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**Financial Determinants of Market Reactions to FDA Drug  
Approvals in the Biopharmaceutical Sector**

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## Abstract

This thesis examines how firm-level financial characteristics influence stock market reactions to FDA drug approval announcements among U.S. biopharmaceutical companies. Using an event study design and panel regressions on data from 2014 to 2024, the analysis finds that approvals lead to significant positive abnormal returns. However, the magnitude of these returns varies systematically across firms. Smaller firms and those with higher R&D intensity experience stronger market reactions, consistent with signaling theory and the view that approvals are more transformative for innovation-driven firms. In contrast, higher profitability and capital expenditure are associated with weaker responses. Subsector-level results reveal further variation based on business models. The results suggest that investors interpret FDA approvals through the lens of firm fundamentals. These insights offer practical relevance for investors, managers, and regulators aiming to understand how financial structure shapes market responses to regulatory events.

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# 1. Introduction

The biopharmaceutical sector has experienced substantial growth and rapid technological advancements over recent decades, driven by intensive research and development, significant capital investments, and increasingly complex regulatory landscapes (DiMasi, Grabowski & Hansen, 2016). A pivotal milestone within this industry is drug approval by the Food and Drug Administration (FDA), which significantly influences firm valuation, investor perceptions, and overall market dynamics. FDA approval represents validation of a firm's innovation capability, commercial viability, and potential future success, frequently resulting in substantial stock market reactions (Sarkar & de Jong, 2006).

While prior research has documented generally positive stock-price responses to FDA drug approvals (Rothenstein et al., 2011), considerable variability remains unexplained. Investor responses are not uniform across firms, suggesting that specific firm-level financial characteristics might critically influence the magnitude and nature of these market reactions. However, existing literature often approaches the biopharmaceutical industry as homogeneous, largely neglecting significant differences among distinct subsectors such as Non-System-Specific, Other, and System-Specific Biopharmaceutical firms (Pammolli, Magazzini & Riccaboni, 2011).

Addressing these unexplored dimensions is crucial, as investor responses may differ substantially based on firm attributes like size, R&D intensity, capital expenditure intensity, profitability, and operational efficiency. Firm size, for example, may influence market perceptions of risk and future growth potential, thereby affecting the magnitude of investor reactions to approval announcements (McNamara & Baden-Fuller, 2007). Similarly, a firm's R&D intensity might signal innovation capacity and growth prospects, potentially amplifying positive investor reactions (Grabowski & Wang, 2006). Conversely, high capital expenditures could reflect greater financial risk or resource constraints, possibly dampening market responses (Myers & Majluf, 1984).

Furthermore, variations in profitability and operational efficiency may shape investor expectations differently, influencing how significantly market participants interpret FDA approvals as transformative events (Chen & Siems, 2004). These nuanced effects underscore the importance of investigating not only whether firm characteristics moderate stock-price reactions, but also how these effects differ systematically across biopharmaceutical subsectors.

Given this backdrop, the present thesis seeks to fill critical gaps in existing knowledge by explicitly exploring how firm-level financial characteristics influence stock-price reactions to FDA drug approvals and how these relationships differ across the biopharmaceutical industry's main subsectors. The timeframe of 2014–2024 provides a relevant and contemporary context, capturing recent industry trends, evolving regulatory practices, and current investor behaviors.

## 1.1 Motivation

The motivation for this research is twofold. First, it explores how firm-specific financial characteristics shape stock market responses to regulatory events, offering insights into investor behavior and market dynamics. Second, it addresses a gap in the literature by examining subsector-specific variations within the biopharmaceutical industry. Non-System-Specific firms target broad therapeutic areas, System-Specific firms specialize narrowly, and Other firms pursue diverse or niche strategies. These distinctions likely influence investor responses, offering valuable insights for managers, investors, and policymakers.

## 1.2 Research Question

In line with the motivation, this thesis addresses the following research question:

*How do firm-level financial characteristics (size, R&D intensity, capital-expenditure intensity, profitability, and asset turnover) explain variation in abnormal stock-price reactions to FDA drug-approval announcements for U.S. biopharmaceutical firms during 2014–2024, and how do these relationships differ across the three subsectors (Non-System-Specific, Other, and System-Specific)?*

## 1.3 Hypotheses

To address the research question, the thesis tests the following five hypotheses:

**H1 (Size):** Smaller firms exhibit larger abnormal returns around FDA approval announcements compared to larger firms.

**H2 (R&D Intensity):** Firms with higher R&D intensity experience more significant abnormal returns following FDA approvals.

**H3 (Capex Intensity):** Firms with higher capex intensity experience smaller abnormal returns.

**H4 (Profitability):** Firms with higher profitability exhibit smaller abnormal returns as investors perceive approvals as less transformative.

**H5 (Efficiency):** Firms with higher asset turnover demonstrate weaker abnormal returns.

## 1.4 Contributions

This thesis contributes to the financial economics and corporate finance literature by conducting a comprehensive analysis of multiple firm-level characteristics and their combined impact on investor responses to regulatory announcements. By examining these factors together rather than in isolation, it provides a more complete understanding of how firms are evaluated in the market. The research also identifies meaningful differences in investor reactions across biopharmaceutical subsectors, highlighting the role of industry context in shaping market responses. Using contemporary data from 2014 to 2024, the study offers relevant and actionable insights for researchers, firm managers, and investors navigating today's regulatory and competitive landscape.

## 2. Literature Review

### 2.1 FDA Approvals and Their Significance

FDA drug approvals are formal regulatory authorizations by the U.S. Food and Drug Administration for new pharmaceuticals to be marketed (U.S. Food and Drug Administration, 2022). They mark the culmination of a lengthy, costly R&D process and are pivotal events for biopharmaceutical firms. On average, developing a novel drug can take over a decade and cost upwards of a billion dollars, including multiple trial phases. An FDA approval effectively transforms an R&D investment into a marketable asset, enabling the firm to generate revenue from the new drug. Consequently, approvals carry enormous weight for firm valuation. An approved drug can promise substantial future cash flows, whereas failure to obtain approval may force the company to write off years of investment. For smaller biotechnology companies with no other products, a single approval can be transformational, potentially turning a pre-revenue firm into a commercial entity. Even for large pharmaceutical companies, approvals can secure competitive advantage or entry into new markets. Thus, FDA approvals are closely watched by investors as key information releases that update the market's expectations about a firm's prospects.

In essence, an FDA approval announcement provides a binary resolution of uncertainty surrounding a drug candidate's fate after years of development. Positive approval news often leads investors to revise upward their estimates of the firm's future earnings (e.g. projected drug sales), whereas a negative decision (rejection or request for more data) can substantially diminish those expectations. Because stock prices should reflect the present value of expected future cash flows, one would expect significant stock price movements around these events (Berk & DeMarzo, 2019). Indeed, both anecdotal evidence and academic research confirm that FDA approval decisions are critical inflection points for biopharma stock prices. The importance of FDA approvals extends beyond individual firms as they can signal industry trends, affect competitors, and even influence investor sentiment toward the sector. This makes them an important subject of study in finance and economics, as reviewed below.

## **2.2 Event Study Tradition in Regulatory and Innovation**

### **Announcements**

To measure the impact of FDA approvals on stock prices, researchers have commonly relied on event study methodology. A detailed explanation of this approach is provided in the Methodological Framework section, but broadly, event studies are designed to isolate abnormal returns around specific events by comparing actual stock performance with expected returns derived from historical trends or asset pricing models. This technique has become a standard in empirical finance for analyzing how markets incorporate new information.

The tradition began with Fama et al. (1969), who examined stock price adjustments to new information as a test of market efficiency. It was later refined by Brown and Warner (1980) and formalized in methodological terms by MacKinlay (1997). In the context of regulation, Lamdin (2001) highlights the usefulness of event studies for evaluating policy changes and regulatory announcements, which often have clear timing and significant implications for firm value.

Studies of innovation announcements have similarly demonstrated the method's relevance. Chaney, Devinney, and Winer (1991) found that announcements of new product introductions lead to positive abnormal returns, suggesting that markets anticipate future cash flows from successful innovations. In the pharmaceutical industry, where firms are heavily dependent on R&D outcomes, events such as clinical trial results or FDA approvals represent pivotal moments. As such, event studies have been widely adopted in law, economics, and finance to

examine how these events influence firm valuation by treating them as discrete, information-rich signals to the market.

## **2.3 Prior Empirical Evidence on FDA Approvals and Abnormal Returns**

### **2.3.1 Early Evidence of Market Reactions to FDA Decisions**

A substantial body of empirical work has examined how stock prices respond to FDA drug approval announcements. Early studies in the 1990s laid the foundation by documenting significant market reactions to both positive and negative FDA decisions. Bosch and Lee (1994) found that regulatory decisions, including approvals and denials, produced abnormal stock returns. Their work demonstrated that investors respond meaningfully to these announcements. Similarly, Dranove and Olson (1994) observed that announcements regarding dangerous drugs, such as safety withdrawals, had measurable negative effects on firm value. These early findings established that FDA-related events carry material information for financial markets.

### **2.3.2 Expanding Focus During the Growth of Biotech**

As the biotechnology sector grew in the 2000s, researchers began to examine the stock market impact of FDA approval events in more detail. Sarkar and de Jong (2006) studied investor reactions to four milestones in the FDA review process, including advisory committee meetings and final approvals. They found positive stock price reactions to favorable regulatory signals and negative reactions to adverse ones. Their findings also indicated that contextual factors, such as the novelty of a drug or the characteristics of the sponsoring firm, influence the magnitude of market responses.

Sturm, Dowling, and Röder (2007) explored how the timing of FDA approvals affected stock reactions. Their study found that unexpected delays or faster-than-anticipated decisions had financial consequences for firms. They reported an average stock price increase following approval announcements. Moreover, they observed that market anticipation played a role: when approvals were expected, the stock response was smaller, whereas surprises produced larger price movements.

### **2.3.3 Anticipation Effects and Pre-Announcement Drift**

While markets often anticipate regulatory outcomes to some degree, the evidence on price movements before announcements is mixed. A study of 167 FDA approvals from 1980 to 1999 found no significant price increase before the event. Abnormal returns occurred only on the approval date, suggesting that there was no systematic insider trading or widespread anticipation. This pattern was interpreted as evidence of market efficiency.

In contrast, more recent studies have identified upward trends in stock prices prior to FDA announcements. De Schrijver (2013), examining NASDAQ-listed biotech firms, found an average return of approximately 24 percent in the 60 trading days leading up to FDA decisions. These gains occurred regardless of whether the drug was ultimately approved or rejected, suggesting that they reflected market speculation or partial expectations rather than certainty.

Rothenstein et al. (2011), focusing on oncology drug announcements, also documented price increases in the months before major FDA decisions. Following the announcements, stock prices diverged sharply depending on the outcome. This pattern, where modest gains precede the event and large adjustments follow it, supports the idea that investors price in some probability of success but adjust sharply once the final decision is made.

### **2.3.4 Magnitude and Direction of Abnormal Returns**

Across studies, a consistent finding is that FDA approvals generate positive abnormal returns for the firm receiving approval. These returns typically range from 1 to 2 percent on or immediately after the announcement day. Cumulative abnormal returns over short windows, such as day zero to day one, are frequently significant.

By contrast, FDA rejections or negative regulatory decisions often lead to larger negative stock price reactions. Some research finds that negative surprises have a stronger impact than positive ones, which may reflect investor loss aversion or the fact that failed drugs can eliminate the entire projected value of the project. One study of large pharmaceutical companies noted that while approvals occasionally triggered large gains, negative news such as safety withdrawals caused more severe price drops.

### **2.3.5 Differentiating by Drug Novelty and Approval Type**

Not all FDA approvals have equal market impact. Several studies have examined how the type of drug being approved influences investor response. For instance, one study sorted

approvals by the FDA's chemical classification system. Approvals for Type 1 and Type 2 drugs, which represent new molecular entities or significant innovations, led to strong positive abnormal returns. In contrast, approvals for Types 4 through 7, which involve modifications or new formulations of existing drugs, did not significantly affect stock prices on average.

Hamill, McIlkenny, and Opong (2013) also found that approvals for enhancements to existing drugs, such as new indications or formulations, were still value-relevant but often partially anticipated by the market. Their cross-market analysis showed that FDA approvals increased shareholder wealth for firms listed in both the United States and the United Kingdom, reinforcing the general importance of these events.

### **2.3.6 Timing Effects and Post-Announcement Drift**

Hamill et al. (2013) observed continued positive returns in the days following approval announcements. They interpreted this pattern using the attention-grabbing hypothesis, which suggests that some investors react only after the news gains public attention. As a result, stock prices may continue to rise after the initial event due to delayed investor response.

However, Hamill et al. (2018) later questioned this interpretation. In a study of NYSE-listed biotech firms, they argued that the observed post-event drift resulted from errors in identifying the event date. Because many FDA approvals are released after market hours, the price reaction often occurs on the next trading day. When the timing of announcements was recorded accurately, they found no evidence of delayed market response. Instead, price adjustments occurred immediately, consistent with the semi-strong form of market efficiency. This debate highlights how technical issues in event timing can shape observed patterns in abnormal returns.

### **2.3.7 Competitive Spillovers and Industry-Wide Effects**

While most studies focus on the direct impact of FDA decisions on the sponsoring firm, some have explored spillover effects on competitors and partners. For example, Ahmed, Gardella, and Nanda (2002) found that when a drug was withdrawn, the stock prices of competing firms increased significantly. This suggests that FDA actions can lead to a reallocation of expected market share and value within the industry.

Similar effects likely occur when breakthrough drugs are approved. Competitors may experience stock price declines if the new product threatens their existing offerings. Although

less commonly studied, these broader effects demonstrate that FDA approvals can influence the competitive landscape, not just the sponsoring firm.

### **2.3.8 Summary of Key Patterns and Research Gaps**

In summary, the empirical literature clearly shows that FDA drug approval announcements are major events that affect stock prices. Firms receiving approval typically experience significantly positive abnormal returns, while those receiving denials suffer significant losses. These patterns are consistent across time periods, exchanges, and even international markets.

However, the size of these effects varies depending on the novelty of the drug, the timing of the announcement, market expectations, and other contextual factors. Not all approvals produce the same impact. This variation suggests that other firm-level or product-level characteristics may interact with regulatory outcomes to shape investor response. These possibilities are explored further in the following sections.

## **2.4 Firm Characteristics as Drivers of Investor Response**

While FDA approvals generally trigger positive market reactions, the strength of that response varies significantly with firm-specific characteristics. The impact of a single drug approval depends on the company's size, portfolio, and financial profile. For instance, a one-product biotech startup may experience a substantial value increase, whereas the same approval could have a marginal impact on a large, diversified pharmaceutical firm. This heterogeneity in abnormal returns has been noted in several studies and suggests that firm characteristics influence how investors respond to approval news.

### **2.4.1 Firm Size and Portfolio Concentration**

Firm size is a key interaction variable. Smaller biotech firms tend to exhibit larger percentage stock movements upon FDA announcements compared to large pharmaceutical companies. Empirical evidence supports this. Cho et al. (2024) report that biotechnology firms show significantly higher abnormal returns than large pharmaceutical firms for equivalent news categories. This reflects both the heightened volatility of small-cap stocks and the disproportionate importance of individual products for smaller firms.

Similarly, De Schrijver (2013) argues that firms with narrower drug pipelines experience stronger market reactions to approvals, as each drug represents a larger share of future prospects. For larger companies with extensive portfolios, a single approval contributes only

marginally to overall revenue and thus yields a more muted stock price response. Consistent with this, several event studies have found firm size to be negatively correlated with abnormal returns in cross-sectional regressions.

### **2.4.2 Revenue Status and Commercialization Stage**

The distinction between pre-revenue biotech firms and revenue-generating companies also shapes market responses. Donovan (2019) finds that firms with no existing revenue experienced significantly larger stock price increases than their profitable counterparts upon receiving approval. This likely reflects the transformative nature of approval for pre-revenue firms, signaling their shift toward revenue generation. For established firms, however, a new product is often additive rather than transformational, leading to more subdued investor reactions.

### **2.4.3 R&D Intensity and Pipeline Structure**

Firms also differ in research and development strategies. R&D intensity, typically measured as R&D spending relative to sales or assets, may influence how investors interpret FDA approvals. High R&D intensity might signal innovation and validate the firm's strategy, potentially prompting strong market reactions. However, such firms may already be expected to deliver innovations, which can reduce the surprise effect.

Although direct evidence on R&D intensity in event studies is limited, related research has explored adjacent measures. For example, Sarkar and de Jong (2006) examine firm-level responses to regulatory changes and find that firms with a stronger R&D orientation gained more from the 1997 FDA advertising policy shift. This suggests that innovative firms can better exploit new opportunities. Accordingly, R&D-focused firms may experience stronger reactions to approvals, although this relationship is likely context specific and may vary depending on the firm's overall profile.

### **2.4.4 Capital Investment and Asset Utilization**

Capital expenditure and asset turnover may reflect a firm's capacity to commercialize approved drugs. Firms with substantial investment in infrastructure or manufacturing could be better positioned to launch products rapidly, which may increase investor optimism following an approval. However, a larger asset base might also imply a more diversified operation, potentially diluting the perceived importance of a single approval. There is limited empirical evidence directly addressing these factors in the context of FDA approval reactions.

### **2.4.5 Profitability and Financial Constraints**

A firm's financial condition may also affect investor reactions. For loss-making or cash-constrained firms, a new drug approval could ease concerns about future funding needs by indicating forthcoming revenue streams. Donovan (2019) recommends targeting unprofitable firms for larger post-approval gains. Conversely, approvals for already-profitable firms are unlikely to transform the business, which may lead to less dramatic market responses.

### **2.4.6 Implications and Literature Gaps**

Firm-specific characteristics such as size, revenue status, R&D intensity, capital investment, and profitability materially shape how investors respond to FDA approvals. Earlier event studies often treated approval effects in aggregate, overlooking these cross-sectional differences. Only more recent or specialized work has begun to incorporate interaction terms or subsample splits, such as biotech compared to pharma, to better capture this heterogeneity.

This reveals a gap in the literature. There is a need for systematic analysis exploring how firm profiles condition approval reactions. Addressing this could benefit both practitioners seeking to predict market behavior and scholars aiming to refine models of information diffusion in financial markets.

## **2.5 Subsector Distinctions in Biopharma and Market Behavior**

The biopharmaceutical industry comprises diverse subsectors and therapeutic areas, and these distinctions can influence stock market reactions to FDA drug approval announcements. One approach to categorizing these subsectors is by the degree of specialization, such as whether a firm or drug is system-specific, targeting a particular physiological system or disease area, or non-system-specific, involving broader portfolios or platform technologies. Investor responses may differ depending on whether the approval concerns, for example, an oncology treatment or a cardiovascular drug, or a gene therapy platform versus a traditional small-molecule formulation. Multiple strands of literature have examined such distinctions.

### **2.5.1 Biotechnology versus Pharmaceutical Firms**

A fundamental subsector divide lies between biotechnology firms, which are often younger and focused on novel biologics or genetic therapies, and pharmaceutical firms, which tend to be larger and more diversified across therapeutic areas. Biotech stocks are typically more volatile and sensitive to drug news. Cho et al. (2024) compared the two and found that

biotechnology firms exhibit larger abnormal returns than pharmaceutical firms for similar news events. This is consistent with the higher risk-return profile associated with biotechnology firms.

Pharmaceutical firms respond to a wider array of events, including policy changes and portfolio updates, but any single drug approval usually has a limited effect on their overall valuation. In contrast, biotech investors tend to concentrate their expectations around individual pipeline events. This distinction in investor focus contributes to more pronounced stock reactions in the biotech subsector.

### **2.5.2 Therapeutic Area and Disease Type**

Within a firm's portfolio, the therapeutic area can also influence market reactions. Drugs targeting life-threatening diseases such as cancer or rare disorders may attract more investor attention than treatments for well-served indications such as hypertension. Rothenstein et al. (2011) found significant market reactions to oncology drug announcements, suggesting that certain therapeutic areas command heightened market interest. However, De Schrijver (2013), in a broader cross-industry study, concluded that the disease type alone does not consistently differentiate stock reactions.

This indicates that commercial potential may carry greater weight than the specific therapeutic category. For example, an oncology approval might generate a strong reaction if the drug is expected to be a blockbuster, while a cardiovascular drug could produce a similar effect if it addresses a large and underserved market. In some cases, approvals in niche segments such as orphan diseases may generate especially positive reactions, owing to anticipated pricing power and market exclusivity. Evidence supports this; orphan drug designations have been associated with positive abnormal returns as investors anticipate premium margins and reduced competition.

### **2.5.3 Platform-Based versus Product-Specific Firms**

Another useful distinction is between companies developing broad technological platforms and those focused on single products. For example, a biotech firm engaged in mRNA technology may face different investor expectations than a company with one conventional drug in development. While direct literature on this distinction is limited, it parallels the contrast between system-specific and non-system-specific firms. A highly specialized firm's valuation may be tightly linked to outcomes in one therapeutic domain, whereas a diversified

company is less dependent on the success of a single project. This structural diversification tends to reduce volatility in response to approval events.

#### **2.5.4 Breakthrough versus Routine Innovation**

Perhaps the most pronounced market reactions occur in response to breakthrough innovations. First-in-class therapies, which represent novel mechanisms or treatments, tend to generate stronger stock price increases than routine or incremental innovations. Certain subsectors, such as gene therapy and advanced biologics, are more likely to deliver such breakthroughs.

Chemmanur et al. (2023) provide a theoretical and empirical framework for this phenomenon. They show that high-profile innovation events, such as FDA approvals of novel drugs, trigger immediate and significant price reactions due to elevated investor attention. These reactions are larger and more concentrated than those following more routine developments, such as patent grants. Their findings support the view that the context of an approval, particularly whether it represents a scientific or commercial breakthrough, significantly shapes investor behavior.

#### **2.5.5 Summary and Implications**

Not all FDA approvals are interpreted equally by the market. Subsector characteristics, including firm type, therapeutic area, level of innovation, and strategic orientation, contribute meaningfully to how investors respond. Novel and specialized approvals tend to trigger stronger positive reactions, whereas routine or low-market-potential approvals often result in negligible stock price movements.

Firms operating in cutting-edge areas such as gene therapy generally face more substantial valuation swings on drug news compared to diversified pharmaceutical firms. Although the literature on these distinctions is still developing, existing research suggests that investor responses are conditioned by both the nature of the company and the characteristics of the approval. The present study builds on this foundation by explicitly examining how system-specific versus diversified firm focus interacts with the market reaction to FDA approvals.

## **2.6 Synthesis of Theory and Identification of the Literature Gap**

### **2.6.1 Theoretical Foundations**

Market reactions to FDA approvals can be interpreted through the lens of market efficiency and information signaling. In a semi-strong efficient market (Fama, 1970), stock prices reflect all publicly available information. An FDA approval announcement is a clear example of a new information release that resolves uncertainty about a firm's growth option. The corresponding change in stock price represents the market's revised estimate of the firm's value, incorporating expected future profits from the drug.

This framework aligns with real options theory, where R&D projects are viewed as call options that become valuable only if successful. The FDA approval marks the exercise point of such an option, converting it into a revenue-generating asset. Empirical findings of positive abnormal returns on approval days are consistent with this theoretical view. As noted by Hamill et al. (2013), even approvals for new indications can contribute materially to firm value, illustrating the relevance of real options in the biopharmaceutical sector.

Another theoretical perspective is drawn from investor attention and behavioral finance. While markets generally react rationally to public news, attention constraints and information salience can influence the speed and magnitude of price adjustments. Chemmanur et al. (2023) incorporate limited investor attention into a formal model and demonstrate that high-visibility events, such as FDA approvals, trigger larger and faster stock price responses. In contrast, approvals that receive limited attention may experience slight underreactions that correct over subsequent trading days. These patterns support the attention-grabbing hypothesis, which posits that the visibility of an event affects how quickly markets absorb its implications.

Taken together, these theoretical lenses suggest that FDA approvals convey valuation-relevant information and that investor attention plays a role in shaping the response. Both frameworks support the use of event studies to examine how the characteristics of the firm and the approval influence market outcomes.

### **2.6.2 Identifying the Literature Gap**

The preceding review confirms that FDA approvals typically lead to positive stock price reactions, while non-approvals have negative consequences. However, this general pattern masks considerable variation in the magnitude of responses. Although many studies

document average effects, fewer have systematically investigated how these effects differ depending on firm-level characteristics or subsector dynamics.

One important gap concerns the role of firm heterogeneity. While prior research has examined individual factors such as firm size, R&D spending, or revenue status, few studies have integrated these variables into a unified analytical framework. There is limited empirical understanding of how interactions between characteristics, such as profitability and asset turnover, influence approval-day returns. For instance, it is not yet clear at what threshold a firm's size reduces the market impact of an approval, or how financial constraints may amplify that impact.

A second underexplored area relates to subsector distinctions within the biopharmaceutical industry. Although broad differences between biotechnology and pharmaceutical firms are well documented, there has been less analysis of therapeutic and technological segments. Open questions include whether oncology approvals consistently outperform approvals in other disease areas once expected sales are accounted for, or whether orphan drug designations systematically lead to higher abnormal returns due to pricing advantages and exclusivity. Similarly, differences between platform-based and product-specific firms have not been fully quantified.

## **3. Methodological Framework and Data**

This chapter outlines the methodological framework and empirical foundation of the study, followed by a detailed account of the data collection and preparation process. It begins by describing the event study design and the structure of the panel dataset, which jointly form the basis for the regression analyses. The subsequent sections document the construction of the dataset, including data sources, screening procedures, firm-level matching, and variable creation. The final dataset captures FDA drug approval announcements for publicly listed U.S. healthcare firms over the period 2014 to 2024.

### **3.1 Empirical Design**

This study's empirical design consists of two key components. First, an event study methodology is employed to quantify the stock market impact of specific events. Second, a panel data framework is used to analyze the results across firms and time, incorporating fixed

effects to control for heterogeneity. Together, these methods allow for a robust examination of firm-specific events in a time-series cross-sectional context.

### **3.1.1 Event Study Methodology**

An event study is a statistical method used to evaluate how a specific event affects a firm's stock price. The objective is to isolate the abnormal return attributable to the event, defined as the difference between the actual return and the return expected in the absence of the event. In practice, actual returns around the event date are compared to predicted returns from an asset pricing model (MacKinlay, 1997). A significant deviation from the expected return during the event window is attributed to the event itself (Brown and Warner, 1985). First introduced in early form by Dolley in the 1930s and formalized by Fama et al. (1969), the methodology has become a standard tool for evaluating market efficiency and the impact of corporate announcements.

A critical step in an event study is estimating the expected return. A common approach is to use the Capital Asset Pricing Model (CAPM) or the market model, where expected returns are determined by the firm's exposure to market risk (Sharpe, 1964). In this context, the model is calibrated over a pre-event estimation window, typically 120 to 250 trading days before the event, to estimate the firm's alpha and beta (MacKinlay, 1997). These estimates are used to generate counterfactual returns during the event window, and abnormal returns are calculated as the difference between actual and expected returns.

Researchers often aggregate abnormal returns over time or across firms to capture the overall impact of the event. Statistical tests are applied to determine whether the results are significantly different from zero, under the null hypothesis that the event has no effect on stock prices (MacKinlay, 1997).

Short-horizon event studies typically employ a narrow event window to capture immediate market reaction, along with a longer estimation window to ensure reliable parameter estimation. This structure helps ensure that observed abnormal returns are attributable to the event and not influenced by unrelated market developments.

### **3.1.2 Panel Data Structure**

The analysis is further conducted using a panel data framework, which combines cross-sectional and time-series dimensions by tracking multiple firms over multiple time periods. Panel data consist of repeated observations of the same units, such as firms, across time

(Wooldridge, 2010). This structure is particularly well-suited for firm-event-time analysis, as it captures both within-firm dynamics (e.g. changes before and after an event) and between-firm differences.

Using panel data enhances statistical power by increasing the number of observations (equal to the number of firms multiplied by the number of time periods), thereby improving the precision of estimates relative to a purely cross-sectional analysis (Baltagi, 2008). It also enables more flexible modeling of effects, such as distinguishing an event's immediate impact from longer-term patterns.

A key advantage of panel data is the ability to control for unobserved heterogeneity through fixed effects. This study employs firm fixed effects and year fixed effects in a two-way fixed effects specification. Firm fixed effects account for all time-invariant firm characteristics such as industry, management style, or other persistent traits by removing their influence through either dummy variables or de-meaning transformations. This reduces bias from omitted variables that do not change over time (Wooldridge, 2010).

Year fixed effects control for shocks or conditions common to all firms in a given year, including macroeconomic trends or regulatory changes. Together, these fixed effects eliminate two major sources of confounding: firm-specific heterogeneity and time-specific shocks. As a result, the variation used to identify the event effect comes from within-firm changes over time, net of firm baselines and general trends.

In sum, the panel data approach with fixed effects not only mitigates unobservable confounding but also increases degrees of freedom and variability, allowing for more robust and credible estimation of the event's impact (Baltagi, 2008).

## **3.2 Data Collection and Construction**

### **3.2.1 FDA Approval Data**

FDA approval data were retrieved from the openFDA database through the Drugs@FDA API<sup>1</sup>, which returns structured data in JSON format. From this dataset, relevant fields such as the approval status, decision date, application number, and sponsor name were extracted. The `submission_status` identifies whether a drug was approved or tentatively approved, while `submission_status_date` indicates when the decision was made public. The application

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<sup>1</sup> <https://download.open.fda.gov/drug/drugsfda/drug-drugsfda-0001-of-0001.json.zip>

number allowed verification that the recorded date matched the first public instance of the decision. For a subset of firms, press releases and public records were checked, and it was confirmed that the decision date either coincided with or preceded press coverage by one to two days, reinforcing its use as the appropriate event date.

The dataset was filtered to include only approvals within the 2014–2024 time frame. Subsequently, a pivot table was created to extract a list of unique sponsor names. To focus on relevant firms, a screening was conducted using FactSet’s Universal Screening tool. The screening included only U.S.-based public firms classified under the healthcare industry and listed on either NYSE or NASDAQ. OTC firms were excluded. Industry classifications were based on the RBICS (Revere Business Industry Classification System), a comprehensive and granular taxonomy that assigns firms to sectors and subsectors based on their primary line of business. The resulting firm-level dataset included stock exchange information, RBICS sector and subsector classifications, and ISIN identifiers.

### **3.2.2 Firm Matching and Name Reconciliation**

Firm names listed in the FDA dataset frequently differed from FactSet’s naming convention, making a direct merge infeasible. This discrepancy stems from differences in naming conventions across databases. For example, the FDA data may list a sponsor as "ABC Corp." while FactSet may register the same entity as "ABC Corporation" or include parent company names, abbreviations, or suffixes. These inconsistencies complicate one-to-one matching using exact string comparisons.

To overcome this issue, a Python script was developed to facilitate firm name reconciliation (see [Appendix C](#)). The script relied on two main techniques to match firm names, even when they were written differently. First, it used a semantic similarity method that converts names into numerical formats based on their meaning, allowing it to recognize names that are conceptually similar despite differences in wording. Second, it applied a text-based comparison method that examines the letters in each name and detects matches even when parts are rearranged or only partially match.

To illustrate, a name like "ABC Biotech Inc." in the FDA data might be correctly aligned with "ABC Biotechnology Ltd." in FactSet by identifying a high semantic or textual similarity score. These two techniques ensured a robust automated matching process, accounting for both meaning and appearance.

The output of this script was a ranked list of candidate matches between FDA and FactSet names. These results were manually reviewed and corrected where necessary to ensure accuracy. This combination of algorithmic matching and human verification allowed for precise alignment of firm identities across the two datasets, ensuring that subsequent analyses are based on correctly linked entities.

### 3.2.3 Price and Market Data

For each matched firm, daily stock prices spanning December 2013 to January 2025 were extracted using the FactSet Excel plugin. Market returns, proxied by the S&P 500 index, were obtained for the same period. Daily returns were calculated using:

$$R_{it} = \frac{P_{i,t+1}}{P_{i,t}} - 1 \quad (Eq. 1)$$

where  $P_{i,t}$  denotes the closing price of firm  $i$  at time  $t$ . The U.S. risk-free rate was collected from FRED using the 10-Year Constant Maturity Treasury yield. Missing values were forward-filled to ensure continuity. The individual firm returns were merged with market and risk-free returns to form a long-form panel dataset. Each observation corresponds to a unique firm-date combination, with risk-free and market returns replicated across firms for each date.

### 3.2.4 Sector and Subsector Classification

Industry classifications were obtained from FactSet and appended manually to the dataset. Firms were assigned dummy variables corresponding to their sector and subsector. Three sector dummies were created: Biopharmaceuticals, Healthcare Equipment, and Healthcare Services, as well as three subsector dummies: Non-System-Specific Biopharmaceuticals, Other Biopharmaceuticals, and System-Specific Biopharmaceuticals. Each firm received a value of one for the applicable category and zero for others.

### 3.2.5 Financial Data Construction

Quarterly firm-level financials were obtained using the ISIN identifiers via the FactSet Excel plugin. The selected variables were Total Assets, Capex, Sales, EBITDA, EBIT, Net Income, R&D Expenditure, and Total Debt. Each of these measures adheres to standardized definitions provided by FactSet.

- **Total Assets** include all resources expected to provide future benefits and equal the sum of liabilities and equity.

- **Capex** combines expenditure on fixed and other assets.
- **Sales** represent revenue net of discounts and pass-through taxes.
- **EBITDA** is defined as EBIT plus depreciation and amortization.
- **EBIT** reflects operating income.
- **Net Income** excludes extraordinary items and discontinued operations.
- **R&D Expenditure** encompass all spending related to innovation and testing, excluding market and customer-sponsored research.
- **Total Debt** includes all short- and long-term interest-bearing liabilities.

A Python script was used to merge the calendarized quarterly financial data with the panel dataset by aligning each date with the latest available fiscal quarter (See [Appendix D](#)). This ensured temporal consistency between event dates and firm fundamentals.

### 3.2.6 Event Variable Construction

To capture the timing of FDA approvals, a binary variable was created from the `submission_status_date` field. Using a dedicated Python script ([Appendix E](#)), a dummy was assigned to each firm-date observation. The value was set to one if the firm received an FDA approval on that date and zero otherwise. If the `submission_status_date` fell on a non-trading day, the event date was matched to the next available trading day to ensure proper alignment with return data. The final specification of the variable is as follows:

$$FDA_{Approved_{it}} = f(x) = \begin{cases} 1, & \text{if firm } i \text{ has FDA approval on date } t \\ 0, & \text{otherwise} \end{cases} \quad (\text{Eq. 2})$$

This dummy variable serves as the primary event indicator in subsequent econometric models used to estimate abnormal returns.

## 3.3 Descriptive Statistics

Before conducting the empirical analysis, a series of descriptive statistical procedures were implemented to assess the internal structure of the dataset, detect potential multicollinearity, and provide foundational insights into the relationships among key financial variables. These diagnostics also inform and justify the construction of the interaction variables used in the main regression models.

### 3.3.1 Summary Statistics

Descriptive statistics for all variables used in the regression analysis are presented in Table 1. The table reports the mean, median, standard deviation, minimum, 25th percentile, 75th percentile, maximum, and the number of observations for each variable. All monetary variables are measured in millions of USD. The distribution of firm characteristics reveals considerable variation in firm size, profitability, and financial structure across the sample. For instance, the average total assets amount to USD 9.867,55 million, but the distribution is highly right-skewed, with a median of only USD 356,50 million, suggesting the presence of a few very large firms.

Several financial variables exhibit extreme values, as seen in the wide range between minimum and maximum values. For example, Capex ranges from -188,45 to 4.170,80, and Net Income spans from -11.911,00 to 12.273,00. The presence of large negative values may indicate periods of financial distress or accounting write-downs. The return variable has a mean close to zero and displays significant variation, with a standard deviation of 4,4%, consistent with daily stock price fluctuations. The FDA approval dummy variable is sparse, with a mean of only 1,3%, reflecting the rarity of approval events on any given trading day.

Further analysis of the distributional shape, including skewness and kurtosis for all variables, can be found in [Appendix B](#). These statistics confirm the presence of substantial non-normality in many firm-level indicators, most notably R&D intensity and Capex intensity, which exhibit high levels of skewness and leptokurtosis. These features are relevant when interpreting the regression results, especially regarding potential outlier influence and the appropriateness of OLS estimation.

**Table 1:** Summary Statistics of Key Variables

Variable	Mean	Median	Std. Dev	Min	p25	p75	Max	N
FDA Appr.	0,013	0,000	0,113	0,000	0,000	0,000	1,000	222.322
Total Assets	9.867,55	356,50	28.681,88	0,35	132,05	1.782,26	226.501,00	221.694
Capex	47,81	0,62	175,75	-188,45	0,06	9,87	4.170,80	220.603
Sales	1.013,64	23,29	2.837,79	-3,30	1,30	169,92	27.742,00	221.919
EBITDA	360,85	-6,22	1.189,99	-3.995,00	-24,83	33,54	14.122,00	220.017
EBIT	258,95	-7,02	923,47	-4.898,00	-26,38	20,81	12.947,00	221.919
Net Income	154,51	-8,32	809,14	-11.911,00	-30,47	9,01	12.273,00	221.919
R&D	210,83	19,95	590,64	-4,35	6,22	83,06	12.894,00	221.122
Total Debt	3.596,85	55,29	10.761,54	0,00	2,01	495,79	87.432,00	221.574
Rf	0,024	0,024	0,010	0,005	0,018	0,030	0,050	222.322

Notes: This table reports summary statistics for the main variables in the dataset. The sample consists of calendarized quarterly observations from the healthcare

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sector. All monetary values are in millions of U.S. dollars. "FDA Appr." is a binary variable equal to 1 on days when an FDA approval is announced. "RF" denotes the daily U.S. 10-Year Treasury constant maturity yield.

To support the subsector-level regression analysis, the dataset is partitioned into three biopharmaceutical subsectors: Non-System-Specific, System-Specific, and Other Biopharmaceuticals. Table 2 provides an overview of the composition of the sample by subsector, reporting the number of unique firms and total firm-day observations in each group. The subsample sizes are unbalanced, with System-Specific Biopharmaceuticals representing the largest group both in terms of firms and observations. This breakdown provides context for the heterogeneity analysis that follows and ensures transparency regarding the distribution of data across subsector categories.

**Table 2:** Sample Composition by Subsector

Subsector	Number of Firms	Number of Observations
Non-System-Specific Biopharma.	28	54.808
System-Specific Biopharma.	51	96.266
Other Biopharma.	21	43.988

Notes: This table presents the number of unique firms and the total number of firm-day observations in each biopharmaceutical subsector. "System-Specific Biopharmaceuticals" refers to firms developing drugs targeting specific organs or systems (e.g., cardiovascular, neurological). "Non-System-Specific Biopharmaceuticals" includes firms with a broader or non-targeted focus. "Other Biopharmaceuticals" includes firms that do not fall into the two main categories.

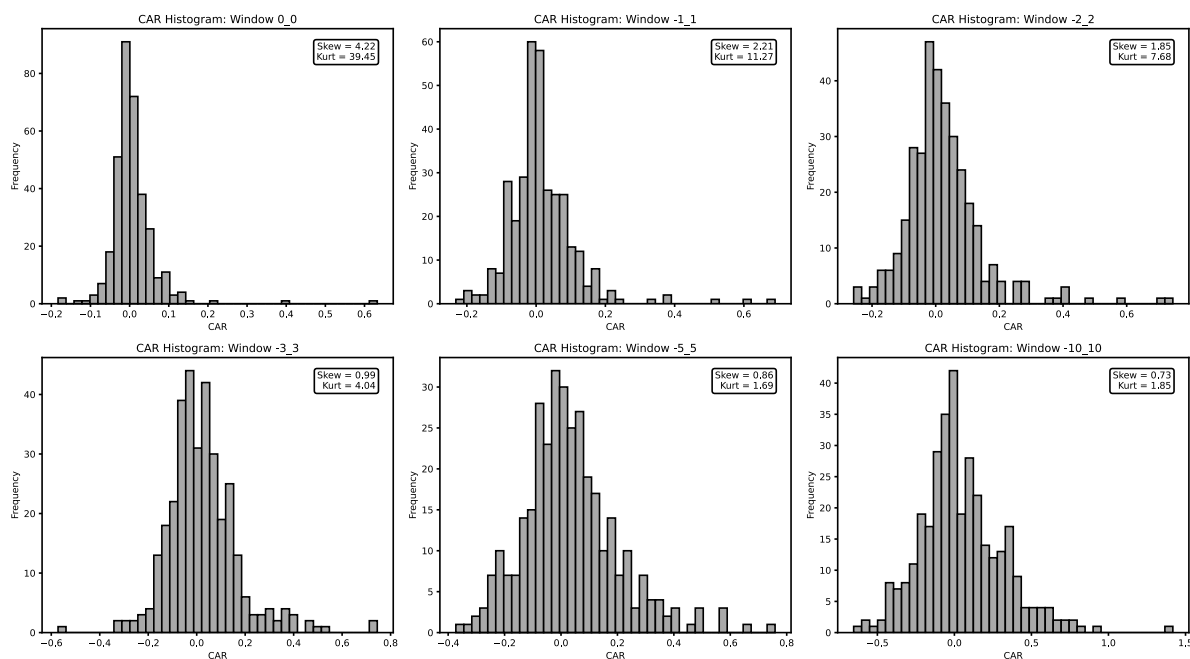
### 3.3.1.1 CAR distributions

To assess the distribution of CARs around FDA approval dates, Figure 1 presents histograms of CARs across all six event windows analyzed in the regressions. The distributions exhibit notable skewness and varying degrees of kurtosis, particularly in shorter windows. In the (0,0) window, the distribution is sharply right-skewed (skewness = 4,22) and leptokurtic (kurtosis = 39,45), suggesting the presence of substantial outliers with strong positive abnormal returns on the day of the announcement. Similar patterns, though less extreme, are observed for the (-1,1) and (-2,2) windows, with skewness values of 2,21 and 1,85 respectively, and kurtosis levels above 7.

As the window length increases, both skewness and kurtosis decline. For example, the (-5,5) and (-10,10) windows exhibit lower skewness (0,86 and 0,73) and kurtosis (1,69 and 1,85), indicating a more symmetric and less heavy-tailed distribution. This pattern is consistent with the view that extreme FDA approval reactions are more concentrated in shorter windows and tend to smooth out over time. Nonetheless, across all windows, the presence of right-skew

and mild to strong leptokurtosis implies that a subset of FDA approvals generates large, positive market reactions, while most events result in modest or negligible returns.

These distributional characteristics raise considerations for the regression analysis. Specifically, the presence of extreme CARs suggests that estimated coefficients may be sensitive to outliers, particularly in short windows. This motivates the interpretation of results with caution.



**Figure 1:** Distribution of CARs Across Event Windows

This figure displays histograms of CARs around FDA approval events for six event windows: (0,0), (-1,1), (-2,2), (-3,3), (-5,5), and (-10,10). CARs are calculated using the CAPM model with a 100-day estimation window. Each panel reports the distribution of CARs across all firm-event observations in the full sample, along with the skewness and kurtosis for each window.

[Appendix B.1](#) present the distribution of CARs across the six event windows for each biopharmaceutical subsector. Across all groups, the histograms reveal varying degrees of positive skewness and kurtosis, particularly in shorter event windows, consistent with the presence of extreme positive market reactions to a limited number of FDA approval events.

In the Non-System-Specific Biopharmaceuticals subsector, skewness peaks at 5,35 in the (0,0) window, with extremely high kurtosis (37,20), indicating that a handful of events generated disproportionately large positive returns. The (-1,1) and (-2,2) windows continue to exhibit skewness above 1,0 and moderate to high kurtosis, while longer windows show declining distortion. By (-10,10), skewness drops to 0,66 and kurtosis to 0,91, suggesting a more symmetric distribution over time.

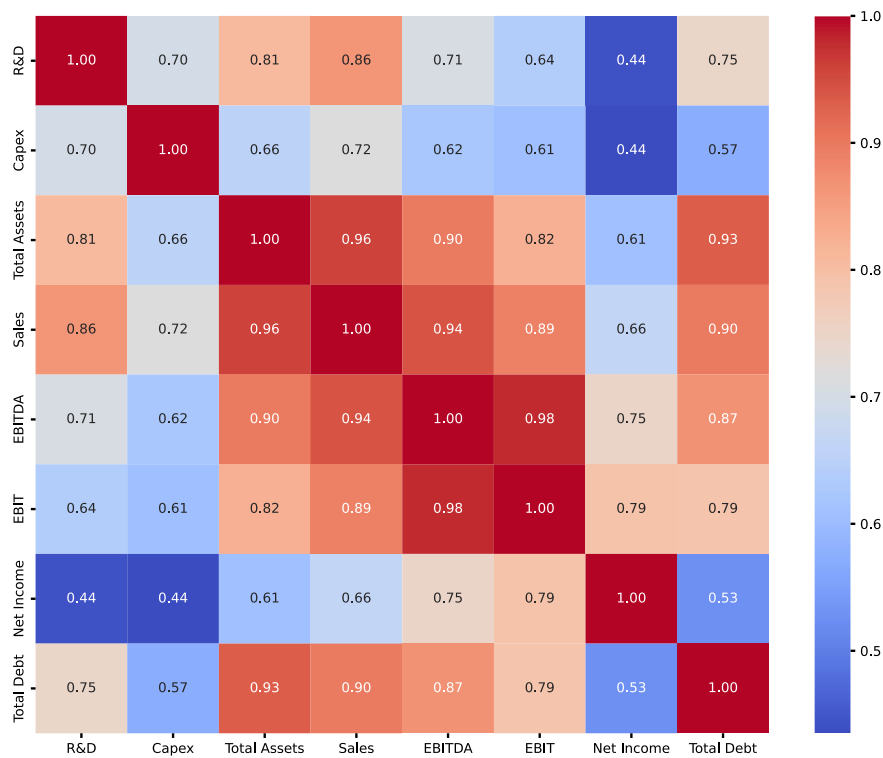
The System-Specific Biopharmaceuticals group also shows consistent positive skew across all windows, with values ranging from 2,07 in (0,0) to 0,86 in (-10,10). Kurtosis values are lower than in the non-system-specific group but remain elevated, particularly in the (0,0) through (-3,3) windows, where kurtosis exceeds 10,00 in multiple cases. This suggests that even in this larger and more diversified group, strong abnormal returns are concentrated among a subset of approval events.

In contrast, the Other Biopharmaceuticals subsector displays the most muted distributional features. The (0,0) window shows modest skewness (1,07) and low kurtosis (3,31), while some windows such as (-1,1) are nearly symmetric (skew = 0,13, kurtosis = 1,25). Longer windows continue this pattern, with skewness below 0,70 and kurtosis near or below 1,0 across the board. This indicates that reactions in this group are generally more moderate and evenly distributed, with less influence from outliers.

Overall, these distributional diagnostics confirm that CARs are not normally distributed in the full sample or subsectors, particularly over short windows. The evidence of skewness and fat tails reinforces the need for careful interpretation of statistical significance, especially when using narrow event windows prone to outlier influence.

### **3.3.2 Correlation Analysis**

An initial Pearson correlation matrix was computed to evaluate the pairwise relationships between the raw financial variables: R&D, Capex, Total Assets, Sales, EBITDA, EBIT, Net Income, and Total Debt. The results are visualized in Figure 2.



**Figure 2:** Correlation Matrix of Firm-Level Financial Variables

This figure presents the Pearson correlation coefficients between the main firm-level financial variables in the dataset. Strong positive correlations are indicated by values close to 1 and warmer colors, while weaker or more moderate relationships are represented by lighter shades. The matrix highlights interdependencies among size, performance, and investment proxies.

As expected, several variables exhibit strong positive correlations. Notably:

- Sales and Total Assets ( $\rho = 0,96$ )
- EBITDA and Sales ( $\rho = 0,94$ )
- Total Assets and Total Debt ( $\rho = 0,93$ )
- R&D and Sales ( $\rho = 0,86$ )

These relationships suggest that larger firms, measured by total assets, tend to generate higher revenues, invest more in innovation, and carry more debt. Similarly, high correlations between EBITDA, EBIT, and Sales reflect operational performance consistency. However, the strength of these correlations also raises concerns regarding multicollinearity, which can inflate the standard errors in regression models and obscure the effects of individual variables (Gujarati and Porter, 2009).

### 3.3.2.1 Construction Interaction Variables

To address potential multicollinearity and enhance interpretability, a set of six interaction variables was constructed using ratio-based transformations. These were selected based on

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theoretical relevance and prior empirical findings linking them to firm-level heterogeneity in investor responses:

**R&D Intensity**  $\left[\frac{R\&D}{Total\ Assets}\right]$ : Captures a firm's investment in innovation relative to its scale. Firms with higher R&D intensity are typically more research-focused and speculative, often operating in earlier stages of product development. This measure serves as a proxy for innovativeness and exploratory capital allocation (Lev and Sougiannis, 1996).

**Capex Intensity**  $\left[\frac{Capex}{Total\ Assets}\right]$ : Reflects capital investment activity relative to firm size. High capex intensity can signal growth-oriented firms, particularly those preparing infrastructure for commercialization.

**Size**  $[Log(Total\ Assets)]$ : The natural logarithm of total assets is used to proxy firm size in a scale-neutral way. The log transformation mitigates the skewness typical of asset distributions and allows for a nonlinear effect of firm size on outcomes (Wooldridge, 2010).

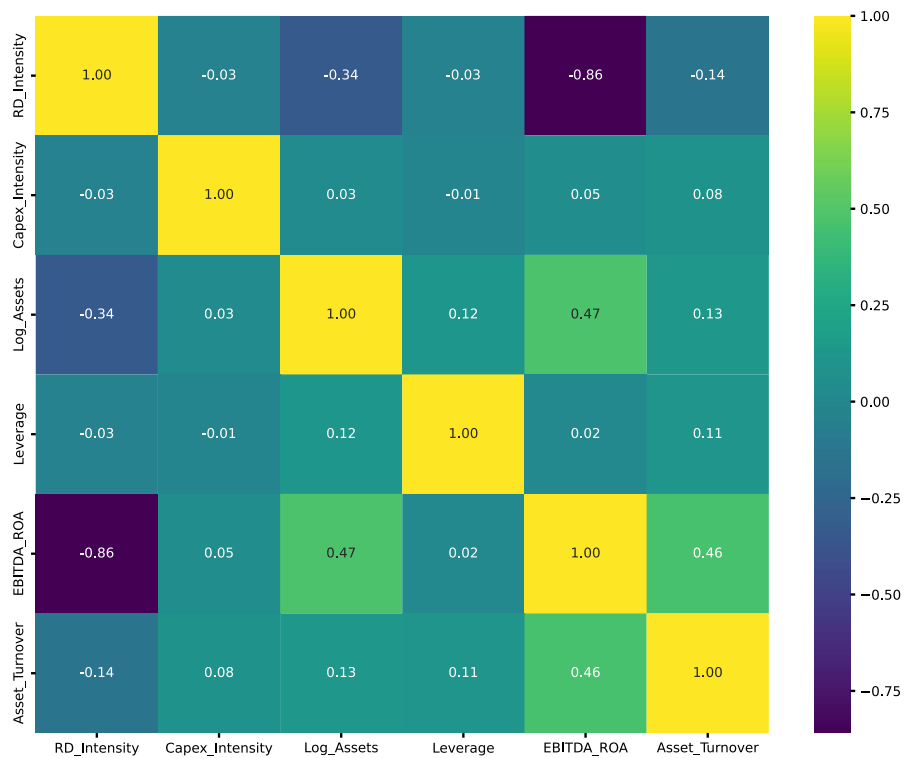
**Leverage**  $\left[\frac{Total\ Debt}{Total\ Assets}\right]$ : Measures a firm's financial risk. Highly leveraged firms may face higher sensitivity to earnings volatility, and investors may interpret news differently based on debt exposure (Titman and Wessels, 1988).

**EBITDA\_ROA**  $\left[\frac{EBITDA}{Total\ Assets}\right]$ : A proxy for operational profitability, indicating how efficiently a firm converts its assets into earnings before interest, taxes, depreciation, and amortization (Damodaran, 2002).

**Asset Turnover**  $\left[\frac{Sales}{Total\ Assets}\right]$ : A measure of efficiency, capturing how effectively a firm utilizes its asset base to generate revenue (Penman, 2012).

These variables were intentionally scaled by total assets to normalize firm-specific measures across heterogeneous firms, allowing for meaningful comparisons between small biotech firms and large corporations. This standardization ensures that firm characteristics are not dominated by scale effects and supports interaction terms with the FDA approval dummy in the regression models.

Following the construction of the interaction terms, a second correlation matrix was computed to assess multicollinearity risks among them. The results are presented in Figure 3.



**Figure 3:** Correlation Matrix of Interaction Variables

This figure displays pairwise Pearson correlation coefficients between the constructed interaction variables used in the regression analysis: R&D Intensity, Capex Intensity, Log(Assets), Leverage, EBITDA\_ROA, and Asset Turnover. The matrix helps assess the degree of linear dependence among explanatory variables that enter interaction models.

The matrix reveals generally low to moderate correlations between most terms, suggesting they capture distinct dimensions of firm heterogeneity. The most notable relationship is a strong negative correlation between R&D Intensity and EBITDA\_ROA ( $\rho = -0,86$ ), indicating that firms investing heavily in R&D tend to report lower short-term operating profitability which consistent with the delayed revenue realization typical of early-stage drug developers. Other variable pairs, such as Log(Assets) and EBITDA\_ROA or Log(Assets) and Asset Turnover, display modest relationships that do not raise immediate multicollinearity concerns.

### 3.3.3 Variance Inflation Factor (VIF)

To formally assess the degree of multicollinearity among the interaction variables, a Variance Inflation Factor test was performed. The VIF quantifies how much the variance of a given regression coefficient is inflated due to linear dependence with other independent variables in the model (Kutner et al., 2004). In essence, it measures how strongly one variable can be explained by the others.

Mathematically, the VIF for variable is defined as:

$$VIF_j = \frac{1}{1 - R_j^2} \quad (Eq. 3)$$

Where  $R_j^2$  is the R-squared obtained when regressing variable  $x_j$  on all other explanatory variables. A VIF value of 1 indicates no multicollinearity, while higher values imply stronger linear relationships between variables.

A common rule of thumb in econometrics is that a VIF exceeding 10 suggests serious multicollinearity concerns that may distort regression estimates and reduce interpretability (Gujarati and Porter, 2009; Wooldridge, 2010). Values between 5 and 10 warrant caution and further investigation, whereas values below 5 are generally considered acceptable in empirical research. Table 4 reports the VIFs for each of the interaction terms used in the empirical models.

**Table 4:** Variance Inflation Factors for Interaction Variables

	const	R&D_Intensity	Capex_Intensity	Log_Assets	Leverage	EBITDA_ROA	Asset_Turnover
VIF	16,10	5,997	1,008	1,442	1,060	8,608	2,003

Notes: The VIFs are calculated from a linear regression model including all interaction variables. The constant term shows a high VIF due to perfect collinearity with the intercept, which is expected and not problematic. All other VIF values fall below the conservative threshold of 10, suggesting that multicollinearity is not a significant concern for the included regressors.

The VIF values for Capex Intensity, Log(Assets), Leverage, and Asset Turnover are all comfortably below the threshold of 5, indicating low multicollinearity risk. R&D\_Intensity (5,997) and EBITDA\_ROA (8,608) approach the cautionary threshold of 10 but remain within acceptable limits. These variables are retained due to their theoretical, representing innovation and profitability respectively.

The constant term (“const”) shows a high VIF (16,10), but this is a known and expected outcome when using centered or standardized data, and it does not affect inference on the explanatory variables (Kutner et al., 2004). In summary, the VIF analysis supports the inclusion of all six interactions in the regression framework without requiring further adjustments or exclusion due to multicollinearity.

## 3.4 Estimation Strategy

### 3.4.1 Baseline Regressions Without Fixed Effects

The first set of regressions examines the stock market's reaction to FDA drug approval announcements using cross-sectional ordinary least squares (OLS) models without firm or year fixed effects. These regressions serve as the baseline specification and provide initial evidence on the presence and direction of abnormal returns following regulatory approvals, as well as the role played by firm-level characteristics.

To isolate the abnormal component of stock returns, the analysis employs a standard market model based on the CAPM. For each approval event, a 100-day estimation window preceding the event date is used to estimate firm-specific betas. The estimation window must not overlap with any other FDA approval for the same firm, ensuring that beta estimates are not distorted by contemporaneous events.

The expected return for each firm on a given day is modeled as:

$$R_{it} - R_{ft} = \alpha_i + \beta_i(R_{mt} - R_{ft}) + \epsilon_{it} \quad (\text{Eq. 4})$$

where  $R_{it}$  is the return of firm  $i$  on day  $t$ ,  $R_{ft}$  is the U.S. risk-free rate on that day (proxied by the 10-Year Treasury constant maturity yield), and  $R_{mt}$  represents the return on the S&P 500 index. The coefficient  $\beta_i$  captures the sensitivity of the firm's return to market movements.

The abnormal return for each day in the event window is calculated as the actual return minus the expected CAPM return:

$$AR_{it} = R_{it} - [R_{ft} + \beta_i(R_{mt} - R_{ft})] \quad (\text{Eq. 5})$$

Cumulative abnormal returns are then computed by summing abnormal returns over multiple event windows of varying length. Six symmetric windows are used: [0,0], [-2,+2], [-1,+1], [-3,+3], [-5,+5], and [-10,+10], allowing for both immediate and delayed market responses to be captured. The choice of these windows is consistent with prior literature in event studies within financial economics, which often includes both narrow and broader timeframes around the event date to detect persistent effects.

If the FDA decision occurred on a non-trading day, the event date is adjusted to the next available trading day to ensure proper alignment with stock market data. Firms lacking 100 valid trading days before the event are excluded from the analysis.

### ***3.4.1.1 Regression Design and Interaction Variables***

Once cumulative abnormal returns are computed for each event, they are used as the dependent variable in cross-sectional OLS regressions. The independent variable in each specification is a firm-specific interaction term, designed to test whether differences in financial structure, investment behavior, or operational efficiency can explain variation in the magnitude of abnormal returns across firms.

The general regression equation is specified as:

$$CAR_i = \alpha + \gamma I_i + \epsilon_i \quad (Eq. 6)$$

where  $CAR_i$  is the cumulative abnormal return for firm  $i$  over a given event window,  $I_i$  is the interaction variable, and  $\gamma$  captures the marginal effect of the interaction on the market reaction. The error term  $\epsilon_i$  is assumed to be independently and identically distributed.

Each interaction is tested in a separate regression to isolate its individual contribution and avoid the confounding effects of high correlation between variables. This approach aligns with the methodological guidance from existing literature on event studies and firm characteristics.

### ***3.4.1.2 Subsector-Specific Estimation***

To investigate whether market reactions differ across distinct segments of the biopharmaceutical industry, the analysis is replicated within each of three RBICS-defined subsectors: Non-System-Specific Biopharmaceuticals, Other Biopharmaceuticals, and System-Specific Biopharmaceuticals. Each firm is uniquely classified into one of these groups based on its primary business model and product focus, as described in the data section.

Within each subsector, the full set of FDA approval events is extracted and the same procedure is followed: beta estimation, CAR calculation across event windows, and regression of CARs on the interaction variable. This allows for a more nuanced understanding of how firm characteristics interact with market expectations in different drug development contexts.

The subsector-level regressions help assess whether the same financial indicators have consistent effects across business models. For example, R&D intensity may be more positively interpreted in system-specific biopharmaceutical firms targeting niche or rare

diseases, while being neutral or even negative in diversified firms where R&D investment is diluted across broader portfolios.

The entire estimation framework is implemented in Python, and the full code is provided in [Appendix F.2](#). The script performs all steps described above: identifying FDA approval events, estimating CAPM betas from the 100-day pre-event window, computing expected returns, calculating abnormal and cumulative abnormal returns, and running OLS regressions for each event window and interaction.

The code also handles subsector segmentation by filtering the dataset based on dummy variables, which identify each firm's subsector. Regression results are stored and reported separately for each group and each window. The modular structure of the script allows for consistent application across all interactions and event windows, ensuring comparability of results across specifications.

Firms with incomplete data, missing financial information, or overlapping event windows are excluded on a case-by-case basis to preserve the reliability of the estimates.

### 3.4.2 Firm Fixed Effects Panel Regressions

To control for time-invariant firm-specific characteristics that may confound the relationship between financial structure and stock price reactions to FDA approvals, the second model specification introduces firm fixed effects. These regressions build directly on the baseline approach but are estimated using a panel data framework that allows for consistent estimation of within-firm variation over time.

The estimation uses the following fixed effects model:

$$CAR_{it} = \alpha_i + \gamma I_{it} + \epsilon_{it} \quad (Eq. 7)$$

where  $CAR_{it}$  is the cumulative abnormal return for firm  $i$  at event date  $t$ ,  $I_{it}$  is the interaction variable of interest,  $\alpha_i$  represents the unobserved firm fixed effect, and  $\epsilon_{it}$  is the idiosyncratic error.

Unlike the OLS models described previously, the inclusion of  $\alpha_i$  absorbs all firm-specific factors that are constant over time, such as corporate culture, management style, or baseline investor expectations. This mitigates the risk of omitted variable bias from stable firm traits that could otherwise distort the estimated effect of interactions like R&D intensity or leverage.

The panel is structured using firm identifiers (ISIN) and event dates as indices, where each observation corresponds to a unique approval event. Interaction values are matched to the fiscal quarter of the event, as in the baseline models.

The regressions are estimated separately for each event window using Python’s “linearmodels” package with robust standard errors. The same procedure is applied to the full sample and to each biopharmaceutical subsector independently. Firms lacking sufficient return history or financial data are excluded from the sample on a rolling basis. The implementation code is provided in [Appendix F.3](#).

### 3.4.3 Firm and Year Fixed Effects Panel Regressions

To further strengthen the causal interpretation of the interaction effects, the final set of regressions incorporates both firm and year fixed effects. This specification controls for two dimensions of unobserved heterogeneity: firm-specific characteristics that do not vary over time and common shocks or trends in specific calendar years that could influence cumulative abnormal returns across the entire market.

While firm fixed effects remove bias stemming from persistent traits such as management quality or long-term strategy, year fixed effects adjust for macroeconomic, regulatory, or industry-wide dynamics, such as changes in FDA policy, market sentiment, or investor behavior, that may simultaneously affect all firms in a given year. The inclusion of both sets of fixed effects yields a more stringent model, relying solely on within-firm, within-year variation for identification.

The model is estimated as follows:

$$CAR_{it} = \alpha_i + \delta_t + \gamma I_{it} + \epsilon_{it} \quad (Eq. 8)$$

Here,  $CAR_{it}$  represents the cumulative abnormal return for firm  $i$  at event date  $t$ ,  $I_{it}$  is the interaction variable of interest,  $\alpha_i$  denotes firm fixed effects, and  $\delta_t$  captures year fixed effects based on the event year. The term  $\epsilon_{it}$  is the idiosyncratic error component.

In practical implementation, year fixed effects are included by adding a categorical variable for the year in which the FDA approval occurred. The interaction term remains defined at the firm-quarter level, matched to the approval date, consistent with the earlier models.

As in the previous stages, abnormal returns are computed using CAPM-based expected returns estimated from a 100-day pre-event window. CARs are calculated for six event

windows ranging from [0,0] to [-10,+10], and the panel is structured using firm identifiers (ISIN) and event dates.

The model is implemented in Python using the same packages as in the previous specification. Each event window is analyzed separately for both the full sample and the three biopharmaceutical subsectors. Year fixed effects are introduced through a categorical variable (EventYear) added to the regression formula. As before, regressions are run only on observations with complete financial and return data, and robust standard errors are used throughout. The full code for implementation is included in [Appendix F.4](#).

#### 3.4.4 Fixed Effects Model Justification (Hausman Test)

In panel data settings, particularly those involving firm-level financial information, the use of fixed effects is widely recognized as a standard approach to control for unobserved heterogeneity across entities. This is especially important in empirical settings where firm-specific characteristics such as size, investment intensity, or operating efficiency may influence both the explanatory variables and the outcome of interest.

As noted by Wooldridge (2010), fixed effects estimation is generally preferred when there is reason to believe that explanatory variables may be correlated with unobserved firm-level traits. Petersen (2009) further emphasizes that fixed effects models are commonly used in corporate finance and accounting research to address firm-specific omitted variables and serial correlation.

To empirically assess whether fixed effects are appropriate in the context of this thesis, a series of Hausman tests was conducted. These tests compare coefficient estimates from fixed effects and random effects regressions to determine whether unobserved firm-level heterogeneity is correlated with the regressors.

Three model specifications were selected for testing. Each model includes CARs following FDA approvals as the primary explanatory variable, along with one of the key financial interaction terms used in the empirical analysis: log-transformed total assets, R&D intensity, or asset turnover. All models were estimated using the (-5, +5) event window. Table 4 summarizes the results of the Hausman tests.

**Table 4:** Hausman Test Results for Model Specification Selection

Interaction Term	FE Coef.	RE Coef.	Hausman Stat	p-value	Preferred Model
Size	0,0044	0,0051	177,66	<0,0001 ***	Fixed Effects
R&D Intensity	0,0048	0,0047	24,13	<0,0001 ***	Fixed Effects

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Asset Turnover	0,0047	0,0046	8,22	0,0164 **	Fixed Effects
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Notes: The Hausman test evaluates the null hypothesis that the random effects estimator is consistent and efficient. Rejection of this null supports the use of fixed effects. Coefficients refer to the impact of FDA approval interacted with the respective variable on CARs in the (-5, +5) window. \*\*\*, \*\*, and \* denote significance at the 1%, 5%, and 10% levels, respectively.

All three tests reject the null hypothesis of no correlation between the explanatory variables and firm-specific effects. This confirms that random effects would produce inconsistent estimates and that fixed effects are the statistically appropriate model specification.

Based on both theoretical guidance and empirical evidence, all panel regressions presented in this thesis are estimated using firm fixed effects.

## 4. Results

### 4.1 Full Sample Results

This section presents the results of the regression analyses conducted on the full sample of publicly listed U.S. biopharmaceutical firms that received FDA drug approvals between 2014 and 2024. The purpose is to examine how firm-level characteristics influence the market reaction to these regulatory events, as measured by cumulative abnormal returns. The findings are structured around three tiers of model complexity: (i) OLS regressions without fixed effects, (ii) panel regressions with firm fixed effects, and (iii) panel regressions incorporating both firm and year fixed effects. Each specification is analyzed by interaction theme to evaluate how results evolve when accounting for heterogeneity across firms and over time. The selected regressions represent the most statistically robust and economically informative results, based on significance levels ( $p \leq 0,05$ ) and theoretical relevance; however, all regressions are presented in [Appendix G](#).

#### 4.1.1 Baseline OLS Regressions (No Fixed Effects)

The baseline OLS models offer an initial, unrestricted perspective on the relationship between FDA approval announcements and CARs, without accounting for firm-specific characteristics or year effects. The results from these regressions are summarized in Table 4.1.

**Table 5:** Selected OLS Regression Results (No Fixed Effects, Full Sample)

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Interaction Term	Event Window	Coefficient	Std. Error	t-Statistic	p-Value
No Interaction	-5_5	0,0329 ***	0,0090	3,603	<0,0001

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Size	-10_10	-0,0209 ***	0,0070	-2,850	0,0050
EBITDA_ROA	-10_10	-0,2339 **	0,0970	-2,421	0,0160
Asset Turnover	-5_5	-0,3030 ***	0,1060	-2,864	0,0040

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Notes: Each row reports results from a separate OLS regression of CARs on FDA approval and one interaction variable. No fixed effects are included. Coefficients represent the marginal effect of FDA approval interacted with the respective variable. Standard errors are robust. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

In the no interaction model, the coefficient for the CAR during the  $[-5,5]$  event window is 0,0329 ( $p < 0,01$ ), indicating that FDA approvals are associated with a statistically significant cumulative abnormal return of approximately 3,3% over an 11-day window. This effect size is both economically meaningful and consistent with prior literature suggesting that FDA approvals act as major valuation events in the biopharmaceutical sector. All event windows were significant.

Controlling for firm size using the logarithm of total assets, we find a significant negative relationship. In the  $[-10,10]$  window, the coefficient of  $-0,0209$  ( $p = 0,005$ ) implies that a  $171,8\%^2$  increase in firm size (i.e., a 1-unit increase in log assets) is associated with a 2,1 percentage point decrease in cumulative abnormal returns. This finding suggests that smaller firms derive more substantial valuation benefits from FDA approvals, potentially because such events represent larger proportional changes to their future revenue streams and risk profiles. This was also significant in all other windows exhibiting negative coefficients.

Profitability, measured as EBITDA relative to total assets, is also negatively associated with abnormal returns in the longer event window. Specifically, in the  $[-10,10]$  window, the coefficient is  $-0,2339$  ( $p = 0,016$ ), implying that less profitable firms tend to experience greater market reactions. This result may reflect investor optimism about the transformative potential of new drug approvals for firms with weaker operating fundamentals. This interaction was also significant in the  $[-5,5]$  window though with a lower coefficient.

Finally, asset turnover is significantly and negatively related to CARs in the  $[-5,5]$  window. The estimated coefficient of  $-0,3030$  ( $p = 0,004$ ) suggests that firms with higher pre-approval efficiency levels tend to experience smaller abnormal returns. This relationship remains significant across all tested event windows, with coefficients becoming progressively more negative as the windows expand. One possible interpretation is that approvals provide less marginal information to firms already performing well in terms of revenue generation relative to their asset base.

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<sup>2</sup> 1-unit increase in log assets:  $(e^1 - 1) \cdot 100 = 171,8\%$

Taken together, the OLS findings indicate that the market response to FDA approvals is not homogeneous but varies according to firm characteristics. Smaller, less efficient, and less profitable firms appear to benefit more strongly from approval events, providing early evidence for the moderating role of firm fundamentals.

### 4.1.2 Panel Regressions with Firm Fixed Effects

To address potential omitted variable bias due to unobservable, time-invariant firm characteristics (e.g., corporate culture, persistent R&D productivity), the analysis is extended using a fixed effects panel model. This specification isolates within-firm variation, thus yielding a cleaner estimate of the temporal relationship between interaction terms and CARs.

**Table 6:** Selected Results from Firm Fixed Effects Models (Full Sample)

Interaction Variable	Event Window	Coefficient	Std. Error	t-Statistic	p-Value
R&D Intensity	-10_10	2,0126 **	0,7798	2,581	0,0104
Capex Intensity	0_0	-0,7415 ***	0,2652	-2,796	0,0056
Size	-10_10	-0,2052 ***	0,0280	-7,316	<0,0001
EBITDA_ROA	-10_10	-1,1051 ***	0,2708	-4,080	<0,0001

Notes: Each row reports results from a separate regression using firm fixed effects. The dependent variable is CAR calculated from CAPM. Coefficients represent the marginal effect of FDA approval interacted with the specified interaction variable. Standard errors are robust. \*\*\*, \*\*, and \* denote significance at the 1%, 5%, and 10% levels, respectively.

The inclusion of firm fixed effects produces several notable changes in the significance and magnitude of interaction effects. Most prominently, R&D intensity, which was not significant in the OLS specification, becomes highly significant in the  $[-10,10]$  window with a coefficient of 2,0126 ( $p = 0,0104$ ). It is also significant in windows  $[0,0]$ ,  $[-3,3]$ , and  $[-5,5]$ . This suggests that for the same firm across time, higher R&D spending is associated with stronger market reactions to drug approvals. The result implies that the market perceives approvals from innovation-heavy firms as signals of long-term viability or pipeline validation.

Capex intensity enters as significantly negative in the  $[0,0]$  window, with a coefficient of  $-0,7415$  ( $p = 0,0056$ ). This suggests that firms with high levels of capital investment may experience smaller same-day abnormal returns, possibly because the market perceives high capex as a constraint on short-term financial flexibility or as an indication that future growth potential is already priced in.

The coefficient on firm size becomes substantially larger in absolute magnitude ( $-0,2052$  vs.  $-0,0209$  in OLS) for the  $[-10,10]$ , reinforcing the earlier finding that smaller firms tend to

benefit more from approvals. The increase in explanatory power after controlling for firm heterogeneity indicates that size is a robust interaction of the market response. It is once again significant in all windows.

Similarly, the negative relationship between profitability and CARs intensifies, with the coefficient on EBITDA/Assets falling to  $-1,1051$  ( $p = 0,0001$ ) in the  $[-10,10]$  window. The relationship is also significant in the longer event windows, but not in the immediate  $[0,0]$  and  $[-1,1]$  windows. This pattern suggests that the market may take additional time to fully incorporate profitability-related implications of FDA approvals, particularly for firms with lower earnings capacity. It further supports the interpretation that such approvals are more valuable to financially weaker firms, as the potential for a transformative impact on future performance becomes more apparent over time.

Overall, the fixed effects model reveals that the interaction effects of R&D, capex, profitability, and size are not spurious artifacts of between-firm differences but hold even within the same firm over time. This significantly strengthens the empirical basis for the interaction-based hypotheses articulated in the research question.

### 4.1.3 Panel Regressions with Firm and Year Fixed Effects

To further control for year-specific shocks, such as macroeconomic fluctuations, changes in healthcare policy, or industry sentiment, the model is extended to include year fixed effects. This final specification ensures that the estimated relationships are not confounded by temporal effects common across firms.

**Table 7:** Selected Results from Firm and Year Fixed Effects Models (Full Sample)

Interaction Variable	Event Window	Coefficient	Std. Error	t-Statistic	p-Value
R&D Intensity	-10_10	1,6446 **	0,6546	2,513	0,0127
Capex Intensity	0_0	-0,8125 ***	0,2341	-3,471	0,0006
Size	-10_10	-0,1353 ***	0,0391	-3,456	0,0007
EBITDA_ROA	-10_10	-0,7682 ***	0,2289	-3,356	0,0009

Notes: Each row reports results from a separate regression using firm and year fixed effects. The dependent variable is CAR calculated from CAPM. Coefficients represent the marginal effect of FDA approval interacted with the respective interaction variable. Standard errors are robust. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

The key interaction variables remain statistically significant in this final specification, indicating the robustness of the findings across different model assumptions. The coefficient for R&D intensity in the  $[-10,10]$  window decreases slightly to  $1,6446$  ( $p = 0,0127$ , standard

error = 0,6546), but remains significant, affirming that the market rewards innovation-intensive firms more for FDA successes even after accounting for economy-wide changes.

Capex intensity, evaluated over the [0,0] window, continues to be negatively associated with CARs, and remains statistically significant with a coefficient of  $-0,8125$  ( $p = 0,0006$ , standard error = 0,2341), suggesting greater estimation precision. Similarly, the effects of firm size and profitability, both assessed over the  $[-10,10]$  window, persist. The coefficient for  $\log(\text{Assets})$  is  $-0,1353$  ( $p = 0,0007$ , standard error = 0,0391), while EBITDA to assets shows a coefficient of  $-0,7682$  ( $p = 0,0009$ , standard error = 0,2289), indicating that both larger and more profitable firms experience smaller abnormal returns on average.

These results collectively demonstrate that firm-level financial and operational characteristics consistently influence the variation in investor reactions to FDA approval announcements. The evidence thus supports the central hypothesis that the abnormal return generated by an approval is conditional upon observable firm attributes, particularly innovation intensity, capital investment strategy, firm size, and earnings performance.

## 4.2 Subsector Results

This section presents the regression results disaggregated by biopharmaceutical subsector to assess whether the interaction effects of firm characteristics differ across distinct firm types within the healthcare industry. The subsectors analyzed are: (i) Non-System-Specific Biopharmaceuticals, (ii) Other Biopharmaceuticals, and (iii) System-Specific Biopharmaceuticals. The empirical analysis mirrors that of the full sample, with three tiers of model complexity, no fixed effects, firm fixed effects, and firm plus year fixed effects, estimated separately for each subsector.

The objective is to examine whether the strength or direction of interaction effects varies across strategic firm categories. This addresses a central component of the research question, which posits that both firm characteristics and business model segmentation may condition how markets respond to regulatory approvals.

### 4.2.1 System-Specific Biopharmaceuticals

#### 4.2.1.1 Baseline OLS Regressions (No Fixed Effects)

The baseline OLS regressions reveal strong positive abnormal returns across multiple event windows in response to FDA approvals. Without fixed effects, the estimates suggest that system-specific biopharmaceutical firms exhibit statistically significant CARs in all six

windows when no interaction variable is included. This indicates a robust baseline market reaction in this subsector.

Additionally, several interaction variables appear to influence the magnitude of this reaction. R&D intensity is significant in the immediate event window [0,0], suggesting that more research-intensive firms receive greater investor attention. Asset Turnover and EBITDA/Assets emerge as significant negative interaction terms, while firm size (Log Assets) shows a mild dampening effect.

**Table 8:** Significant OLS Regressions

Variable	Event Window	Coefficient	Std. Error	t-Stat	p-Value
No Interaction	-5_5	0,0544 ***	0,014	3,915	<0,0001
R&D Intensity	0_0	0,2649 ***	0,080	3,314	0,001
Size	-5_5	-0,0185 **	0,008	-2,339	0,021
EBITDA_ROA	0_0	-0,0904 ***	0,033	-2,709	0,007
Asset Turnover	-5_5	-0,4640 ***	0,168	-2,769	0,006
Asset Turnover	-10_10	-0,7623 ***	0,270	-2,820	0,005

Notes: Each row reports results from a separate OLS regression within the System-Specific Biopharmaceuticals subsector. The dependent variable is CAR, and each model includes an FDA approval indicator interacted with one interaction variable. Standard errors are robust. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

These results suggest that the positive CARs are most pronounced for firms with stronger research orientation and lower operating efficiency ratios. The negative effect of high asset turnover indicates that highly efficient firms do not benefit as strongly from FDA announcements in this subsector, possibly due to already embedded expectations.

#### ***4.2.1.2 Panel Regressions with Firm Fixed Effects***

Controlling for unobserved firm-level heterogeneity, the firm fixed effects specification largely preserves the strong positive CARs seen previously. In fact, the coefficients for the baseline response (no interaction) become even more pronounced, particularly for longer windows. For instance, the coefficient for [-5,5] increases to 0,0544 with a highly significant t-statistic of 4,3672 ( $p < 0,001$ ), reinforcing the robustness of the event impact.

Log(Assets) becomes even more strongly significant across all event windows, with the magnitude and significance increasing. This underscores a consistent pattern where larger firms exhibit a muted market response. Meanwhile, the interaction effect of EBITDA/Assets deepens as the window widens, with the coefficient at -1,4113 ( $p = 0,0006$ ) in the [-10,10] window, suggesting that profitability significantly dampens investor reactions to FDA approvals.

**Table 9:** Significant Firm Fixed Effects Regressions

Variable	Event Window	Coefficient	Std. Error	t-Stat	p-Value
No Interaction	-5_5	0,0544 ***	0,0125	4,3672	<0,001
R&D Intensity	0_0	0,3597 **	0,1767	2,0358	0,0440
Size	-10_10	-0,1850 ***	0,0374	-4,9481	<0,0001
EBITDA_ROA	-10_10	-1,4113 ***	0,4020	-3,510	0,0006
EBITDA_ROA	-5_5	-0,5116 **	0,2328	-2,198	0,0299
Asset Turnover	0_0	-0,1520 **	0,0712	-2,136	0,0347

Notes: Each row reports results from a separate OLS regression within the System-Specific Biopharmaceuticals subsector with firm fixed effects. The dependent variable is CAR, and each model includes an FDA approval indicator interacted with one interaction variable. Standard errors are robust. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

The fixed effects results confirm the importance of firm-specific characteristics in shaping investor responses. R&D intensity remains a positive interaction term, though its significance narrows to the shortest window. Meanwhile, profitability and firm size systematically reduce abnormal returns across longer windows.

#### 4.2.1.3 Panel Regressions with Firm and Year Fixed Effects

Once both firm and year fixed effects are included, only three significant interactions remain. R&D intensity continues to be positively associated with abnormal returns in the [0,0] window, reinforcing earlier findings. Capex intensity becomes significant with a negative coefficient (-0,6813,  $p = 0,0281$ ), suggesting that capital-intensive firms receive a more muted reaction.

Notably, EBITDA/Assets retains significance in the [-10,10] window, albeit with a smaller coefficient of -0,9354 compared to earlier specifications. This implies that the moderating effect of profitability remains robust even under more conservative estimation.

**Table 10:** Significant Firm + Year Fixed Effects Regressions

Variable	Event Window	Coefficient	Std. Error	t-Stat	p-Value
R&D Intensity	0_0	0,3597 **	0,1767	2,036	0,0440
Capex Intensity	0_0	-0,6813 **	0,3062	-2,225	0,0281
EBITDA_ROA	-10_10	-0,9354 **	0,4425	-2,114	0,0368

Notes: Each row reports results from a separate OLS regression within the System-Specific Biopharmaceuticals subsector with firm and year fixed effects. The dependent variable is CAR, and each model includes an FDA approval indicator interacted with one interaction variable. Standard errors are robust. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

Overall, the final specification strengthens the conclusion that firm-specific financial characteristics, especially those related to investment intensity and profitability, significantly moderate the market response to FDA announcements in system-specific biopharmaceuticals.

These patterns are directly relevant to the research question, as they provide clear evidence of heterogeneity in investor responses across firm types.

## 4.2.2 Non-System-Specific Biopharmaceuticals

### 4.2.2.1 Baseline OLS Regressions (No Fixed Effects)

In the simplest specification without fixed effects, only one regression is statistically significant at the 5% level. The estimated coefficient for the CAR in the [-2,2] event window is 0,0314 ( $p = 0,022$ ), indicating a positive market reaction to FDA approvals within this narrow window.

However, the overall lack of statistical significance across interaction variables in the OLS specification may reflect omitted variable bias or unobserved heterogeneity between firms. This model does not control for firm-specific characteristics or time trends, potentially attenuating the precision of the estimates.

**Table 11:** Significant OLS Regression

Variable	Event Window	Coefficient	Std. Error	t-Stat	p-Value
No Interaction	-2_2	0,0314 **	0,013	2,341	0,022

Notes: Each row reports results from a separate OLS regression within the Non-System-Specific Biopharmaceuticals subsector. The dependent variable is CAR, and each model includes an FDA approval indicator interacted with one interaction variable. Standard errors are robust. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

This initial result provides some evidence that investors respond positively to FDA approvals in this subsector, but the limitations of the OLS model likely mask more nuanced relationships.

### 4.2.2.2 Panel Regressions with Firm Fixed Effects

When firm-level fixed effects are included, a broader and more coherent set of statistically significant results emerges. The CARs remain significant in both the [0,0] and [-2,2] windows without any interaction variables, which reinforces the initial finding that positive market reactions exist, especially immediately following an FDA approval.

Several interaction variables also become significant. R&D intensity positively moderates CARs in the [-2,2] and [-5,5] windows, with coefficients of 0,5801 ( $p = 0,0373$ ) and 1,1420 ( $p = 0,0371$ ), respectively. This implies that firms with higher research investment receive more pronounced positive reactions in the days surrounding an approval.

Log-transformed assets consistently exhibit a negative interaction effect across all longer event windows. For example, the coefficient for Log(Assets) in the [-10,10] window is -0,2871 ( $p = 0,0001$ ), indicating that larger firms in this subsector experience more muted stock market responses.

Profitability, as measured by EBITDA/Assets, is negatively associated with abnormal returns across multiple event windows. In the [-5,5] window, the coefficient is -0,5694 ( $p = 0,0152$ ), suggesting that investors react less favorably to approvals from highly profitable firms, possibly due to already high expectations.

**Table 12:** Significant Firm Fixed Effects Regressions

Variable	Event Window	Coefficient	Std. Error	t-Stat	p-Value
No Interaction	0_0	0,0126 **	0,0051	2,447	0,0182
R&D Intensity	-5_5	1,1420 **	0,5318	2,147	0,0371
Size	-10_10	-0,2871 ***	0,0669	-4,293	0,0001
EBITDA_ROA	-5_5	-0,5694 **	0,2258	-2,522	0,0152
EBITDA_ROA	-10_10	-1,0147 **	0,4618	-2,197	0,0331

Notes: Each row reports results from a separate OLS regression within the Non-System-Specific Biopharmaceuticals subsector with firm fixed effects. The dependent variable is CAR, and each model includes an FDA approval indicator interacted with one interaction variable. Standard errors are robust. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

The sharp increase in significant results under firm fixed effects highlights the importance of controlling for firm-level heterogeneity. This specification allows for more precise estimation of how firm characteristics interact with event-driven market behavior, particularly in a subsector that may be less homogenous than system-specific biopharmaceuticals.

#### ***4.2.2.3 Panel Regressions with Firm and Year Fixed Effects***

Adding year fixed effects further tightens the estimation by accounting for macroeconomic and sector-wide shocks. The most consistent pattern remains the positive interaction effect of R&D intensity. The coefficient remains at 1,1420 in the [-5,5] window ( $p = 0,0371$ ), confirming the robustness of the result.

Capex intensity also becomes significant in the [-1,1] window, with a large positive coefficient of 2,0072 ( $p = 0,0039$ ), suggesting that capital-intensive firms in this subsector benefit strongly from FDA approvals. This pattern was not present in earlier specifications, potentially reflecting the importance of controlling for time variation in macroeconomic conditions that may correlate with capital expenditures.

EBITDA/Assets retains its negative moderating effect in the longest window, with a coefficient of -0,6778 ( $p = 0,0296$ ), providing further evidence that high profitability may dampen investor excitement around FDA-related news.

**Table 13:** Significant Firm + Year Fixed Effects Regressions

Variable	Event Window	Coefficient	Std. Error	t-Stat	p-Value
R&D Intensity	-5_5	1,1420 **	0,5318	2,147	0,0371
Capex Intensity	-1_1	2,0072 ***	0,6512	3,082	0,0039
EBITDA_ROA	-10_10	-0,6778 **	0,2992	-2,266	0,0296

Notes: Each row reports results from a separate OLS regression within the Non-System-Specific Biopharmaceuticals subsector with firm and year fixed effects. The dependent variable is CAR, and each model includes an FDA approval indicator interacted with one interaction variable. Standard errors are robust. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

The final model confirms that investor responses to FDA approvals in non-system-specific biopharmaceuticals are significantly shaped by firm-level financial characteristics, particularly those related to innovation, capital structure, and profitability. Notably, these patterns only become evident once firm and year-level variation are properly controlled for, emphasizing the role of interaction variables in explaining heterogeneity in market response.

## 4.2.3 Other Biopharmaceuticals

### 4.2.3.1 Baseline OLS Regressions (No Fixed Effects)

In the baseline OLS regressions, several interaction variables are significantly associated with CARs across a wide range of event windows. Most notably, R&D intensity is strongly and consistently positive, with significant coefficients in all windows from [-2,2] to [-10,10]. For instance, in the [-10,10] window, the coefficient is 2,9989 ( $p = 0,001$ ), indicating that firms with greater research investment receive considerably more favorable market reactions over the long run. The persistence of significance across shorter windows like [-1,1] (0,9098,  $p = 0,001$ ) and medium-term windows like [-5,5] (1,8450,  $p = 0,002$ ) suggests that innovation is rewarded both immediately and over time in this subsector.

Profitability, measured by EBITDA/Assets, shows a consistently negative interaction with CARs. The coefficient in the [-2,2] window is -0,5842 ( $p < 0,0001$ ), and it remains negative and significant in all tested windows. The strongest effect is observed in the [-10,10] window (-1,3014,  $p < 0,0001$ ), indicating that highly profitable firms in this group receive more muted market responses to FDA approvals.

Asset turnover also appears negatively associated with CARs in the [-2,2] window (-0,4298,  $p = 0,012$ ), though this effect is not robust across other windows in this specification.

**Table 14:** Significant OLS Regressions

Variable	Event Window	Coefficient	Std. Error	t-Stat	p-Value
R&D Intensity	-10_10	2,9989 ***	0,896	3,346	0,001
EBITDA_ROA	-10_10	-1,3014 ***	0,313	-4,154	<0,0001
R&D Intensity	-5_5	1,8450 ***	0,570	3,236	0,002
EBITDA_ROA	-5_5	-0,8201 ***	0,199	-4,128	<0,0001
R&D Intensity	-1_1	0,9098 ***	0,263	3,463	0,001

Notes: Each row reports results from a separate OLS regression within the Other Biopharmaceuticals subsector. The dependent variable is CAR, and each model includes an FDA approval indicator interacted with one interaction variable. Standard errors are robust. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

These findings point to clear patterns in investor behavior: innovation is rewarded, while high profitability may signal maturity or limited growth, leading to more subdued stock price reactions.

#### 4.2.3.2 Panel Regressions with Firm Fixed Effects

Once firm-level fixed effects are introduced, the breadth of significant results narrows, but the key patterns persist. R&D intensity remains significantly positive in the [-2,2] window (1,8519,  $p = 0,0388$ ), supporting the earlier findings, though fewer windows remain significant. This drop may be due to the removal of firm-level bias that previously inflated estimates, especially among smaller, R&D-heavy firms.

Firm size, proxied by Log(Assets), now appears as a consistently negative interaction across nearly all event windows. In the [-10,10] window, the coefficient is -0,2466 ( $p = 0,0001$ ), indicating that larger firms in this subsector receive weaker investor responses to FDA approvals. This may reflect market expectations already being priced in for well-established firms.

EBITDA/Assets maintains its negative influence, though fewer windows remain significant. In the [-2,2] window, the coefficient is -0,3844 ( $p = 0,0075$ ), and a weaker but still significant effect is seen in the [-3,3] window (-0,5608,  $p = 0,0371$ ). Asset turnover is again negatively related to CARs, with a coefficient of -0,2824 ( $p = 0,0135$ ) in the [-2,2] window.

**Table 15:** Significant Firm Fixed Effects Regressions

Variable	Event Window	Coefficient	Std. Error	t-Stat	p-Value
R&D Intensity	-2_2	1,8519 **	0,872	2,124	0,0388
Size	-10_10	-0,2466 ***	0,0582	-4,235	0,0001
EBITDA_ROA	-2_2	-0,3844 ***	0,1380	-2,786	0,0075
Asset Turnover	-2_2	-0,2824 **	0,1102	-2,562	0,0135

Notes: Each row reports results from a separate OLS regression within the Other Biopharmaceuticals subsector with firm fixed effects. The dependent variable is

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CAR, and each model includes an FDA approval indicator interacted with one interaction variable. Standard errors are robust. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

The re-emergence of asset-based and profitability interaction terms at this stage underscores the importance of firm-level heterogeneity in explaining market responses to FDA events.

#### **4.2.3.3 Panel Regressions with Firm and Year Fixed Effects**

When year-level controls are included, most results are attenuated, though the main signals remain. R&D intensity continues to positively influence CARs in the [-2,2] window (1,8519,  $p = 0,0388$ ), replicating the earlier fixed effects estimate exactly, which suggests temporal shocks had limited influence on this interaction.

Log(Assets) remains negative in the [-10,10] window (-0,1740,  $p = 0,0269$ ), suggesting a persistent size effect. Additionally, EBITDA/Assets continues to exert a negative effect in the [-2,2] (-0,3009,  $p = 0,0224$ ) and [-3,3] (-0,4764,  $p = 0,0306$ ) windows, reinforcing the profitability pattern observed throughout.

**Table 16:** Significant Firm + Year Fixed Effects Regressions

Variable	Event Window	Coefficient	Std. Error	t-Stat	p-Value
R&D Intensity	-2_2	1,8519 **	0,872	2,124	0,0388
Size	-10_10	-0,1740 **	0,0757	-2,297	0,0269
EBITDA_ROA	-2_2	-0,3009 **	0,1266	-2,376	0,0224
EBITDA_ROA	-3_3	-0,4764 **	0,2125	-2,242	0,0306

Notes: Each row reports results from a separate OLS regression within the Other Biopharmaceuticals subsector with firm and year fixed effects. The dependent variable is CAR, and each model includes an FDA approval indicator interacted with one interaction variable. Standard errors are robust. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

Compared to earlier subsectors, the findings in this group reinforce the overall research question: financial characteristics, particularly those reflecting innovation and profitability, significantly shape how investors respond to FDA drug approval announcements. Even under stricter controls, these effects persist, particularly for firms that are not easily categorized into system-specific or non-system-specific groups, highlighting the broader applicability of the interaction-based approach.

#### **4.2.4 Cross-Subsector Summary of Key Interaction Effects**

Across all subsectors, the interaction between firm characteristics and CARs reveals consistent patterns. The most robust finding is the positive effect of R&D intensity, particularly in Other Biopharmaceuticals, where significance holds across all windows. The effect is also present in System-Specific and Non-System-Specific groups, especially around

[0,0], [-2,2], and [-5,5]. This suggests that innovation-driven firms are more strongly rewarded by the market upon FDA approval.

Firm size, measured by log-transformed total assets, shows a consistent negative relationship with CARs across all subsectors, especially in wider windows like [-5,5] and [-10,10]. This indicates that larger firms tend to experience more muted reactions, likely due to diversification effects.

Profitability, proxied by EBITDA/Assets, also exhibits a negative relationship in all three subsectors, with effects most pronounced in longer windows such as [-5,5] and [-10,10]. This suggests that growth-oriented firms are more sensitive to approval news than already profitable ones.

Asset turnover has a negative effect in System-Specific and Other Biopharmaceuticals, but no effect in the Non-System-Specific group. Capex intensity shows limited and isolated significance and does not emerge as a robust factor.

In summary, R&D intensity, firm size, and profitability are the most reliable interaction variables shaping investor responses to FDA approvals, aligning with the central research focus.

### 4.3 Additional Robustness Checks

#### 4.3.1 Clustered Standard Errors

To address potential intra-firm correlation in residuals, the main regressions were re-estimated using standard errors clustered at the firm level ([Appendix F.5.1](#)). Table 11 presents the results for the full sample with firm and year fixed effects.

**Table 11:** Robustness Check Using Clustered Standard Errors (Firm and Year Fixed Effects, Full Sample)

Interaction Variable	Event Window	Coefficient	Std. Error	t-Statistic	p-Value
R&D Intensity	(-10,10)	1,6446 ***	0,5744	2,8630	0,0046
Capex Intensity	(0,0)	-0,8125 ***	0,2381	-3,4128	0,0008
EBITDA_ROA	(-10,10)	-0,7682 ***	0,1995	-3,8501	0,0002
Size	(-10,10)	-0,1353 ***	0,0363	-3,7254	0,0002

Notes: Each row reports results from a separate regression using firm and year fixed effects on the full sample. Regressions are based on CAPM and use standard errors clustered by firm. The dependent variable is CAR. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

The findings remain robust. R&D intensity continues to have a positive and statistically significant association with CARs (coefficient: 1,645,  $p = 0,0046$ ). Capex intensity retains a

negative effect ( $-0,813$ ,  $p = 0,0008$ ), indicating that capital-intensive firms experience more muted market reactions. Profitability, proxied by EBITDA-to-assets, is also significant ( $-0,768$ ,  $p = 0,0002$ ), reinforcing that firms with stronger earnings respond less to approval events. Notably,  $\log(\text{assets})$  becomes highly significant ( $-0,135$ ,  $p = 0,0002$ ), suggesting that the size effect observed earlier was understated under standard errors that did not account for firm-level dependence.

These results confirm that the effects of innovation, profitability, and size remain robust under more conservative inference.

### 4.3.2 Alternative Return Model: Fama-French Three-Factor

The main regressions were also re-estimated using abnormal returns based on the Fama-French three-factor model to assess sensitivity to return model choice. This model adjusts for market, size (SMB), and value (HML) factors. The data for these factors was sourced from the Fama/French Data Library<sup>3</sup> (French, 2025). Regressions were estimated using a new python script presented in [Appendix F.5.2](#). Results are reported in Table 12.

**Table 12:** Robustness Check Using Fama–French Three-Factor Model (Firm and Year Fixed Effects, Full Sample)

Interaction Variable	Event Window	Coefficient	Std. Error	t-Statistic	p-Value
R&D Intensity	(-10,10)	1,0203 ***	0,2737	3,7278	0,0002
Capex Intensity	(0,0)	-0,7112 ***	0,2552	-2,7866	0,0058
EBITDA_ROA	(-10,10)	-0,3334 **	0,1494	-2,2310	0,0266
Size	(-10,10)	-0,0301	0,0252	-1,1944	0,2335

Notes: Each row reports results from a separate regression using firm and year fixed effects on the full sample, replacing CAPM with the Fama–French three-factor model. The dependent variable is CAR. Standard errors are robust. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

R&D intensity remains positive and highly significant ( $1,020$ ,  $p = 0,0002$ ), while Capex intensity retains a negative and significant coefficient ( $-0,711$ ,  $p = 0,0058$ ). Profitability continues to exhibit a negative association ( $-0,333$ ,  $p = 0,0266$ ). However,  $\log(\text{assets})$  is no longer statistically significant ( $-0,030$ ,  $p = 0,234$ ). This reduction in significance is consistent with the inclusion of the SMB factor, which captures variation previously attributed to firm size. The result suggests that the size effect observed under CAPM may be partly due to priced risk rather than firm-specific characteristics.

<sup>3</sup> [https://mba.tuck.dartmouth.edu/pages/faculty/ken.french/ftp/F-F\\_Research\\_Data\\_Factors\\_daily\\_CSV.zip](https://mba.tuck.dartmouth.edu/pages/faculty/ken.french/ftp/F-F_Research_Data_Factors_daily_CSV.zip)

Together, these checks support the robustness of the primary findings, particularly for R&D and profitability, while highlighting that the effect of firm size is more sensitive to model specification.

## 5. Concluding Remarks

### 5.1 Discussion

This thesis has demonstrated that FDA drug approvals yield statistically significant abnormal stock returns among U.S. biopharmaceutical firms. However, these market reactions are not uniform; they are shaped by firm-level financial characteristics that influence how investors interpret and price the informational value of such regulatory events. The findings support the semi-strong form of the Efficient Market Hypothesis (Fama, 1970), indicating that markets absorb new, value-relevant information quickly. At the same time, consistent with signaling theory (Spence, 1973; Connelly et al., 2011), the magnitude of the stock price reaction depends not only on the occurrence of an FDA approval but also on which type of firm receives it.

Smaller firms show significantly larger abnormal returns following approval announcements. This pattern reflects higher investor sensitivity to developments that may transform the firm's future outlook, particularly in cases where a single product drives expected cash flows. For such firms, approvals often represent a transition from development to commercialization, reducing information asymmetry and signaling increased viability. In contrast, larger and more diversified firms tend to exhibit weaker stock responses, possibly because new approvals have limited marginal value relative to existing product portfolios (Barney, 1991), or because investor expectations are already reflected in market prices.

R&D intensity emerges as the strongest positive interaction variable across models and subsectors. This confirms that investors reward firms perceived to be research-driven, especially in more innovation-oriented subsectors such as Other Biopharmaceuticals. These results align with prior research emphasizing the role of innovation signaling in investor reactions to R&D activity (Chan et al., 2001). FDA approval serves as validation of a firm's technological capabilities and strengthens confidence not only in the approved product but also in the firm's broader development pipeline.

In contrast, high profitability, measured by EBITDA-to-assets, is associated with weaker abnormal returns. This suggests that approval events offer less informational surprise for already profitable firms, potentially due to their stronger financial visibility and broader revenue bases. Capex intensity also shows a consistently negative interaction where significant, particularly in the short window [0,0]. This supports the idea that high investment levels may dampen the market's immediate response, possibly due to concerns about capital efficiency or future flexibility. Asset turnover delivers weaker and more model-sensitive effects but suggests that highly efficient firms may generate fewer valuation surprises, consistent with a lower risk-return profile.

The interaction between firm characteristics and market response is also influenced by business model differences. System-Specific Biopharmaceuticals demonstrate the highest baseline abnormal returns, reflecting concentrated product strategies and narrower pipelines. In comparison, Other and Non-System-Specific Biopharmaceuticals show more pronounced interaction effects, particularly with innovation and profitability measures. These patterns indicate that investor expectations are not only conditioned by financial indicators but also shaped by the firm's strategic context and therapeutic focus.

### **5.1.1 Implications**

The findings have important implications for investors, pharmaceutical managers, and regulators. For investors, especially those focused on event-driven or sector-specific strategies, firm-level characteristics offer a valuable lens for assessing the likely market response to FDA approvals. Smaller firms with high R&D intensity tend to yield stronger positive reactions but may also carry higher risk due to uncertainty and limited diversification. These dynamics are especially relevant for institutional investors seeking to identify asymmetric return opportunities around regulatory catalysts. Long-term investors can also benefit by incorporating firm attributes such as innovation capacity and profitability into valuation frameworks (Donovan, 2019).

Pharmaceutical managers can use these insights to shape strategic decisions and investor communication around approval milestones. For smaller firms, approval events provide opportunities to raise capital, attract licensing or acquisition interest, and reinforce credibility. The consistent market premium associated with innovation-focused firms indicates that maintaining a robust pipeline and communicating R&D progress remain essential for market positioning. Larger firms, whose valuation gains from single approvals are more modest, may

emphasize consistency and scalability across broader portfolios to sustain investor confidence (Teece, 1986).

For regulators, the findings highlight the capital market relevance of transparent and predictable approval processes. The strong investor response to breakthrough and orphan designations supports the notion that regulatory signals carry meaningful financial implications (Ahmed et al., 2002; Miller, 2017). These programs not only accelerate access to treatment for patients with unmet medical needs but also encourage continued private-sector investment in high-risk therapeutic areas. Maintaining the credibility and efficiency of such programs is therefore essential both from a public health and market perspective.

In sum, FDA approvals are not interpreted in isolation by the market. Their valuation impact is mediated by firm-level characteristics and business models that shape investor expectations. This underscores the importance of considering financial fundamentals when evaluating regulatory news and contributes to a more detailed understanding of how capital markets respond to health innovation.

## **5.2 Conclusion**

The analysis conducted in this thesis provides clear evidence that FDA drug approval announcements generate statistically and economically meaningful stock market reactions among U.S. biopharmaceutical firms. However, the magnitude and direction of these reactions are not uniform. Instead, they are systematically shaped by firm-level financial characteristics and differ across business models within the sector.

The results demonstrate that cumulative abnormal returns are consistently positive across all event windows, affirming the valuation relevance of regulatory approval events. Yet, this effect is amplified or dampened depending on a firm's size, R&D investment, profitability, and capital intensity. Smaller firms exhibit stronger market reactions, reflecting the greater informational impact of approvals for companies with limited revenue bases and fewer diversification options. R&D intensity strengthens the market response across all model specifications and subsectors, reinforcing the notion that investors reward firms perceived to be research-driven. Conversely, profitability and capital expenditures are generally associated with weaker abnormal returns, suggesting that markets may interpret high earnings or investment intensity as indicators of lower marginal gains from individual drug approvals.

The subsector-level analyses reinforce the role of business model heterogeneity. Firms categorized as System-Specific Biopharmaceuticals show the highest baseline responses to approvals, while firms in the Other and Non-System-Specific groups exhibit stronger sensitivity to interaction variables such as R&D intensity and profitability. These patterns confirm that approval effects are not only shaped by firm traits but also by the strategic context in which these firms operate.

Robustness checks further validate these conclusions. The core results remain consistent when clustered standard errors are applied, and most findings persist when abnormal returns are recalculated using the Fama-French three-factor model. Although the effect of firm size becomes less pronounced under the latter specification, likely due to the inclusion of a size factor, the impacts of innovation intensity, profitability, and capital expenditures remain intact. This supports the generalizability of the findings and underlines the reliability of the empirical design.

Taken together, the findings provide a comprehensive answer to the research question by showing that the market does not respond to FDA approvals in isolation but rather in the context of who the firm is. Financial characteristics condition the extent to which approval events translate into valuation gains, and this relationship holds across both the full sample and within distinct subsectors. Each hypothesis tested is either confirmed or partially supported in a manner consistent with both theory and empirical evidence. In doing so, this thesis contributes to a more nuanced understanding of how firm fundamentals shape investor interpretation of regulatory news.

While the focus here has been on approval events, future research may explore the effects of negative regulatory outcomes such as rejections, clinical trial failures, or regulatory delays. Additionally, analyzing how investor sentiment, media framing, or information diffusion mediates the market reaction could offer further insight into behavioral dimensions. Finally, considering cross-border spillovers in global markets could enrich understanding of how FDA decisions influence not only domestic valuations but also international competitors and suppliers.

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# Appendix

## Appendix A: Variable Definitions

Variable Name	Definition	Construction / Source	Unit / Format
<b>CAR</b>	Cumulative Abnormal Return over specified event window	Actual return minus expected CAPM return using 100-day estimation window	Percentage (%)
<b>Return</b>	Daily stock return of each firm	$\frac{P_{t+1}}{P_t} - 1$ , where $P_t$ is closing price on day $t$	Decimal
<b>S&amp;P 500</b>	Daily return of the S&P 500 index	Downloaded from FactSet	Decimal
<b>RiskFreeRate (RF)</b>	Daily U.S. 10-year Treasury yield	Downloaded from FRED (constant maturity)	Percentage (%)
<b>Excess Return</b>	Return minus RiskFreeRate	Return – RiskFreeRate	Decimal
<b>Excess Market</b>	S&P 500 return minus RiskFreeRate	S&P 500 – RiskFreeRate	Decimal
<b>FDA Approved</b>	Dummy variable equal to 1 on FDA approval date	Constructed from submission_status_date, matched to nearest trading day	Binary (0/1)
<b>R&amp;D Intensity</b>	Research and Development expenditures relative to total assets	$\frac{R\&D}{Total\ Assets}$	Ratio
<b>Capex Intensity</b>	Capital expenditures relative to total assets	$\frac{Capex}{Total\ Assets}$	Ratio
<b>Size</b>	Natural logarithm of total assets	$\log(Total\ Assets)$	Log-transformed
<b>Leverage</b>	Total debt relative to total assets	$\frac{Total\ Debt}{Total\ Assets}$	Ratio
<b>EBITDA_ROA</b>	Operating profitability (EBITDA over total assets)	$\frac{EBITDA}{Total\ Assets}$	Ratio
<b>Asset Turnover</b>	Efficiency ratio, measured as sales over total assets	$\frac{Sales}{Total\ Assets}$	Ratio
<b>ISIN</b>	International Securities Identification Number	Used as firm identifier	String (alphanumeric)
<b>Date</b>	Calendar date of each observation	Matched for returns and financial data	DD-MM-YYYY
<b>EventDate</b>	Date on which a firm received FDA approval	From submission_status_date, matched to trading calendar	DD-MM-YYYY
<b>EventYear</b>	Calendar year of the FDA approval event	Extracted from EventDate	Integer
<b>Subsector_</b>	Dummy variables for firm classification by biopharma subsector	Constructed from FactSet RBICS industry codes	Binary (0/1)

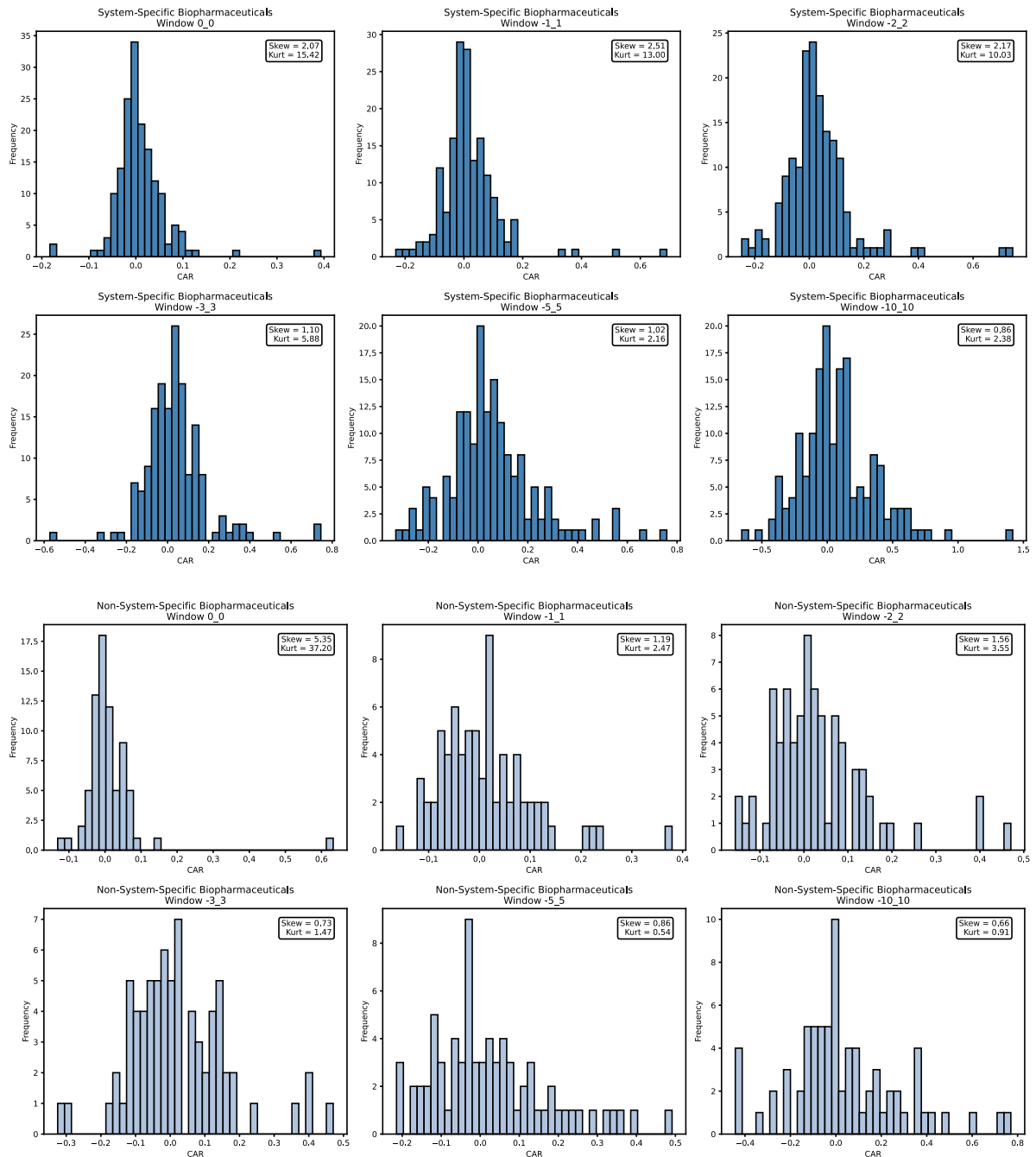
## Appendix B: Extended Summary Statistics

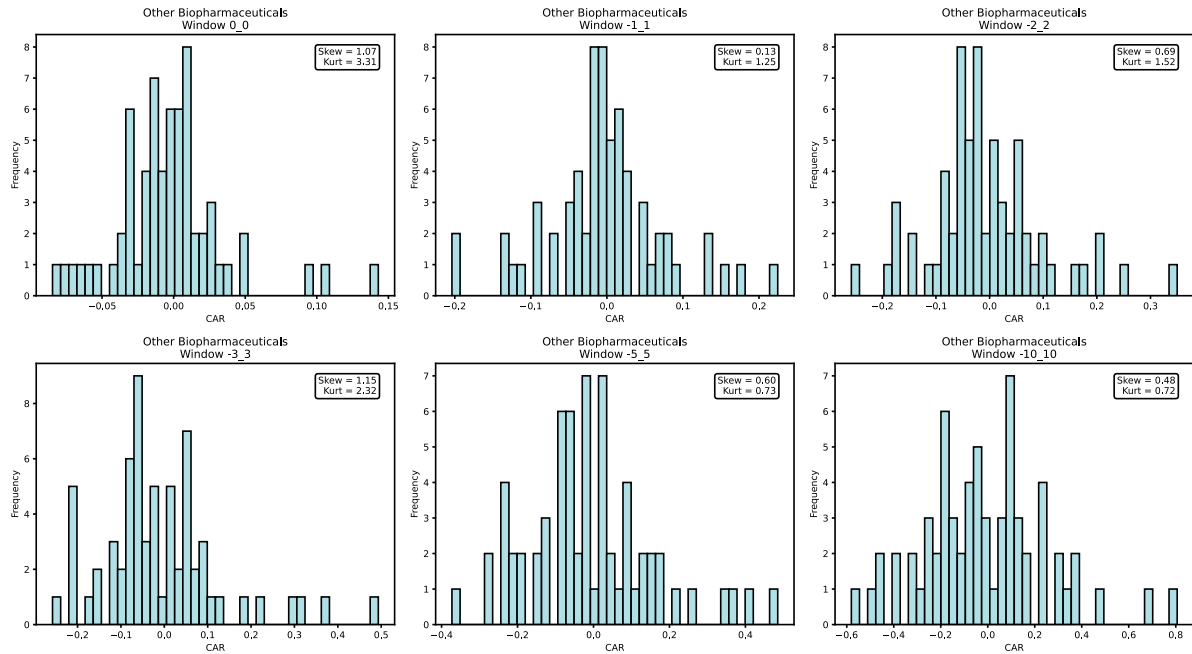
Variable	mean	median	std	min	p25	p75	max	N	skewness	kurtosis
FDA_Appr.	0,013	0,000	0,113	0,000	0,000	0,000	1,000	222.322	8,582	71,651
Total Assets	9.867,548	356,499	28.681,884	0,347	132,047	1.782,263	226.501,000	221.694	4,050	18,205
Capex	47,809	0,615	175,749	-188,452	0,061	9,869	4.170,800	220.603	10,166	177,727
Sales	1.013,639	23,286	2.837,791	-3,300	1,303	169,915	27.742,000	221.919	3,832	17,226
EBITDA	360,854	-6,215	1.189,989	-3.995,000	-24,833	33,541	14.122,000	220.017	4,105	21,093
EBIT	258,949	-7,023	923,465	-4.898,000	-26,379	20,812	12.947,000	221.919	4,475	29,497
Net Income	154,510	-8,319	809,138	-11.911,000	-30,474	9,007	12.273,000	221.919	2,850	61,189
R&D	210,833	19,948	590,638	-4,347	6,219	83,061	12.894,000	221.122	6,671	87,297
Total Debt	3.596,850	55,294	10.761,539	0,000	2,011	495,787	87.432,000	221.574	3,961	17,694
RF	0,024	0,024	0,010	0,005	0,018	0,030	0,050	222.322	0,355	-0,390
Return	-0,000	0,000	0,044	-1,552	-0,017	0,016	1,672	222.322	-0,005	101,716
S&P 500	0,000	0,001	0,011	-0,128	-0,004	0,006	0,090	222.322	-0,826	16,296

RD_Int.	0,073	0,050	0,117	-0,231	0,021	0,092	2,684	220.960	11,079	191,967
Capex_Int.	0,005	0,002	0,018	-0,056	0,000	0,005	0,579	220.540	18,701	473,082
EBITDA_Int.	-0,068	-0,053	0,182	-3,859	-0,119	0,027	2,567	219.885	-6,553	122,187
Debt_Int.	0,285	0,214	0,334	0,000	0,013	0,433	3,442	221.574	2,403	10,640
Log_Assets	6,378	5,876	2,297	-1,059	4,883	7,486	12,331	221.694	0,697	0,100
Sales_Int.	0,090	0,079	0,102	-0,054	0,010	0,135	3,278	221.694	9,644	271,588

Notes: This table reports summary statistics for the full set of variables used in the empirical analysis. All monetary values are in millions of U.S. dollars (mUSD). Interaction terms are also included. All interaction terms have been normalized. "FDA Appr." is a binary variable equal to 1 on FDA approval days. Skewness and kurtosis measure distributional characteristics. Compared to Table 1, this appendix table includes the full set of interaction variables.

## Appendix B.1: Subsector CAR Distribution





### Distribution of CARs Across Event Windows for each Subsector

This figure displays histograms of CARs around FDA approval events for six event windows: (0,0), (-1,1), (-2,2), (-3,3), (-5,5), and (-10,10). CARs are calculated using the CAPM model with a 100-day estimation window. Each panel reports the distribution of CARs across all firm-event observations in the full sample, along with the skewness and kurtosis for each window.

## Appendix C: Name Matching Script

```
import pandas as pd
from sentence_transformers import SentenceTransformer, util
from rapidfuzz import fuzz, process

def read_firm_names(filepath):
    df = pd.read_excel(filepath)
    firm_names = df.iloc[:, 0].dropna().astype(str).tolist()
    return firm_names

def match_with_embeddings(list1, list2, threshold=0.8):
    model = SentenceTransformer('all-MiniLM-L6-v2')
    emb1 = model.encode(list1, convert_to_tensor=True)
    emb2 = model.encode(list2, convert_to_tensor=True)

    matches = []
    for i, firm1_vec in enumerate(emb1):
        cos_scores = util.cos_sim(firm1_vec, emb2)[0]
        best_idx = cos_scores.argmax()
        best_score = cos_scores[best_idx].item()
        if best_score >= threshold:
            matches.append((list1[i], list2[best_idx], round(best_score, 3)))
    return matches

def match_with_fuzzy(list1, list2, threshold=80):
    matches = []
    for firm1 in list1:
        best_match, score, _ = process.extractOne(firm1, list2, scorer=fuzz.token_sort_ratio)
        if score >= threshold:
```

```

        matches,append((firm1, best_match, score))
    return matches

def save_results(matches, output_path):
    df = pd.DataFrame(matches, columns=["Firm List 1", "Matched Firm List 2", "Score"])
    df.to_excel(output_path, index=False)
    print(f"Match results saved to {output_path}")

def match_firms_excel(file1, file2, output_file="matched_firms.xlsx", method="embedding"):
    list1 = read_firm_names(file1)
    list2 = read_firm_names(file2)

    if method == "embedding":
        print("Using semantic matching with embeddings,,,")
        matches = match_with_embeddings(list1, list2)
    else:
        print("Using fuzzy string matching,,,")
        matches = match_with_fuzzy(list1, list2)

    save_results(matches, output_file)

# Entering File Names
file_path_1 = "Drug Approval Firms.xlsx"
file_path_2 = "Factset.xlsx"

match_firms_excel(file_path_1, file_path_2, output_file="Drug Approval Firms Matched 2.xlsx",
method="embedding")

```

## Appendix D: Financial Data Script

```

import pandas as pd

# Loading FDA data with dates
panel = pd.read_excel("panel_data.xlsx")
panel['Date'] = pd.to_datetime(panel['Event_Trading_Date'])

# Load quarterly financial matrix
quarterly = pd.read_excel("Quarterly_Data.xlsx", index_col=0)
quarterly.index = pd.to_datetime(quarterly.index)
quarterly = quarterly.sort_index()

# Function to find closest previous quarter
def get_closest_quarter(date, available_dates):
    prev_quarters = available_dates[available_dates <= date]
    return prev_quarters.max() if not prev_quarters.empty else None

# Loop through panel and adding financials
sizes = []
for _, row in panel.iterrows():
    isin = row['ISIN']
    event_date = row['Date']

    if isin not in quarterly.columns:
        sizes.append(None)
        continue

```

```

quarter = get_closest_quarter(event_date, quarterly, index)
if quarter is not None:
    size = quarterly.at[quarter, isin]
    sizes.append(size)
else:
    sizes.append(None)

# Add new column to panel data
panel['Financial Data'] = sizes

# Save to Excel
panel.to_excel("panel_with_quarter.xlsx", index=False)

```

## Appendix E: Approval Dummy Script

```

# Loading the panel data
returns_df = pd.read_excel('abnormal_returns_long.xlsx')

# Loading the FDA approvals
approvals_df = pd.read_excel('Drug Approvals.xlsx', sheet_name='10Y')

# Converting date columns to datetime
returns_df['Date'] = pd.to_datetime(returns_df['Date'])
approvals_df['submission_status_date'] = pd.to_datetime(approvals_df['submission_status_date'])

# Filtering relevant columns
approvals_df = approvals_df[['ISIN', 'submission_status_date', 'submission_status']]

# Creating two sets: one for AP and one for TA
approved_set = set(approvals_df[approvals_df['submission_status'] == 'AP']
                    , apply(lambda row: (row['ISIN'], row['submission_status_date']), axis=1))

# Function to generate dummies
def check_dummy(row, approval_set):
    return int((row['ISIN'], row['Date']) in approval_set)

# Add dummy columns
returns_df['FDA_Approved'] = returns_df.apply(lambda row: check_dummy(row, approved_set), axis=1)
returns_df['FDA_Tentative'] = returns_df.apply(lambda row: check_dummy(row, tentative_set), axis=1)

# Save to Excel
returns_df.to_excel('abnormal_returns_with_fda_flags.xlsx', index=False)

```

## Appendix F: Python Codes

This appendix presents the code used for the analysis. For brevity, only one example of the regression code is shown, as the same structure is applied to all interaction terms.

### Appendix F.1: Descriptive Statistics

```

# Installing needed packages
!pip install linearmodels

import pandas as pd
import numpy as np
import seaborn as sns
import matplotlib.pyplot as plt

```

```
import statsmodels.api as sm
from statsmodels.stats.outliers_influence import variance_inflation_factor
from statsmodels.tools.tools import add_constant

from linearmodels.panel import PanelOLS, RandomEffects, compare
from scipy.stats import chi2, skew, kurtosis
```

## Appendix F.1.1: Summary Statistics, Corr. Matrix & VIFs Scripts

### Summary Statistics

```
# Load dataset
file_path = '/content/abnormal_returns_with_financial.xlsx'
df = pd.read_excel(file_path, sheet_name='Sheet1')

# Create moderator variables if not already present
df['RD_Intensity'] = df['R&D'] / df['Total Assets']
df['Capex_Intensity'] = df['Capex'] / df['Total Assets']
df['EBITDA_Intensity'] = df['EBITDA'] / df['Total Assets']
df['Debt_Intensity'] = df['Total Debt'] / df['Total Assets']
df['Sales_Intensity'] = df['Sales'] / df['Total Assets']
df['Log_Assets'] = df['Total Assets'].apply(lambda x: np.log(x) if x > 0 else None)

# Variables used in regressions
variables = [
    'FDA Approved', 'Total Assets', 'Capex', 'Sales', 'EBITDA', 'EBIT', 'Net Income', 'R&D', 'Total Debt',
    'RiskFreeRate', 'Return', 'S&P 500',
    'RD_Intensity', 'Capex_Intensity', 'EBITDA_Intensity', 'Debt_Intensity', 'Log_Assets',
    'Sales_Intensity'
]

# Compute base summary statistics
summary_stats = df[variables].describe(percentiles=[.25, .5, .75]).T
summary_stats = summary_stats.rename(columns={
    "25%": "p25", "50%": "median", "75%": "p75"
})[['mean', 'median', 'std', 'min', 'p25', 'p75', 'max']]

# Add observation count (N), skewness, and kurtosis
summary_stats['N'] = df[variables].count()
summary_stats['skewness'] = df[variables].skew()
summary_stats['kurtosis'] = df[variables].kurtosis()

# Round for cleaner display
summary_stats = summary_stats.round(3)

# Print result
print(summary_stats)

# Optional: export to CSV
summary_stats.to_csv("summary_statistics_extended.csv", index=True)

# Optional: export to LaTeX
with open("summary_statistics_extended.tex", "w") as f:
    f.write(summary_stats.to_latex(float_format="%.3f"))
```

### Subsample Count

```
# Load your data (if not already loaded)
file_path = '/content/abnormal_returns_with_financial.xlsx'
df = pd.read_excel(file_path, sheet_name='Sheet1')

# Subsector dummy columns
subsector_cols = [
    'Subsector_Non-System-Specific Biopharmaceuticals',
    'Subsector_System-Specific Biopharmaceuticals',
    'Subsector_Other Biopharmaceuticals'
]

# Subsector names for readability
subsector_names = {
    'Subsector_Non-System-Specific Biopharmaceuticals': 'Non-System-Specific Biopharmaceuticals',
    'Subsector_System-Specific Biopharmaceuticals': 'System-Specific Biopharmaceuticals',
    'Subsector_Other Biopharmaceuticals': 'Other Biopharmaceuticals'
}

# Initialize result container
results = []

for col in subsector_cols:
```

```

# Filter rows where this subsector is 1
subset = df[df[col] == 1]

# Unique firms
firm_count = subset['ISIN'].nunique()

# Total observations (firm-day level)
observation_count = subset.shape[0]

# Append to results
results.append({
    'Subsector': subsector_names[col],
    'Number of Firms': firm_count,
    'Number of Observations': observation_count
})

# Convert to DataFrame
subsector_table = pd.DataFrame(results)

# Display
print(subsector_table)

# Optional: Export to CSV or LaTeX
subsector_table.to_csv("subsector_counts.csv", index=False)

with open("subsector_counts.tex", "w") as f:
    f.write(subsector_table.to_latex(index=False, float_format="%.0f"))

```

## Correlation Matrix

```

# Load data
file_path = '/content/abnormal_returns_with_financial.xlsx'
df = pd.read_excel(file_path, sheet_name='Sheet1')

# Prepare
df['Date'] = pd.to_datetime(df['Date'])
df = df.sort_values(by=['ISIN', 'Date'])

# 1. Raw financial input variables
raw_vars = ['R&D', 'Capex', 'Total Assets', 'Sales', 'EBITDA', 'EBIT', 'Net Income', 'Total Debt']
raw_df = df[raw_vars].dropna()
corr_raw = raw_df.corr()

# Plot correlation matrix - raw variables (without title)
plt.figure(figsize=(10, 8))
sns.heatmap(corr_raw, annot=True, cmap='coolwarm', fmt='.2f')
plt.tight_layout()
plt.savefig('correlation_raw_variables.svg', format='svg')
plt.close()

# 2. Final moderator variables
df['RD_Intensity'] = df['R&D'] / df['Total Assets']
df['Capex_Intensity'] = df['Capex'] / df['Total Assets']
df['Log_Assets'] = np.log(df['Total Assets'])
df['Leverage'] = df['Total Debt'] / df['Total Assets']
df['EBITDA_ROA'] = df['EBITDA'] / df['Total Assets']
df['Asset_Turnover'] = df['Sales'] / df['Total Assets']

mod_vars = ['RD_Intensity', 'Capex_Intensity', 'Log_Assets', 'Leverage', 'EBITDA_ROA', 'Asset_Turnover']
mod_df = df[mod_vars].dropna()
corr_mods = mod_df.corr()

# Plot correlation matrix - final moderators (without title)
plt.figure(figsize=(10, 8))
sns.heatmap(corr_mods, annot=True, cmap='viridis', fmt='.2f')
plt.tight_layout()
plt.savefig('correlation_moderator_variables.svg', format='svg')
plt.close()

```

## Variance Inflation Factor (VIF)

```

# Define the same moderator variables
df['RD_Intensity'] = df['R&D'] / df['Total Assets']
df['Capex_Intensity'] = df['Capex'] / df['Total Assets']
df['Log_Assets'] = np.log(df['Total Assets'])
df['Leverage'] = df['Total Debt'] / df['Total Assets']
df['EBITDA_ROA'] = df['EBITDA'] / df['Total Assets']
df['Asset_Turnover'] = df['Sales'] / df['Total Assets']

# Prepare the VIF dataframe
mod_vars = ['RD_Intensity', 'Capex_Intensity', 'Log_Assets', 'Leverage', 'EBITDA_ROA', 'Asset_Turnover']

```

```

mod_data = df[mod_vars].dropna()

# Add constant for VIF calculation
X = add_constant(mod_data)

# Calculate VIFs
vif_df = pd.DataFrame()
vif_df['Variable'] = X.columns
vif_df['VIF'] = [variance_inflation_factor(X.values, i) for i in range(X.shape[1])]

# Display VIFs
print(vif_df)

```

## Appendix F.1.2: Hausman Test Script

### Testing for Size

```

# Load and prepare data
df = pd.read_excel('/content/abnormal_returns_with_financial.xlsx', sheet_name='Sheet1')
df['Date'] = pd.to_datetime(df['Date'])
df = df.sort_values(['ISIN', 'Date'])

# Compute CAR for (-5, +5) using MKAR
df['CAR_m5_p5'] = (
    df.groupby('ISIN')['MKAR']
    .rolling(window=11, center=True, min_periods=11)
    .sum()
    .reset_index(level=0, drop=True)
)

# Add log(Total Assets)
df['LogAssets'] = np.log(df['Total Assets'].replace(0, np.nan))

# Set panel index
df = df.set_index(['ISIN', 'Date'])

# Prepare data
df_model = df[['CAR_m5_p5', 'FDA_Approved', 'LogAssets']].dropna().copy()

# Run models
# FE model
fe_model = PanelOLS.from_formula('CAR_m5_p5 ~ FDA_Approved + LogAssets + EntityEffects', data=df_model)
fe_result = fe_model.fit()

# RE model WITHOUT constant
re_model = RandomEffects.from_formula('CAR_m5_p5 ~ FDA_Approved + LogAssets', data=df_model)
re_result = re_model.fit()

# Manual Hausman Test
beta_names = ['FDA_Approved', 'LogAssets']

b_fe = fe_result.params[beta_names]
b_re = re_result.params[beta_names]

V_fe = fe_result.cov.loc[beta_names, beta_names]
V_re = re_result.cov.loc[beta_names, beta_names]

diff = b_fe - b_re
V_diff = V_fe - V_re

try:
    H = float(diff.T @ np.linalg.inv(V_diff) @ diff)
    pval = 1 - chi2.cdf(H, df=len(beta_names))
    decision = 'Fixed Effects' if pval < 0.05 else 'Random Effects'

    print("\n=== MODEL COMPARISON ===")
    print("Fixed Effects Coefficients:\n", b_fe)
    print("Random Effects Coefficients:\n", b_re)
    print(f"\nManual Hausman Test Statistic: {H:.4f}")
    print(f"Manual Hausman p-value: {pval:.4f}")
    print(f"→ Hausman Decision: {decision} preferred.")
except np.linalg.LinAlgError:
    print("Variance matrix not invertible - cannot compute Hausman test.")

```

## Appendix F.1.3: CAR Distribution Script

```

# Load dataset
file_path = '/content/abnormal_returns_with_financial.xlsx' # Adjust path as needed
df = pd.read_excel(file_path, sheet_name='Sheet1')

# Prepare data

```

```

df['Date'] = pd.to_datetime(df['Date'])
df = df.sort_values(by=['ISIN', 'Date'])

# Calculate excess returns
df['Excess_Return'] = df['Return'] - df['RiskFreeRate']
df['Excess_Market'] = df['S&P 500'] - df['RiskFreeRate']

# Define event windows
event_windows = [(0, 0), (-1, 1), (-2, 2), (-3, 3), (-5, 5), (-10, 10)]
car_by_window = {f"{a}_{b}": [] for (a, b) in event_windows}

# Get FDA approval events
approval_days = df[df['FDA_Approved'] == 1]

# Loop through each FDA approval event
for idx, row in approval_days.iterrows():
    firm = row['ISIN']
    event_date = row['Date']

    # 100-day estimation window before the event
    estimation_window = df[
        (df['ISIN'] == firm) &
        (df['Date'] < event_date)
    ].sort_values('Date').tail(100)

    if len(estimation_window) < 100:
        continue
    if (estimation_window['FDA_Approved'] == 1).any():
        continue

    # Estimate CAPM beta
    X = sm.add_constant(estimation_window['Excess_Market'])
    y = estimation_window['Excess_Return']
    model = sm.OLS(y, X).fit()
    beta = model.params['Excess_Market']

    # Calculate CARs for each event window
    for (start, end) in event_windows:
        window_data = df[
            (df['ISIN'] == firm) &
            (df['Date'] >= event_date + pd.Timedelta(days=start)) &
            (df['Date'] <= event_date + pd.Timedelta(days=end))
        ]

        if window_data.empty:
            continue

        rf = window_data['RiskFreeRate']
        rm = window_data['S&P 500']
        expected = rf + beta * (rm - rf)
        ar = window_data['Return'] - expected
        car = ar.sum()

        window_key = f"{start}_{end}"
        car_by_window[window_key].append(car)

#compute skewness and kurtosis
print("\nSkewness and Kurtosis of CARs by Event Window:")
for win, cars in car_by_window.items():
    if len(cars) > 0:
        sk = skew(cars)
        kt = kurtosis(cars, fisher=True) # Fisher=True makes normal = 0
        print(f"Window {win}: Skewness = {sk:.3f}, Kurtosis = {kt:.3f}")

# Plot histograms with skewness and kurtosis annotations
fig, axes = plt.subplots(2, 3, figsize=(18, 10))
axes = axes.flatten()

for i, (key, car_list) in enumerate(car_by_window.items()):
    if car_list:
        # Plot histogram
        axes[i].hist(car_list, bins=40, color='darkgray', edgecolor='black')
        axes[i].set_title(f"CAR Histogram: Window {key}")
        axes[i].set_xlabel('CAR')
        axes[i].set_ylabel('Frequency')

        # Calculate skewness and kurtosis
        sk = skew(car_list)
        kt = kurtosis(car_list, fisher=True) # Normal dist = 0

        # Annotate
        axes[i].text(
            0.95, 0.95,
            f"Skew = {sk:.2f}\nKurt = {kt:.2f}",
            ha='right', va='top',
            transform=axes[i].transAxes,
            fontsize=10,
            bbox=dict(boxstyle="round,pad=0.3", edgecolor='black', facecolor='white')

```

```

)

plt.tight_layout()
plt.savefig("CAR_histograms.svg", format='svg') # Save as SVG
plt.show()

```

## Appendix F.2: No Fixed Effects Regression Script

### Example Code for R&D Intensity.

```

# Load dataset
file_path = '/content/abnormal_returns_with_financial.xlsx'
df = pd.read_excel(file_path, sheet_name='Sheet1')

# Prepare data
df['Date'] = pd.to_datetime(df['Date'])
df = df.sort_values(by=['ISIN', 'Date'])

# Compute excess returns
df['Excess_Return'] = df['Return'] - df['RiskFreeRate']
df['Excess_Market'] = df['S&P 500'] - df['RiskFreeRate']

# Create moderator variable
df['RD_Intensity'] = df['R&D'] / df['Total Assets']

# Define event windows
event_windows = [(0, 0), (-2, 2), (-1, 1), (-3, 3), (-5, 5), (-10, 10)]
car_data = []

# Loop through FDA approval events
approval_days = df[df['FDA_Approved'] == 1]

for idx, row in approval_days.iterrows():
    firm = row['ISIN']
    event_date = row['Date']

    # 100-day estimation window before event
    estimation_window = df[
        (df['ISIN'] == firm) & (df['Date'] < event_date)
    ].sort_values('Date').tail(100)

    if len(estimation_window) < 100:
        continue

    if (estimation_window['FDA_Approved'] == 1).any():
        continue

    # CAPM regression
    X = sm.add_constant(estimation_window['Excess_Market'])
    y = estimation_window['Excess_Return']
    model = sm.OLS(y, X).fit()
    beta = model.params['Excess_Market']

    # Loop over event windows
    for (start, end) in event_windows:
        window_data = df[
            (df['ISIN'] == firm) &
            (df['Date'] >= event_date + pd.Timedelta(days=start)) &
            (df['Date'] <= event_date + pd.Timedelta(days=end))
        ]

        if window_data.empty:
            continue

        rf = window_data['RiskFreeRate']
        rm = window_data['S&P 500']
        expected = rf + beta * (rm - rf)
        ar = window_data['Return'] - expected
        car = ar.sum()

        # Get moderator value on event day
        mod_row = df[(df['ISIN'] == firm) & (df['Date'] == event_date)]
        if mod_row.empty or pd.isna(mod_row['RD_Intensity'].values[0]):
            continue
        rd_intensity = mod_row['RD_Intensity'].values[0]

    # Store CAR and moderator
    car_data.append({
        'CAR': car,
        'RD_Intensity': rd_intensity,
        'Window': f'{start}_{end}'
    })

```

```

# Convert to DataFrame
car_df = pd.DataFrame(car_data)

# Run regression for each event window
for win in car_df['Window'].unique():
    data = car_df[car_df['Window'] == win]

    X = sm.add_constant(data[['RD_Intensity']])
    y = data['CAR']
    model = sm.OLS(y, X).fit()

    print(f"\n\n==== Event Window {win} - R&D Intensity Only =====")
    print(model.summary())

```

## Appendix F.3: Firm Fixed Effects Regression Script

### Example Code for R&D Intensity.

```

# Load dataset
file_path = '/content/abnormal_returns_with_financial.xlsx'
df = pd.read_excel(file_path, sheet_name='Sheet1')

# Prepare
df['Date'] = pd.to_datetime(df['Date'])
df = df.sort_values(by=['ISIN', 'Date'])
df['Excess_Return'] = df['Return'] - df['RiskFreeRate']
df['Excess_Market'] = df['S&P 500'] - df['RiskFreeRate']
df['RD_Intensity'] = df['R&D'] / df['Total Assets']

event_windows = [(0, 0), (-2, 2), (-1, 1), (-3, 3), (-5, 5), (-10, 10)]
car_data = []

approval_days = df[df['FDA_Approved'] == 1]

for idx, row in approval_days.iterrows():
    firm = row['ISIN']
    event_date = row['Date']

    est_window = df[(df['ISIN'] == firm) & (df['Date'] < event_date)].sort_values('Date').tail(100)
    if len(est_window) < 100 or (est_window['FDA_Approved'] == 1).any():
        continue

    X = sm.add_constant(est_window['Excess_Market'])
    y = est_window['Excess_Return']
    model = sm.OLS(y, X).fit()
    beta = model.params['Excess_Market']

    for (start, end) in event_windows:
        window_data = df[
            (df['ISIN'] == firm) &
            (df['Date'] >= event_date + pd.Timedelta(days=start)) &
            (df['Date'] <= event_date + pd.Timedelta(days=end))
        ]
        if window_data.empty:
            continue

        rf = window_data['RiskFreeRate']
        rm = window_data['S&P 500']
        expected = rf + beta * (rm - rf)
        ar = window_data['Return'] - expected
        car = ar.sum()

        mod_row = df[(df['ISIN'] == firm) & (df['Date'] == event_date)]
        if mod_row.empty or pd.isna(mod_row['RD_Intensity'].values[0]):
            continue

        rd = mod_row['RD_Intensity'].values[0]

        car_data.append({
            'ISIN': firm,
            'EventDate': event_date,
            'Window': f'{start}_{end}',
            'CAR': car,
            'RD_Intensity': rd
        })

# Convert to panel DataFrame
car_df = pd.DataFrame(car_data)
car_df['EventDate'] = pd.to_datetime(car_df['EventDate'])
car_df = car_df.set_index(['ISIN', 'EventDate'])

# Run firm fixed effects regression for each window

```

```

for win in car_df['Window'].unique():
    data = car_df[car_df['Window'] == win].dropna()

    if data.empty:
        continue

    model = PanelOLS.from_formula('CAR ~ RD_Intensity + EntityEffects', data=data)
    results = model.fit(cov_type='robust')

    print(f"\n\n==== Firm Fixed Effects | Window {win} =====")
    print(results.summary)

```

## Appendix F.4: Firm + Year Fixed Effects Regression Script

### Example Code for R&D Intensity.

```

# Load data
file_path = '/content/abnormal_returns_with_financial.xlsx'
df = pd.read_excel(file_path, sheet_name='Sheet1')

# Prepare data
df['Date'] = pd.to_datetime(df['Date'])
df = df.sort_values(by=['ISIN', 'Date'])
df['Excess_Return'] = df['Return'] - df['RiskFreeRate']
df['Excess_Market'] = df['S&P 500'] - df['RiskFreeRate']
df['RD_Intensity'] = df['R&D'] / df['Total Assets']

# Define event windows
event_windows = [(0, 0), (-2, 2), (-1, 1), (-3, 3), (-5, 5), (-10, 10)]
car_data = []
approval_days = df[df['FDA_Approved'] == 1]

for idx, row in approval_days.iterrows():
    firm = row['ISIN']
    event_date = row['Date']

    est_window = df[(df['ISIN'] == firm) & (df['Date'] < event_date)].sort_values('Date').tail(100)
    if len(est_window) < 100 or (est_window['FDA_Approved'] == 1).any():
        continue

    X = sm.add_constant(est_window['Excess_Market'])
    y = est_window['Excess_Return']
    model = sm.OLS(y, X).fit()
    beta = model.params['Excess_Market']

    for (start, end) in event_windows:
        window_data = df[
            (df['ISIN'] == firm) &
            (df['Date'] >= event_date + pd.Timedelta(days=start)) &
            (df['Date'] <= event_date + pd.Timedelta(days=end))
        ]
        if window_data.empty:
            continue

        rf = window_data['RiskFreeRate']
        rm = window_data['S&P 500']
        expected = rf + beta * (rm - rf)
        ar = window_data['Return'] - expected
        car = ar.sum()

        mod_row = df[(df['ISIN'] == firm) & (df['Date'] == event_date)]
        if mod_row.empty or pd.isna(mod_row['RD_Intensity'].values[0]):
            continue

        rd = mod_row['RD_Intensity'].values[0]

        car_data.append({
            'ISIN': firm,
            'EventDate': event_date,
            'EventYear': event_date.year,
            'CAR': car,
            'RD_Intensity': rd,
            'Window': f'{start}_{end}'
        })

# Build panel dataframe
car_df = pd.DataFrame(car_data)
car_df['EventDate'] = pd.to_datetime(car_df['EventDate'])
car_df = car_df.set_index(['ISIN', 'EventDate'])

# Run regressions
for win in car_df['Window'].unique():
    data = car_df[car_df['Window'] == win].drop(columns='Window').dropna()

```

```

if data.empty:
    print(f"Skipping event window {win}: no data.")
    continue

data = data.copy().reset_index().set_index(['ISIN', 'EventDate'])

try:
    model = PanelOLS.from_formula('CAR ~ RD_Intensity + C(EventYear) + EntityEffects', data=data)
    results = model.fit(cov_type='robust')
    print(f"\n==== Event Window {win} | Firm + Year FE + R&D Intensity =====")
    print(results.summary)
except Exception as e:
    print(f"Error for window {win}: {e}")

```

## Appendix F.5: Additional Robustness Checks

```

# Load data
file_path = '/content/abnormal_returns_with_financial.xlsx'
df = pd.read_excel(file_path, sheet_name='Sheet1')

```

### Appendix F.5.1: Clustering Standard Errors

Example Code for R&D Intensity.

```

# Prepare data
df['Date'] = pd.to_datetime(df['Date'])
df = df.sort_values(by=['ISIN', 'Date'])
df['Excess_Return'] = df['Return'] - df['RiskFreeRate']
df['Excess_Market'] = df['S&P 500'] - df['RiskFreeRate']
df['RD_Intensity'] = df['R&D'] / df['Total Assets']

# Only one event window
event_window = (-10, 10)
car_data = []
approval_days = df[df['FDA_Approved'] == 1]

for idx, row in approval_days.iterrows():
    firm = row['ISIN']
    event_date = row['Date']

    est_window = df[(df['ISIN'] == firm) & (df['Date'] < event_date)].sort_values('Date').tail(100)
    if len(est_window) < 100 or (est_window['FDA_Approved'] == 1).any():
        continue

    X = sm.add_constant(est_window['Excess_Market'])
    y = est_window['Excess_Return']
    model = sm.OLS(y, X).fit()
    beta = model.params['Excess_Market']

    start, end = event_window
    window_data = df[
        (df['ISIN'] == firm) &
        (df['Date'] >= event_date + pd.Timedelta(days=start)) &
        (df['Date'] <= event_date + pd.Timedelta(days=end))
    ]
    if window_data.empty:
        continue

    rf = window_data['RiskFreeRate']
    rm = window_data['S&P 500']
    expected = rf + beta * (rm - rf)
    ar = window_data['Return'] - expected
    car = ar.sum()

    mod_row = df[(df['ISIN'] == firm) & (df['Date'] == event_date)]
    if mod_row.empty or pd.isna(mod_row['RD_Intensity'].values[0]):
        continue

    rd = mod_row['RD_Intensity'].values[0]

    car_data.append({
        'ISIN': firm,
        'EventDate': event_date,
        'EventYear': event_date.year,
        'CAR': car,
        'RD_Intensity': rd
    })

# Build panel dataframe

```

```

car_df = pd.DataFrame(car_data)
car_df['EventDate'] = pd.to_datetime(car_df['EventDate'])
car_df = car_df.set_index(['ISIN', 'EventDate'])

# Run regression with clustered standard errors (by firm)
data = car_df.dropna().copy().reset_index().set_index(['ISIN', 'EventDate'])

try:
    model = PanelOLS.from_formula('CAR ~ RD_Intensity + C(EventYear) + EntityEffects', data=data)
    results = model.fit(cov_type='clustered', cluster_entity=True)
    print(f"\n===== Event Window (-10,10) | Firm + Year FE + R&D Intensity | Clustered by Firm =====")
    print(results.summary)
except Exception as e:
    print(f"Error in regression: {e}")

```

## Appendix F.5.2: Fama-French 3 Factor as Return Model

### Example Code for R&D Intensity.

```

# Prepare data
df['Date'] = pd.to_datetime(df['Date'])
df = df.sort_values(by=['ISIN', 'Date'])
df['Excess_Return'] = df['Return'] - df['RF']
df['RD_Intensity'] = df['R&D'] / df['Total Assets']

# Define event windows
event_windows = [(-10, 10)] # Add or replace with other windows as needed
car_data = []
approval_days = df[df['FDA_Approved'] == 1]

for idx, row in approval_days.iterrows():
    firm = row['ISIN']
    event_date = row['Date']

    est_window = df[(df['ISIN'] == firm) & (df['Date'] < event_date)].sort_values('Date').tail(100)
    if len(est_window) < 100 or (est_window['FDA_Approved'] == 1).any():
        continue

    # Check for necessary Fama-French columns
    if est_window[['Mkt-RF', 'SMB', 'HML']].isnull().any().any():
        continue

    # Estimate Fama-French 3-factor model
    X = est_window[['Mkt-RF', 'SMB', 'HML']]
    X = sm.add_constant(X)
    y = est_window['Excess_Return']
    model = sm.OLS(y, X).fit()
    beta = model.params[['Mkt-RF', 'SMB', 'HML']]

    for (start, end) in event_windows:
        window_data = df[
            (df['ISIN'] == firm) &
            (df['Date'] >= event_date + pd.Timedelta(days=start)) &
            (df['Date'] <= event_date + pd.Timedelta(days=end))
        ]

        if window_data.empty or window_data[['Mkt-RF', 'SMB', 'HML']].isnull().any().any():
            continue

        expected = (
            beta['Mkt-RF'] * window_data['Mkt-RF'] +
            beta['SMB'] * window_data['SMB'] +
            beta['HML'] * window_data['HML']
        ) + window_data['RF']

        ar = window_data['Return'] - expected
        car = ar.sum()

        mod_row = df[(df['ISIN'] == firm) & (df['Date'] == event_date)]
        if mod_row.empty or pd.isna(mod_row['RD_Intensity'].values[0]):
            continue

        rd = mod_row['RD_Intensity'].values[0]

        car_data.append({
            'ISIN': firm,
            'EventDate': event_date,
            'EventYear': event_date.year,
            'CAR': car,
            'RD_Intensity': rd,
            'Window': f'{start}_{end}'
        })

# Build panel dataframe

```

```

car_df = pd.DataFrame(car_data)
car_df['EventDate'] = pd.to_datetime(car_df['EventDate'])
car_df = car_df.set_index(['ISIN', 'EventDate'])

# Run regressions
for win in car_df['Window'].unique():
    data = car_df[car_df['Window'] == win].drop(columns='Window').dropna()
    if data.empty:
        print(f"Skipping event window {win}: no data.")
        continue

    data = data.copy().reset_index().set_index(['ISIN', 'EventDate'])

    try:
        model = PanelOLS.from_formula('CAR ~ RD_Intensity + C(EventYear) + EntityEffects', data=data)
        results = model.fit(cov_type='robust')
        print(f"\n==== Event Window {win} | Firm + Year FE + R&D Intensity (Fama-French) =====")
        print(results.summary)
    except Exception as e:
        print(f"Error for window {win}: {e}")

```

## Appendix G: All Significant Regressions

### Full Sample Regressions (No Fixed Effects)

Interaction	Event Window	Coefficient	Std. Error	t-Statistic	p-Value
No Interaction	0_0	0,0071 **	0,0030	2,193	0,0290
No Interaction	-2_2	0,0230 ***	0,0070	3,484	0,0010
No Interaction	-1_1	0,0158 ***	0,0050	2,940	0,0040
No Interaction	-3_3	0,0235 ***	0,0080	2,957	0,0030
No Interaction	-5_5	0,0329 ***	0,0090	3,603	<0,0001
No Interaction	-10_10	0,0448 ***	0,0150	3,045	0,0030
Size	0_0	-0,0040 **	0,0020	-2,458	0,0140
Size	-2_2	-0,0083 **	0,0030	-2,506	0,0130
Size	-1_1	-0,0053 **	0,0030	-1,977	0,0490
Size	-3_3	-0,0103 ***	0,0040	-2,597	0,0100
Size	-5_5	-0,0139 ***	0,0050	-3,061	0,0020
Size	-10_10	-0,0209 ***	0,0070	-2,850	0,0050
EBITDA_ROA	-5_5	-0,1340 **	0,0600	-2,232	0,0260
EBITDA_ROA	-10_10	-0,2339 **	0,0970	-2,421	0,0160
Asset Turnover	0_0	-0,1208 ***	0,0370	-3,232	0,0010
Asset Turnover	-2_2	-0,1762 **	0,0770	-2,294	0,0220
Asset Turnover	-1_1	-0,1297 **	0,0630	-2,066	0,0400
Asset Turnover	-3_3	-0,2190 **	0,0930	-2,365	0,0190
Asset Turnover	-5_5	-0,3030 ***	0,1060	-2,864	0,0040
Asset Turnover	-10_10	-0,4447 ***	0,1710	-2,603	0,0100

Notes: Each row reports results from a separate OLS regression of CARs on FDA approval and one interaction variable. No fixed effects are included. Coefficients represent the marginal effect of FDA approval interacted with the respective variable. Standard errors are robust. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

### Full Sample Regressions (Firm Fixed Effects)

Interaction	Event Window	Coefficient	Std. Error	t-Statistic	p-Value
No Interaction	0_0	0,0071 ***	0,0024	2,9985	0,0030
No Interaction	-2_2	0,0230 ***	0,0055	4,1513	<0,0001

No Interaction	-1_1	0,0158 ***	0,0046	3,4747	0,0006
No Interaction	-3_3	0,0235 ***	0,0069	3,3985	0,0008
No Interaction	-5_5	0,0329 ***	0,0079	4,1578	<0,0001
No Interaction	-10_10	0,0448 ***	0,0128	3,4909	0,0006
R&D Intensity	0_0	0,2108 **	0,1029	2,0487	0,0416
R&D Intensity	-3_3	0,5951 **	0,2947	2,0191	0,0446
R&D Intensity	-5_5	0,8669 **	0,3984	2,1759	0,0305
R&D Intensity	-10_10	2,0126 **	0,7798	2,5809	0,0104
Capex Intensity	0_0	-0,7415 ***	0,2652	-2,7956	0,0056
Size	0_0	-0,0179 ***	0,0048	-3,7237	0,0002
Size	-2_2	-0,0467 ***	0,0111	-4,1913	<0,0001
Size	-1_1	-0,0289 ***	0,0090	-3,2223	0,0014
Size	-3_3	-0,0709 ***	0,0136	-5,2023	<0,0001
Size	-5_5	-0,0968 ***	0,0157	-6,1581	<0,0001
Size	-10_10	-0,2052 ***	0,0280	-7,3160	<0,0001
EBITDA_ROA	-2_2	-0,2412 ***	0,0798	-3,0210	0,0028
EBITDA_ROA	-3_3	-0,3393 ***	0,1132	-2,9969	0,0030
EBITDA_ROA	-5_5	-0,4802 ***	0,1404	-3,4205	0,0007
EBITDA_ROA	-10_10	-1,1051 ***	0,2708	-4,0800	0,0001

Notes: Each row reports results from a separate OLS regression of CARs on FDA approval and one interaction variable. Firm fixed effects are included. Coefficients represent the marginal effect of FDA approval interacted with the respective variable. Standard errors are robust. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

### Full Sample Regressions (Firm + Year Fixed Effects)

Interaction	Event Window	Coefficient	Std. Error	t-Statistic	p-Value
R&D Intensity	-10_10	1,6446 **	0,6546	2,5125	0,0127
Capex Intensity	0_0	-0,8125 ***	0,2341	-3,4711	0,0006
Size	-10_10	-0,1353 ***	0,0391	-3,4562	0,0007
EBITDA_ROA	-5_5	-0,2730 **	0,1203	-2,2705	0,0241
EBITDA_ROA	-10_10	-0,7682 ***	0,2289	-3,3562	0,0009

Notes: Each row reports results from a separate OLS regression of CARs on FDA approval and one interaction variable. Firm + year fixed effects are included. Coefficients represent the marginal effect of FDA approval interacted with the respective variable. Standard errors are robust. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

### Subsector Sample Regressions (No Fixed Effects)

Subsector	Variable	Event Window	Coef.	Std. Error	t-Stat	p-Value
NSSB	No Interaction	-2_2	0,0314 **	0,013	2,341	0,022
SSB	No Interaction	0_0	0,0089 **	0,004	2,082	0,039
SSB	No Interaction	-2_2	0,0287 ***	0,010	2,899	0,004
SSB	No Interaction	-1_1	0,0204 **	0,008	2,527	0,012
SSB	No Interaction	-3_3	0,0348 ***	0,012	2,923	0,004
SSB	No Interaction	-5_5	0,0544 ***	0,014	3,915	<0,0001
SSB	No Interaction	-10_10	0,0759 ***	0,022	3,386	0,001
OB	R&D Intensity	-2_2	1,5066 ***	0,341	4,424	<0,0001

OB	R&D Intensity	-1_1	0,9098 ***	0,263	3,463	0,001
OB	R&D Intensity	-3_3	1,4544 ***	0,475	3,059	0,003
OB	R&D Intensity	-5_5	1,8450 ***	0,570	3,236	0,002
OB	R&D Intensity	-10_10	2,9989 ***	0,896	3,346	0,001
SSB	R&D Intensity	0_0	0,2649 ***	0,080	3,314	0,001
SSB	Size	0_0	-0,0051 **	0,002	-2,072	0,040
SSB	Size	-5_5	-0,0185 **	0,008	-2,339	0,021
OB	EBITDA_ROA	-2_2	-0,5842 ***	0,121	-4,816	<0,0001
OB	EBITDA_ROA	-1_1	-0,3131 ***	0,096	-3,248	0,002
OB	EBITDA_ROA	-3_3	-0,7225 ***	0,162	-4,471	<0,0001
OB	EBITDA_ROA	-5_5	-0,8201 ***	0,199	-4,128	<0,0001
OB	EBITDA_ROA	-10_10	-1,3014 ***	0,313	-4,154	<0,0001
SSB	EBITDA_ROA	0_0	-0,0904 ***	0,033	-2,709	0,007
OB	Asset Turnover	-2_2	-0,4298 **	0,166	-2,596	0,012
SSB	Asset Turnover	0_0	-0,2032 ***	0,050	-4,044	<0,0001
SSB	Asset Turnover	-3_3	-0,3133 **	0,145	-2,163	0,032
SSB	Asset Turnover	-5_5	-0,4640 ***	0,168	-2,769	0,006
SSB	Asset Turnover	-10_10	-0,7623 ***	0,270	-2,820	0,005

Notes: Each row reports results from a separate OLS regression of CARs on FDA approval and one interaction variable. No fixed effects are included. SSB, NSSB, and OB denominates System-Specific Biopharmaceuticals, Non-System-Specific Biopharmaceuticals, and Other Biopharmaceuticals, respectively. Coefficients represent the marginal effect of FDA approval interacted with the respective variable. Standard errors are robust. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

### Subsector Sample Regressions (Firm Fixed Effects)

Subsector	Variable	Event Window	Coef.	Std. Error	t-Stat	p-Value
NSSB	No Interaction	0_0	0,0126 **	0,0051	2,4473	0,0182
NSSB	No Interaction	-2_2	0,0314 ***	0,0116	2,7092	0,0094
SSB	No Interaction	0_0	0,0089 **	0,0036	2,4992	0,0138
SSB	No Interaction	-2_2	0,0287 ***	0,0086	3,3344	0,0011
SSB	No Interaction	-1_1	0,0204 ***	0,0072	2,8567	0,0050
SSB	No Interaction	-3_3	0,0348 ***	0,0107	3,2566	0,0015
SSB	No Interaction	-5_5	0,0544 ***	0,0125	4,3672	<0,001
SSB	No Interaction	-10_10	0,0759 ***	0,0199	3,8109	0,0002
NSSB	R&D Intensity	-2_2	0,5801 **	0,2706	2,1441	0,0373
NSSB	R&D Intensity	-5_5	1,1420 **	0,5318	2,1475	0,0371
OB	R&D Intensity	-2_2	1,8519 **	0,8719	2,1238	0,0388
SSB	R&D Intensity	0_0	0,3597 **	0,1767	2,0358	0,0440
NSSB	Size	-2_2	-0,0754 ***	0,0261	-2,8919	0,0058
NSSB	Size	-3_3	-0,0984 ***	0,0324	-3,0366	0,0039
NSSB	Size	-5_5	-0,1516 ***	0,0368	-4,1180	0,0002
NSSB	Size	-10_10	-0,2871 ***	0,0669	-4,2928	0,0001
OB	Size	-2_2	-0,0623 ***	0,0223	-2,8000	0,0072
OB	Size	-1_1	-0,0401 **	0,0173	-2,3190	0,0245
OB	Size	-3_3	-0,1090 ***	0,0299	-3,6451	0,0006

OB	Size	-5_5	-0,1132 ***	0,0359	-3,1533	0,0027
OB	Size	-10_10	-0,2466 ***	0,0582	-4,2345	0,0001
SSB	Size	0_0	-0,0208 ***	0,0055	-3,7523	0,0003
SSB	Size	-2_2	-0,0381 **	0,0153	-2,4929	0,0140
SSB	Size	-1_1	-0,0251 **	0,0122	-2,0575	0,0418
SSB	Size	-3_3	-0,0577 ***	0,0176	-3,2804	0,0014
SSB	Size	-5_5	-0,0881 ***	0,0210	-4,1924	0,0001
SSB	Size	-10_10	-0,1850 ***	0,0374	-4,9481	<0,0001
NSSB	EBITDA_ROA	-2_2	-0,2776 **	0,1139	-2,4375	0,0187
NSSB	EBITDA_ROA	-3_3	-0,3658 **	0,1419	-2,5774	0,0132
NSSB	EBITDA_ROA	-5_5	-0,5694 **	0,2258	-2,5222	0,0152
NSSB	EBITDA_ROA	-10_10	-1,0147 **	0,4618	-2,1971	0,0331
OB	EBITDA_ROA	-2_2	-0,3844 ***	0,1380	-2,7855	0,0075
OB	EBITDA_ROA	-3_3	-0,5608 **	0,2618	-2,1421	0,0371
SSB	EBITDA_ROA	0_0	-0,1414 **	0,0706	-2,0024	0,0475
SSB	EBITDA_ROA	-5_5	-0,5116 **	0,2328	-2,1979	0,0299
SSB	EBITDA_ROA	-10_10	-1,4113 ***	0,4020	-3,5104	0,0006
OB	Asset Turnover	-2_2	-0,2824 **	0,1102	-2,5619	0,0135
SSB	Asset Turnover	0_0	-0,1520 **	0,0712	-2,1356	0,0347

Notes: Each row reports results from a separate OLS regression of CARs on FDA approval and one interaction variable. Firm fixed effects are included. SSB, NSSB, and OB denominates System-Specific Biopharmaceuticals, Non-System-Specific Biopharmaceuticals, and Other Biopharmaceuticals, respectively. Coefficients represent the marginal effect of FDA approval interacted with the respective variable. Standard errors are robust. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.

### Subsector Sample Regressions (Firm + Year Fixed Effects)

Subsector	Variable	Event Window	Coef.	Std. Error	t-Stat	p-Value
NSSB	R&D Intensity	-2_2	0,5801 **	0,2706	2,1441	0,0373
NSSB	R&D Intensity	-5_5	1,1420 **	0,5318	2,1475	0,0371
OB	R&D Intensity	-2_2	1,8519 **	0,8719	2,1238	0,0388
SSB	R&D Intensity	0_0	0,3597 **	0,1767	2,0358	0,0440
NSSB	Capex Intensity	-1_1	2,0072 ***	0,6512	3,0820	0,0039
SSB	Capex Intensity	0_0	-0,6813 **	0,3062	-2,2249	0,0281
OB	Size	-10_10	-0,1740 **	0,0757	-2,2971	0,0269
NSSB	EBITDA_ROA	-10_10	-0,6778 **	0,2992	-2,2655	0,0296
OB	EBITDA_ROA	-2_2	-0,3009 **	0,1266	-2,3760	0,0224
OB	EBITDA_ROA	-3_3	-0,4764 **	0,2125	-2,2416	0,0306

Notes: Each row reports results from a separate OLS regression of CARs on FDA approval and one interaction variable. Firm + year fixed effects are included. SSB, NSSB, and OB denominates System-Specific Biopharmaceuticals, Non-System-Specific Biopharmaceuticals, and Other Biopharmaceuticals, respectively. Coefficients represent the marginal effect of FDA approval interacted with the respective variable. Standard errors are robust. \*\*\*, \*\*, and \* indicate significance at the 1%, 5%, and 10% levels, respectively.