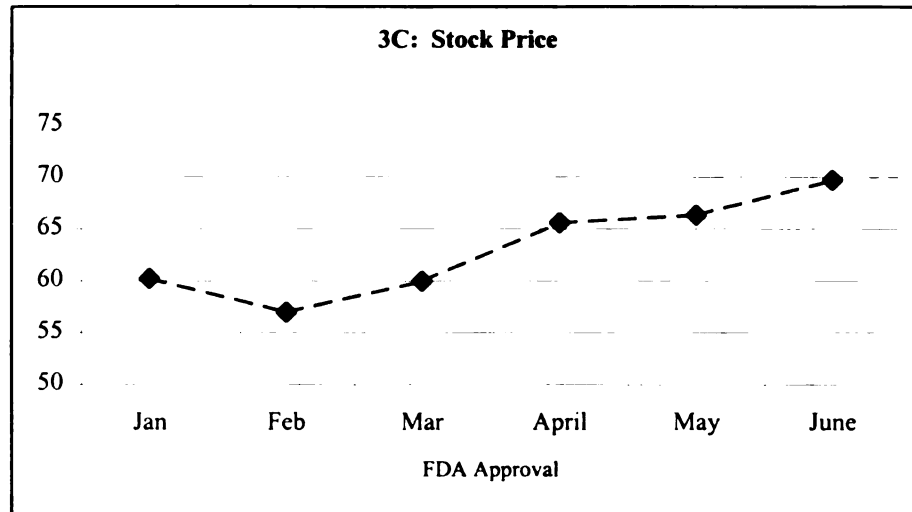


Table 1
Descriptive Statistics^a

Panel A: All Firms (119 firms, 695 firm-years)					
Variable	Mean	Standard Deviation	Min	Median	Max
Assets	1,391	3,597	0.4	47	24,293
Sales	1,215	3,100	0.0	8.7	21,620
R&D	124	300	0.0	7.8	1,905
NI	173	495	-352	-1.8	3,881
Price	19.77	21.94	0.14	10.63	97.50
NDA	2.40	6.53	0.0	0.0	64
Panel B: Traditional Firms (23 firms, 220 firm-years)					
Assets	4,269	5,368	1.6	2,292	24,293
Sales	3,771	4,564	0.0	1,392	21,620
R&D	370	442	0.0	222	1,905
NI	559	746	-352	133	3,881
Price	41.27	26.82	0.88	40.94	97.50
NDA	5.13	9.19	0.0	1.0	64
Panel C: Development Firms (80 firms, 353 firm-years)					
Assets	34	36	0.4	21	221
Sales	4.9	10	0.0	1.4	89
R&D	10	12	0.0	6.6	74
NI	-10	10	-64	-7.5	13
Price	8.76	6.34	0.14	7.25	43.63
NDA	0.05	0.28	0.0	0.0	3
Panel D: Generic Firms (16 firms, 122 firm-years)					
Assets	127	171	4.5	55	778
Sales	107	157	0.0	50	778
R&D	8	12	0.0	3.2	61
NI	7	25	-63	1.1	121
Price	12.86	9.97	0.59	9.94	45.00
NDA	4.28	7.61	0.0	0.5	37

Where:

Assets	total assets at the fiscal year end;
Equity	total equity at the fiscal year end;
Sales	revenues, including royalties and licensing fees and excluding non-operating revenues such as interest;
R&D	research and development expenditures incurred during the year;
NI	net income before discontinued operations, extraordinary items, and changes in accounting methods;
Price	stock price at the end of the first quarter following the fiscal year end;
NDA	the number of New Drug Applications approved during the fiscal year for each firm by the Food and Drug Administration.

^aAccounting variables are in millions of dollar.

Table 2**NDA Model^{a,b}**

$$\text{NDA}_{j,t} = \alpha_t + \beta_1 \text{R\&D}_{j,t} + \beta_2 \text{Assets}_{j,t} + \varepsilon_{j,t}$$

	Coefficient (Standard Error) [Chi-Square] ^c		
	R&D _{j,t}	Assets _{j,t}	N
Traditional Firms	2.0630 (0.4956) [17.33] ³	-0.0105 (0.0382) [0.08]	217
Generic Firms	27.4562 (11.7039) [5.50] ²	1.5448 (0.8378) [3.40] ¹	122

Where:

NDA_{j,t}: the number of New Drug Applications approved by the Food and Drug Administration for firm j during fiscal year t;
 α_t: year specific indicator intercepts (untabulated);
 R&D_{j,t}: research and development expenditures incurred by firm j during year t;
 Assets_{j,t}: total assets for firm j at fiscal year end t.

^aThis model is fitted using a Poisson regression with a log-linear relationship.^bR&D_{j,t} and Assets_{j,t} are included in the model in billions of dollars.^c1, 2, and 3 indicate significance at the 0.10, 0.05, and 0.01 levels respectively.

Table 3**Sales Model^a**

$$\text{Sales}_{j,t} = \alpha_t + \beta_1 \text{NDA}_{j,t-1} + \beta_2 \text{R\&D}_{j,t-1} + \beta_3 \text{Assets}_{j,t-1} + \epsilon_{j,t}$$

Coefficient (Standard Error) [adjusted T or Z] ^{b,c,d}					
Panel A: Traditional Firms					
	NDA _{j,t-1}	R&D _{j,t-1}	Assets _{j,t-1}	Adj. R ²	N
Pooled with year intercepts	0.0096 (0.0030) [3.20] ³	-0.0800 (0.0586) [-1.37] ¹	1.1642 (0.0631) [18.45] ³	0.95	185
1986	-0.0134 (0.0246) [-0.54]	-0.8690 (0.3454) [-2.52] ²	2.4551 (0.4400) [5.58] ³	0.96	14
1987	-0.0000 (0.0045) [-0.00]	-0.3611 (0.0788) [-4.58] ³	1.5612 (0.1156) [13.51] ³	0.99	14
1988	0.0004 (0.0079) [0.05]	-0.4219 (0.1493) [-2.83] ³	1.7033 (0.2146) [7.94] ³	0.97	14
1989	0.0037 (0.0057) [0.65]	-0.3987 (0.1674) [-2.38] ²	1.6434 (0.2244) [7.32] ³	0.96	13
1990	0.0083 (0.0146) [0.57]	-0.1121 (0.0937) [-1.20]	1.2085 (0.0916) [13.19] ³	0.98	16
1991	0.0115 (0.0443) [0.26]	-0.0293 (0.1680) [-0.17]	0.9770 (0.1770) [5.52] ³	0.95	16
1992	0.0321 (0.0202) [1.59] ¹	-0.0957 (0.1212) [-0.79]	1.0581 (0.1207) [8.77] ³	0.97	19
1993	0.0083 (0.0323) [0.26]	-0.2531 (0.1759) [-1.44] ¹	1.4815 (0.2022) [7.33] ³	0.96	20
1994	0.0190 (0.0198) [0.96]	-0.1541 (0.1918) [-0.80]	1.2861 (0.2010) [6.40] ³	0.95	19
1995	0.0205 (0.0203) [1.01]	-0.0506 (0.1922) [-0.26]	1.0777 (0.1903) [5.66] ³	0.95	20
1996	0.0183 (0.0208) [0.88]	0.1133 (0.1678) [0.68]	0.8704 (0.1708) [5.10] ³	0.96	20
Across Years	0.0099 (0.0124) [1.62] ²	-0.2393 (0.2680) [-4.57] ³	1.3929 (0.4502) [24.35] ³		
Z1					
Z2					

Table 3 (continued)

Panel B: Generic Firms					
	NDA _{j,t-1}	R&D _{j,t-1}	Assets _{j,t-1}	Adj. R ²	N
Pooled with year intercepts	-0.0045 (0.0054) [-0.83]	-0.3546 (0.0528) [-6.72] ³	1.2731 (0.0528) [24.11] ³	0.93	94
1993	-0.0016 (0.0535) [-0.03]	-0.3282 (0.1942) [-1.69] ¹	1.2342 (0.1749) [7.06] ³	0.88	12
1994	-0.0091 (0.0169) [-0.54]	-0.3017 (0.1241) [-2.43] ²	1.3081 (0.1235) [10.59] ³	0.96	13
1995	-0.0022 (0.0162) [-0.14]	-0.3191 (0.1010) [-3.16] ³	1.3705 (0.1091) [12.56] ³	0.97	14
1996	-0.0359 (0.0234) [-1.53] ¹	-0.2785 (0.1125) [-2.48] ²	1.2671 (0.1151) [11.01] ³	0.97	13
Across Years	-0.0122 (0.0162)	-0.3069 (0.0219)	1.2950 (0.0587)		
Z1	[-1.03]	[-4.49] ³	[18.97] ³		
Z2	[-1.42] ¹	[-7.04] ³	[7.67] ³		

Where:

Sales_{j,t}: revenues, including royalties and licensing fees and excluding non-operating revenues such as interest, for firm j during year t;
 α_t : year specific indicator intercepts (untabulated);
NDA_{j,t-1}: the number of New Drug Applications approved by the Food and Drug Administration for firm j during fiscal year t-1;
R&D_{j,t-1}: research and development expenditures incurred by firm j during fiscal year t-1;
Assets_{j,t-1}: total assets of firm j at fiscal year end t-1.

^aAll financial variables, Sales, R&D, and Assets, are in millions of dollars. Further, they are included in the model in logarithmic form.

^b1, 2, and 3 indicate significance at the .10, .05, and .01 levels respectively for a one-tailed t-test or for a normal distribution.

^cT-scores are adjusted if they failed White's test of homoskedasticity (White 1980).

^dAcross Years row reports the mean coefficient and standard deviation of the coefficient of the cross-sectional regressions. Z1 equals $1/\sqrt{N} \sum_{j=1}^N t_j / \sqrt{k_j/(k_j - 2)}$ where t_j is the t-statistic for year j, k_j is the degrees of freedom for year j, and N is the number of years. Z2, which corrects for cross-sectional and serial correlation, equals $\bar{t} / \left(\text{stddev}(t) / \sqrt{N-1} \right)$. (See Barth 1994.)

Table 4**Earnings Model^a**

$$\text{NIBRD}_{j,t} = \alpha_i + \beta_1 \text{NDA}_{j,t-1} + \beta_2 \text{R\&D}_{j,t-1} + \beta_3 \text{Assets}_{j,t-1} + e_{j,t}$$

Coefficient (Standard Error) [adjusted T or Z] ^{b,c,d}					
Panel A: Traditional Firms					
	NDA _{j,t-1}	R&D _{j,t-1}	Assets _{j,t-1}	Adj. R ²	N
Pooled with year intercepts	0.0075 (0.0019) [3.95] ³	0.2279 (0.0501) [4.55] ³	0.8499 (0.0634) [13.41] ³	0.98	169
1986	0.0122 (0.0033) [3.69] ³	-0.0825 (0.0543) [-1.52] ¹	1.1458 (0.0748) [15.31] ³	0.99	12
1987	0.0049 (0.0073) [0.67]	0.2216 (0.1288) [1.72] ¹	0.7818 (0.1889) [4.14] ³	0.97	14
1988	0.0053 (0.0049) [1.09]	0.2866 (0.0925) [3.10] ³	0.8058 (0.1329) [6.06] ³	0.99	14
1989	0.0039 (0.0047) [0.83]	0.0873 (0.1372) [0.64]	1.0284 (0.1839) [5.59] ³	0.97	13
1990	0.0084 (0.0123) [0.68]	-0.0172 (0.1661) [-0.10]	1.2237 (0.2395) [5.11] ³	0.98	14
1991	0.0127 (0.0235) [0.54]	0.1948 (0.1002) [1.94] ²	0.7730 (0.1108) [6.98] ³	0.98	14
1992	0.0180 (0.0177) [1.02]	0.2364 (0.1059) [2.23] ²	0.7460 (0.1062) [7.02] ³	0.98	18
1993	0.0031 (0.0220) [0.14]	0.1858 (0.1347) [1.38] ¹	1.0885 (0.1686) [6.46] ³	0.98	18
1994	0.0115 (0.0183) [0.63]	-0.1191 (0.1775) [-0.67]	1.4173 (0.1860) [7.62] ³	0.97	19
1995	0.0087 (0.0126) [0.69]	0.4774 (0.1290) [3.70] ³	0.6232 (0.1309) [4.76] ³	0.98	19
1996	0.0102 (0.0213) [0.48]	0.5176 (0.1812) [2.86] ³	0.5386 (0.1805) [2.98] ³	0.96	19
Across Years	0.0090 (0.0045) [2.92] ³	0.1808 (0.2061) [4.32] ³	0.9247 (0.2735) [20.20] ³		
Z1					
Z2					

Table 4 (continued)

Panel B: Generic Firms					
	NDA _{j,t-1}	R&D _{j,t-1}	Assets _{j,t-1}	Adj. R ²	N
Pooled with year intercepts	0.0128 (0.0091) [1.41] ¹	0.2356 (0.1037) [2.27] ²	0.7423 (0.0965) [7.69] ³	0.86	78
1993	-0.0637 (0.1173) [-0.54]	0.9955 (0.5511) [1.81] ²	0.3434 (0.4278) [0.80]	0.76	10
1994	0.0466 (0.0309) [1.51] ¹	-0.1321 (0.2276) [-0.58]	1.0028 (0.2280) [4.40] ³	0.87	12
1995	0.0302 (0.0216) [1.40] ¹	0.2339 (0.1444) [1.62] ¹	0.7880 (0.1560) [5.05] ³	0.93	12
Across Years	0.0044 (0.0595)	0.3658 (0.5753)	0.7114 (0.3363)		
Z1	[1.25]	[1.48] ¹	[5.40] ³		
Z2	[0.96]	[1.01]	[2.11] ²		

Where:

NIBRD_{j,t}: net income from continuing operations before depreciation and amortization and before research and development expenditures for firm j during year t;
 α_t : year specific indicator intercepts (untabulated);
NDA_{j,t-1}: the number of New Drug Applications approved by the Food and Drug Administration for firm j during fiscal year t-1;
R&D_{j,t-1}: research and development expenditures incurred by firm j during year t-1;
Assets_{j,t-1}: total assets of a firm at fiscal year end t-1.

^aAll financial variabes, Sales, R&D, and Assets, are in millions of dollars. Further, they are included in the model in logarithmic form.

^b1, 2, and 3 indicate significance at the .10, .05, and .01 levels respectively for a one-tailed t-test.

^cT-scores are adjusted if they failed White's test of homeskedaticity (White 1980).

^dAcross Years row reports the mean coefficient and standard deviation of the coefficient of the cross-sectional regressions. Z1 equals $1/\sqrt{N} \sum_{j=1}^N t_j / \sqrt{k_j/(k_j-2)}$ where t_j is the t-statistic for year j, k_j is the degrees of freedom for year j, and N is the number of years. Z2, which corrects for cross-sectional and serial correlation, equals $\bar{t} / \left(\text{stddev}(t) / \sqrt{N-1} \right)$. (See Barth 1994.)

Table 5**Price Model**

$$\text{Price}_{j,t} = \alpha_t + \beta_1 \text{NDA}_{j,t} + \beta_2 \text{R\&DPS}_{j,t} + \beta_3 \text{EPS}_{j,t} + \beta_4 \text{BVPS}_{j,t} + \epsilon_{j,t}$$

Coefficient (Standard Error) [adjusted T or Z] ^{a,b,c}						
Panel A: Traditional Firms						
	NDA _{j,t}	R&DPS _{j,t}	EPS _{j,t}	BVPS _{j,t}	Adj. R ²	N
Pooled with year intercepts	0.3352 (0.1064) [3.15] ³	-3.2779 (2.1572) [-1.52] ¹	6.5073 (1.0646) [6.11] ³	0.1515 (0.2592) [0.58]	0.62	212
1985	1.9061 (0.8728) [2.18] ²	-2.0825 (9.4497) [-0.22]	-3.9785 (4.0675) [-0.98]	3.4735 (2.4193) [1.44] ¹	0.54	13
1986	0.5759 (0.5300) [1.09]	24.9604 (12.5183) [1.99] ²	-4.1799 (4.8596) [-0.86]	0.5873 (1.9332) [0.30]	0.34	15
1987	0.3957 (0.2891) [1.37] ¹	11.8573 (7.6962) [1.54] ¹	-0.7597 (3.2556) [-0.23]	1.4591 (0.7880) [1.85] ²	0.77	15
1988	0.0332 (0.3743) [0.09]	-18.9163 (14.7830) [-1.28]	16.4024 (7.0994) [2.31] ²	-2.6210 (1.7793) [-1.47] ¹	0.50	16
1989	0.9731 (1.1184) [0.87]	13.7395 (17.5843) [0.78]	-7.9598 (6.4806) [-1.23]	3.1985 (1.6167) [1.98] ²	0.15	16
1990	0.4424 (2.1504) [0.21]	10.4792 (13.3067) [0.79]	4.6124 (3.9380) [1.17]	-2.5707 (2.0539) [-1.25]	0.01	17
1991	1.6836 (0.7137) [2.36] ²	1.2541 (5.3972) [0.23]	3.8668 (2.6870) [1.44] ¹	0.1808 (1.3590) [0.13]	0.57	20
1992	0.2690 (0.4819) [0.56]	-5.4465 (3.0969) [-1.76] ²	8.0286 (1.4718) [5.45] ³	0.1057 (0.7103) [0.15]	0.78	21
1993	-0.2155 (0.2658) [-0.81]	-5.0196 (2.5912) [-1.94] ²	7.5232 (1.4142) [5.32] ³	0.0580 (0.4320) [0.13]	0.80	21
1994	0.0527 (0.2202) [0.24]	-10.0805 (2.5656) [-3.93] ³	10.2361 (1.0950) [9.35] ³	0.2520 (0.3924) [0.64]	0.92	21
1995	0.8766 (0.9348) [0.94]	-6.1764 (9.3545) [-0.66]	1.6934 (3.7536) [0.45]	1.4299 (1.3892) [1.03]	-0.04	22

Table 5 (continued)

	NDA _{j,t}	R&DPS _{j,t}	EPS _{j,t}	BVPS _{j,t}	Adj. R ²	N
1996	0.4809 (0.6494) [0.74]	-21.9735 (5.1654) [-4.25] ³	14.8008 (2.7228) [5.44] ³	1.6185 (0.7898) [2.05] ³	0.75	22
Across Years	0.6228 (0.6443) [2.66] ³ [3.07] ³	-0.6171 (13.8131) [2.41] ² [-1.21]	4.1905 (7.6250) [7.60] ³ [2.28] ²	0.5976 (1.8766) [1.90] ² [1.66] ²		
Panel B: Generic Firms						
Pooled with year intercepts	0.4733 (0.1110) [4.26] ³	-0.0107 (1.6864) [-0.01]	4.1340 (1.3068) [3.16] ³	-0.1185 (0.3950) [-0.30]	0.39	120
1992	1.3269 (1.1047) [1.20]	-1.5113 (10.3764) [-0.15]	16.6588 (12.0474) [1.38] ¹	-1.7025 (2.7394) [-0.62]	0.56	13
1993	0.2511 (0.3815) [0.66]	4.8993 (7.2803) [0.67]	9.1440 (6.8099) [1.34]	-1.7680 (2.2438) [-0.79]	0.07	13
1994	0.5549 (0.2527) [2.20] ²	-3.3725 (2.7425) [-1.23]	7.9339 (2.5157) [3.15] ³	0.0438 (0.8449) [0.05]	0.79	15
1995	1.4072 (0.6741) [2.09] ²	-0.0172 (8.2967) [-0.00]	-0.7089 (4.9908) [-0.14]	1.4991 (1.4294) [1.05]	0.51	15
1996	0.8680 (0.4209) [2.06] ²	0.7826 (4.2754) [0.18]	5.2868 (4.0313) [1.31]	-0.7228 (1.2417) [-0.58]	0.40	14
Across Years	0.8816 (0.4947) [3.40] ³ [4.83] ³	0.1562 (3.0884) [-0.22] [-0.30]	7.6629 (6.3033) [2.92] ³ [2.41] ³	-0.5301 (1.3593) [-0.36] [-0.47]		

Table 5 (continued)

Where:

Price _{j,t} :	stock price for firm j at the end of the first quarter following the fiscal year end;
α _t :	year specific indicator intercepts (untabulated);
NDA _{j,t} :	the number of New Drug Applications approved by the Food and Drug Administration for firm j during fiscal year t;
R&DPS _{j,t} :	research and development expenditures incurred by firm j during year t divided by the number of shares outstanding;
EPS _{j,t} :	net income from continuing operations before depreciation and amortization and before research and development expenditures for firm j during year t divided by the number of shares outstanding;
BVPS _{j,t} :	total assets minus total liabilities for firm j at the fiscal year end t divided by the number of shares outstanding.

^a1, 2, and 3 indicate significance at the .10, .05, and .01 levels respectively for a one-tailed t-test.

^bT-scores are adjusted if they failed White's test of homoskedasticity (White 1980).

^cAcross Years row reports the mean coefficient and standard deviation of the coefficient of the cross-sectional regressions. Z1 equals $1/\sqrt{N} \sum_{j=1}^N t_j / \sqrt{k_j/(k_j - 2)}$ where t_j is the t-statistic for year j, k_j is the degrees of freedom for year j, and N is the number of years. Z2, which corrects for cross-sectional and serial correlation, equals $\bar{t} / \left(\text{stddev}(t) / \sqrt{N-1} \right)$. (See Barth 1994.)

Table 6

Returns Model

$$\text{Return}_{j,t} = \alpha_t + \beta_1 \text{NDA}_{j,t} + \beta_2 \Delta \text{NDA}_{j,t} + \beta_3 \text{R\&DPS}_{j,t} + \beta_4 \Delta \text{R\&DPS}_{j,t} + \beta_5 \text{EPS}_{j,t} + \beta_6 \Delta \text{EPS}_{j,t} + \varepsilon_{j,t}$$

Coefficient (Standard Error) [Adjusted T or Z] ^{a,b,c}								
Panel A: Traditional Firms								
	NDA _{j,t}	ΔNDA _{j,t}	R&DPS _{j,t}	ΔR&DPS _{j,t}	EPS _{j,t}	ΔEPS _{j,t}	Adj. R ²	N
Pooled with year intercepts	-0.0012 (0.0026) [-0.46]	0.0013 (0.0036) [0.36]	0.0040 (0.0319) [0.13]	-0.1500 (0.0607) [-2.47] ³	-0.0014 (0.0143) [-0.10]	0.0413 (0.0186) [2.22] ²	0.17	193
1986	-0.0083 (0.0174) [-0.48]	0.0047 (0.0309) [0.15]	-0.0327 (0.2088) [-0.16]	-0.1118 (0.1809) [-0.62]	-0.0328 (0.0726) [-0.45]	-0.0027 (0.0486) [-0.06]	-0.05	14
1987	0.0007 (0.0099) [0.07]	0.0160 (0.0329) [0.49]	0.1101 (0.2632) [0.42]	-0.0078 (0.3586) [-0.02]	-0.0367 (0.0965) [-0.38]	-0.0231 (0.0817) [-0.28]	-0.56	15
1988	-0.0006 (0.0070) [-0.09]	0.0023 (0.0161) [0.14]	-0.0873 (0.1875) [-0.47]	-0.8861 (0.4893) [-1.81] ²	0.0236 (0.0683) [0.35]	0.2867 (0.1620) [1.77] ³	0.05	15
1989	0.0486 (0.0370) [1.31]	0.0208 (0.0187) [1.11]	0.5961 (0.3916) [1.52] ¹	-0.7894 (0.6189) [-1.28]	-0.2316 (0.1417) [-1.63] ²	0.2696 (0.2191) [1.23]	-0.27	15
1990	0.0196 (0.0194) [1.01]	0.0135 (0.0136) [0.99]	-0.0664 (0.1693) [-0.39]	-0.0656 (0.2510) [-0.26]	0.0266 (0.0643) [0.41]	0.0290 (0.0871) [0.33]	-0.13	17
1991	-0.0007 (0.0293) [-0.02]	-0.0164 (0.0372) [-0.44]	-0.1699 (0.1340) [-1.27]	-0.4916 (0.4501) [-1.09]	0.0084 (0.0591) [0.14]	0.1843 (0.1179) [1.56] ¹	0.17	16
1992	-0.0077 (0.0100) [-0.77]	0.0148 (0.0120) [1.23]	0.0283 (0.0684) [0.41]	-0.0150 (0.1437) [-0.10]	-0.0058 (0.0331) [-0.18]	0.0271 (0.0351) [0.77]	-0.04	19

Table 6 (continued)

	NDA _{it}	ΔNDA _{it}	R&DPS _{it}	ΔR&DPS _{it}	EPS _{it}	ΔEPS _{it}	Adj. R ²	N
1993	-0.0037 (0.0160) [-0.23]	0.0085 (0.0245) [0.35]	0.1689 (0.0978) [1.73] ²	-0.7274 (0.5534) [-1.31] ¹	-0.0977 (0.0487) [-2.01] ²	0.1666 (0.0716) [2.33] ²	0.15	21
1994	0.0101 (0.0090) [1.12]	0.0028 (0.0098) [0.29]	-0.0591 (0.0832) [-0.71]	0.0100 (0.2660) [0.04]	0.0166 (0.0456) [0.36]	0.1839 (0.0981) [1.87] ²	0.16	20
1995	0.0013 (0.0145) [0.09]	0.0043 (0.0201) [0.21]	0.0568 (0.1419) [0.40]	0.0479 (0.3449) [0.14]	-0.0363 (0.0625) [-0.58]	-0.0617 (0.1350) [-0.46]	-0.28	21
1996	-0.0088 (0.0145) [-0.61]	-0.0008 (0.0140) [-0.06]	-0.2069 (0.1254) [-1.65] ¹	0.0398 (0.2210) [0.18]	0.1428 (0.0690) [2.07] ²	-0.0060 (0.0694) [-0.09]	0.04	22
Across Years	0.0046 (0.0168) [0.40]	0.0064 (0.0102) [1.27] ¹	0.0307 (0.2186) [-0.05]	-0.2724 (0.3720) [-1.73] ²	-0.0203 (0.0919) [-0.53]	0.0958 (0.1247) [2.55] ³		
Z1	[0.57]	[2.49] ³	[-0.04]	[-2.52] ³	[-0.50]	[2.63] ³		
Z2								

Panel B: Generic Firms

	NDA _{it}	ΔNDA _{it}	R&DPS _{it}	ΔR&DPS _{it}	EPS _{it}	ΔEPS _{it}	Adj. R ²	N
Pooled with year Intercepts	-0.0119 (0.0077) [-1.55] ¹	-0.0095 (0.0085) [-1.12]	0.0795 (0.1314) [0.61]	-0.4572 (0.2187) [-2.09] ²	-0.0291 (0.0539) [-0.54]	0.3481 (0.0739) [4.71] ³	0.29	103
1993	0.1669 (0.1616) [1.03]	-0.3255 (0.2709) [-1.20]	-1.6435 (1.5906) [-1.03]	4.3424 (4.9198) [0.88]	-0.0080 (0.2510) [-0.03]	0.6174 (0.2687) [2.30] ²	0.32	13
1994	0.0394 (0.0531) [0.74]	0.0270 (0.0594) [0.45]	-0.3577 (0.3567) [-1.00]	0.9645 (1.7102) [0.56]	0.0478 (0.5215) [0.09]	-0.0052 (0.4849) [-0.01]	-0.01	13
1995	0.0337 (0.0530) [0.64]	-0.0129 (0.0495) [-0.26]	0.6963 (0.6138) [1.13]	-0.0431 (0.6728) [-0.06]	-0.5648 (0.3187) [-1.77] ¹	0.5019 (0.3824) [1.31] ¹	0.01	15

Table 6 (continued)

	NDA _{j,t}	ΔNDA _{j,t}	R&DPS _{j,t}	ΔR&DPS _{j,t}	EPS _{j,t}	ΔEPS _{j,t}	Adj. R ²	N
1996	-0.0299 (0.0340) [-0.88]	-0.0284 (0.0608) [-0.47]	0.2234 (0.5686) [0.39]	-0.6643 (0.5225) [-1.27]	0.0753 (0.1985) [0.38]	0.5744 (0.3894) [1.48] ¹	0.39	15
Across Years	0.0525 (0.0825)	-0.0850 (0.1621)	-0.2704 (1.0118)	1.1499 (2.2317)	-0.1124 (0.3036)	0.4221 (0.2888)		
Z1	[0.70]	[-0.68]	[-0.23]	[0.04]	[-0.62]	[2.35] ³		
Z2	[0.77]	[-0.94]	[-0.21]	[0.05]	[-0.59]	[2.30] ³		

Where:

- Return_{j,t}: market return for firm j from the end of the first quarter for year t to the end of the first quarter for year t+1;
α_i: year specific indicator intercepts (untabulated);
NDA_{j,t}: the number of New Drug Applications approved by the Food and Drug Administration for firm j during fiscal year t;
ΔNDA_{j,t}: the change in the number of New Drug Applications approved by the FDA for firm j between fiscal year t and t-1;
R&DPS_{j,t}: research and development expenditures incurred during year t divided by the number of shares outstanding;
ΔR&DPS_{j,t}: the change in R&DPS from year t-1 to year t;
EPS_{j,t}: net income from continuing operations before depreciation and amortization and before research and development expenditures during year t divided by the shares outstanding;
ΔEPS_{j,t}: the change in EPS from year t-1 to year t.

^a1, 2, and 3 indicate significance at the .10, .05, and .01 levels respectively for a one-tailed t-test.

^bT-scores are adjusted if they failed White's test of homoskedasticity (White 1980).

^cAcross Years row reports the mean coefficient and standard deviation of the coefficient of the cross-sectional regressions. Z1 equals

$1/\sqrt{N} \sum_{j=1}^N t_j / \sqrt{k_j/(k_j-2)}$ where t_j is the t-statistic for year j, k_j is the degrees of freedom for year j, and N is the number of years. Z2, which corrects for

cross-sectional and serial correlation, equals $t / \left(\frac{\text{stdev}(t)}{\sqrt{N-1}} \right)$. (See Barth 1994.)

Table 7**Sales Model with Patents (Traditional Firms Only)**

$$\text{Sales}_{j,t} = \alpha_t + \beta_1 \text{NDA}_{j,t-1} + \beta_2 \text{Patents}_{j,t-x} + \beta_3 \text{R\&D}_{j,t-x} + \beta_4 \text{Assets}_{j,t-1} + \varepsilon_{j,t}$$

	Coefficient (Standard Error) [adjusted T] ^{a,b,c}	
NDA _{j,t-1}	0.0110 (0.0027) [4.07] ³	0.0234 (0.0080) [2.93] ³
Patents _{j,t-1}	0.0010 (0.0006) [1.67] ²	-0.0023 (0.0025) [-0.92]
Patents _{j,t-2}		-0.0007 (0.0034) [-0.21]
Patents _{j,t-3}		-0.0022 (0.0035) [-0.63]
Patents _{j,t-4}		0.0041 (0.0042) [0.97]
Patents _{j,t-5}		0.0032 (0.0036) [0.89]
R&D _{j,t-1}	-0.1190 (0.0498) [-2.39] ³	-0.7673 (0.1971) [-3.89] ³
R&D _{j,t-2}		0.6516 (0.2466) [2.64] ³
R&D _{j,t-3}		-0.0989 (0.2237) [-0.44]
R&D _{j,t-4}		0.1578 (0.2270) [0.70]
R&D _{j,t-5}		-0.0157 (0.1579) [-0.10]
Assets _{j,t-1}	1.1660 (0.0592) [19.67] ³	1.0832 (0.0823) [13.16] ³
Adj. R ²	0.96	0.96
N	185	103

Table 7 (continued)

Where:

$Sales_{j,t}$	revenues for firm j during year t, excludes interest other non-operating revenues;
α_t	year specific indicator intercepts (untabulated);
$NDA_{j,t-1}$	the annual number of New Drug Application approved for each firm by the Food and Drug Administration for year t-1;
$Patents_{j,t-x}$	the number of patents obtained by firm j during year(s) t-x, x ranges from one to five years;
$R\&D_{j,t-x}$	research and development expenditures incurred during year(s) t-x, x ranges from one to five years;
$Assets_{j,t-1}$	total assets of a firm at the fiscal year ended t-1.

^aAll financial variabes, Sales, R&D, and Assets, are in millions of dollars. Further, they are included in the model in logarithmic form.

^b1, 2, and 3 indicate significance at the .10, .05, and .01 levels respectively for a one-tailed t-test.

^cT-scores are adjusted if they failed White's test of homeskedaticity (White 1980).

Table 8**Earnings Model with Patents (Traditional Firms Only)**

$$NIBRD_{j,t} = \alpha_t + \beta_1 NDA_{j,t-1} + \beta_2 Patents_{j,t-1} + \beta_3 R\&D_{j,t-1} + \beta_4 Assets_{j,t-1} + \varepsilon_{j,t}$$

	Coefficient (Standard Error) [adjusted T] ^{a,b,c}	
NDA _{j,t-1}	0.0077 (0.0018) [4.28] ³	0.0141 (0.0050) [2.82] ³
Patents _{j,t-1}	0.0008 (0.0004) [2.00] ²	0.0006 (0.0016) [0.38]
Patents _{j,t-2}		-0.0009 (0.0021) [-0.43]
Patents _{j,t-3}		0.0001 (0.0022) [0.04]
Patents _{j,t-4}		0.0008 (0.0027) [0.30]
Patents _{j,t-5}		-0.0001 (0.0023) [-0.04]
R&D _{j,t-1}	0.2218 (0.0495) [4.48] ³	0.1063 (0.1519) [0.70]
R&D _{j,t-2}		-0.4841 (0.2120) [-2.28] ³
R&D _{j,t-3}		0.5900 (0.1548) [3.81] ³
R&D _{j,t-4}		0.3033 (0.1514) [2.00] ²
R&D _{j,t-5}		-0.1842 (0.1052) [-1.75] ²
Assets _{j,t-1}	0.8409 (0.0632) [13.31] ³	0.6764 (0.0569) [11.89] ³
Adj. R ²	0.98	0.98
N	169	101

Table 8 (continued)

Where:

$NIBRD_{j,t}$	net income from continuing operations before depreciation and amortization and before research and development expenditures;
α_t :	year specific indicator intercepts (untabulated);
$NDA_{j,t-1}$:	the annual number of New Drug Application approved for each firm by the Food and Drug Administration for year t-1;
$Patents_{j,t-x}$:	the number of patents obtained by firm j during year(s) t-x, x ranges from one to five years;
$R\&D_{j,t-x}$:	research and development expenditures incurred during year(s) t-x, x ranges from one to five years;
$Assets_{j,t-1}$:	total assets of a firm at the fiscal year ended t-1.

^aAll financial variables, Sales, R&D, and Assets, are in millions of dollars. Further, they are included in the model in logarithmic form.

^b1, 2, and 3 indicate significance at the .10, .05, and .01 levels respectively for a one-tailed t-test.

^cT-scores are adjusted if they failed White's test of homoskedasticity (White 1980).

Table 9**Price Model with Patents (Traditional Firms Only)**

$$\text{Price}_{j,t} = \alpha_1 + \beta_1 \text{NDA}_{j,t} + \beta_2 \text{Patents}_{j,t-x} + \beta_3 \text{R\&DPS}_{j,t-x} + \beta_4 \text{EPS}_{j,t-1} + \beta_5 \text{BVPS}_{j,t-1} + \varepsilon_{j,t}$$

	Coefficient (Standard Error) [adjusted T] ^{a,b}	
NDA _{j,t}	0.2783 (0.0986) [2.82] ³	0.6337 (0.2535) [2.50] ³
Patents _{j,t}	0.0630 (0.0256) [2.46] ³	-0.0987 (0.0729) [-1.35] ¹
Patents _{j,t-1}		-0.1004 (0.1107) [-0.91]
Patents _{j,t-2}		-0.1111 (0.1162) [-0.96]
Patents _{j,t-3}		0.0788 (0.1184) [0.67]
Patents _{j,t-4}		0.3039 (0.1211) [2.51] ³
R&DPS _{j,t}	-3.0656 (1.96) [-1.56] ¹	-10.5340 (3.0790) [-3.42] ³
R&DPS _{j,t-1}		-1.2601 (3.1755) [-0.40]
R&DPS _{j,t-2}		7.6731 (3.4631) [2.22] ³
R&DPS _{j,t-3}		1.9471 (3.5683) [0.55]
R&DPS _{j,t-4}		6.3086 (2.8271) [2.23] ³
EPS _{j,t}	4.0885 (1.1002) [3.72] ³	1.1591 (1.1571) [1.00]
BVPS _{j,t}	0.3309 (0.2597) [1.27] ¹	1.2681 (0.3926) [3.23] ³
Adj. R ²	0.64	0.53
N	212	129

Table 9 (continued)

Where:

$Price_{j,t}$:	stock price at the end of the first quarter following the fiscal year end;
α_t :	year specific indicator intercepts (untabulated);
$NDA_{j,t}$:	the annual number of New Drug Application approved for each firm by the Food and Drug Administration for year t;
$Patents_{j,t-x}$:	the number of patents obtained by firm j during year(s) t-x, x ranges from zero to four years;
$R\&DPS_{j,t-x}$:	research and development expenditures incurred during year(s) t-x, x ranges from zero to four years, divided by the number of shares outstanding;
$EPS_{j,t}$:	net income from continuing operations before depreciation and amortization and before research and development expenditures during year t divided by the number of shares outstanding;
$BVPS_{j,t}$:	total assets minus total liabilities at the fiscal year end t divided by the number of shares outstanding.

^a1, 2, and 3 indicate significance at the .10, .05, and .01 levels respectively.

^bT-scores are adjusted if they failed White's test of homoskedasticity (White 1980).

Table 10**Successful Price Model**

$$\text{Price}_{j,t} = \alpha_t + \beta_1 \text{Success}_{j,t} + \beta_2 \text{R\&DPS}_{j,t} + \beta_3 \text{Success}_{j,t} * \text{R\&DPS}_{j,t-1} + \beta_4 \text{EPS}_{j,t} + \beta_5 \text{BVPS}_{j,t} + \varepsilon_{j,t}$$

Coefficient (Standard Error) [Adjusted T or Z] ^{a,b,c}							
Panel A: Traditional Firms							
	Success _j	R&DPS _{j,t}	Success* R&DPS _{j,t-1}	EPS _{j,t}	BVPS _{j,t}	Adj. R ²	N
Pooled with year intercepts	11.2955 (3.4029) [3.32] ³	-1.4585 (1.4661) [-0.99]	6.2564 (1.7972) [3.48] ³	2.9752 (0.8116) [3.67] ³	0.3615 (0.2647) [1.37] ¹	0.71	212
1985	32.8540 (21.3188) [1.54] ¹	34.1536 (23.5194) [1.45] ¹	-33.0876 (22.5664) [-1.47] ¹	2.0491 (3.8030) [0.54]	0.0767 (2.7200) [0.03]	0.41	13
1986	25.8607 (31.9377) [0.81]	35.8060 (47.8843) [0.75]	-16.0443 (48.2880) [-0.33]	-3.3709 (5.4270) [-0.62]	0.1281 (2.0888) [0.06]	0.23	15
1987	18.1761 (13.8960) [1.31]	30.3771 (17.3307) [1.75] ¹	-24.0469 (17.3776) [-1.38] ¹	1.3384 (3.2425) [0.41]	1.0104 (0.8294) [1.22]	0.76	15
1988	40.4523 (18.4346) [2.19] ²	0.6786 (15.6044) [0.04]	-27.1332 (16.7564) [-1.62] ¹	17.4236 (6.2004) [2.81] ³	-3.3794 (1.5134) [-2.23] ²	0.63	16
1989	30.0187 (22.0731) [1.36] ¹	11.2218 (19.2138) [0.58]	-6.2697 (20.8108) [-0.30]	-6.0489 (5.7159) [-1.06]	2.7849 (1.6328) [1.71] ²	0.17	16
1990	16.9116 (26.6284) [0.64]	10.9238 (14.8157) [0.74]	-9.1787 (19.0969) [-0.48]	5.8084 (6.2865) [0.92]	-2.2167 (2.3145) [-0.96]	-0.05	17
1991	11.9319 (10.6385) [1.12]	-5.6313 (4.5101) [-1.25]	14.8592 (6.1767) [2.41] ²	-0.4767 (2.4162) [-0.20]	1.9738 (1.1663) [1.69] ²	0.76	20
1992	7.0286 (6.3974) [1.10]	-3.8259 (2.8763) [-1.33] ¹	3.5433 (4.2670) [0.83]	5.2540 (2.1115) [2.49] ³	0.3833 (0.6827) [0.56]	0.82	21
1993	3.1609 (6.5987) [0.48]	-2.1893 (2.6717) [-0.82]	3.9526 (2.7982) [1.41] ¹	4.2536 (1.4657) [2.90] ³	0.2042 (0.4611) [0.44]	0.85	21
1994	-2.8063 (4.7911) [-0.59]	-5.9245 (2.2232) [-2.66] ³	10.4448 (2.5015) [4.18] ³	4.6895 (1.3557) [3.46] ³	0.9994 (0.3385) [2.95] ³	0.97	21
1995	41.3031 (21.1936) [1.95] ²	5.3208 (11.4374) [0.46]	-9.3064 (10.7519) [-0.87]	-0.6947 (6.0477) [-0.11]	-0.0723 (1.5184) [-0.05]	0.07	22
1996	11.1120 (10.1224) [1.10]	-17.5444 (3.9274) [-4.47] ³	6.1405 (5.9947) [1.02]	11.5476 (2.0930) [5.52] ³	1.5419 (0.6502) [2.37] ²	0.86	22

Table 10 (continued)

	Success _j	R&DPS _{j,t}	Success _j * R&DPS _{j,t-1}	EPS _{j,t}	BVPS _{j,t}	Adj. R ²	N
Across Years	19.6670 (14.4588)	7.7805 (17.3544)	-7.1772 (15.5343)	3.4811 (6.3789)	0.2862 (1.6953)		
Z1	[3.53] ³	[-1.34] ¹	[0.97]	[4.67] ³	[2.14] ²		
Z2	[4.97] ³	[-0.73]	[0.54]	[2.37] ³	[1.49] ¹		
Panel B: Generic Firms							
Pooled with year Intercepts	8.0788 (1.8767) [4.30] ³	7.3052 (4.9662) [1.47] ¹	-11.7805 (5.3833) [-2.19] ²	4.9133 (1.3392) [3.67] ³	-0.2209 (0.4472) [-0.49]	0.41	118
1992	-8.8603 (11.0108) [-0.80]	-53.4245 (68.1486) [-0.78]	65.2241 (70.6562) [0.92]	32.2099 (10.7711) [2.99] ³	-5.1361 (2.4496) [-2.10] ²	0.47	13
1993	5.7964 (7.9234) [0.73]	12.3656 (41.4010) [0.30]	-8.3423 (40.2763) [-0.21]	9.7774 (7.5280) [1.30]	-2.1018 (2.3903) [-0.88]	-0.03	13
1994	8.0935 (4.3905) [1.84] ²	12.3984 (16.6238) [0.75]	-19.3259 (17.0571) [-1.13]	8.3275 (2.8165) [2.96] ³	0.2928 (1.0183) [0.29]	0.75	15
1995	7.1544 (6.1750) [1.16]	24.4275 (15.9983) [1.53] ²	-35.8778 (16.1250) [-2.22] ²	-1.7375 (5.2743) [-0.33]	3.9690 (1.6959) [2.34] ²	0.49	15
1996	6.7785 (6.4760) [1.05]	5.8685 (8.2568) [0.71]	-13.2178 (10.8082) [-1.22]	6.1720 (4.7644) [1.30]	0.3098 (1.4874) [0.21]	0.18	14
Across Years	3.7925 (7.1209)	0.3271 (30.7872)	-2.3079 (39.1553)	10.9499 (12.6889)	-0.5333 (3.3656)		
Z1	[1.65] ¹	[1.04]	[-1.61] ¹	[3.39] ³	[-0.04]		
Z2	[1.62] ¹	[1.18]	[-1.30] ¹	[2.37] ³	[-0.03]		

Table 10 (continued)

Where:

Price _{j,t} :	stock price at the end of the first quarter following the fiscal year end;
α _t :	year specific indicator intercepts (untabulated);
Success _j :	a dummy variable that is set to 1 if a firm's mean NDA's (across the sample period) is greater than the median of all firms of the same type;
R&DPS _{j,t} :	research and development expenditures incurred during year t divided by the number of shares outstanding;
Success*	
R&DPS _{j,t-1} :	the success dummy variable multiplied by R&DPS during year t-1;
EPS _{j,t} :	net income from continuing operations before depreciation and amortization and before research and development expenditures during year t divided by the number of shares outstanding;
BVPS _{j,t} :	total assets minus total liabilities at the fiscal year end t divided by the number of shares outstanding.

^a1, 2, and 3 indicate significance at the .10, .05, and .01 levels respectively for a one-tailed t-test.

^bT-scores are adjusted if they failed White's test of homoskedasticity (White 1980).

^cAcross Years row reports the mean coefficient and standard deviation of the coefficient of the cross-sectional regressions. Z1 equals $1/\sqrt{N} \sum_{j=1}^N t_j / \sqrt{k_j/(k_j-2)}$ where t_j is the t-statistic for year j , k_j is the degrees of freedom for year j , and N is the number of years. Z2, which corrects for cross-sectional and serial correlation, equals $\bar{t} / \left(\text{stddev}(t) / \sqrt{N-1} \right)$. (See Barth 1994.)

Table 11

Successful Returns Model

$$\text{Return}_{j,t} = \alpha_0 + \beta_1 \text{Success}_{j,t} + \beta_2 \text{R\&DPS}_{j,t} + \beta_3 \text{Success}_{j,t} * \text{R\&DPS}_{j,t} + \beta_4 \text{AR\&DPS}_{j,t} + \beta_5 \text{Success}_{j,t} * \text{AR\&DPS}_{j,t} + \beta_6 \text{EPS}_{j,t} + \beta_7 \Delta \text{EPS}_{j,t} + \varepsilon_{j,t}$$

Panel A: Traditional Firms									
	Success _j	R&DPS _{j,t}	Success _j *R&DPS _{j,t}	AR&DPS _{j,t}	Success* AR&DPS _{j,t}	EPS _{j,t}	ΔEPS _{j,t}	Adj. R ²	N
Pooled with year intercepts	-0.0532 (0.0784) [-0.62]	0.0147 (0.0420) [0.35]	-0.0062 (0.0337) [-0.18]	-0.2295 (0.1062) [-2.16] ²	0.0921 (0.1080) [0.85]	0.0014 (0.0649) [0.02]	0.0375 (0.0172) [2.18] ²	0.17	193
1986	-0.2461 (0.1004) [-2.45] ²	3.4275 (0.4174) [8.21] ³	-3.1924 (0.4025) [-7.93] ³	7.7058 (0.7721) [9.98] ³	-7.8099 (0.7728) [-10.11] ³	-0.1055 (0.0181) [-5.85] ¹	-0.0014 (0.0093) [-0.15]	0.95	14
1987	-0.2699 (0.4592) [-0.59]	-0.0717 (0.6830) [-0.10]	0.3042 (0.6696) [0.45]	-1.0355 (2.3456) [-0.44]	0.8154 (2.0315) [0.40]	-0.0699 (0.1057) [-0.66]	0.0469 (0.1516) [0.31]	-0.67	15
1988	0.2587 (0.1483) [1.74] ²	0.7885 (0.3251) [2.43] ²	-0.7315 (0.3087) [-2.37] ²	-3.4151 (0.7844) [-4.35] ¹	3.2660 (0.8232) [3.97] ¹	-0.0417 (0.0321) [-1.30]	0.0544 (0.0907) [0.60]	0.78	15
1989	0.1153 (0.4742) [0.24]	0.2887 (0.3611) [0.80]	-0.1422 (0.3786) [-0.38]	-0.4958 (0.7019) [-0.71]	0.4279 (0.7142) [0.60]	-0.0706 (0.1206) [-0.59]	0.0275 (0.2205) [0.12]	-0.67	15
1990	0.6482 (0.2329) [2.78] ¹	3.3308 (1.0549) [3.16] ¹	-3.2813 (1.0185) [-3.22] ¹	-6.3027 (1.9496) [-3.23] ¹	6.4020 (1.9865) [3.22] ¹	-0.0231 (0.0459) [-0.50]	-0.0024 (0.0788) [-0.03]	0.34	17
1991	-0.4365 (0.4199) [-1.04]	-1.0460 (0.4113) [-2.54] ²	0.8101 (0.4327) [1.87] ¹	3.2224 (1.7530) [1.84] ¹	-3.3591 (1.5043) [-2.23] ²	0.0170 (0.0954) [0.18]	-0.0017 (0.2070) [-0.01]	0.43	17
1992	0.0163 (0.1289) [0.13]	0.0887 (0.0845) [1.05]	-0.2167 (0.0873) [-2.48] ²	-0.4424 (0.2674) [-1.65] ¹	0.3536 (0.2241) [1.58] ¹	0.0378 (0.0388) [0.97]	0.0662 (0.0309) [2.14] ²	0.37	19

Table 11 (continued)

	Success _{ij}	R&DPS _{it}	Success _{ij} *R&DPS _{it}	AR&DPS _{it}	Success _{ij} *AR&DPS _{it}	EPS _{it}	ΔEPS _{it}	Adj. R ²	N
1993	-0.1094 (0.2317) [-0.47] ¹	0.3507 (0.1285) [2.73] ¹	0.0880 (0.1350) [0.65] ¹	-1.9989 (1.0492) [-1.91] ¹	1.3952 (1.1191) [1.25] ¹	-0.1999 (0.0599) [-3.34] ¹	0.2642 (0.0883) [2.99] ¹	0.33	21
1994	0.0460 (0.2258) [0.20] ¹	-0.0740 (0.1160) [-0.64] ¹	0.0009 (0.1109) [0.01] ¹	-0.2850 (0.4367) [-0.65] ¹	0.4068 (0.5833) [0.70] ¹	0.0238 (0.0677) [0.35] ¹	0.1317 (0.1011) [1.30] ¹	-0.01	20
1995	-0.3376 (0.2997) [-1.11] ¹	0.3481 (0.2234) [1.55] ¹	0.1902 (0.2345) [0.81] ¹	-0.5164 (0.6120) [-0.84] ¹	0.6237 (0.7234) [0.86] ¹	-0.1514 (0.1081) [-1.40] ¹	-0.0810 (0.1356) [-0.60] ¹	0.13	21
1996	-0.1183 (0.3106) [-0.38] ¹	-0.3948 (0.1903) [-2.07] ¹	0.1657 (0.1956) [0.85] ¹	1.0570 (0.7097) [1.49] ¹	-1.0836 (0.7123) [-1.52] ¹	0.1312 (0.0743) [1.77] ¹	0.0168 (0.0874) [0.19] ¹	0.10	22
Across Years	-0.0389 0.3077 [-0.27] [-0.19] ¹	0.6397 (1.4338) [4.09] ¹ [1.42] ¹	-0.5459 (1.3821) [-3.28] ¹ [-1.21] ¹	-0.2279 (3.5715) [-0.17] [-0.04] ¹	0.1307 (3.5832) [-0.33] [-0.10] ¹	-0.0411 (0.0933) [-2.91] ¹ [-1.41] ¹	0.0474 (0.0892) [1.96] ¹ [1.82] ¹		
Z1									
Z2									

Panel B: Generic Firms									
Pooled with year	-0.0933 (0.1306) [-0.71] ¹	0.1145 (0.5276) [0.22] ¹	0.0135 (0.5510) [0.02] ¹	0.1611 (0.8834) [0.18] ¹	-0.7861 (0.9341) [-0.84] ¹	-0.0305 (0.0571) [-0.54] ¹	0.3547 (0.0765) [4.63] ¹	0.25	103
Intercepts									
1993	0.2734 (0.5485) [0.50] ¹	4.4732 (4.6974) [0.95] ¹	-4.2017 (4.6926) [-0.90] ¹	-7.9070 (9.1545) [-0.86] ¹	6.1418 (9.1507) [0.67] ¹	-0.2850 (0.2530) [-1.13] ¹	0.6045 (0.3606) [1.68] ¹	-0.11	12
1994	0.2761 (0.5580) [0.49] ¹	1.7508 (2.5145) [0.70] ¹	-2.2511 (2.5177) [-0.89] ¹	-3.6016 (2.8652) [-1.26] ¹	3.8882 (2.7723) [1.40] ¹	0.4513 (0.3380) [1.34] ¹	-0.1674 (0.5097) [-0.33] ¹	-0.01	13
1995	-0.2415 (0.5181) [-0.47] ¹	-0.9248 (1.6203) [-0.57] ¹	1.3611 (1.7689) [0.77] ¹	2.9100 (3.0776) [0.95] ¹	-3.4009 (3.0670) [-1.11] ¹	-0.3933 (0.2563) [-1.53] ¹	0.4588 (0.4637) [0.99] ¹	0.04	15

Table 11 (continued)

	Success _j	R&DPS _{j,t}	Success _j *R&DPS _{j,t}	ΔR&DPS _{j,t}	Success _j [*] ΔR&DPS _{j,t}	EPS _{j,t}	ΔEPS _{j,t}	Adj. R ²	N
1996	-0.4823 (0.3062) [-1.58] ¹	0.5558 (1.1613) [0.48]	-0.5949 (1.1941) [-0.50]	-1.4505 (2.0769) [-0.70]	0.2580 (2.2518) [0.11]	0.1840 (0.2277) [0.81]	0.2243 (0.4637) [0.48]	0.24	15
Across Years	-0.0436 (0.3805) [0.71]	1.4638 (2.2854) [0.71]	-1.4217 (2.3695) [-0.69]	-2.5123 (4.5025) [-0.86]	1.7218 (4.1879) [0.49]	-0.0108 (0.3971) [-0.24]	0.2801 (0.3369) [1.30] ¹		
Z1	[1.01]	[1.01]	[-0.83]	[-0.84]	[0.44]	[-0.16]	[1.45] ¹		
Z2									

Where:

Return_{j,t}:

market return from the end of the first quarter at t-1 to the end of the first quarter at t for each firm, j;

α_i:

year specific indicator intercepts (untabulated);

Success_j:

a dummy variable that is set to 1 if a firm's mean NDAs are greater than the median of the same class of firms;

R&DPS_{j,t}:

research and development expenditures incurred during year t divided by the number of shares outstanding;

ΔR&DPS_{j,t}:

the change in R&DPS from year t - 1 to year t;

Success^{*}:

Success variable for firm j multiplied by ΔR&DPS from year t - 1 to year t;

ΔR&DPS_{j,t-1}:

net income from continuing operations before depreciation and amortization and before research and development expenditures during

EPS_{j,t}:

year t divided by the number of shares outstanding, scaled by the firm price at fiscal year ended t-1;

ΔEPS_{j,t}:

the change in net income per share from year t-1 to year t scaled by the firm price at the fiscal year ended t-1.

^a1, 2, and 3 indicate significance at the .10, .05, and .01 levels respectively for a one-tailed t-test.

^bT-scores are adjusted if they failed White's test of homoskedasticity (White 1980).

^cAcross Years row reports the mean coefficient and standard deviation of the coefficient of the cross-sectional regressions. Z1 equals

$$1 / \sqrt{N} \sum_{j=1}^N t_j / \sqrt{k_j / (k_j - 2)}$$
 where t_j is the t-statistic for year j , k_j is the degrees of freedom for year j , and N is the number of years. Z2, which corrects for cross-

sectional and serial correlation, equals $\bar{r} / \left(\text{stddev}(t) / \sqrt{N-1} \right)$. (See Barth 1994.)

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