THE PENNSYLVANIA STATE UNIVERSITY
SCHREYER HONORS COLLEGE

DEPARTMENT OF FINANCE

IMPACT OF REGULATORY DECISIONS AFTER PHASE III CLINICAL TRIALS RELATING TO ONCOLOGY DRUGS ON PHARMACEUTICAL STOCK RETURNS

ANDREW CUROTTO
FALL 2018

A thesis
submitted in partial fulfillment
of the requirements
for a baccalaureate degree
in Finance
with honors in Finance

Reviewed and approved* by the following:

Brian Davis
Clinical Associate Professor of Finance
Thesis Supervisor and Honors Adviser

Christoph Hinkelmann
Clinical Associate Professor of Finance
Faculty Reader

* Signatures are on file in the Schreyer Honors College.

ABSTRACT

The aim of this paper is to identify the impact of public FDA announcements related to oncology drugs in Phase III clinical trials. By utilizing an event study methodology, the research will analyze Phase III news announcements, daily stock returns, and historical market capitalizations in order to test the impact of these factors against cumulative abnormal returns over a three-day event window. These abnormal returns will be compared to an expected return based on a market-adjusted beta calculated using each individual companies' historical trading data. By further understanding the stock price movements of biopharmaceutical companies after Phase III results for their oncology drugs, investors will be able to construct more efficient portfolios after either positive or negative news announcements.

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

ACKNOWLEDGEMENTS

I would like to thank Dr. Brian Davis for all of the time and energy he put into helping me create the best research possible. The faith he showed in me throughout the process was truly inspiring. I would also like to thank my family and friends, especially my parents, who have always pushed me to pursue my passions.

Chapter 1

Introduction

Investor Interest

Some of the most important moments for the success or failure of biopharmaceutical companies are regulatory announcements on the results of their clinical trials. There are few industries where the flow of wealth can shift so suddenly based on a government organization's announcement as in the pharmaceutical industry. Decisions by the US Food and Drug Administration (FDA) are high-profile events that not only dictate the success of individual drugs but also can have large impacts on the market capitalization of the sponsoring organization. As such, investors heavily scrutinize these events in order to find signals as to the viability of their position in the market.

Accurate speculation about the tone of the FDA's decisions can be quite lucrative regardless of the success or failure of a clinical trial. Much of this investor interest is rooted in the extreme capital investments made in research and development (R&D) to create a new therapy. The pharmaceutical industry has long relied on the Tufts Center for the Study of Drug Development to provide a barometer of anticipated spending to bring a new drug to market. In 2017, the center estimated the total cost for a pharma company to be $2.7 billion to develop a new treatment (Herper). This figure includes failed drugs as well as the opportunity cost of investing that money on other initiatives. On top of this overwhelming total investment, 9 out of 10 medicines fail FDA approval, increasing the individual impact each new drug development can have on the valuation of pharma companies.

Despite the low success rate and high initial investment, capital continues to flow into biopharmaceutical companies in hopes of finding a blockbuster drug. Through the first half of 2018, venture capitalists have invested over $10.6 billion into healthcare startups. In the second quarter alone, $5.3 billion was put towards 216 healthcare deals, placing the industry at number two in total investment behind only internet companies. This level of investing is on track to set a record for venture capital investment – ready to blow past the $15 billion invested in 2017. Over the last decade, one of the most attractive areas for investment has been in the oncology market, which accounted for just under 12% of pharmaceutical revenues in 2017. The two largest fundraising rounds in 2018 have been for oncology-related ventures. Allogene Therapeutics and Grail each closed rounds of $300 million alone. They are developing breakthrough therapies to fight cancer by allowing the body's immune system to identify and kill cancer cells that were previously undetected – a group of therapies also known as immuno-oncology (Weintraub).

This enthusiasm is not contained simply to private investors and venture capitalists; Wall Street has been enthusiastic about healthcare investments recently as well. The initial public offering (IPO) market is a clear demonstration of this. Through June of 2018, eight biotechnology companies went public with a combined initial value of over $3.3 billion. Four have entered the market since and several more are planning to list in the second half of the year. These IPOs have often been floated at or above the initial range set by the deals' underwriters, offering rich paydays for investors who backed these firms early in the private market. This lends a great deal of validity to those risky initial investments and has done nothing to dampen investor enthusiasm.

Industry Outlook

The pharmaceutical market has been experiencing significant pressures in recent years as the public agenda has shifted to reducing drug prices. Public opinion is fairly aligned on the issue of prescription drug prices as 80% of Americans say the prices are currently unreasonable. On top of that, 72% believe pharmaceutical companies have too much influence in Washington, leading to a swell of support to reel in not only prices but also the power of pharmaceutical companies. This has caused many pharmas to reevaluate their strategic operations. Politicians, who introduced 80 bills in 2017 to try to tackle the issue in state legislatures, have heard the strong public support. For example, Vermont passed a price transparency law that requires the state to identify up to 15 drugs that account for significant state spending and which have seen dramatic price increases. Manufacturers of those products must submit price increase justifications to the Attorney General and that information will be made public (Horvath).

Prices will continue to be pressured not only by politicians, but also by an aging population that is squeezing public and private health insurers' budgets. In this difficult climate, it has become increasingly important to focus on the return on investment (ROI) for new drug ventures. In order to remain viable in the future, pharmaceutical companies have had to try to reduce R&D costs and timelines to preserve returns. Large pharma companies are particularly susceptible to poor R&D productivity as they have multiple workstreams in development at the same time.

This overcrowded pipeline often experiences externalities that have forced companies to become more efficient in selecting the right types of projects to take on. Some have turned to artificial intelligence (AI) to analyze vast amounts of patient data and identify emerging therapeutic areas to focus their next drug discovery. AI is also able to help screen large numbers

of potential molecules to identify those with the highest therapeutic potential once management identifies a disease class. At other times, companies choose simply to enter markets with the highest revenue potential, such as oncology, or those markets where they have the highest likelihood of grabbing market share. While identifying which molecule to develop is costly, the brunt of R&D costs come after initial development during clinical trials – which account for the largest portion of R&D expenditures. Companies have begun to look for efficiencies in this stage of drug development as well. Personalized medicine, or the practice of segmenting pools of patients by their predicted response or risk of disease, has helped reduce failure rates and time-to-approval. Data from Ernst & Young suggests that drugs developed with predictive biomarkers (to help select patients likely to respond to treatment) are three times more likely to be approved than those without (Giovannetti).

Oncology Market

All the industry trends laid out above are amplified in the highly scrutinized oncology market. Many cancer therapies have received breakthrough designation by the FDA – reserved for drugs thought to provide a marked improvement over existing therapies to treat acute diseases – and have drawn serious interest from investors. Global spending on cancer medicines rose to $133 billion in 2017, up from $96 billion in 2013. Over 700 drugs are in late-stage development – up over 60% from a decade ago (Gesme). More than a third of these drugs utilize personalized medicine, a market which grew over 40% from 2015 to 2017 and is predicted to reach $2.7 trillion by 2020 (Kubassova).

Additionally, cancer-related therapies tend to be approved quicker than others. More than a third of the new indications for cancer drugs over the past 25 years entered the clinical trial process through the FDA's accelerated approval program – an expedited review process designed for high-impact drugs. The use of the program has grown significantly in recent years, to the point that more new indications gained approval through the accelerated approval program than through the regular review process in 2017 (Smith). This means companies investing in new oncology therapies are able to shorten the timeline between costly investments and claiming revenue on their breakthrough drugs – as well as deliver value to their shareholders even quicker.

All of this has led many investors to believe the oncology market to be their best bet within the pharmaceutical industry. Combining the flurry of new drug development and increased venture capital support with an expanding market is a recipe many investors believe in. Cancer is a grim sort of growth market. By 2030, there will be over 22 million new cases per year, up from 14 million in 2012. The increasing prevalence, combined with an expanding middle class (who can afford the necessary insurance coverage to allow for these costly treatments) and a more robust suite of therapies ready to combat cancers are an indication for high returns on investment for many investors.

All of these factors have led to this research. While there is substantial research on the effect of FDA announcements on stock prices, there is limited analysis on the effects within the oncology space. With such a burgeoning industry facing strong external influences, it is important for investors to understand the impact of the FDA and prepare for how stock prices will react to positive and negative decisions.

Chapter 2

Literature Review

Cumulative Abnormal Returns and EMH

The purpose of this paper is to determine the effect of FDA announcements relating to oncology drugs on pharmaceutical stock returns. Specifically, it will be testing for cumulative abnormal returns (CAR) versus a Capital Asset Pricing Model (CAPM) return. CAPM is a model used to determine the appropriate rate of return for an asset based on its systematic risk factor, Beta. Multiple researchers originally created the model but the work of Treynor, Sharpe, Lintner, and Mossin has been recognized as the most influential. All returns for this study will be compared to the return predicted by their Beta using the following CAPM formula:

Figure 1 CAPM Formula

$$E(R_i) = R_f + \beta_i(E(R_m) - R_f)$$

$E(R_i)$ represents the expected return of the asset while R_f and $E(R_m)$ are the risk-free rate and the expected return of the market, respectively. β_i denotes the asset's Beta and is the main driving factor of returns.

Participants in the financial markets are constantly trying to beat this benchmark expected return. Earning a return above what CAPM predicts is considered abnormal. The existence of such returns would contrast the widely held view in financial literature that markets are efficient. The majority of research supports the basic thesis of the Efficient Market Hypothesis (EMH) that financial markets are efficient in valuing publicly traded firms such that stock prices reflect all

publicly available information (Fama and French, 1993). Supporting studies have found that new information of various types is absorbed quickly and efficiently into the market value of the firm.

Earnings and dividend announcements are among the factors included in subsequent studies. Basu (1977) finds that portfolios with lower price to earnings (P/E) ratios tended to slightly outperform those with high P/E ratios. Once returns were adjusted for transaction and search costs as well as taxes, abnormal returns faded away. Then, in 1982, Rendleman et al. completed a study of returns during the 1970s, which supports EMH. They found abnormal returns that persisted for at least two years indicating an issue with the one-factor CAPM model, not EMH. Ahorny and Swary (1980) find dividend announcements provide additional useful information to investors not found in normal earnings announcements. They are unable to identify any abnormal returns after the dividends are made public.

There is also plenty of research supporting the idea that investors tend to underreact to new information. DeBond and Thaler (1985) take a look at winners in the stock market over 3 and 5-year windows. Their study shows the tendencies for these stocks to reverse course and become future losers in a predictable pattern. This predictability of returns is echoed in future studies on financial announcements. Bernard and Thomas (1990) find a drift in abnormal returns corresponding to surprises in earnings announcements for up to twelve months after the announcement. The shorter period of abnormal returns indicates investors are slow to fully understand the implications of the earnings surprise. Michaely et al. (1995) find evidence of under reaction after dividend announcements as well as after surprise dividend omissions. Michaely and Womack (1999) find a lag in reactions to new analyst recommendations. Finally, Ikenberry and Ramnath (2002) identify an underreaction to stock splits.

The existence of such cases has continued to bring EMH into debate throughout the years. Fama-French (1993) proposes that the problem is not with the markets but with the model used to judge abnormal returns. He in turn tests the size effect of companies on stock price returns and finds that average returns for portfolios comprised of smaller companies by market cap tend to outperform portfolios made of large cap stocks. He also finds a value effect noting companies with low book value to market value ratios (value stocks) outperform those with high ratios. Fama-French decide to add these size and value factors into the CAPM model, creating a three-factor model. He includes the SMB (small minus big) factor to adjust for size and HML (high minus low) to account for the value effect of small and large cap stocks. These factors, along with Beta predict returns as below:

Figure 2 Fama-French Three Factor Model

$$r = R_f + \beta_3(K_m - R_f) + b_s \cdot SMB + b_v \cdot HML + \alpha$$

Research & Development and the News Effect

Ensuing research has adopted the three-factor model and added to it to explain anomalies creating abnormal returns. One such study models the effects of R&D expenditures on stock prices, returns, and volatility. Bastin and Hubner (2006) cluster biotechnology stocks based on responsiveness to political and scientific events following the release of publicly available human genome data. They identify an industry-specific factor relating to the number of patents held by a company in relation to their market value. This patent market value (PMV) factor is the difference in average daily returns of high a PMV portfolio and one with low PMV. This factor directly fluctuates with good and bad news announcements and is inversely related to their R&D

measure. This indicates that portfolios with high patent value – such as pharmaceutical companies – tend to outperform those with low patent value.

Some have classified these types of variables as "soft." For example, Hand (2001) identifies PMV as a soft variable along with the likes of human capital, strategic alliances, and joint ventures. His research concludes that, contrary to popular belief, these soft variables are not the main driving factor of biotechnology valuations. Rather, 70% of the variance in these valuations are determined by fundamental analysis of the firms' financial statements. He does find that the timing of R&D expenses is directly related and has a significant effect on the elasticity of biotechnology a firm's market value. Earlier investment and higher investment growth rates produce significantly larger elasticity of equity values than do lower ones. This proved to be the stepping-stone to more recent research on the effects of R&D on pharma stock prices.

Titi (2014) follows the research of Bastin and Hubner as well as Hand by examining the effects of R&D spending in the pharmaceutical industry on stock returns, price, and volatility between 2002 and 2013. She confirms one of her initial hypotheses that higher R&D expenditures are directly related to significant positive stock returns. The significance of these positive returns is even greater after R&D spending surpasses the $100 million threshold. She also concludes that stocks with high R&D to market value ratios tend to be historically poor performers in the market. This trend tends to reverse as the stocks recover showing the market's under reaction to managers' signals. Had the market been acting efficiently, they would have priced in the higher R&D expenses in anticipation of the future returns produced by those projects. These findings are similar to the Fama-French conclusion in the 1990s showing why value stocks tend to outperform growth stocks.

Existing research is equally split on the efficiency of markets in the context of public news about research and development investment. Eddy and Saunders (1980) use a sample of 66 firms and find no evidence that new product announcements affected monthly stock returns. Then, a little over a decade later, Chaney et al. (1991) find a small positive effect on the stock price during a three-day window around the announcement date. Additionally, they find that this effect is largest for more technologically advanced firms such as those in the computer, chemical, and pharmaceutical industries. The cumulative abnormal return observed after product announcements is likely directly related to the boom-or-bust potential of new drugs.

A 2016 report published by BIO – the world's largest trade association representing biotechnology companies found that the likelihood of approval (LOA) after Phase I trials for a new drug across all indications is only 9.6%. While less than 1 in 10 new drugs make it out of Phase I trials, the LOA for cancer drugs is even worse at only 5.1%. This is the lowest of all 15 disease classes published in the report (Thomas et al.). A 2016 study by DiMasi et al. found the price to develop a new drug before it is approved is $2.59 Billion. That price jumps to $2.87 Billion after the drug has been approved and these numbers are increasing at an inflation-adjusted annual rate of 8.5%. The extremely costly gamble biopharmaceutical companies are taking when bringing a new drug to market makes it easy to see why investors should react to news events.

FDA News Effect

The purpose of this paper is to determine the effect of FDA announcements relating to oncology drugs on pharmaceutical stock returns. The effect of public news on stock prices has been well documented in recent years. Chan (2003) provides a thorough analysis of this news effect by comparing stock price reactions to news and no-news events. He looks at news events mainly in the 1980s and 1990s for a randomly selected group of 1557 stocks. He finds a strong post-announcement movement for both positive and negative announcements. The magnitude of the price movement as well as the subsequent drift is larger on the negative side than the positive. The study also finds that those stocks that experienced large price movements with no identifiable news accompanying it saw quick reversals and returns to normal. Chan interprets these findings to show investors' tendency to underreact to public news and overreact to private news signals.

The biopharmaceutical industry, like many others, relies heavily on news and regulatory announcements. Decisions made by the Food and Drug Administration (FDA) become the difference between the life and death of large capital projects in the form of new drug development. Bosch and Lee (1994) investigate the value effects of FDA product approvals, rejections, and disciplinary actions on the companies within its industries. They find very large wealth effects for the drug, food, and other (medical devices and cosmetics) industries. Their results suggest FDA decisions are not fully anticipated by the market and as such are not built into the stock price during the days preceding an announcement. Their analysis of 138 drug-related products showed significant abnormal returns of +1.10% on the day of a positive announcement in the drug industry and significant average abnormal returns of -1.43% on the day of negative announcements for all three categories. Like Chan, Bosch and Lee found that

negative events had consistently higher magnitudes of abnormal returns than did positive announcements.

Further research has solidified these findings within the pharmaceutical industry. Some, like Sharma and Lacey (2004) have found massive differences in magnitude between positive and negative news events. Like Bosch and Lee, they identified statistically significant values in both directions, finding a +1.56% abnormal return on the day following an FDA approval and -21.03% abnormal returns on the day following a rejection or negative signal by the FDA. They also find that this new information is incorporated into returns quickly and cleanly – there is no residual effect after the event window at +2 days from the announcement.

More recent studies like Hwang (2013) have shown much more modest returns when focusing on large pharmaceutical companies (revenue relating to branded pharmaceutical sales greater than $5 billion). He identifies significant abnormal returns of +0.8% for positive FDA signals and -2.0% for negative ones. Both values were found significant at the 95% confidence interval. Hwang also finds that positive abnormal returns were associated with stock price corrections, with their returns falling back to normal levels in the two days following the announcement. For negative events, however, he shows sustained negative numbers over the two-day event window.

From the general acknowledgement that positive FDA reviews are good for stock performance and negative announcements hurt performance, several authors have branched off to isolate the news effect on individual areas of the pharmaceutical industry. Sarkar and de Jong (2006) isolated FDA announcements at each of the three stages of pre-market drug testing.

As defined by the FDA's website, the three stages are:

- Phase I: Drug tested on healthy volunteers to prove the safety and required dosage. Usually lasts a couple of months.
- Phase II: Several hundred people are tested in order to determine the efficacy and any side effects of the drug. Can last up to two years.
- Phase III: Up to 3,000 participants with the relevant disease or condition are tested to ensure efficacy and monitor for adverse results. Generally lasts 1 to 4 years.

This paper once again finds that investors react positively to positive results from the FDA and react more negatively to negative results. Interestingly, the pair finds diminishing abnormal returns as the drug moves through the three approval phases. Each of the three results (both positive and negative) are statistically significant, however, showing continued investor feedback throughout the lifecycle of the drug.

Beyond the approval process, some authors have found convincing evidence of differences between different types of drugs as well. In a follow-up to their 2004 paper, Lacey and Sharma (2008) once again examine the returns of pharmaceutical stocks during an event window immediately preceding, during, and following an FDA decision. Their research agrees with all the previously analyzed research. Approvals show statistically significant abnormal returns while rejections show larger statistically significant declines on the day of the announcement. Lacey and Sharma also divide their results by two different FDA classifications.

The first is review classification, including Priority and Standard reviews. Priority review is reserved for drugs that will show significant improvement in safety or effectiveness of serious conditions when compared to what is currently on the market. They also are to be reviewed in 6 months as opposed to 10 for Standard review drugs. The authors find that abnormal returns in

either direction are approximately three times larger for priority drugs than for others. This indicates investors' expectations of blockbuster drugs creating high cash flows.

The second classification used to split these drugs is molecular design. The FDA ranks drugs applying for a New Drug Application, or NDA, on a scale from 1 to 7. Molecules with a rating of 1 are completely new molecules with a new ingredient that has never been marketed in the United States. These are seen as the most lucrative and important to the industry. Those drugs receiving a rating of 7 are already approved and marketed in the United States but are simply applying for a new use. The scale between these two extremes fluctuates accordingly. Lacey and Sharma find market participants are able to discriminate between molecular types. FDA approvals associated with drugs rated 4-7 are associated with statistically insignificant abnormal returns. Those with ratings 1, 2, and 3 all demonstrate significant abnormal returns distributed according to their tier with category 1 showing the greatest magnitude.

All of this market segmentation leads to where this research will find its place. Finding the effect of FDA announcements relating to oncology drugs within the last five years will further the current academic knowledge on pharmaceutical stock movements for the modern age. Oncology is one of the most important sectors for the pharmaceutical industry and accounts for the largest share of pharma revenues. The category has seen significant advances since the turn of the century and many new drugs receive priority review status from the FDA. Since 2000, 77% of specialty drug approvals were categorized as priority reviews by the FDA compared to only 24% for non-specialty drugs (Cooperman). As Lacey and Sharma (2008) showed, investors pay special attention to priority-designated drugs and reward (or penalize) them accordingly in the open markets. The aim of this paper is to identify the impact of public FDA announcements related to oncology drugs in Phase III clinical trials. The research will take a look at not only the

impact of news type on cumulative abnormal returns but also test the significance of positive and negative news announcements, market capitalization, as well as test for any leakage of returns before and persistence of returns after the announcement.

Chapter 3

Data & Methodology

Data Collection

The sample for this study consists of events between January 1, 2013 and September 28, 2018 for 31 biopharmaceutical companies. Factiva was used to search for FDA decisions within this period. The keywords “Phase (3 or III)”, “FDA”, “result*”, and “oncology or cancer” were used to find the specific types of news announcements for this study. Factiva’s duplicate-eliminating settings were switched to “Similar” in order to eliminate articles that talk about the same topic. The company setting was filtered for the FDA in order to ensure only FDA decisions would be included, subject was filtered on “New Product/Service Testing”, and the industry was set to “Biotech or Pharmaceuticals” and “Cancer Drugs”. This search yielded 795 results that were filtered manually to find relevant news events. All companies had to be publicly traded and be the majority sponsor of the clinical trial. Only final decisions were included in the study – interim announcements were ignored. This initial search yielded 52 announcements to be included. The majority of these results were positive news announcements, however, so a second search was used to identify further negative decisions.

This second Factiva search was done over the same timeframe as the first. It used keywords “Phase (3 or III)”, (oncology and cancer), and “fail or reject or did not meet or didn’t meet”. Similar duplicates were once again eliminated, the industry was filtered down to “Biotech or Pharmaceuticals” and “Cancer Drugs”, and “New Product/Service Testing” was selected as the subject. This search yielded 3045 results that were once again filtered manually to identify

further negative results. 23 additional negative decisions were added to the study from this secondary search.

Phase III trial outcomes were logged as either positive (1) or negative (0). Positive trials are those that are the first randomized Phase III clinical trial for a given indication in which there was a statistically significant improvement in their primary endpoint (Rothstein et al., 2011). Orphan drugs and drugs that received accelerated approval were excluded. Negative trials were those which did not receive FDA approval during Phase III trials either due to a failure to reach their primary endpoint or the company's decision to shut down the trial before failing during testing. The company's stock ticker, the earliest date of the press release, and notes on the announcement were also logged for the analysis.

Factset was subsequently used to obtain daily stock prices for each of the companies from 1/1/2013 to 9/28/2018. For this analysis, Day 0 was defined as the day active trading could take place following the announcement. If the announcement took place before the stock market closed, the event day was Day 0. If it took place after the market had closed, the ensuing trading day was used as Day 0. The daily stock price returns from -120 trading days to day +10 were calculated for each of the companies.

Statistical Methodology

Using this information, the abnormal returns for each company on trading days 0, +1, and +2 were calculated. The summation of these three returns represent the cumulative abnormal return during the event window {0, +2}. To calculate the abnormal returns for each of these days, the predicted stock price movement was subtracted from the actual stock return (obtained through Factset). As mentioned in the literary review, the best way to calculate the predicted return of a stock is the CAPM formula. The 120 preceding trading days to the news announcement were used as a baseline to calculate the company beta. The return of the S&P 500 (also acquired through Factset) were multiplied by the calculated beta to calculate the daily expected return.

In order to test the significance of news type on CAR, a regression was run using news type (0 or 1) as the independent variable and CAR as the dependent variable. This analysis sought to find if there was a statistically significant difference between positive and negative news announcements. A second set of regressions were run in order to test the significance of average abnormal returns (AAR) for both the positive and negative announcement data sets. The average abnormal return was defined as the sum of all abnormal returns on each day divided by the number of events in the data set. The three average abnormal returns for each day between {0, +2} were then summed to calculate a total cumulative abnormal return over the three-day

Figure 3 Average Abnormal Return Calculation

$$AAR_t = \frac{\sum_{i=1}^{n} AR_{i,t}}{n}$$

event window. These average abnormal returns were then divided by the standard deviation of the baseline window (120 preceding trading days) in order to get a z-score and subsequent p-value to test against a 95% confidence interval.

The same process was used to test the significance of returns immediately before and after the event window. This test seeks to identify any leakage of news before the announcement is made public or the persistence of abnormal returns after the event window. The existence of either would be contrary to the efficient market hypothesis and could indicate insider trading. In order to identify these returns, the average abnormal return was calculated for ten days preceding and trailing the announcement day. Those returns were then divided by the baseline standard deviation and regressed in order to test against the 95% confidence interval.

In order to calculate the significance of market cap on cumulative abnormal returns, Factset was used to collect daily market capitalization values for each of the 31 companies within the study. The market cap on the last day of the 3-day event window (Day +2) was used to run a regression versus the absolute CAR values for each event. Several companies had multiple events that were studied and different market caps were used corresponding to the timing of each separate event. The regression used the natural log of market cap as the independent variable and the absolute value of CAR as the dependent variable. The natural log of market cap was used in order to normalize the data over the duration of the study. The absolute value of cumulative abnormal returns was used to eliminate the news type effect and focus the market cap effect only on the magnitude of changes in stock price – not the direction.

Chapter 4

Statistical Analysis

News and Market Cap Effects

Several regressions were performed on 75 news events for Phase III clinical trials. The first tested the independent variable news type – either positive (given a value of 1) or negative (given a value of 0) – while the second tested the natural log of market capitalization as the independent variable. Each regression used cumulative abnormal returns as the dependent variable. The following coefficient results were obtained for news type and market capitalization:

Table 1 Summary of News and Market Cap Factor Coefficients

	Coefficients	*Standard Error*	*t Stat*	*P-value*
Intercept	-0.1063	0.0264	-4.02	0.00014
Result Type (0 or 1)	0.1184	0.0351	3.38	0.00119
LN of Market Cap	-0.0260	0.0044	-5.91	0.00001

As indicated by the P-values, each factor within the regression was found to be statistically significant at a 95% confidence interval. The type of news (positive or negative) had a highly significant impact on cumulative abnormal returns, with a P-value of 0.001. A coefficient of .1184 indicates an 11.84% difference in CAR between the average successful and unsuccessful announcement. The market cap of the sponsoring company also demonstrates a statistically significant impact at the 95% confidence interval on the price movement of the company's stock. The slope coefficient between absolute CAR and the natural log of market cap is negative, indicating an inverse relationship between the two. This is to say that larger

companies experience smaller impacts on the price of their stocks while small companies have price shocks of greater magnitude.

The average three-day CAR is drastically different in both the positive and negative subsamples for the top 50% of market caps than it is for the bottom 50%.

Table 2 Comparison of News Effect for Smallest and Largest Companies

	Positive Events	Negative Events
Top 50%	0.88%	-0.13%
Bottom 50%	1.54%	-12.33%

For positive news events, the smallest companies in the sample demonstrated a return of 1.54%, which is approximately 1.75 times larger than that of the largest companies. The difference is more striking for negative news announcements, where the smallest companies provided a pullback of 12.33% – over 98 times greater than the largest companies in the set.

This finding is consistent with previous research on the topic of market cap's impact on stock price movements and is easily seen in many of the individual stories within the larger sample. For example, the largest absolute CAR for a stock over the three-day event window was a 68% pullback by Peregrine Pharmaceuticals (stock ticker CDMO) in 2016 after they announced the failure of a lung cancer drug in Phase III trials. The company did not have any drugs approved to sell on the market but had several in the pipeline. Without any supporting revenue to dampen the negative news announcement and a market cap of only $89 million on the day of the announcement, the stock took a greater loss than a larger firm would have. To further illustrate this point, if you take a subset of events that includes the 20 smallest absolute CARs, the set of companies contains market caps all greater than $39 billion. The event corresponding

to the $39 billion company belongs to Takeda Pharmaceuticals, the largest pharma company in Asia and one of the 20 largest in the world.

Positive vs Negative Announcements

This market cap effect also holds when you separate the entire sample into positive and negative news announcements. Both subsets have a statistically significant negative correlation at the 95% confidence interval between absolute CAR and the natural log of market cap. The significance of the size effect was greater within the negative sample than it was for positive news events.

Table 3 Summary of Market Cap Effect Coefficients

	Coefficients	*Standard Error*	*t Stat*	*P-value*
LN Market Cap (Positive Events)	-0.0119	0.0031	-3.85	0.0004
LN Market Cap (Negative Events)	-0.0282	0.0079	-3.56	0.0014

This indicates that investors have a greater downside reaction to smaller companies for negative events than they do on the upside for positive events. In order to further analyze the disparity between investors' reactions to positive and negative trial results, the data set was again split into the two subsets and analyzed for average abnormal returns.

Over the three-day event window, stocks whose drugs were approved by the FDA showed an average cumulative abnormal return of 1.21% while those companies who received negative news from their clinical trials had an average 3-day CAR of -10.63%. Only the negative news announcements were found to be significant at the 95% confidence level but the large disparity between the two CAR values confirms the difference in investors' reactions to the news. This finding is consistent with much of the existing research in this space, which finds that investors often punish negative news harsher than they reward positive events. This may be

explained by the reasonable expectations theory. Investors may have already adjusted their portfolios and most of the expectation for a positive announcement effect has already been factored into the price (Sarkar, de Jong 2006). Another explanation could be overconfidence from investors who assume they have made a good bet and as such under react to positive news. Since they already expect to see returns on their investment, they are not surprised when they get confirmation of this bias. But, if they receive downside news, it causes a strong reevaluation of their position and an appropriate repricing of the assets.

Table 4 Summary of Positive and Negative Event Window CARs

3 Day CAR			
Event Type	**Day**	**AAR**	**t-test**
Positive	0	0.09%	0.05
	1	0.50%	0.28
	2	0.62%	0.35
	Cumulative	**1.21%**	**0.69**
Negative	0	-10.41%	-3.92
	1	0.63%	0.24
	2	-0.85%	-0.32
	Cumulative	**-10.63%**	**-4.01**

Efficient Market Analysis

Expanding the analysis beyond the three-day event window to include the ten days before and after the announcement demonstrates that none of the individual abnormal returns or cumulative abnormal returns over this timeline are significant. The greatest average abnormal return seen before a positive event happens two days before the event where there is a 0.34% AAR. This value is not statistically significant and is consistent with the lack of significance for any of the values leading up to a positive or negative announcement. Neither cumulative AARs over the preceding 10-day window are more than one standard deviation away from the mean average abnormal return.

Table 5 Summary of Pre and Post Event Window Abnormal Returns

Leakage Before Announcement			
Event Type	Day	AAR	t-test
Positive	-9	-0.13%	-0.07
	-8	-0.16%	-0.09
	-7	-0.29%	-0.17
	-6	-0.25%	-0.14
	-5	-0.20%	-0.12
	-4	0.07%	0.04
	-3	-0.10%	-0.06
	-2	0.34%	0.19
	-1	0.07%	0.04
	Cumulative	**-0.64%**	**-0.37**
Negative	-9	0.06%	0.02
	-8	-0.10%	-0.04
	-7	0.69%	0.26
	-6	0.58%	0.22
	-5	0.17%	0.06
	-4	-0.51%	-0.19
	-3	0.12%	0.05
	-2	-0.61%	-0.23
	-1	-2.18%	-0.82
	Cumulative	**-1.77%**	**-0.67**

Persistence of Returns			
Event Type	Day	AAR	t-test
Positive	3	-0.04%	-0.03
	4	-0.17%	-0.10
	5	0.22%	0.12
	6	-0.26%	-0.15
	7	-0.32%	-0.18
	8	0.02%	0.01
	9	0.17%	0.09
	10	-0.39%	-0.22
	Cumulative	**-0.77%**	**-0.44**
Negative	3	-1.16%	-0.44
	4	-0.47%	-0.18
	5	0.59%	0.22
	6	0.95%	0.36
	7	-0.55%	-0.21
	8	0.37%	0.14
	9	-0.49%	-0.18
	10	0.11%	0.04
	Cumulative	**-0.65%**	**-0.24**

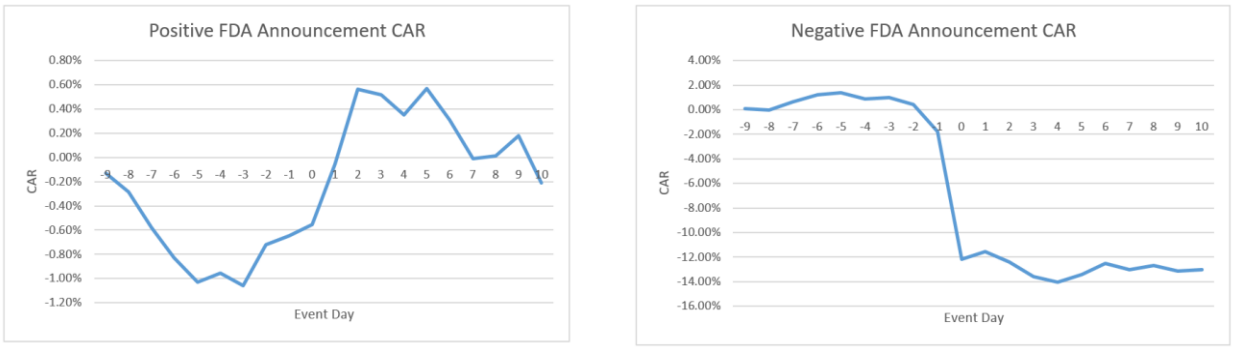
The same can be seen over the ten days following an announcement. None of the individual days following the three-day event window are statistically significant and the average CAR for this timeline falls short of statistical significance as well. Both findings indicate that the market is working efficiently. No significant leakage can be seen in the lead up to a news announcement (the preceding ten days) and no significant persistence of abnormal returns is seen over the ten days following an announcement, whether positive or negative. All significant abnormal returns are seen over the three-day event window where investors are appropriately reacting to new information in the appropriate direction of the positive or negative news.

This price adjustment does not appear before the event happens, indicating investors had no knowledge of the news beforehand and could not trade on the information early. Once the news is released, the information is absorbed quickly into the price of the stock, which promptly returns to normal expected returns. This reaction from investors is consistent with what the efficient market hypothesis would predict. No abnormal returns should be seen in the days leading up to a news announcement if there is no leakage of information. Once positive or negative news is received, the stock price should move accordingly to adjust for the new information and return to normal returns after the bump. No persistent returns should exist if there is no additional news.

The lack of leakage and persistence of returns is best seen below in Figure 4 which illustrates cumulative abnormal returns over the {-10, +10} window. A marked difference can be seen in the volatilities of the two graphs. This is due to the significance of abnormal returns for positive and negative events. For positive events, none of the abnormal returns proved statistically significant, which explains the return to approximately 0% CAR by day +10. For

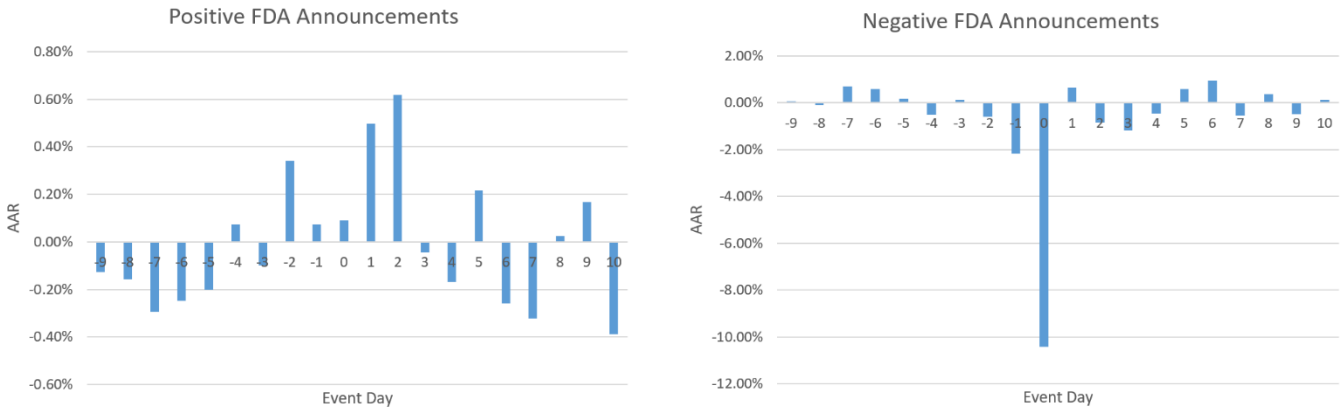
negative events, there is a large statistically significant price shock on Day 0 that is immediately incorporated into the price of the stock. From there, the returns remain relatively flat at this new price level.

Figure 4 Positive and Negative Cumulative Abnormal Returns



The significant movements during days {0, +2} are best seen below in Figure 5. Positive events have a bit more volatility in movements in the preceding and trailing ten days with more modest increases in returns on days +1 and 2 which can be confirmed by the insignificant three-day CAR of 1.28%. The more significant abnormal returns on days +1 and 2 could be explained by investors waiting to hear from the sponsoring company before reacting. The previously mentioned confirmation bias, which causes investors to assume they have made the right bet on a

Figure 5 Positive and Negative Average Abnormal Returns



clinical trial means the FDA announcement is not substantial information. Instead, they are waiting to hear the sponsoring company's operational plan for bringing the drug to market. This information does not usually come until the day or two following the FDA's announcement. The significant pullback following negative news announcements is striking in the graph, however. The surrounding days are much less volatile and the pullback on the day of the announcement is about five times greater in magnitude than any of the other trading days. This could also be explained by confirmation bias, where investors are instead proven to have made the wrong judgement. They immediately and harshly react to the unsuccessful trial, causing an efficient repricing of the underlying stocks.

Chapter 5

Conclusion

Summary of Findings

The aim of this paper was to identify the impact of public FDA announcements related to oncology drugs in Phase III clinical trials. Phase III trials are the last hurdle a drug must overcome before being approved for market. Years of costly research totaling, on average, $2.7 billion are put on the line and shareholders look to these announcements as validation for their investments. This study, like many others, finds that there are average cumulative abnormal returns after both positive and negative news events in the direction of those announcements. The pullback after negative FDA decisions in three-day returns of -10.63% found in this study is both statistically significant and larger than the statistically insignificant increase of 1.28% after FDA approvals.

This statistically significant disparity in returns between positive and negative news events is also consistent with much of the previous research surrounding FDA announcements. The sample of clinical trials for this study could help explain some of the difference. Phase III trials tend to serve as more of a confirmation of success for investors than an event shrouded in uncertainty. That is to say, most investors assume to have made the correct bet going into the third round of trials and are anticipating a positive result. The price of the equities already has this optimism built in, dampening the increase after an FDA approval at this stage of clinical trials. Conversely, if they receive a negative signal – whether from the FDA or from

management – investors pull back harshly, as shown by the very significant CAR for negative news events.

It is important for investors to keep in mind, however, that it is not only the nature of the results of an FDA decision that impact stock returns, but also the size of the company sponsoring the clinical trial. The difference between small and large companies is seen in Table 2 and is further demonstrated by analyzing some of the largest magnitude CARs in the entire sample. There were six events with absolute three-day CAR values greater than 10%. All were negative announcements with negative returns. All six of the sponsoring companies were also in the bottom 21% of the sample by size. This information is extremely important for investors of small cap pharmaceutical companies relying on investigational compounds to provide excess returns. In order to evaluate their positions properly, investors need to take into account the extremely risky nature of these companies due to the complete bust potential of some drugs.

Another important point for investors to keep in mind is that they have to already hold a position in order to enjoy the benefits of clinical trial results. This study does not find the existence of any signals before Phase III trial announcements. This means investors are not receiving any prior notice leading them to trade before the announcement occurs. The lack of leakage before the event also indicates there is no evidence of insider trading on non-public information. This is good news for individual investors worried about the efficiency of the pharmaceutical market when competing with institutional investors.

The same themes hold true for abnormal returns after the news announcement. This study does not find any persistence in returns after the event window. For investors looking to reap the benefits of any news effect, they need to have a position in the market to take advantage of the returns. Trading after the announcement makes it difficult to generate profit of the same

magnitude as those already holding a position. Also important to note is that this study does not find a significant reversal of returns after a Phase III news announcement. This indicates investors' patience to hold onto their positions rather than lock-in profits once they receive advantageous news.

It is often difficult for investors to perfectly time the FDA announcement date for clinical trial results. In an effort to be more transparent with testing timelines, the government passed the Prescription Drug User Fee Act, or PDUFA. This authorizes the FDA to collect fees from pharmaceutical companies in order to fund the drug approval process. In return, the FDA sets PDUFA dates for these drugs, which are deadlines the Administration must complete testing by. The FDA, as a matter of policy, does not publish an official list of PDUFA dates (fda.gov). Many pharmaceutical companies choose to publish their own dates, however, in an effort to be more transparent with investors and increase their stock price.

The frustrating piece for investors looking to get an insight into product development timelines is that the FDA rarely hits these deadlines perfectly. Often times, announcements will come before they are expected, and if any supplemental information is submitted during testing, the deadline will often be pushed back. One way for investors to take advantage of uncertain clinical trial results over an uncertain window of time is to trade options on the underlying stock.

Topics for Further Exploration

Identifying options trading strategies to take advantage of both the upside and downside potential of regulatory announcements in the oncology space is one of the areas for future research following the findings of this paper. The research would be beneficial for both individual and institutional investors alike. Options trading strategies could be applied not only during Phase III of clinical trials, but throughout the entire testing timeline of a new drug. Further research is needed to understand the impact of FDA announcements throughout each of the three clinical trial phases within the oncology market. This study focused solely on the impact of Phase III trials for cancer drugs. Previous studies such as Sarkar and de Jong (2006) have shown there is a difference in abnormal returns between developmental compounds in each of the three trial phases. In order to fully understand the best way to invest in the oncology market, it is important to understand where to invest during the product development timeline. Expanding this study to the full set of specialty drugs would also make for a more robust study.

Finally, further research is needed to identify the effect of regulatory announcements on other specialty drug classes – not just oncology. While oncology currently offers the most revenue and has some of the most robust pipelines, other specialty classes such as Hepatitis C and Alzheimer's have similar growth characteristics that will make them lucrative for biopharmaceutical companies in the coming years. Understanding how FDA announcements affect all of these blockbuster drugs is important not only for investors but also for the companies that invest billions of dollars in research and development to bring them to market.

This study had several limitations that should be addressed. The first is the sample size of the study. Performing this analysis with a larger sample of events would provide more robust results and more clarity on the effects of Phase III trials on oncology drugs. Further studies could

also investigate alternative asset pricing models as well as other cross-sectional variables in order to enhance the results of this analysis. Some of these variables could include research and development expenditures, the size of the prospective market, or a governmental factor to test the use of public funds in drug development. The study was limited by the statistical acumen of the author although confirmed by third party statistical consultants. Additional testing methods combined with a larger sample size would provide further credence to this analysis.

Appendix A

List of Positive News Event

Date	Result	Company	Ticker	Notes
9/13/2018	1	AstraZeneca	AZN	certain patients hairy cell leukaemia
6/21/2018	1	BMY	BMY	supplemental
5/9/2018	1	JNJ	JNJ	combination multiple myeloma
4/30/2018	1	BMY	BMY	First immuno-oncology combo therapy renal cell carcinoma
4/19/2018	1	AstraZeneca	AZN	lung cancer
4/6/2018	1	Clovis Oncology	CLVS	Ovarian cancer maintenance drug
4/4/2018	1	AstraZeneca	AZN	hairy cell leukaemia
2/19/2018	1	AstraZeneca	AZN	lung cancer
2/9/2018	1	JNJ	JNJ	combination therapy with other drug for prostate cancer
1/1/2018	1	Novocure	NVCR	pancreatic cancer
12/22/2017	1	Roche	RHHBY	combo with chemo for breast cancer
12/13/2017	1	BMY	BMY	renal cell carcinoma combination therapy
12/11/2017	1	Eli Lilly	LLY	breast cancer
11/20/2017	1	AstraZeneca	AZN	expanded indication
11/17/2017	1	Roche	RHHBY	follicular lymphoma
11/17/2017	1	AstraZeneca	AZN	expanded approval breast cancer
11/9/2017	1	Seattle Genetics	SGEN	large cell lymphoma
11/7/2017	1	Roche	RHHBY	lung cancer
10/27/2017	1	Roche	RHHBY	combo with chemo for ovarian cancer
7/17/2017	1	Puma	PBYI	breast cancer
7/5/2017	1	JNJ	JNJ	combination treatment for multiple myeloma
5/24/2017	1	MRK	MRK	expanded approval
3/23/2017	1	Merck Germany	MKKGY	carcinoma
3/13/2017	1	Novartis	NVS	breast cancer
12/9/2016	1	Roche	RHHBY	combo with chemo for ovarian cancer
11/10/2016	1	BMY	BMY	head and neck cancer
10/25/2016	1	MRK	MRK	lung cancer
10/19/2016	1	Roche	RHHBY	lung cancer
3/7/2016	1	JNJ	JNJ	leukaemia
3/3/2016	1	AstraZeneca	AZN	new indication for breast cancer
2/29/2016	1	Roche	RHHBY	follicular lymphoma
1/29/2016	1	Eisai	ESALY	liposarcoma
12/11/2015	1	Roche	RHHBY	lung cancer
11/21/2015	1	Takeda	TKPYY	multiple myeloma
10/29/2015	1	BMY	BMY	new indication melanoma
10/10/2015	1	BMY	BMY	new indication lung cancer
7/14/2015	1	AstraZeneca	AZN	lung cancer
2/16/2015	1	Eisai	ESALY	thyroid cancer
2/3/2015	1	Pfizer	PFE	breast cancer
10/2/2014	1	Pfizer	PFE	prostate cancer
5/2/2014	1	Novartis	NVS	lung cancer
4/22/2014	1	Eli Lilly	LLY	gastric cancer

Appendix B

List of Negative News Events

Date	Result	Company	Ticker	Notes
9/13/2018	0	JNJ	JNJ	non hodgkin lymphoma
9/13/2018	0	AbbVie	ABBV	non hodgkin lymphoma
7/31/2018	0	Astex Pharma	ASTX	missed phase 3 endpoints for leukaemia
7/13/2018	0	AbbVie	ABBV	fials phase 3 trial
6/27/2018	0	Pfizer	PFE	fails combo phase 3 to improve breast cancer
4/25/2018	0	AstraZeneca	AZN	lung cancer combo failure phase 3
4/11/2018	0	Pfizer	PFE	stops liver cancer phase 3 trial
4/6/2018	0	Incyte	INCY	failed phase 3 trial to improve efficacy of Keytruda for melanoma
1/25/2018	0	MRK	MRK	gastric cancer phase 3 failure
1/25/2018	0	Pfizer	PFE	gastric cancer phase 3 failure
11/29/2017	0	Merck Germany	MKKGY	phase 3 failure gastric cancer
10/10/2017	0	Eli Lilly	LLY	phase 3 failure lung cancer
9/12/2017	0	Onxeo	ONXEO	phase 3 failure liver cancer
9/11/2017	0	Roche	RHHBY	phase 3 failure melanoma
8/16/2017	0	BMY	BMY	phase 3 failure combination renal cell carcinoma
6/23/2017	0	Seattle Genetics	SGEN	FDA halt on all myeloid leukemia treatments
5/10/2017	0	Roche	RHHBY	phase 3 advanced bladder cancer failure
5/2/2017	0	Aeterna Zentaris	AEZS	phase 3 failure endometrial cancer
3/29/2017	0	ArQule	ARQL	phase 3 failure liver cancer
11/29/2016	0	Spectrum Pharma	SPPI	phase 3 bladder cancer failure rejected by FDA
5/10/2016	0	NewLink	NLNK	phase 3 failure pancreatic cancer
3/14/2016	0	Immunomedics	IMMU	terminates phase 3 pancreatic cancer
2/26/2016	0	Peregrine Pharma	CDMO	terminates phase 3 lung cancer
12/7/2015	0	Threshold Pharma	MTEM	halted testing soft tissue sarcoma phase 3 trial
6/30/2015	0	AstraZeneca	AZN	failed phase 3 eye cancer
3/17/2015	0	Sirtex	SXMDF	failed phase 3 trial metastatic colorectal cancer
2/17/2015	0	Nektar Therapeutic	NKTR	fialed phase 3 for breast cancer
12/19/2014	0	Roche	RHHBY	failed phase 3 for breast cancer - solo and combo
12/3/2014	0	Exelixis	EXEL	phase 3 prostate cancer failure
11/5/2014	0	Amgen	AMGN	phase 3 ovarian cancer failure
6/26/2014	0	AstraZeneca	AZN	ovarian cancer
9/5/2013	0	Glaxosmithkline	GSK	treatment of lung cancer after surgery
6/3/2013	0	Sanofi	SNY	add on to triple negative breast cancer

BIBLIOGRAPHY

Ahorony, Joseph and Swary, Iizhak (1980). Quarterly Dividend and Earnings Announcements and Stockholders' Return: An Empirical Analysis. Journal of Finance 35 (1): 1–12.

Bastin, V., & Hubner, G. (2006). Concentrated Announcements on Clustered Data: An Event Study on Biotechnology Stocks. SSRN Electronic Journal, 35(1).

Basu, S. (1977). Investment Performance of Common Stocks in Relation to the Price-Earnings Ratio: A Test of the Efficient Market Hypothesis. Journal of Finance 32 (3): 663–682.

Bernard, Victor and Jacob Thomas, 1990, Evidence that stock prices do not fully reflect the implications of current earnings for future earnings, Journal of Accounting and Economics 13, 305-340.

Bosch, J. C., & Lee, I. (1994). Wealth effects of Food and Drug Administration (FDA) decisions. Managerial and Decision Economics, 15, 589–599.

Center for Biologics Evaluation and Research. “Prescription Drug User Fee Amendments.” U S Food and Drug Administration Home Page, Center for Drug Evaluation and Research, www.fda.gov/forindustry/userfees/prescriptiondruguserfee/.

Chan, W. (2003). Stock price reaction to news and no-news: Drift and reversal after headlines. Journal of Financial Economics, 70(2), 223-260.

Chaney, P. K., Devinney, T. M., & Winer, R. S. (1991). The impact of new product introductions on the market value of firms. The Journal of Business, 64, 573–610.

De BONDT, Werner F. M., and Richard Thaler. “Does the Stock Market Overreact?” Journal of Finance, vol. 40, no. 3, July 1985, pp. 793–805.

Dimasi, Joseph A., et al. “Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs.” Journal of Health Economics, vol. 47, May 2016, pp. 20–33.

Eddy, Albert A. and George B. Saunders (1980), "New Product Announcements and Stock Prices," Decision Sciences, 11 (1), 90-97.

Fama, Eugene and Kenneth French. (1993). “Common Risk Factors in the Returns on Stocks and Bonds.” Journal of Finance. 33:1, pp. 3–56.

Gesme, Dean H. “The 2018 Genetech Oncology Trend Report.” *Genetech*, Genetech, Apr. 2018, www.genentech-forum.com/content/dam/gene/managedcare/forum/pdfs/Oncology-Trends/2018_Genentech_Oncology_Trend_Report.pdf.

Giovannetti, Glen T. “Biotechnology Report 2017.” *EY*, Ernst & Young, 11 July 2017, www.ey.com/Publication/vwLUAssets/ey-beyond-borders-biotech-report-2017/$FILE/ey-beyond-borders-biotech-report-2017.pdf.

Hand, J. (2001). The Market Valuation of Biotechnology Firms and Biotechnology R&D. SSRN Electronic Journal, 12.

Herper, Matthew. “The Cost Of Developing Drugs Is Insane. That Paper That Says Otherwise Is Insanely Bad.” *Forbes*, Forbes Magazine, 16 Oct. 2017, www.forbes.com/sites/matthewherper/2017/10/16/the-cost-of-developing-drugs-is-insane-a-paper-that-argued-otherwise-was-insanely-bad/#4f4763f62d45.

Horvath, Jane. “Update: What's New in State Drug Pricing Legislation?” *NASHP*, National Academy for State Health Policy, 7 May 2018, nashp.org/update-whats-new-in-state-drug-pricing-legislation/.

Hwang, T. J. Stock market returns and clinical trial results of investigational compounds: an event study analysis of large biopharmaceutical companies. PLoS ONE 8, e71966 (2013).

Ikenberry, David L., and Sundaresh Ramnath. “Underreaction to Self-Selected News Events: The Case of Stock Splits.” Review of Financial Studies, vol. 15, no. 2, 2002, pp. 489–526.

Kubassova, Olga. “The Future of Investments in Immuno-Oncology.” *IAG*, Image Analysis Group and Venture Partners, 1 Feb. 2018, www.ia-grp.com/views/digital-clinical-trials-imaging-2/. Economics of Innovation and New Technology, 13: 747-760.

Lacey, Nelson, and Anurag Sharma. “Market Responses Around FDA Announcements.” University of West Georgia, 2008, www.westga.edu/~bquest/2008/FDA08.pdf.

Lintner, John. "The Valuation of Risk Assets and the Selection of Risky Investments in Stock Portfolios and Capital Budgets." Rev. Econ. and Statis. 47 (February 1965): 768-83

Michaely, R, et al. “Conflict of Interest and the Credibility of Underwriter Analyst Recommendations.” Review of Financial Studies, vol. 12, no. 4, 2 Sept. 1999.

Michaely, Roni, et al. “Price Reactions to Dividend Initiations and Omissions: Overreaction or Drift?” Journal of Finance, vol. 50, no. 2, June 1995, pp. 573–608.

Mossin, Jan. "Equilibrium in a Capital Asset Market." Econometrica 34 (October 1966): 768-83

Rendleman, Richard J., Jones, Charles P. and Latane, Henry A. (1982). Empirical Anomalies Based on Unexpected Earnings and the Importance of Risk Adjustments. Journal of Financial Economics 10 (3): 269–287.

Rothenstein, J., Tomlinson, G., Tannock, I., & Detsky, A. (2011). Company Stock Prices Before and After Public Announcements Related to Oncology Drugs. JNCI Journal of the National Cancer Institute, 103(20), 1507-1512.

Sarkar, S. K., De Jong, P. J. 2006. Market response to FDA announcements. Quarterly Review of Economics & Finance, 46: 586-597.

Sharma A, Lacey N (2004) Linking product development outcomes to market valuation of the firm: The case of the U.S. pharmaceutical industry. Journal of Product Innovation Management 21: 297–308.

Sharpe, William F. "Capital Asset Prices: A Theory of Market Equilibrium Under Conditions of Risk." J. Finance 19 (September 1964): 425-42

Smith, Andrew D. “It's Fast-Forward for Cancer Drugs.” *OncLive*, 11 May 2018, www.onclive.com/publications/oncology-live/2018/vol-19-no-10/its-fastforward-for-cancer-drugs.

Titi, A. (2014). The Effect of R&D Expenditures on Stock Returns, Price. A study on biotechnological and pharmaceutical industry in the US market.

Thomas, David W, et al. “Clinical Development Success Rates 2006-2015.” Biotechnology Innovation Organization, BIO, Informa, Amplion, June 2016, www.bio.org/sites/default/files/Clinical%20Development%20Success%20Rates%202006-2015%20-%20BIO,%20Biomedtracker,%20Amplion%202016.pdf.

Treynor, J. L. (1961). “Market Value, Time, and Risk.” Unpublished manuscript. “Rough Draft” dated 8/8/61, #95-209

Weintraub, Arlene. “Healthcare VC Investing Could Hit A Record High In 2018.” *Forbes*, Forbes Magazine, 13 July 2018, www.forbes.com/sites/arleneweintraub/2018/07/12/healthcare-vc-investing-could-hit-a-record-high-in-2018/#26b3cd5c65d2.

ACADEMIC VITA

Andrew J. Curotto

EDUCATION

The Pennsylvania State University | Schreyer Honors College — **University Park, PA**
Smeal College of Business, — Aug 2014 – Dec 2018
- Bachelor of Science in Finance; Minor in Economics

Universidad Complutense de Madrid — **Madrid, Spain**
IES Abroad, — Jan 2016 – May 2016
- Completed 16 credits instructed entirely in Spanish including Spain and the International Economy, Spanish Models of Organization, Spain and the European Union

EXPERIENCE

Ernst & Young — **New York, NY**
Business Advisory Intern — June 2018 – August 2018
- Delivered procurement transformation project for large Media & Entertainment client through deployment of new Ariba procurement system with a strong focus on the source-to-pay cycle
- Developed savings tracking approach to ensure clear, valid reporting of over $60MM in Ariba-enabled savings
- Created and presented custom dashboards to client which consolidated savings information allowing further insight to project metrics
- Collaborated with client to design recommended process flows demonstrating transformation between current and future state sourcing operating model
- Wrote user guides and test scripts for client use to ensure proper training and testing for Ariba deployment

Pfizer Consumer Healthcare — **Madison, NJ**
Display Innovation & Supply Chain Co-op — June 2017 – December 2017
- Partnered with production, marketing, sales, and graphics teams to launch over 40 custom displays valued at more than $22MM
- Identified cost savings of more than $1.5MM in club store SKUs by challenging current packaging design and securing reduced quotes from additional 3rd party co-packers
- Developed Cost/Sales threshold for display program decision-making across all consumer brands in order to guide strategic revenue management initiatives
- Reduced cost of trade show program by 56% by leveraging new bidding strategy of key component across multiple consumer brands
- Collaborated with business technology team to identify and fix financial reporting software errors causing over $1MM in costs to fall out of monthly forecasts
- Facilitated production of mock display requests to support sell-in of new displays, leading production and graphics teams to accelerate design solutions and meet customer demands

Johnson & Johnson Consumer Inc. — **Fort Washington, PA**
Supply Chain Financial Analyst Co-op — June 2016 – Jan 2017
- Reduced outstanding liabilities by $4.3MM by partnering with cross-functional business partners in order to understand strategic focus and mitigate risk across completed projects
- Developed new Quarterly Capital Reporting process for presentation to senior management by automating generation of executive summary which cut cycle time from 8 hours to 30 minutes
- Created and implemented a specialized budget phasing methodology for over $2.9MM in planned expenses that improved forecasting accuracy by 7% year-over-year
- Partnered with plant maintenance Sr. Manager to develop 2017 business plan totaling over $8MM, including building a comprehensive Outside Services plan that included vendor mix, timing of services, and financial commitments to successfully manufacture over-the-counter consumer products
- Led monthly and quarterly plant close activities, including journal entries, accruals, plant waste reporting and account reconciliation along with weekly reporting of liability across two internal consumer plants and 16 home office budgets
- Analyzed monthly Budget vs. Actual statements and communicated variance drivers to senior management and team leads to influence strategic conversations

HONORS, ACTIVITIES, & SERVICE

- Team lead in developing business plan including 5-year financial projections for MTN Testing Group
- Finalist in TE Connectivity M&A pitch competition; presented acquisition target to head of business development including business rationale, stand-alone valuation, and synergy calculations
- Recipient of two monetary leadership awards at Johnson & Johnson for demonstrating the qualities 'Lead' and 'Deliver'
- Awarded the 2014 Mini Maxwell Award in Southeast Pennsylvania for performance in football and leading a fundraiser that donated over $700 to a local food pantry in order to purchase new refrigeration units
- Volunteer monthly at local food pantry by serving clients, facilitating food drives, and stocking shelves