

**The Influence of *Target* Pharmaceutical and Biotechnology Companies'**

**Pipelines on *Acquiring* Company Value**

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## Abstract

Biotechnology and pharmaceutical companies have become involved in increasingly costly research and innovation. This is largely due to large capital investments and years-long clinical trials. Therefore, to minimize the loss of time and money from taking on bad projects, it has become critical for biotechnology and pharmaceutical companies to be able to better gauge which projects would add value to the firm. However, given long project timelines of drug development, it is often difficult to estimate the value that projects can add to a firm. While academic studies have focused on general event studies as well as real options valuation of pipelines, there have been few attempts to value drug pipelines based on specific characteristics of the drugs. This study attempts to quantify the value of drugs based on their specific phases of the drug development process through an event study.

This study utilized acquiring biotechnology and pharmaceutical companies' cumulative abnormal stock market returns at the time of M&A announcement with biotechnology and pharmaceutical target companies. From there, multiple variable and single variable linear regressions were run, where the dependent variable was the cumulative abnormal returns and the independent variables were the number of target company drugs at each specific phase in the drug development process. The results from the study found that there is not a statistically significant correlation between a particular phase of the drug development process and extra value added to the firm. Therefore, in this sample, the market does not consider the acquisition of a drug at a particular phase to be a great bargain/value-adding nor a bad decision/value-losing on the acquiring firm's part.

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## Introduction

Historically, the role of pharmaceutical companies has been to provide patients with medicinal remedies for their ailments. For example, in 1899, Bayer Co. became the first company to manufacture and market Aspirin, a drug that still remains integral in relieving the common fever<sup>1</sup>. Traditional pharmaceutical companies like Bayer Co. will often use chemicals as the basis of their drugs. However, more recently, biotechnology companies have started using components of living organisms as the basis for their medicines. For example, Pfizer, a pharmaceutical and biotechnology company, created their BioNTech COVID-19 Vaccine using mRNA, a molecule found in cells<sup>2</sup>. While pharmaceutical and biotechnology companies have opted to use different inputs for their medicines, the two types of companies share the same goal: perform research to develop innovative medicines that can be marketed to patient populations.

To achieve their goals, pharmaceutical and biotechnology companies must first have their drugs approved by the Food and Drug Administration (FDA). The FDA requires companies to complete an arduous and costly set of clinical trials. As a company progresses through each phase, the drug approval process becomes increasingly more expensive. In 2021, studies estimated that “the average R&D cost per new drug range[d] from less than \$1 billion to more than \$2 billion per drug.”<sup>3</sup> Moreover, the likelihood of completing all clinical trials is very low where “only about 12 percent of drugs entering clinical trials are ultimately approved for introduction by the FDA.”<sup>4</sup> Therefore, pharmaceutical and biotechnology drug research and

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<sup>1</sup>“The Story of Aspirin: The International Aspirin Foundation.” Aspirin Foundation, 8 June 2020, <https://www.aspirin-foundation.com/history/the-aspirin-story/>.

<sup>2</sup>“Pfizer-Biontech COVID-19 Vaccine Overview and Safety.” Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 27 Apr. 2022, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/Pfizer-BioNTech.html>.

<sup>3</sup>“Research and Development in the Pharmaceutical Industry.” Congressional Budget Office, Apr. 2021, <https://www.cbo.gov/publication/57126>.

<sup>4</sup>“Research and Development in the Pharmaceutical Industry.” Congressional Budget Office, Apr. 2021, <https://www.cbo.gov/publication/57126>.

development has historically been known as a high risk and high reward pursuit where large sums of a firm's resources are at stake.

Recently, established pharmaceutical and biotechnology companies have chosen to avoid the initial drug development process and the risks that are associated with it. Instead, they've opted for external research and development where they purchase an existing pipeline of drugs through mergers and acquisitions.

These mergers and acquisitions benefit young pharmaceutical and biotechnology companies. While both parties appear to benefit from merging, drawbacks also exist. For example, acquiring companies would take on the burden of funding the increasingly more expensive clinical trials that the target companies must still undergo.

With both the benefits and drawbacks of M&A in the pharmaceutical and biotechnology space, we're interested in learning whether the market views the benefits of acquiring a target company's pipeline as larger than the drawbacks of the acquisition. More specifically, we hope to learn whether there is a particular phase that brings in the most benefit for the acquiring company, balancing the higher costs of running clinical trials with the positive outlook on being closer to completing the FDA approval trials.

## Literature Review

Event studies pertaining to pharmaceutical and biotechnology research have long been interested in the market's reaction to patent or clinical trial news. For example, in a 1993 publication of *The American Economic Review*, David H. Austin published an event study about biotechnology patents. Austin found that, when biotechnology companies disclosed specific characteristics of their new patents, the stock price of these companies would vary with the characteristics. For example, he notes that “patents readily identifiable with end products tend to be more valuable than the average patent.”<sup>5</sup> While Austin's work uncovers information about patents, it does not reflect information about pharmaceutical and biotechnology company outlook when they choose to pursue or to continue to pursue clinical trials for drugs.

In 2013, Thomas Hwang authored “Stock Market Returns and Clinical Trial Results of Investigational Compounds: An Event Study Analysis of Large Pharmaceutical Companies.” In his study, Hwang records the market's reaction to both positive and negative clinical trial results from biopharmaceutical companies. He notes that “The median decline in cumulative abnormal returns due to negative events was larger in magnitude than gains due to positive events.”<sup>6</sup> Here, the study is focused on how the market reacts to general news pertaining to the clinical trials in the drug approval process.

Research pertaining to pharmaceutical and biotechnology research and development are largely focused on productivity. For example, in “Drug Development Portfolio and Spending Practices after Mergers and Acquisitions,” Kenneth Getz tries to uncover how biopharmaceutical

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<sup>5</sup> Austin, David H. “An Event-Study Approach to Measuring Innovative Output: The Case of Biotechnology.” *The American Economic Review*, vol. 83, no. 2, 1993, pp. 253–58, <http://www.jstor.org/stable/2117673>. Accessed 17 Apr. 2022.

<sup>6</sup> Hwang, Thomas J. “Stock market returns and clinical trial results of investigational compounds: an event study analysis of large biopharmaceutical companies.” *PloS one* vol. 8,8 e71966. 7 Aug. 2013, doi:10.1371/journal.pone.0071966

companies alter their research and development after a merger or acquisition. He concludes that “drug development companies completing M&As between 1998 and 2004 initially limit growth in R&D spending, but then follow with rapid relative growth.”<sup>7</sup> Here, the research is focused on the effects of the merger or acquisition on the productivity of the firm’s research and development.

Literature on pharmaceutical and biotechnology drug development has also been published by government assisting organizations. For example, the Assistant Secretary for Planning and Evaluation (ASPE), who reports to the Secretary of the Department of Health and Human Services on policy development, released an “Examination of Clinical Trial Costs and Barriers for Drug Development.” In the report, the Eastern Research Group (ERG) identifies “factors that may delay, hinder, or lead to unsuccessfully completed trials.”<sup>8</sup> These factors are important because they can indicate the uphill battle a firm may encounter when acquiring a company with drugs that are in clinical trials.

On top of lengthy timelines, participant recruiting difficulties, and increasing competition for qualified investigators and sites, the ERG also found that “the largest barrier to conducting clinical research (...) is the high cost.”<sup>9</sup> There are largely three factors that cause the high costs in clinical research: the challenge to create novel drugs that are more innovative than current drugs, a shift to chronic disease research which involves complex and expensive testing, and additional health cost containment strategies in the US. Reports like these present different factors that can

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<sup>7</sup> Getz, Kenneth A., et al. “Drug Development Portfolio and Spending Practices after Mergers and Acquisitions.” *Drug Information Journal*, vol. 43, no. 4, July 2009, pp. 493–500, doi:[10.1177/009286150904300415](https://doi.org/10.1177/009286150904300415).

<sup>8</sup>Sertkaya, Aylin. “Examination of Clinical Trial Costs and Barriers for Drug Development.” ASPE, 24 July 2014, <https://aspe.hhs.gov/reports/examination-clinical-trial-costs-barriers-drug-development-0>.

<sup>9</sup>Sertkaya, Aylin. “Examination of Clinical Trial Costs and Barriers for Drug Development.” ASPE, 24 July 2014, <https://aspe.hhs.gov/reports/examination-clinical-trial-costs-barriers-drug-development-0>.



influence the outlook of a company who currently has drugs in the clinical trial process. However, they do not specify if these factors are phase specific.

## **The FDA Drug Approval Process**

In order for their drugs to be sold to patients, pharmaceutical and biotechnology companies must have their drugs approved by the FDA via a drug approval process that consists of four stages of clinical trials. First, pharmaceutical and biotechnology companies must initially test the safety of their drugs on animals. After sufficiently proving their drug's safety, they must submit an Investigational New Drug (IND) Application to the FDA. After having their application approved by the FDA, pharmaceutical and biotechnology companies must pass three phases in the FDA's approval process: Phase I, Phase II, and Phase III. In Phase I, companies must enlist about 20 to 80 volunteers and test the safety and effectiveness of the drug. By Phase II, they must test the safety and effectiveness of their drug on 100 volunteers. Finally, in Phase III, pharmaceutical and biotechnology companies must test their drug's safety and effectiveness on about 1,000 volunteers.<sup>10</sup> Each additional phase comes with additional costs and risks.

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<sup>10</sup>U.S. Food and Drug Administration. Drug Approval Process, 2021.

## Data and Methodology

To test the hypothesis, an event study was performed because the share price reflects the value that the stock market believes the firm is worth. More specifically, the change in acquirer share price is a representation of the additional value the market places on the acquisition of the target company and its pipeline. The target company pipeline drugs were collected and organized by phase. A regression was run to see if there was a correlation between the types of drugs (by phase) in a target company's pipeline and the additional value the market placed on the acquiring company. To better understand the result of this regression, it is important to further explore the key data in this study.

### I. Event Window

This study collected market returns from the day before until the day after the announcement of a merger between two pharmaceutical or biotechnology companies. It is important to have an event window because “it captures the price effects of announcements which occur after the stock market closes on the announcement date.”<sup>11</sup> For this study, 46 merger announcements from January 2013 to May 2020 were used. A small event window was chosen because the small window limited potential movements in stock price from other smaller events that could have taken place before and after the announcement.

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<sup>11</sup> MacKinlay, A. Craig. “Event Studies in Economics and Finance.” *Journal of Economic Literature*, vol. 35, no. 1, 1997, pp. 13–39, <http://www.jstor.org/stable/2729691>. Accessed 7 May 2022.

## **II. Abnormal Returns and Cumulative Abnormal Returns (CAR) of Pharmaceutical and Biotechnology Companies**

Event studies can take the form of two models: constant mean return model and the market adjusted model. The constant mean return model assumes that the mean return of a stock will remain constant over time. Moreover, the market model accounts for a linear relationship between the overall market return and the return of a stock. These two models provide different ways of estimating normal returns. This normal return is subtracted from the cumulative return of a stock over the event window to find the extra value the market adds or deducts upon learning new information; this is the cumulative abnormal return. For this study, Wharton's Research Data Services (WRDS) provided cumulative abnormal returns adjusted for normal returns via the market adjusted model.

## **III. Target Pharmaceutical and Biotechnology Company Pipeline Drugs**

This study was largely interested in the relationship between the market's outlook on a company that is acquiring a particular pipeline of drugs. Cortellis reports were used to record and organize the number of drugs in phase I, II, and III. Cortellis is a common data collection service that pharmaceutical and biotechnology companies utilize to record and organize the breakdown of their drug pipeline. These reports were published every month from 2014 until 2021. Reports closest to the event date were used.

## Results and Discussion

### I. Summary Statistics

	Number of Target Company Drugs				Acquirer CAR
	Phase I	Phase II	Phase III	Phase IV	
<b>Mean</b>	13.3	12.8	9.1	4.2	-0.011
<b>Standard Error</b>	1.8	2.6	2.6	2.7	0.006
<b>Median</b>	10.5	7.5	3	0	-0.004
<b>Minimum</b>	0	0	0	0	-0.107
<b>Maximum</b>	57	109	102	117	0.114

*Table 1 Summary Statistics*

Table 1 presents information about the data at a glance. On average, the sample target pharmaceutical and biotechnology companies have more drugs in Phase I and Phase II than in Phase III and Phase IV. This makes sense because it becomes increasingly more difficult to have drugs approved at each successive phase of the clinical trial process. Therefore, it should be expected that target companies will have more drugs in earlier phases of the clinical trial process because the barriers to get to Phase I or II are lower than the ones needed to reach Phase III or IV.

### II. Correlation Analysis

	Phase I	Phase II	Phase III	Phase IV	Acquirer CAR
<b>Phase I</b>	1				
<b>Phase II</b>	0.72	1			
<b>Phase III</b>	0.45	0.83	1		
<b>Phase IV</b>	0.35	0.86	0.89	1	
<b>Acquirer CAR</b>	0.05	0.14	0.25	0.15	1

*Table 2 Correlation Analysis*

Correlations between two variables are useful because the correlation represents the strength in which two variables move together in a data set. The closer the correlation is to 1, the more strongly one variable moves in the same direction as the other variable. In *Table 2*, a correlation analysis is presented. The analysis took the correlations between the number of drugs in Phase I, II, III, and IV and the acquirer's adjusted cumulative abnormal return during the event window.

There are three outstanding observations from this analysis. First, the majority of the correlations between the number of drugs in a particular phase with the number of drugs in a different phase are large. Therefore, as seen in later sections, the data might be at risk of multicollinearity where two or more independent variables are strongly correlated to another independent variable in a multiple variable linear regression. Second, all of the correlation coefficients between the acquirers' cumulative abnormal returns and the number of drugs at each individual phase in are positive but statistically insignificant. Third, the number of drugs in Phase III is the most correlated with the acquiring company's cumulative abnormal return where the correlation is equal to 0.25. This relationship should be further studied by running an ordinary least squares single variable linear regression between the number of drugs that a target company has in Phase III and the acquirer's cumulative abnormal return.

### III. Ordinary Least Squares Single Variable Linear Regression

Regression Statistics	
<b>Multiple R</b>	0.2429
<b>R Square</b>	0.0590
<b>Adjusted R Square</b>	0.0376
<b>Standard Error</b>	0.0413
<b>Observations</b>	46

  

	<b>Coefficients</b>	<b>Standard Error</b>	<b>T Stat</b>	<b>P-value</b>
<b>Intercept</b>	-0.0161	0.0069	-2.3405	0.0239
<b>Number of Target Phase III Drugs</b>	0.0006	0.0004	1.6607	0.1039

*Table 3. Phase 3 Drugs and Acquirer Cumulative Abnormal Return Single Variable Regression*

An ordinary single variable linear regression was taken between the number of drugs that are in a particular phase in a target company's pipeline and the respective acquirer's cumulative abnormal return. In *Table 3*, the regression between the number of drugs in Phase III and the acquirer's cumulative abnormal return is presented. The number of Phase III drugs in a target's pipeline is positively correlated with the acquirer's cumulative abnormal return. For example, for every increase in the number of drugs in Phase III, the acquirer's cumulative abnormal return is expected to increase by 0.0006. The coefficient for the independent variable, the number of Phase III drugs has an insignificant P-value (greater than 0.05). Therefore, there is not sufficient evidence to believe that the number of target company drugs in Phase 3 explains the acquiring company's cumulative abnormal return. However, the intercept has a significant P-value. Moreover, the R-Square is objectively low. Despite this, it is the highest R-Square relative to other single variable regressions between the number of drugs in other phases and respective target cumulative abnormal returns.

#### IV. Multiple Variable Linear Regression

Regression Statistics	
<b>Multiple R</b>	0.31505924
<b>R Square</b>	0.09926232
<b>Adjusted R Square</b>	0.01138548
<b>Standard Error</b>	0.04185847
<b>Observations</b>	46

  

	Coefficients	Standard Error	T Stat	P-value
<b>Intercept</b>	-0.0172	0.0096	-1.7830	0.0820
<b>Phase I</b>	-0.0007	0.0010	-0.7859	0.4364
<b>Phase II</b>	0.0006	0.0012	0.5188	0.6067
<b>Phase III</b>	0.0015	0.0008	1.8178	0.0764
<b>Phase IV</b>	-0.0014	0.0011	-1.1682	0.2495

*Table 4. Multiple Variable Linear Regression*

Multiple variable regressions reflect relationships between multiple independent variables and the dependent variable. This differs from a single ordinary regression because the existence of all of the independent variables influences their relationship to the dependent variable. The regression equation can be extrapolated from *Table 4*:

$$\begin{aligned} \text{Target Company Cumulative Abnormal Return} = & (-0.0007) * (\text{Number of Drugs in Phase I}) \\ & + (0.0006) * (\text{Number of Drugs in Phase II}) \\ & + (0.0015) * (\text{Number of Drugs in Phase III}) \\ & + (-0.0014) * (\text{Number of Drugs in Phase IV}) - 0.017 \end{aligned}$$

There are three observations to note about this regression. First, there appears to be a positive relationship between cumulative abnormal returns and the number of Phase II and III drugs in a target company's pipeline. Moreover, there appears to be a negative relationship between cumulative abnormal returns and the number of Phase I and IV drugs in a target company's

pipeline. Regardless of the direction of the coefficients, the magnitude of the coefficients are very small. Therefore, the market does not feel strongly about the particular phases of the drug development process that each drug is in. The market does not believe the acquisition is a bargain nor is it a value destroying acquisition. Second, the R-Square is about 10%. This means that about 10% of the variance in target company cumulative abnormal returns from the mean can be explained by the regression. Third, the p-value for each coefficient is greater than 5%. Therefore, the coefficients are not statistically significant. This could be due to the relatively small sample size.



## **Conclusion**

### **I. Limitations**

Both regressions presented were statistically insignificant. The statistical strength of this study may have been weakened due to the lack of data. Specifically, the data was limited to pipeline information from January 2014 to May 2021. Moreover, this pipeline data is sourced from Cortellis reports, a service that pharmaceutical and biotechnology companies can choose not to partake in. Therefore, the sample of pharmaceutical and biotechnology companies utilized may only be ones that can afford the services offered by Cortellis.

### **II. Potential for Further Research**

While this study was limited to uncovering relationships between particular phases of pipeline drugs and the cumulative abnormal returns of acquiring companies, it has the potential to be expanded to understand if other aspects of the drug development or pipeline configuration process create a positive or negative market outlook on the value of the acquiring company. For example, it may be interesting to study the relationship between target cumulative abnormal returns in relation to the number of drugs that treat similar ailments in both the target and acquirer's pipeline. Moreover, because the number of pipeline drugs in Phase III was the most correlated to the acquirer's cumulative abnormal return in the single ordinary least squares regression and the closest to statistical significance, it may be interesting to study what makes Phase III especially challenging or rewarding relative to other phases.

### **III. Real World Applications**

When deciding whether to pursue a particular project or not, pharmaceutical and biotechnology companies must consider whether the project will add value to their firm. Similarly, when acquiring another firm, pharmaceutical and biotechnology companies must consider whether acquiring the target firm's pipeline, collection of ongoing projects, will increase or decrease firm value. This study identifies potential methods of estimating the addition or loss of market value that can come from taking on these new projects.