# Do mandatory disclosure requirements for private firms increase the propensity of going public?\*

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#### Abstract

This paper investigates the effect of mandatory disclosure requirements for private firms on their decision to go public. Using detailed project-level data for biopharmaceutical firms, we explore the effects of a legal reform that exogenously required firms to publicly disclose information regarding clinical trials. Exploiting cross-sectional heterogeneity in firms' exposure to the regulation based on their internal development portfolios, we find that affected firms are significantly more likely to transition to public equity markets following the reform. Moreover, firms that go public due to the increased disclosure requirements subsequently reduce the size of their project portfolios while shifting to safer investments acquired externally. We provide additional evidence for the main hypothesis using a second setting: a 2006 German reform which enhanced the enforcement of mandatory disclosure requirements for private firms. The results suggest that private firms' general information environment and disclosure requirements influence the propensity of going public.

*Keywords*: Initial public offerings, mandatory disclosure, proprietary cost, innovation, private firms.

JEL classification: D82, G31, G32, G34, G38, O31.

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## 1 Introduction

Private companies in the U.S. typically face limited public disclosure requirements. Unlike public companies, which must publicly release financial statements as well as information that is materially relevant for shareholders, private firms generally face no such obligations. Indeed, one of the primary benefits of remaining private is often said to be limited transparency (e.g., Farre-Mensa (2017)). While the effects of mandatory disclosure for public firms have been well-studied, the effects for private firms are not yet well-understood (Minnis and Shroff (2017)). In this paper, we seek to address the following question: How do public disclosure requirements for private firms influence the decision to transition to public equity markets?<sup>1</sup> Furthermore, being public may lead to different investment incentives for firms, which may illuminate important real downstream consequences for altering the information environment firms operate in.

Conceptually, information disclosure can affect the going-public decision because firms face a trade-off between the cost of revealing confidential information that could be used by competitor firms and the benefit of raising external financing at a lower or more efficient rate (Bhattacharya and Ritter (1983), Maksimovic and Pichler (2001)). Hence, if the proprietary costs of disclosure from becoming a public firm are sufficiently low or are outweighed by the financing benefits, the firm is inclined to go public. An implication of this analysis is that the introduction of mandatory disclosure requirements of proprietary or confidential information would make going public relatively more attractive; firms can no longer avoid proprietary disclosure costs by remaining private and hence the net marginal benefit from going public becomes relatively higher.

However, cleanly testing the effect of disclosure requirements on private firms is difficult. First, one needs data on private firms as well as the information they disclose, but the vast majority of privately-held firms in the U.S. are subject to almost no public disclosure requirements. Second, since the amount of disclosure by firms is endogenous, an exogenous shock to mandatory disclosure requirements is needed in order to ascertain its effect on private firms.

We attempt to overcome these difficulties and investigate the aforementioned question using detailed project-level data for a particular industry—the biopharmaceutical (biopharma) industry. The biopharma industry provides an ideal setting to empirically test these ques-

<sup>&</sup>lt;sup>1</sup>The determinants of what drive a private company to go public are of significant interest to both academics and policymakers. For example, Lowry et al. (2017) notes that "Why firms go (or do not go) public is perhaps one of the most important questions related to IPOs, with significant possible implication on policies, governance, and on firms' cost of capital. It would be wonderful to have more, and more complete evidence on this issue." The interest of this issue to policymakers is evidenced by recent legislative attempts to encourage more IPOs, such as the 2012 Jumpstart Our Business Startups Act.

tions due to the importance of proprietary information costs for firms in the industry, an active market for initial public offerings (IPOs), and the existence of a legislative change where public disclosure of information was directly mandated.<sup>2</sup> Specifically, we use the passage of the Food and Drug Administration Amendments Act (FDAAA) by the U.S. government in 2007 as an exogenous shock to information disclosure requirements. The FDAAA required that the results, as well as other important information, of all clinical trials in Phase II or above of the drug development process be publicly reported. Prior to the reform, firms faced limited reporting requirements; however, the government mandated that companies have a legal obligation to make such disclosures in the FDAAA. Importantly, the law applied to all companies conducting clinical trials, including private firms. Consistent with this, we show that general disclosures per drug by private firms increased relative to those by public firms, and at the same time disclosures related to drugs in Phase II or above rose sharply compared to disclosures related to Phase I drugs following FDAAA enactment.<sup>3</sup>

We employ a difference-in-differences (hereafter DID) methodology over a six-year window around the reform, 2004–2009, to investigate the effects of strengthened mandatory disclosure requirements for private firms on the propensity to transition to public equity markets. Our sample includes 1,264 private biotechnology and pharmaceutical firms, with 53 IPOs among these firms. Our dataset includes detailed information concerning firms' (both public and private) project portfolios, such as the status, phase, therapeutic (disease) area, and likelihood of approval, of each firm's drug development project at any point in time, as well as other actions such as trial suspensions and initiations. This detailed data is an important feature of our setting as it allows us to track the project and investment decisions of *private* firms, which is generally difficult to observe. We utilize this data on private firms' project portfolios for both cross-sectional variation in the treatment, as well as to later examine project decisions following the transition to public equity markets. Specifically, we identify treatment intensity using cross-sectional variation in private firms' exposure to the FDAAA disclosure provisions. Because the FDAAA disclosure requirements are for projects in Phase II or above of the development process, firms with a greater proportion

 $<sup>^{2}</sup>$ The disclosure of project-level information by biopharma firms is especially salient given that the industry is extremely competitive, reliant on innovation, and information releases can work to the detriment of the disclosing firm (Guo et al. (2004), Krieger (2017)). Mandatory disclosure of information pertaining to innovations can thus impose substantial proprietary costs on private firms.

<sup>&</sup>lt;sup>3</sup>Public firms faced greater pressure to publicly disclose details related to their R&D prior to the reform due to materiality disclosure requirements, demand for information by capital market participants, and a greater risk of shareholder litigation for withholding information (see Section 2 for more discussion). Therefore, an increase in mandated disclosure should affect public firms relatively less than private firms, which is what we find. See also Kankanhalli et al. (2019), who study redacted information by firms, and show evidence in an additional test consistent with biopharma firms experiencing a decreased incentive to redact information following the FDAAA, which is in line with the effect of increased mandatory disclosure.

of these projects immediately preceding the enactment of the law are more affected by the regulation.<sup>4</sup>

Our main analysis consists of three parts. First, we test whether the disclosure requirements influenced the decision to go public. We then examine the mechanism driving this effect. Finally, we explore the (indirect) consequences of the disclosure requirements through changes in project and investment decisions following the transition to public equity markets.

The main result is that private firms which are more affected by the legislation also significantly increase their likelihood of going public relative to less affected firms. For example, the mean IPO propensity for firms in the bottom decile of our treatment variable the proportion of projects in Phase II or above—in the pre-FDAAA period is 1.6%, and the mean IPO propensity for these firms in the post-FDAAA period is 1.6%. In contrast, the mean IPO propensity for firms in the top decile of our treatment variable in the pre-FDAAA period is 2.5%, while the mean propensity for these firms in the post-FDAAA period is 4.6%.<sup>5</sup> The overall treatment effect is economically significant, with a one standard deviation increase in our treatment variable leading to a 1.3 percentage point increase in the probability of going public following the law change; this represents a 41.3% increase in IPO propensity relative to the pre-treatment sample mean. This result is robust to a number of specifications and research design choices, including controlling for a wide variety of project portfolio attributes (e.g., risk, number of drugs in development, therapeutic areas of projects) and firm and year fixed effects. The results suggest that the information environment of private firms and their disclosure requirements significantly influence the decision to transition to public equity markets.

We conduct several robustness tests, and show that time trends, portfolio composition changes, and life-cycle effects do not drive our results. We note that, while previous studies have documented life-cycle patterns for IPOs, our empirical strategy is unlikely to be confounded by such effects because (i) the DID specification considers the *change* in IPO propensity for more-treated versus less-treated firms specifically following FDAAA passage; (ii) it is common for firms in the biopharma industry to go public even though the bulk or the entirety of their projects are in early-stage (e.g., preclinical or Phase I) development;<sup>6</sup>

<sup>&</sup>lt;sup>4</sup>One potential limitation of this setting is the small sample size, which may limit external validity. We overcome this by using a second empirical setting, described later in the paper.

<sup>&</sup>lt;sup>5</sup>We show that the parallel trends assumption holds in our setting—specifically, there is no statistically significant difference in IPO propensity between firms with different values of our treatment variable in the pre-FDAAA period, and these firms exhibit no discernible trends during this period.

<sup>&</sup>lt;sup>6</sup>As noted in recent media coverage: "Early stage biotechs—whose products aren't yet tested in human clinical trials or are tested only in early Phase 1 studies—represented 37% of biotech IPOs through the third quarter of 2018 and had an average market value of \$535 million ... that is up from 35% of biotech IPOs with an average market value of \$471 million in 2015." See "Biotechs With No Drugs in Trial Are Raising Millions in IPOs," *The Wall Street Journal*, October 31, 2018.

(iii) firms in this industry often go public even though they have not had a single quarter with positive revenues; and (iv) early-stage projects in certain therapeutic categories may have a shorter time to approval than later-stage projects in other categories (Kaitin and DiMasi (2011)).<sup>7</sup>

In the second part of our analysis, we further explore the mechanism which drives the increase in IPO likelihood. If, as argued above, proprietary disclosure costs had prevented firms from going public prior to FDAAA enactment, then firms with higher ex ante proprietary costs from disclosure should have a disproportionate increase in their propensity of going public. We test this channel by partitioning our sample and re-running our analysis on the resulting sub-samples. First, we run our analysis after partitioning our sample based on pre-FDAAA disclosure levels. The reasoning is that firms which disclosed more in the pre-FDAAA period, where reporting was largely voluntary, likely had lower ex ante proprietary costs from disclosure (Verrecchia (1983)). Consistent with this argument, we find that the increase in IPO propensity is concentrated among firms that disclosed *less* prior to the reform. Second, we run our analysis after splitting our sample based on the degree of competition that a firm's development portfolio faced prior to the reform—measured by the the number of competing drugs that operated in the same granular therapeutic area that a firm operated in—the idea being that firms exposed to greater competition face higher proprietary disclosure costs. In line with this, we find that the increase in IPO propensity is centered around firms that operate in more competitive areas. Put together, these results suggest that a primary mechanism driving the increased IPO propensity is the inability to save proprietary disclosure costs by remaining private following FDAAA implementation.

Finally, in the third part of our analysis, we explore how investment and innovation outcomes are affected by the going-public decision due to increased disclosure requirements. Increased access to equity markets through an IPO may alleviate financial constraints and allow increased investment. Conversely, going public may exacerbate agency frictions, which may lead to less investment and innovation, or alter the riskiness or nature of investments (Jensen and Meckling (1976), Holmström (1999), Aghion et al. (2013)). In particular, due to dispersed ownership, public firms generally have less direct monitoring of management. As a result, shareholders may mistakenly attribute negative outcomes following project decisions to poor managerial ability rather than due to chance (some empirical evidence for this is documented in Jenter and Kanaan (2015)). Consequently, due to career concerns, managers in public firms are less inclined to invest (innovate) and more inclined to adopt less risky

<sup>&</sup>lt;sup>7</sup>This is also in line with the observations of industry practitioners regarding IPO activity. For example, Rubius Therapeutics CEO Pablo Cagnoni notes that "...scientific and technology advances enable companies to tackle multiple diseases over a short span, attracting investors regardless of companies' development stage" (*The Wall Street Journal*, October 31, 2018).

projects in order to minimize the likelihood of negative project outcomes. Furthermore, private firms, with their more closely held and illiquid ownership, typically have more direct and intensive monitoring of management. This has the benefit that managers are not held responsible for negative project outcomes that were beyond their control, since, through the stricter monitoring, owners can recognize that management made a reasonable decision ex ante. Hence, the transition to public equity markets, and its less direct monitoring by owners, can lead managers to scale back innovation and to shift to safer projects due to career concerns.

Using a two-stage estimation procedure, which allows us to capture the (exogenous) component of going public due to increased disclosure requirements and its subsequent effect on investment/innovation decisions, we find that firms which tend to go public due to the FDAAA's disclosure requirements reduce the number of drugs that they develop. In particular, they initiate relatively fewer new drug projects in-house, and suspend more projects in development. This scaling-back of development efforts lead to a reduction in the overall risk of projects that they choose to develop. In line with this, we also find evidence that these firms turn more to external acquisitions of relatively less risky, later-stage projects. Thus, affected firms exhibit a reduction in both the overall size and riskiness of their project portfolios. These findings are consistent with the career concerns hypothesis discussed above; managers of newly public firms are less inclined to begin new projects that could result in failure, and shift to relatively "safer" innovation developed externally.

One potential limitation of our study is that, since we focus on one industry, our sample does not include a high number of IPOs. To help address this concern and to establish the external validity of our results, we investigate our central research question using a second empirical setting based on a 2006 German reform (Bernard (2016), Breuer et al. (2018)). Based on European Union directives, EU member states adopted disclosure requirements of financial statement information for private companies. While Germany implemented such laws as well, the disclosure requirements had minimal enforcement, amounting to a *de facto* voluntary disclosure regime for German private firms. Following increased pressure from the EU, Germany passed a reform (known as "EHUG") in 2006 which centralized enforcement, created a public electronic registry for disclosures, and implemented sizable, escalating fines for noncompliance. This led to over 90% of private firms disclosing in the two years following the reform, relative to a 5-10% compliance rate prior to the reform (Henselmann and Kaya (2008)). Hence, disclosure became effectively mandatory for private firms following the enhanced enforcement through EHUG.

Similar to our main analysis, we use a difference-in-differences specification at the firmyear level with a six-year window around the year of the reform (we provide more detail in Section 6). We find that German private firms exhibited a significantly higher propensity to transition to public equity markets relative to other EU member state private firms following the reform. In additional analyses, we consider a related specification which is restricted to German firms and exploits variation in their exposure to the law based on proprietary disclosure costs (using industry competitiveness). We also utilize variation in the size thresholds for private firm disclosure across EU member states for further investigation of the main hypothesis. The consistent findings between the two distinct empirical settings strongly support the hypothesis that private firms are more inclined to transition to public equity markets when faced with greater public disclosure requirements.

Our study is related to several different literatures. We contribute to the literature on the economic effects of mandatory disclosure requirements. A number of papers have examined the economic consequences of mandatory disclosure by *public* firms (see Leuz and Wysocki (2016) and Roychowdhury et al. (2019) for reviews).<sup>8</sup> However, research on the effects of mandatory disclosure requirements for U.S. *private* firms has been quite limited to date.<sup>9</sup> As noted by Minnis and Shroff (2017), this is due to the fact that U.S. private firms face almost no public disclosure requirements. Our study contributes to this growing literature by studying the effect of mandated disclosure on private firms' likelihood of seeking public financing. Specifically, we identify an important economic consequence—the transition to public equity markets—which contributes to our understanding of the determinants of public and private ownership in the economy. We also provide evidence of downstream consequences in investment decisions as a result of going public due to the disclosure requirements.

This paper is also related to the literature studying IPOs. First, we contribute to the stream of research that examines the role of disclosure in IPOs. Dambra et al. (2015) consider the 2012 Jumpstart Our Business Startups (JOBS) Act and find that the U.S. market saw significantly more public offerings following the JOBS Act relative to foreign markets. Relatedly, Guo et al. (2004), Hanley and Hoberg (2010), and Boone et al. (2016) investigate the incentives to withhold information in the IPO prospectus and the informativeness of

<sup>&</sup>lt;sup>8</sup>These include, for example, lower cost of capital (e.g., Lambert et al. (2007), Shroff et al. (2017)), increased liquidity (Bushee and Leuz (2005)), more efficient investment decisions (Biddle et al. (2009), Cheng et al. (2013), Shroff et al. (2014)), information spillovers (Badertscher et al. (2013), Shroff et al. (2017), Durnev and Mangen (2020)), and innovation consequences (Kim and Valentine (2020)).

<sup>&</sup>lt;sup>9</sup>Å small but growing literature utilizes European data and the disclosure requirements for EU member states to examine the economic effects of mandatory disclosure for private firms (which, as discussed above, we also use as our second empirical setting). These studies find that mandatory disclosure for private firms entails competitive costs (Bernard (2016)), facilitates external financing (Breuer et al. (2018), Baik et al. (2020)), increases market entry and lowers concentration (Breuer (2020)), and negatively affects innovation (Breuer et al. (2019)). We contribute to this literature by showing that disclosure requirements can positively influence the IPO decisions of private firms.

prospectus disclosures.<sup>10</sup> These studies consider disclosure requirements in the IPO filings, such as the prospectus, and thus primarily apply to firms that have already made the decision to go public. In contrast, we examine broad disclosure requirements that affect private firms during the regular course of their operations, rather than specifically related to IPO prospectus disclosure. In doing so, we consider the effects of disclosure requirements on IPO propensity specifically for *private* firms that have not yet decided to go public, which provides us with a counter-factual relative to existing studies that focus on firms that have already gone public. Second, we contribute to the literature which investigates the determinants of IPO propensity, such as Pagano et al. (1998) and Lowry and Schwert (2002).<sup>11</sup> Our paper builds on this literature by providing detailed firm-level evidence using exogenous variation that a private firm's information environment plays a significant role in the going-public decision.

Finally, we explore firm-level project and innovation outcomes following IPOs. Hence, our work contributes to the literature examining post-IPO firm performance, such as Jain and Kini (1994), Pagano et al. (1998), Pástor et al. (2008), Chemmanur et al. (2010), Aggarwal and Hsu (2013), Bernstein (2015), and Acharya and Xu (2017). Using project-level data, we provide novel evidence that firms going public in our context shift their development efforts to safer projects.

The paper proceeds as follows. In the next section, we discuss the first institutional setting and the conceptual framework. In Section 3 we present the research design and the dataset, while in Section 4 we present the main results as well as robustness tests. Section 5 investigates innovation effects due to the increased IPO propensity, and Section 6 presents the second empirical setting and its results. The final section concludes.

## 2 Institutional background and conceptual framework

In this section, we provide more detail and background regarding FDAAA implementation and its corresponding mandatory disclosure requirements. We then discuss the conceptual underpinnings for our main predictions. We present the institutional details of our second setting regarding the 2006 German reform (EHUG) in Section 6.

<sup>&</sup>lt;sup>10</sup>Lowry et al. (2018) examine SEC comment letters to IPO firms as a form of information revelation and the corresponding effects on prospectus disclosure and the time to IPO.

<sup>&</sup>lt;sup>11</sup>Other studies include Ritter (1984, 1991), Lerner (1994), Loughran et al. (1994), Benveniste et al. (2003), Brau et al. (2003), Lowry (2003), Brau and Fawcett (2006), Kim and Weisbach (2008), Chemmanur et al. (2010), Gao et al. (2013), Farre-Mensa (2017), Ewens and Farre-Mensa (2020), and Aghamolla and Thakor (2021).

#### 2.1 Institutional setting

Drug development in the U.S. is regulated by the Food and Drug Administration (FDA), and all drugs must pass certain phases in the FDA's approval process before they can be marketed and sold to consumers. The FDA approval process consists of three main phases—Phase I, II, and III—followed by a final NDA/BLA (new drug application/biologic license application) approval phase. Prior to Phase I, firms also engage in a more exploratory preclinical phase before deciding to spend substantial resources to enter Phase I. Overall, the development process typically takes a long time to complete (8 years on average; see DiMasi and Grabowski (2007)), entails substantial risk—the unconditional approval probability for drugs ranges from 5% to 25%, depending on the therapeutic area (Thomas et al. (2016))—and requires very high investment costs often exceeding \$2 billion per drug (DiMasi et al. (2016)).

While it may take several years for a drug to be developed, it is common for firms in this industry to go public even though their drug portfolios are primarily in preclinical or Phase I status. As mentioned previously, 37% of recent biotech IPOs exclusively had projects in Phase I or below. Accordingly, newly public biopharma firms generally have no revenues and negative earnings. Anecdotal evidence suggests that IPO firms with early-stage projects generally rouse investor interest through the potential of the drug and the reputation of management.<sup>12</sup>

An important feature of the three clinical phases is that the trials involve human experimentation. For ethical and practical reasons, the United States government established the website, registry, and searchable database ClinicalTrials.gov through passage of the Food and Drug Administration Modernization Act (FDAMA) in 1997. The purpose of Clinical-Trials.gov is to track the progress of all clinical trials regardless of their funding source (e.g., public, industry, academic). The database was created to provide greater transparency to human experimentation and to ensure that all trials and results could be publicly accessible (U.S. Congress (1997)). The website, operated by the U.S. National Library of Medicine at the National Institutes of Health (NIH), launched and was made publicly available in 2000.

While the database was established by law, reporting on the registry of clinical trials and results was limited and largely voluntary, as the 1997 FDAMA legislation very narrowly defined the legal requirements for reporting. Specifically, the 1997 law required only the *registration* of clinical trials, and only drug trials related to life-threatening diseases had to be registered (Miller (2010)). Moreover, the 1997 legislation did not require that the

<sup>&</sup>lt;sup>12</sup>Media coverage of a recent biotech IPO, *Allogene*, whose main product was in an early phase, quotes an analyst: "Deals like Allogene's are 'a bet on management, reputation and the board of directors. [...] It's not a validation of the product or technology—that's going to take many quarters, if not years." See "Biotechs With No Drugs in Trial Are Raising Millions in IPOs," *The Wall Street Journal*, October 31, 2018.

results of clinical trials be reported. However, in 2007, the U.S. government passed the Food and Drug Administration Amendments Act (FDAAA), which heavily expanded the mandatory reporting requirements for clinical trials on the database (Title VIII, Section 801). In particular, the FDAAA required that the summary *results* from clinical trials in Phase II or above must be reported, and widely expanded the types of trials subject to the mandatory reporting requirements to include all interventional studies of drugs, medical devices, and biologics.<sup>13</sup> However, the legislation did not require the reporting of trials in Phase I or in the preclinical phase. The law also specified penalties for noncompliance, which include monetary penalties (U.S. Congress (2007)).

The disclosures in ClinicalTrials.gov following FDAAA are typically quite detailed and include drug information, participant information (such as age and gender distribution and health conditions), disease application, clinical design (number and distribution of participants who received each drug and the dosage), outcomes, adverse events, and other descriptive information regarding the company and scientists involved. Importantly, the disclosures contain elaborate information regarding results and outcomes; this can include, for example, the precise reactions for participants over the course of the study and may be accompanied by statistical analyses. The disclosures also include detailed information regarding adverse events (side effects). A sample disclosure is included in Section B of the Online Appendix.

The CinicalTrials.gov database is publicly accessible and easily searchable. The database is also closely watched by practitioners in the biopharma industry. Indeed, an industry has developed with products that synthesize and report the information in ClinicalTrials.gov along with other analyses for biopharma industry professionals. Moreover, media outlets often generate and release news articles based on drug information disclosed through ClinicalTrials.gov.

To confirm the intended disclosure effects of the legislation, we examine the disclosure frequency over time. As shown in the top panel of Figure 1, we see a sharp increase in disclosures by private firms regarding Phase II or above projects in the year that FDAAA was implemented. The bottom panel of Figure 1 depicts the difference between Phase II (and above) disclosures and Phase I disclosures following FDAAA implementation; we see a sharp jump in 2007, which implies that private firms disproportionately increased their disclosures regarding projects in Phase II or above following the reform.<sup>14</sup>

<sup>&</sup>lt;sup>13</sup>The FDAAA mandates that trials subject to the requirement must be registered on ClinicalTrials.gov within 21 days of the first patient being enrolled, and the results from the trial must be reported on ClinicalTrials.gov within 12 months of collecting data for the primary outcome measure, i.e., the "Primary Completion Date," of the trial.

<sup>&</sup>lt;sup>14</sup>While a central provision of the FDAAA is the expanded disclosure requirements for clinical trials, the law also included other provisions regarding FDA oversight. The regulation expanded the FDA's authority to require firms to conduct additional clinical trials for approved drugs, and allowed the FDA to require

### 2.2 Conceptual framework

The biopharma industry is often characterized as fiercely competitive. Firms survive on their ability to innovate and the proprietary costs from releasing information are high (Guo et al. (2004), Thakor and Lo (forthcoming)). Proprietary costs arise from competition in the industry; disclosure by one firm can lead to information spillovers, with competitor firms adopting the innovations or using the disclosed information to advance their own projects, at the eventual expense of the disclosing firm (Krieger (2017)). For example, both negative and positive results information can be expropriated by competitors to suspend or advance their own trials.<sup>15</sup> This informational freeriding allows competitors to more efficiently allocate resources or to initiate new projects based on the positive information provided by their competitors disclosures. In particular, information about the biological mechanism of a drug can be gleaned given the amount of detail disclosed—in many cases the detailed reactions from the drug for each specific biological system in a patient, such as cardiovascular and gastrointestinal reactions—which can potentially allow competitors to better design their own studies or to more efficiently explore new disease targets for the drug. As documented by Guo et al. (2004), proprietary cost considerations significantly impacted prospectus disclosure decisions in their sample of biotech IPOs from 1995-1997.

Bhattacharya and Ritter (1983), Maksimovic and Pichler (2001), and Spiegel and Tookes (2008) model the going-public decision as the trade-off from increased disclosure of confidential information, which carries proprietary costs, and the benefit of raising public equity financing. This implies that firms would prefer to remain private if the proprietary disclosure costs from going public are sufficiently high. In the pre-FDAAA period, private firms faced limited disclosure requirements. Public firms, meanwhile, receive much stricter regulatory scrutiny and are required to disclose financial statement information. Moreover, public firms faced strong pressure to disclose project-level information in the pre-FDAAA era, and thus incurred greater proprietary costs from disclosure relative to private firms before the reform.

This heightened disclosure pressure for public firms is due to several factors. First,

companies to amend the safety information on drug labels. The FDAAA also created an electronic (nonpublic) surveillance system to record medication use based on prescription fills and medical encounters in order to systematically track adverse effects (known as "Sentinel"). The FDAAA additionally expanded the FDA's authority to regulate medical advertising, and implemented REMS (risk evaluation and mitigation strategy) requirements for high-risk drugs (such as opioids), which can include additional physician certification. Along with these new provisions, the FDAAA reauthorized previously established laws regarding user fees and pediatric studies that were set to expire. We discuss the potential implications of expanded FDA oversight in Section 4.4.

<sup>&</sup>lt;sup>15</sup>Anecdotal evidence includes the biopharma company NewLink Genetics suspending their trials of an IDO inhibitor, a cancer drug, due to "the failure of a competitor's trial of its enzymatic IDO inhibitor in a similar clinical setting." See "In light of Incyte's epacadostat debacle, NewLink scraps PhIII plans for its own IDO drug," *Endpoints News*, April 17, 2018.

public firms are required to disclose material information. The current judicial standard for materiality was established by the Supreme Court, whereby information is material if there exists a "substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available."<sup>16</sup> Second, there is greater demand by capital market participants, such as sell-side security analysts and institutional investors, for information concerning public companies. Moreover, managers of public firms cannot disclose otherwise non-public information to analysts or selected investors due to Regulation Fair Disclosure (RegFD). As a result, any project-level information the firm wishes to convey to security analysts or certain investors must be publicly disclosed. Finally, public firms face greater threats of shareholder litigation for withholding news (e.g., Skinner (1994, 1997)), which increases pressure to disclose private information.

Figure 2 illustrates the project-level disclosure frequency over time for public and private firms. Following the passage of FDAAA, we see in the top panel an increase in disclosure frequency for both groups. However, the increase is sharper for private firms. Indeed, as shown in the bottom panel of Figure 2, the difference in the number of project-level disclosures between public and private firms substantially diminishes in the post-FDAAA era. This is consistent with the notion that public firms faced greater pressure to disclose proprietary information prior to FDAAA implementation.

In contrast to public firms, private firms generally face no such regulatory or capital market demand for public disclosure. Although private firms may also be pressured to reveal information to investors, there is no requirement that such disclosures must be *publicly* made. Hence, private firms were largely shielded from the proprietary costs of disclosure in the pre-FDAAA era. However, with the passage of FDAAA, private firms were required to publicly disclose project-level information. This effectively minimized one of the major benefits from remaining private—reduced disclosure costs—as private firms must now endure these costs. This implies that the *marginal benefit* of remaining private is lower and going public becomes relatively more appealing following FDAAA implementation. Put differently, based on the models of Bhattacharya and Ritter (1983) and Maksimovic and Pichler (2001), if proprietary costs from disclosure are unavoidable for the firm regardless of whether or not they are private, then firms will be more inclined to go public. Therefore, following the passage of FDAAA, we expect an increase in the propensity of private biopharma firms to go public.

<sup>&</sup>lt;sup>16</sup>From *TSC Industries v. Northway, Inc.* (1976). See Heitzman et al. (2010) for a thorough discussion. Additionally, in the MD&A section, public firms must disclose "such other information that the registrant believes to be necessary to an understanding of its financial condition, changes in financial condition, and results of operations" (Item 303, Regulation SK).

## 3 Research Design and Data

### 3.1 Empirical Methodology

In order to explore the impact of increased mandatory disclosure requirements of the FDAAA on the propensity to go public, we exploit within-industry heterogeneity across firms with respect to their exposure to the FDAAA disclosure requirements. In particular, because the FDAAA mandates that Phase II and above projects are subject to increased disclosure, while Phase I (and preclinical) projects are exempt, we construct a continuous treatment variable that measures the proportion of a firm's drug development projects that are in Phase II or above immediately prior to FDAAA implementation. The idea is that firms with a higher proportion of their drug portfolio in Phase II or above will be more affected by the requirements of the FDAAA.<sup>17</sup>

Specifically, we estimate the following linear probability difference-in-differences (DID) regression at the firm-year level:

$$IPO_{i,t} = \alpha + \beta_1 PropPhaseII_i \times FDAAA_t + \beta_2 PropPhaseII_i + \beta_3 FDAAA_t + \gamma' X_{i,t} + \varepsilon_{i,t}.$$
(1)

In equation (1),  $PropPhaseII_i$  is our treatment variable, which measures the proportion of firm *i*'s (actively in development) drug portfolio as of 2006 that is in Phase II or above.  $FDAAA_t$  is a dummy variable that takes a value of one if year *t* falls in 2007 or later, and zero otherwise. The interaction between these two variables is therefore the DID estimator, and the associated coefficient  $\beta_1$  gives the marginal impact of a change in the treatment variable following FDAAA enactment.<sup>18</sup> Our dependent variable is  $IPO_{i,t}$ , which is a dummy variable that takes a value of one if a firm has undertaken an IPO, and zero otherwise.<sup>19</sup>

<sup>&</sup>lt;sup>17</sup>For example, consider two firms, A and B, each with a single project in development as of the time of the FDAAA. If firm A's project is in Phase II, it will immediately have to disclose additional detailed information about the project. If firm B's project is in Phase I, then it will not face any immediate requirement to disclose additional information about its project. While firm B may face disclosure requirements *in the future* if its project were to succeed and move to Phase II, there is substantial ex ante uncertainty regarding both whether and when it will pass Phase I (given the low success rates in drug development and the long development times; see DiMasi et al. (1991) and DiMasi et al. (2016)).

<sup>&</sup>lt;sup>18</sup>We use a linear probability model, rather than a probit or logit specification, due to the fact that marginal effects for interaction terms do not have a clear interpretation in such nonlinear models. Moreover, with the inclusion of fixed effects, these terms may not be feasibly computed (e.g., Ai and Norton (2003), Powers (2005), Greene (2010), Karaca-Mandic et al. (2012)). Nonetheless, we show that our main results hold when estimating probit and logit specifications in Table A1 in the Online Appendix.

<sup>&</sup>lt;sup>19</sup>In Section 5, we run analyses examining how firms change their project decisions after IPOs induced by the FDAAA. However, project decisions may not be made in the same year as the IPO. Thus, in order to account for these potential differences in timing related to the project decisions that we examine in Section

Our main prediction specifies that firms more subject to the regulation should be significantly more likely to go public since they can no longer avoid incurring the proprietary costs from disclosure. With the above specification, we test the *change* in the propensity of going public for firms with various levels of Phase I and Phase II (and above) concentration following FDAAA implementation. In other words, we should see a disproportionately greater change in IPO propensity following the reform for firms with a greater concentration of projects that are subject to the regulation as compared to the change in IPO propensity for firms with a lower concentration of projects subject to the regulation.

A potential concern is that firms with a higher proportion of their drug portfolio in Phase II or above are intrinsically different from firms with a higher proportion of Phase I drugs. For example, there may be less asymmetric information about such firms and investors may view them as being less risky, which may naturally give them a higher propensity to go public irrespective of the rule change we examine. While we will demonstrate that the parallel trends assumption holds in our setting, and moreover our results are robust to a variety of placebo tests, we also address this general concern by including a battery of control variables and fixed effects, denoted by  $X_{i,t}$  in equation (1).

First, we include a wide variety of controls at the firm-year level related to a firm's drug portfolio.<sup>20</sup> Specifically, in order to control for firm size, we include  $NumDrugs_{i,t-1}$ , which is the (lagged) total number of drugs in a firm's development portfolio. In order to control for firm risk, we include  $LOA_{i,t-1}$ , which is the average (lagged) likelihood of approval of all drugs in the firm's portfolio. This is an important control because Phase II drugs, given that they are further along the development process, inherently have a higher likelihood of succeeding conditional on a given drug. However, different drugs in different therapeutic areas would have different likelihoods of approval—i.e., a cancer drug in Phase II may still have a lower likelihood of success than a hematology drug in Phase I, since cancer drugs are substantially riskier than hematology drugs (see Hay et al. (2014) and Jørring et al. (2017)). (The therapeutic category dummies that we describe next also help to account for this.)

We include a set of 624 dummy variables that indicate whether a firm has a drug in development in a given year in each of the individual therapeutic categories in the database. This allows us to control for inherent differences in the nature of developing in one therapeutic area versus another, which may affect IPO propensity. These categories represent the intended disease/condition target of the drug. Examples of these therapeutic categories include "Asthma", "Hematologic Cancer", and "Rheumatoid Arthritis". The median firm

<sup>5,</sup> and to maintain consistency between the tests in Sections 4 and 5, we do not drop firms after they go public. However, all of our results are robust to dropping firms once they go public.

<sup>&</sup>lt;sup>20</sup>Our results are also robust to including all of our controls interacted with the post-reform dummy,  $FDAAA_t$ , which alleviates concerns related to the nature of our sample firms changing around the reform.

in our sample operates in two different indication categories.

Second, in equation (1), we include year fixed effects and we also include firm fixed effects in our most stringent specifications. With the inclusion of these controls and fixed effects, the interpretation of regression (1) is therefore that we are examining the decision of a firm to go public due to the requirements of the FDAAA, conditional on a given firm and year, and controlling for differences in the size and risk of a firm's project portfolio as well as the therapeutic areas that the firm is working in.<sup>21</sup>

We estimate equation (1) from 2004 to 2009, which gives us a window of six years surrounding the enactment of the FDAAA (three years in the pre-period, three years in the treatment period). We choose a relatively short window since, as noted by Bertrand et al. (2004), DID estimators may be biased when run over a long sample period due to auto-correlation. Moreover, since we define our treatment variable as of the year before the implementation of the FDAAA, as a practical matter this identification will become less valid as more time passes.

The key to our identification strategy is that our treatment variable, the proportion of the firm's drug portfolio as of 2006 that is in Phase II or above, is "as-if" random with respect to the implementation of the FDAAA in 2007. In other words, firms should not self-select their level of treatment (proportion of their drug portfolio in Phase II or above) in 2006 in order to affect their level of exposure to the mandated disclosure requirements in 2007. We believe that this assumption holds in our setting for the following reasons. First, as we will show in Section 4, the parallel trends assumption holds in our setting with regard to our main outcome variable. Second, decreasing the number of projects in Phase II or above to avoid disclosure cost requirements is likely an infeasible strategy for firms given that they would have to abandon later-stage projects or increase their initiations of new projects.<sup>22</sup> The high development costs associated with drug development (e.g., DiMasi et al. (2016)), and thus high adjustment costs, would also render such a strategy generally intractable.

<sup>&</sup>lt;sup>21</sup>We allow entry of new private firms over our sample period; since they do not have existing projects, the proportion of projects in Phase II or above for such firms is zero. Our results are robust to excluding these entering firms.

<sup>&</sup>lt;sup>22</sup>We find no evidence that firms in our sample engage in these actions. In Table A2 in the Online Appendix, we examine whether firms change their drug portfolios based on the proportion of their projects in Phase II or above in the years leading up to the passage of the FDAAA. If firms are strategically changing their investments before the FDAAA's requirements became active, then we should see a significant correlation between firms' Phase II and drug portfolio composition and their subsequent investment behavior in the pre-FDAAA period. This correlation is insignificant for the number of drugs under development, initiations of new drugs, suspensions of existing drugs, and drug acquisitions.

## **3.2** Data and Summary Statistics

We obtain our dataset of private firms from the BioMedTracker (BMT) database, which is a competitive intelligence database that compiles information on the drug portfolios of every biotechnology and pharmaceutical firm (both public and private) that operates in the U.S. The database includes detailed information on each drug project that a firm is developing at any given point in time, what phase in the FDA development process the drug is in, and the therapeutic indication category the drug falls into. The BMT database also contains information on disclosures, news updates, and regulatory events for each drug. Thus, the database allows us to identify private firms, and track the make-up and progress of their drug portfolios over time.<sup>23</sup>

The BMT database also includes estimates of the eventual likelihood of approval by the FDA of each drug at any given point in time, which we include as a control variable. These probabilities are updated any time that there is an announcement or news related to the particular drug. In order to construct these likelihood of approval probabilities, BMT uses historical approval rates as well as analyst adjustments based on development events. In particular, when a drug initially begins development, BMT assigns it an approval probability based on the historical approval rates of drugs in the project's particular disease/condition group. This probability is then updated for the drug each time there is relevant news about the drug. If the event conveys no relevant information about the eventual development success of the drug, then the approval probability is unchanged. However, if the event does contain relevant information (such as trial results), then the approval probability is adjusted either upward or downward depending on the nature of the information (i.e., if it is positive or negative). The magnitude of the change in the approval probability is determined by BMT, who evaluates the event and assigns a change in likelihood based on pre-specified criteria.

The BMT database also allows us to identify when a firm has initiated trials of a new drug project, whether it has suspended trials of an existing drug project, and when it acquires a drug project (i.e., in-licenses a project) from another firm. We use these outcomes for additional tests exploring how firms' innovation incentives are affected as a result of IPOs induced by increased mandatory disclosure.

Finally, we manually match these private firms in the BMT database to Compustat, to identify the dates of when any of the firms went public over our sample period. In order to

 $<sup>^{23}</sup>$ In particular, the BMT database collects information for drug portfolios from *all* sources, including any regulatory filings, press releases, conference calls with management, news articles, disclosures by the company, and also postings on ClinicalTrials.gov. Furthermore, information for the previous development history of drugs will also be back-dated into the database if any relevant information is released at a later date.

exclusively focus on private firms, we exclude any firms that had undertaken an IPO prior to our sample period (i.e., before 2004). This provides us with a base sample of 1,264 firms and 5,199 firm-year observations, with 53 IPOs, from 2004 to 2009. This number of IPOs is in line with previous firm-level IPO studies—for example, Pagano et al. (1998), who study the reasons for going public over an 11 year period, have a sample of 40 independent IPO listings. In our setting, with the inclusion of fixed effects, we are able to exploit differences both within and across firms with respect to the propensity to go public, thus providing sufficient variation for the analysis. Moreover, our analysis with a second, distinct empirical setting in Section 6 indicates that the results are not driven by the number of IPOs in our sample.

Panel A of Table 1 provides summary statistics for our key variables and controls, while Panel B provides the number of IPOs per year in our sample period. Across our sample,  $PropPhaseII_i$  has a mean of 59.1% and a median of 73.9%, indicating that more than half of firms' drug portfolios over our sample consist of projects in Phase II or above. However, the standard deviation is 42.7%, indicating that there is substantial variability across firms, which we exploit in our empirical tests.  $IPO_{i,t}$  has a mean of 3.9% and a median of 0%, indicating that the majority of our firms do not undertake an IPO during the sample period.  $LOA_{i,t-1}$ , the (lagged) likelihood of approval, has a mean of roughly 28% and a standard deviation of 20%, showing that while firms have a relatively low probability of eventual development success—in line with evidence on the riskiness of the biopharma industry—there is still substantial variability both across firms and across time regarding the riskiness of the projects that they are developing. Finally, the mean number of drugs,  $NumDrugs_{i,t-1}$ , that firms have in their development portfolios is between five and six, with a standard deviation of about 16. This indicates that, similar to public firms, there is heterogeneity in the size of private firms. We directly account for this variation by including this variable as a control in our analysis.

## 4 Results

In this section we provide our main results. We first examine the propensity to go public following FDAAA enactment. We then perform a variety of robustness tests.

#### 4.1 Main Results: Propensity to go public

As a prelude to our main results, we first establish that the parallel trends assumption likely holds in our setting. This amounts to showing that there is no significant difference between firms with higher versus lower values of  $PropPhaseII_i$  (the proportion of their portfolios comprised of Phase II and above projects in 2006) in terms of their propensity to go public prior to the implementation of the FDAAA. In order to show this, we estimate regression (1), but interact the treatment variable with a fixed effect for each year. We use 2006, the year immediately preceding the FDAAA, as the base year in our estimation (i.e., excluded category)—thus, all coefficients are estimated relative to the effect in 2006. The resulting coefficients, along with confidence intervals, are plotted in Figure 3. We expand the sample to include two additional years before our regression sample in order to provide a broader examination of any pre-trends.

As can be seen in the figure, for the years prior to 2006, the coefficients are *all* insignificantly different from zero (i.e., the effect in 2006). Put differently, there is no significant difference in terms of the propensity to go public between firms with different levels of *PropPhaseII*<sub>i</sub> in the pre-period. In contrast, beginning in 2007, the coefficients increase in magnitude and are all significant, indicating that firms with a higher value of *PropPhaseII*<sub>i</sub> begin to significantly increase their propensity to go public compared to other firms once the FDAAA was in place. This provides evidence of the validity of the parallel trends assumption for our empirical tests.

Table 2 provides results for regression (1). Across specifications (1) to (5), the interpretation is that we are comparing the IPO propensity of firms with different levels of the treatment before and after FDAAA implementation, controlling for differences in their project portfolios (size, risk, and project areas) and time effects affecting all firms. In all of these specifications, the DID estimator is positive and significant. Column (6) shows results for our most stringent specification, which includes all controls, project portfolio therapeutic category indicators, and year fixed effects, but also adds firm fixed effects. The disadvantage to including firm fixed effects in our setting is that we run the risk of reducing our power, given that our outcome variable is binary and therefore firm fixed effects may absorb much of its variation. However, the advantage is that firm fixed effects allows us to examine *within*firm effects. In other words, conditional on a given firm and a given year and controlling for the firm's project portfolio, the test examines whether the FDAAA increased the propensity for each specific firm to go public. Even when including firm fixed effects, our result remains significant, and with a similar magnitude as the other specifications.

The magnitudes of the coefficients indicate that on average, compared to before FDAAA enactment, shifting from a firm with no projects in Phase II or above to a firm with all of its projects in Phase II or above increases the likelihood of going public by 2.5 to 3.6 percentage points. For example, focusing on the specification in column (6), a one standard deviation increase in the treatment variable leads to a 1.3 percentage point increase in the probability

of transitioning to public equity markets following FDAAA implementation, which represents a 41.3% increase in IPO propensity relative to the pre-treatment sample mean. To put these numbers in context, the mean IPO propensity for firms in the bottom treatment decile in the pre-FDAAA period is 1.6%, and the mean IPO propensity for these firms in the post-FDAAA period is 1.6%. In contrast, the mean IPO propensity for firms in the top treatment decile in the pre-FDAAA period is 2.5%, while the mean propensity for these firms in the post-FDAAA period is 4.6%.<sup>24</sup>

### 4.2 Mechanism of the effect

We now further investigate the mechanism driving the main results. As discussed in Section 2, firms are more inclined to go public in the post-FDAAA period as they can no longer save the proprietary costs of disclosure by remaining private. One implication of this mechanism is that firms for which the proprietary costs of disclosure are greater should be more affected by FDAAA implementation. This occurs because proprietary costs from disclosure, as the benefit of raising equity financing at a lower rate would exceed the cost from disclosing confidential information (Bhattacharya and Ritter (1983)). As a consequence, FDAAA implementation would not significantly alter the propensity of going public for low disclosure cost firms.

To proxy for the variation in firms' level of proprietary disclosure costs, we first consider firm disclosure behavior prior to FDAAA enactment. Recall that in the pre-FDAAA era, reporting requirements were extremely limited, and hence most of the project-level disclosures were *voluntary*. Consequently, firms which disclosed more frequently per drug likely had lower proprietary disclosure costs (Jovanovic (1982), Verrecchia (1983)). To test this implication, we track the annual number of disclosures per drug made by each firm between 2000 and 2006. We then split our sample based on whether a firm made an above-median or below-median number of disclosures per drug during this period, and re-run our main test for each sub-sample. Columns (1) and (2) of Table 3 present the results of these tests. For firms that engaged in a relatively low number of disclosures prior to the FDAAA, the DID estimator is again positive and significant, indicating that these firms are more likely to go public as a result of the increased mandatory disclosure requirements. However, for firms that engaged in relatively greater disclosure prior to FDAAA implementation, the DID estimator is insignificant.

As an additional proxy for firms' level of proprietary disclosure costs, we also consider the

<sup>&</sup>lt;sup>24</sup>The bottom decile corresponds to having no projects in Phase II or above, while the top decile corresponds to having all projects in Phase II or above.

competitiveness of the development areas that firms operate in. The intuition is that firms which operate in more competitive areas will be more exposed to the competitive costs of disclosure. To examine this, we re-run our main tests after partitioning our sample based on whether a firm's drugs faced an above-median or below-median number of competing drugs in the same therapeutic class developed by other firms in 2006. As shown in columns (3) and (4) of Table 3, we find that our IPO results are stronger for firms whose drug portfolios faced greater competition.<sup>25</sup> These findings provide additional evidence to our hypothesized mechanism that, once proprietary disclosure costs became unavoidable for private firms, the marginal benefit of going public became relatively higher following FDAAA implementation and led to increased IPO propensity.

### 4.3 Robustness

We now examine robustness of the main results through a variety of additional tests.

#### 4.3.1 Placebo Test for FDAAA

A potential concern in any DID setting is that the effects are driven by some type of pre-trend that is unrelated to the event in question. Although our examination of the parallel trends in Figure 3 suggests that this is not the case, we further examine this possibility through a placebo test in which we falsely specify the year in which the FDAAA was enacted.

More specifically, we re-run regression (1), but over an earlier period prior to the FDAAA, from 2000 to 2006. We define a variable,  $PlaceboTime_t$ , that falsely defines the enactment of the FDAAA as 2004. We also re-define our treatment variable ( $PropPhaseII_i'$ ) as the proportion of the firm's drug development portfolio in 2003 that is in Phase II or above, to stay consistent with our previous methodology. The results are provided in Table 4. In all of the different specifications, the DID estimator is insignificant. This provides evidence that the effects we document in the previous subsection are not simply the continuation of a trend that began before our sample period.

#### 4.3.2 The Financial Crisis

A possible shortcoming of our setting is that our treatment period (2007–2009) includes the financial crisis of 2008–2009. In general, the increase in financial frictions during the

<sup>&</sup>lt;sup>25</sup>As an additional test of this channel, we also examine firms that developed orphan drugs compared to those that did not prior to the FDAAA. Since orphan drugs target diseases with few or no existing therapies, they thus face less development competition by their definition. These results are provided in Table A3 in the Online Appendix. In line with the previous test, our results are stronger for firms that did not develop orphan drugs prior to the FDAAA.

crisis should make IPOs more difficult for firms, and thus work against us finding an effect. However, if financial frictions related to the crisis differentially affect firms based on our treatment variable, it raises the possibility that our effects are driven partly by the crisis. For example, there may be more asymmetric information surrounding firms with higher proportions of Phase I drugs (i.e., firms that have a lower treatment intensity in our setting). The financial crisis could amplify the effect of such frictions, and may make it especially difficult for these types of firms to raise equity through an IPO. This could cause us to find an effect in our tests because these "control" firms are simply displaying a relatively lower propensity to go public due to the crisis.

To address this in our main specification, we include a wide variety of fixed effects and drug portfolio controls in order to control for differences between firms. However, we now attempt to more formally preclude this possibility. We re-run our analysis with three alternative specifications: expanding the sample to 2003–2010, excluding 2008–2009 from our sample, and including only the first six months of 2007 and the last six months of 2009 in the sample. These results are provided in Table 5. Across all specifications, the DID estimator remains positive and significant, which suggests that the effects are not driven by events during the financial crisis.

As another test of this channel, we run a placebo test where we re-estimate our main specification, but define our treatment variable in a different way. In particular, we re-define our treatment variable as *PropPhaseIII<sub>i</sub>*, which is the proportion of firm *i*'s drug development portfolio in 2006 that is in Phase III or above, excluding companies with drugs in Phase I. Thus, our placebo treatment variable captures the number of Phase III (or New Drug Application (NDA)/Biologic License Application (BLA), the final approval phase) projects relative to the number of Phase II projects that a firm is developing. The idea is that, since Phase III or above projects are more mature and closer to being approved, there is less asymmetric information about such projects. If the channel described above for the crisis is driving our results, then firms with a relatively higher proportion of Phase III or above projects should have a higher propensity to go public in the post-2007 period because they face less adverse selection.<sup>26</sup> Put differently, finding such an effect would mean that our results are not driven by the threshold between Phase I and Phase II established by

<sup>&</sup>lt;sup>26</sup>An implicit assumption for this test is that the uncertainty inherent in moving from Phase I to Phase II is comparable to the uncertainty in moving from Phase II to Phase III. Recent evidence on clinical development success rates calculated by Wong et al. (2019) indicate that this is indeed the case, suggesting that our placebo effect is not simply picking up less uncertainty in moving between phases. Relatedly, there are a substantial number of clinical trials in Phase III (Wong et al. (2019)), indicating that the proportion of drugs in Phase III represents meaningful variation even when compared to Phase II. In line with this, conditional on not having any Phase I projects,  $PropPhaseIII_i$  has a mean of 0.392, and 48% of firms in this group have at least one Phase III project in 2006.

the FDAAA, but more generally by having more mature or "proven" projects in the crisis period.

The results of this placebo test are provided in Table 6. Across all specifications in columns (1) to (6), the placebo DID estimator  $PropPhaseIII_i \times FDAAA_t$  is insignificant. We also provide an additional test in column (7), where we run our main specification examining  $PropPhaseII_i \times FDAAA_t$ , but add  $PropPhaseIII_i \times FDAAA_t$ . In contrast to the previous specifications, we define  $PropPhaseIII_i$  here as the proportion of firm *i*'s drug portfolio in Phase III or above, without excluding firms that have drug projects in Phase I. This allows us to include firms with Phase I drugs, and explore whether our placebo treatment variable has a direct marginal effect relative to our main treatment. We find that the coefficient for our main treatment effect  $PropPhaseIII_i \times FDAAA_t$  remains positive and significant, while  $PropPhaseIII_i \times FDAAA_t$  continues to be insignificant. Put together, these tests provide further evidence suggesting that the results are not driven by a channel unrelated to the FDAAA, such as adverse selection effects during the crisis. The additional analysis using the second empirical setting in Section 6 also helps to alleviate concerns of the financial crisis.

#### 4.3.3 Life-cycle Effects

A more general concern along the lines of the above is if our results are driven mainly by life-cycle effects for firms, i.e., firms with a greater concentration of later-stage projects or recent development successes may simply be further along in their life-cycle and thus could be more likely to go public (e.g., Jain and Kini (1994), Chemmanur et al. (2010)). We attempt to rule out this channel here.

If such an effect is driving our results, then one would expect to find that firms with a higher proportion of later-stage projects should go public in our sample irrespective of the passage of the FDAAA. We test if this is the case by exploring whether the relative phase composition of a firm's portfolio predicts its propensity to do an IPO in the pre-FDAAA period from 2000 to 2006.

The results are provided in Table 7. In Panel A, we define  $PropPhaseII_i$  as the proportion of projects in Phase II or above that a firm has at the beginning of the pre-FDAAA period, and examine whether a portfolio that has a relatively higher concentration of later-stage projects predicts IPO propensity. In all of the specifications, we find that the portfolio composition at the beginning of the period does not have any significant predictive power for the propensity to do an IPO. In Panel B, we conduct a similar exercise, but allow the proportion of the firm's projects in Phase II or above to vary over time. We find that the relative proportion of a firm's portfolio in Phase II or above does not significantly predict the firm's propensity to go IPO in the subsequent year. Put together, these findings are inconsistent with the notion that our results are being driven by firm life-cycle effects.

We note that our results should not be interpreted as providing evidence contrary to documented IPO life-cycle effects, but rather that our treatment is unlikely to be correlated with or driven by such effects. For example, previous studies such as Jain and Kini (1994) and Chemmanur et al. (2010) find that, consistent with life-cycle effects, firms tend to go public at the peak of their innovation. In contrast,  $PropPhaseII_i$  focuses on incremental progress within the drug development process. Moreover,  $PropPhaseII_i$  may not capture firm or drug maturity, because, depending on the therapeutic category (which we control for), some drugs in early-stage development may ultimately take less time to receive FDA approval than later-stage traditional drugs (Kaitin and DiMasi (2011)). Beyond this, the stylized facts of IPO activity in the biopharma industry suggest that the life-cycle channel may be relatively less salient for firms in this industry. As we discussed previously, firms in the biopharma industry often go public while their drug portfolios are in early-stage development and when they have not had a quarter with positive revenues.

#### 4.3.4 Autocorrelation

A general concern with DID estimators is that the results may be biased toward finding an effect if there is autocorrelation in the data (Bertrand et al. (2004)). Although one reason why we choose a relatively short sample window is to allay this concern, we also more explicitly control for autocorrelation here by re-running our main results using Newey and West (1987) heteroskedasticity and autocorrelation adjusted (HAC) standard errors with up to two lags. The results are shown in Table 8. All of our results continue to hold when explicitly adjusting for autocorrelation in our sample using HAC standard errors.

#### 4.4 Other FDAAA provisions

As noted in Section 2, the FDAAA contained other provisions aside from increased disclosure requirements that include expanded FDA oversight of post-approval drugs, medical advertising, and drug labels. In this section, we discuss our results in light of the enhanced FDA oversight. In particular, the FDA could require companies to conduct additional clinical trials or studies (known as post-marketing requirements or "PMRs") for approved drugs. While the FDA had such authority prior to the FDAAA, the new legislation expanded the FDA's authority if observational evidence indicated that the drug may carry potential adverse effects that were not documented at the time of approval.<sup>27</sup> This allows the FDA to ensure the safety of drugs currently available to consumers, and to scientifically evaluate potentially adverse effects from an approved drug that were not previously documented.

One potential concern is whether this increased regulatory cost from the possibility of receiving a PMR from the FDA confounds our main result in Table 2, as an IPO can provide additional resources to handle higher regulatory costs. We note that this is unlikely to be the case, as this PMR provision of the FDAAA applied to all firms, while the mandatory disclosure requirements applied only to drugs in Phase II or above. Consequently, under this alternative explanation, we should not observe differential effects in IPO propensity based on the proportion of a firm's drug portfolio that is in Phase II or above, which is inconsistent with our main result.

## 5 Project Decisions and IPOs

Having provided evidence of the increased propensity to go public following the increased mandatory disclosure requirements of the FDAAA, we now turn to the effect this had on project investment decisions by firms. Specifically, we examine whether IPO decisions driven by information disclosure requirements lead firms to alter their investment and innovation decisions. An advantage of our setting is that our detailed project-level data allows us to track firms' investment projects at a granular level, enabling us to closely track changes in firms' investment portfolios and innovation activity over time. Furthermore, it enables us to not rely on patent data as a measure of innovation, given the shortcomings of patent measures. As has been noted in the innovation literature (e.g., Kelly (1990), Freilich (2019), Freilich and Ouellette (2019)), patents may not necessarily reflect actual innovation activity. For example, patents may be issued either for projects that do not exist, or for projects that a firm does not intend to invest further in. Exploring such an effect also allows us to ascertain a potential downstream effect on investment and innovation related to increased information disclosure requirements.

Our hypotheses in this section are drawn from the theoretical work of Jensen and Meckling (1976) and Holmström (1999).<sup>28</sup> Conceptually, the transition to public equity markets may exacerbate agency frictions within the firm. Public firms are characterized by disbursed

<sup>&</sup>lt;sup>27</sup>Specifically, the FDA had authority prior to the FDAAA to impose post-approval requirements for drugs that received accelerated approval; see, e.g., the FDA's website: https://www.fda.gov/drugs/guidance-compliance-regulatory-information/postmarket-requirements-and-commitments.

 $<sup>^{28}</sup>$ Aghion et al. (2013) and Bernstein (2015) provide similar arguments with respect to the link between monitoring and innovation. See also Roychowdhury et al. (2019) for a review of the theoretical literature relating to public and private firm investment decisions.

ownership and maintain less direct monitoring of management. Consequently, managers fear they may be punished by shareholders or the board for unfavorable outcomes ex post (e.g., drug failures), even for project decisions that were optimal or reasonable ex ante. In particular, due to weaker monitoring, shareholders may mistakenly attribute bad project outcomes to managerial incompetence rather than to bad luck. Indeed, as documented by Jenter and Kanaan (2015), managers are often dismissed for factors beyond their control. Hence, due to career and reputation concerns, managers may be less inclined towards investing in risky projects to minimize the downside risk of project failures. As shown by Holmström (1999), even risk neutral managers are disincentivized from taking risky projects when monitoring is weak.

Conversely, private firms generally have more closely held and illiquid ownership, which results in stronger and more direct monitoring by owners. As such, negative outcomes from previous project decisions are less likely to be held against management, as owners can recognize that the manager made the correct decision ex ante. Consequently, due to stronger monitoring, managers are more inclined to take risky projects. This implies that firms which have recently gone public should also be met with less risky project decisions by management.<sup>29</sup> In our setting, this translates to a less risky project portfolio (as captured by  $LOA_{i,t}$ ). Moreover, to minimize risk, managers may seek to acquire projects developed externally, as early positive signs from an on-going project may imply a higher likelihood that the drug is eventually approved. This can be less risky than in-house development of new projects which may carry greater uncertainty. Additionally, the transition to public equity markets can induce greater managerial mypoia (e.g., Stein (1989)), which can shift innovation towards acquisitions of later-stage projects in order to more expeditiously generate results.

We note that the influx of cash from the IPO could alternatively lead to *increased* innovation following the equity issuance. In particular, due to capital constraints, private firms may not have been able to innovate at their optimal level. Following the IPO and its cash infusion, firms can use the newly raised capital to reach the optimal innovation level that was not attainable while private. This is consistent with previous findings that capital constraints can impede investment (e.g., Gan (2007), Chava and Roberts (2008)). Hence, in contrast to the prediction above, the transition to public equity markets may lead to an increase in innovation if going public helps to ease capital constraints.

<sup>&</sup>lt;sup>29</sup>This hypothesis is consistent with other theoretical work as well. Ferreira et al. (2014) predict that it is optimal for private firms to explore more innovative ideas and public firms to invest in existing ideas, due to agency and informational frictions. Boot and Vladimirov (2018) predict that private firms will pursue more early-stage innovation, while public firms will coordinate on existing technologies, due to informational frictions.

### 5.1 Empirical Strategy

Our empirical approach is to exploit the variation in the propensity to undertake an IPO induced by the FDAAA, and use that to examine drug development portfolio decisions over time. In order to do so, we use a two-stage estimation strategy, as suggested in Pagano et al. (1998).<sup>30</sup> In the first stage, we utilize equation (1) to capture the variation in IPOs due to the FDAAA once it went into effect. The idea of the first stage is that the proportion of a firm's projects in Phase II or above in 2006 measures the exposure of a firm to the information disclosure requirements of the FDAAA. We therefore use this exposure to instrument for the propensity to go public in the post-FDAAA period. This allows us to capture the exogenous component of engaging in an IPO (due to increased disclosure requirements) and thus its direct effect on investment and innovation decisions.

Using instrumented IPO from the first stage, in the second stage we examine how IPOs driven by these disclosure requirements affect a firm's project decisions:

$$Y_{i,t} = \alpha + \eta \widehat{IPO}_{i,t} + \delta X_{i,t} + \epsilon_{i,t}.$$
(2)

This two-stage procedure is a fully-estimated instrumented difference-in-differences (DDIV) specification (see Hudson et al. (2017); a similar approach has also been used in Duflo (2001) and Abdulkadiroğlu et al. (2016), among others). This methodology allows us to estimate the local average treatment effect (LATE) of a firm whose private-public status was changed by the treatment (i.e., compliers).<sup>31</sup> To further underscore the validity of this approach, in Table A4 of the Online Appendix, we use regression (1) to explore whether the law affects innovation outcomes for firms that choose to remain private, and we do not find a significant effect on these outcomes. This suggests that the effect of the FDAAA on our innovation outcomes operates specifically through the IPO channel, thus validating the exclusion restriction.

We estimate the above over the same sample window as our main tests, from 2004 to  $2009.^{32}$  In each stage, we include in  $X_{i,t}$  our previous set of lagged controls, project portfolio

 $<sup>^{30}</sup>$ Pagano et al. (1998) note that "in estimating the expost consequences of IPOs, we face a potential endogenous selection problem: the companies that went public have chosen to do so. In principle this problem could be solved via a two-stage procedure, where the first stage involves estimating a model of the decision to go public" (p. 47).

 $<sup>^{31}</sup>$ In contrast, a DID specification here, similar to that of equation (1), would only allow for estimation of the *average* treatment effect, thus capturing the potential change in project decisions made by firms that choose to go public irrespective of the change in disclosure requirements, as well as those that stayed private. This would confound the conclusions we could draw from the estimation.

<sup>&</sup>lt;sup>32</sup>Our results are also robust to running these 2SLS regressions in the post-FDAAA period from 2007 to 2009, but including only  $PropPhaseII_i$  as a cross-sectional instrument for  $IPO_{i,t}$  in the first stage.

therapeutic category indicators, and year fixed effects.<sup>33</sup>

As our main outcomes for  $Y_{i,t}$ , we explore a number of different variables. We look at the number of drugs that a firm is developing in the given year,  $NumDrugs_{i,t}$ , in order to see if a firm expands or contracts the size of its project portfolio. To further investigate what might drive a change in the size of a firm's project portfolio, we examine the number of exploratory trial initiations for new drugs that a firm is undertaking,  $Initiation_{i,t}$ , as well as the number of drugs in development that a firm decides to suspend or terminate,  $Suspension_{i,t}$ , as additional outcome measures. These variables give us a glimpse into whether a firm is deciding to internally innovate by starting the development of new drugs, or whether that firm is deciding to end development of projects. We also consider the number of acquisitions of drug projects from other firms that a firm undertakes,  $Acquisition_{i,t}$ . This allows us to see whether a firm decides to externally acquire existing innovation from other firms, rather than develop something new in-house. Finally, we examine the overall risk of a firm's portfolio,  $LOA_{i,t}$ , as an outcome variable.<sup>34</sup>

### 5.2 **Project Decision Results**

The results of regression (2) are provided in Table 9. The first stage of the regression is the same as in Table 2. This indicates that the proportion of projects in Phase II or above in a firm's portfolio in 2006 makes it more likely to go public in subsequent years. Using instrumented IPO,  $\widehat{IPO}_{i,t}$ , as an estimate for predicted IPOs due to the increased disclosure requirements of the FDAAA, we examine project decisions in columns (1) through (4) of Table 9. The results in column (1) indicate that firms with a greater propensity to go public due to the FDAAA significantly reduce the number of drugs in development in their project portfolios. The magnitude suggests that firms that go public due to disclosure requirements develop an average of roughly four fewer drugs compared to other firms. While the magnitude of the coefficient suggests a large decline in the number of drugs, the point estimate is partly influenced by the presence of firms with large development portfolios. Excluding firms in

<sup>&</sup>lt;sup>33</sup>We do not include firm fixed effects because doing so absorbs the majority of our variation jointly between the first and second stages, since our first-stage has a 0-1 outcome variable, we include project therapeutic category fixed effects, and most firms develop low numbers of drugs and therefore engage in few initiations/suspensions/acquisitions in any given year.

<sup>&</sup>lt;sup>34</sup>Using this specification, in untabulated results we use Compustat data to compare the observable financial characteristics, such as stock returns, of firms that went public due to the disclosure requirements compared to other newly-public firms. We do not find any significant difference in terms of post-IPO financial characteristics between these two sets of firms. This suggests that, in terms of their financial and accounting characteristics, firms that went public due to the increased disclosure requirements are not significantly different from other firms that went public, which provides evidence against other potential channels driving our results.

the extreme 1% tails of the pre-FDAAA size distribution yields a reduction in the number of drugs in development of just over two.

Peering more closely into the cause of this decline in development projects, in column (2) we find that this is due to such firms reducing their innovation—they initiate significantly fewer new projects in-house. This is consistent with previous evidence by Bernstein (2015), whereby internally-developed innovation falls following the IPO. Our findings suggest that this result also holds when examining actual project investment decisions rather than patenting activity, and also when such IPOs are driven by increased disclosure requirements unrelated to filing an IPO. Column (3) examines project suspensions, and we find that these firms are also more likely to suspend or terminate existing projects. To provide some additional color to these results, IPO firms in the bottom decile of *PropPhaseII* had an average of 0.40 new drug project initiations in the post-FDAAA period, while IPO firms in the top decile of *PropPhaseII* had an average of 0.19 new drug project initiations in the post-FDAAA period. Similarly, IPO firms in the top decile of *PropPhaseII* had an average of 0.33 project suspensions in the post-FDAAA period, while IPO firms in the bottom decile of PropPhaseII had an average of 0.10 project suspensions. Overall, this provides evidence that post-IPO firms may be reducing their innovation activity by terminating existing innovation that they had already begun.

Column (4) examines acquisitions of existing projects from other firms, and shows that firms tend to increase their acquisition activity and thus seem to turn to in-sourcing existing projects that were developed externally. To examine the overall effect of these actions on the nature of the firm's investments, we examine the risk of the firm's development portfolio in column (5). We find that firms' development portfolios become significantly *safer* (i.e., higher likelihood of approval) following going public, when the IPO is driven by a change to disclosure requirements.

In order to further understand these effects, we run a final analysis in which we examine the nature of the new projects that firms acquire after going public. In columns (1) and (2) of Table 10, we examine whether the new acquisitions are either more or less risky than a firm's existing portfolio (based on the average likelihood of approval of the firm's development portfolio). We find that post-IPO firms engage in acquisitions of projects that are relatively less risky than their existing portfolios, while they do not engage in acquisitions that are more risky than their current portfolios. Examining the stage in development of these acquisitions in columns (3) and (4), we find that firms increase their acquisitions of late-stage development projects (Phase II and above), but not early-stage projects (Phase I or preclinical).<sup>35</sup> This

<sup>&</sup>lt;sup>35</sup>A potential concern is that these results are driven by a life-cycle effect in which post-IPO firms invest in later stage projects. We note that this is not likely to be the case, since our first stage isolates IPO

also helps to explain the move towards less-risky acquisitions documented in columns (1) and (2); since later-stage drugs are closer to approval, they will be less risky than early-stage drugs, all else being equal.

Put together, the evidence suggests that firms which transition to public equity markets due to non-prospectus increased disclosure requirements appear to reduce the number of drugs that they hold in development. They do so by reducing the number of new drugs that they initiate in-house and abandoning projects currently in development. Firms replace some of these projects through acquisitions of projects from other companies, but the acquisitions are of relatively less risky, later-stage projects. This effect substantially reduces the overall risk of the firm's development portfolio, and provides evidence that firms gravitate towards safe projects following going public.<sup>36</sup>

These results are in line with the hypothesis that newly public firms shift towards less risky project decisions. This is exemplified by the finding that the number of new in-house project initiations decreases, consistent with the notion that managers are less inclined to begin new projects that could result in failure to avoid potentially damaging their reputation. Likewise, managers are more inclined to acquire later-stage projects externally which generally carry less uncertainty than newly developed projects. We note that the findings of Asker et al. (2014) and Bernstein (2015) are also consistent with the hypothesis of lower innovation for newly public firms, however we also provide novel evidence of decreases in *risk-taking* which, to our knowledge, has not been explored elsewhere in the literature. Additionally, our results suggest that these effects may be viewed as an unintended consequence of increased mandatory disclosure requirements for private firms.

## 6 External validity: Second empirical setting

While the results of our main setting support the hypothesis that mandatory disclosure requirements for private firms increase the propensity of going public, we supplement this analysis with a second setting as a robustness for external validity. In particular, we utilize the strengthening of mandatory disclosure requirements for private firms in Germany in

propensity that is driven by disclosure requirements (firms with a higher *PropPhaseII*) compared to other firms. As previously discussed, our robustness tests in Section 4.4 provide evidence inconsistent with the first stage being driven by life-cycle effects, therefore implying that the project responses are also independent of such effects.

<sup>&</sup>lt;sup>36</sup>This replacement effect helps to explain the magnitude of the increase in likelihood of approval provided in Table 9. For example, acquiring drugs in different, less risky therapeutic areas or acquiring later-stage drugs could substantially increase the average likelihood of approval of the drug portfolio (Wong et al. (2019)). We note that our results concerning acquisitions undertaken by firms in this setting are also consistent with previous papers that have shown that access to equity markets enables firms to issue stock as a currency for acquisitions (e.g., Celikyurt et al. (2010)).

2006 (Bernard (2016), Breuer et al. (2018)), exploiting variation between German and other European private firms in a difference-in-differences research design. As additional tests, we also exploit variation between firms within Germany following the enhanced enforcement, as well as variation in size thresholds for mandatory disclosure across European countries. We find support for our main hypothesis across all specifications, implying that the effect we document in our main analysis is a robust economic phenomenon.

### 6.1 Institutional setting

In 1978, the European Union established accounting directives regarding mandatory disclosure requirements for private companies that member states were expected to follow (Fourth Council Directive 78/660/EEC). The EU allowed more lenient disclosure requirements for smaller firms in order to reduce the regulatory burden, although the EU directives also specified maximum exemption thresholds (European Union (2009)). National governments were responsible for enforcing these directives and for determining the size thresholds for disclosure. As an example, "small" private firms in Italy are required to disclose only an abbreviated balance sheet and income statement, while firms designated "medium" or "large" must disclose a full balance sheet and income statement along with corresponding notes and a director's report. These thresholds are based on asset value, number of employees, or annual sales (firms meeting two of the three thresholds classify as "medium"). Moreover, thresholds for disclosure vary markedly across European countries. Nevertheless, most EU member states generally saw high compliance of these disclosure requirements among private firms.

One notable exception was Germany. Seeming to abide by the EU directives, the German federal government passed the Accounting and Reporting Law of 1985, which required private companies to publicly disclose annual financial statement information based on size thresholds (in German, the law is *Bilanzrichtliniengesetz*.). However, enforcement of the legislation, delegated to local courts, was extremely weak due to the lack of penalties. As a result, disclosure was essentially voluntary and only about 5-10% of German private firms complied with the requirements (Noack (2002), Theile and Nitsche (2006)). Due to increased pressure and directives from the European Union, the federal government introduced and endorsed the Electronic Commercial and Company Register law ("EHUG"),<sup>37</sup> which centralized monitoring of financial statement disclosures by the Federal Office of Justice and created a national register for filings so that financial statements could be electronically ac-

<sup>&</sup>lt;sup>37</sup>In German, Gesetz ber das elektronische Handelsregister und Genossenschaftsregister sowie das Unternehmensregister.

cessible (similar to EDGAR in the U.S.). The law also mandated much stricter enforcement of the disclosure requirements, including sizable, escalating monetary penalties for noncompliance. EHUG was first proposed in April 2005, and was passed by the National Parliament in September 2006 (Bernard (2016)). The law applied to firm fiscal years ending on or after December 31, 2006. The enhanced enforcement resulted in an effective mandatory disclosure regime, with over 90% of private firms disclosing within two years of the law's passage (Henselmann and Kaya (2008), Eierle (2011)).

### 6.2 Research design and results

The aforementioned setting allows us to test additional empirical specifications with regard to our main hypothesis. We first explore the effect of the enhanced enforcement of disclosure requirements in Germany for German private firms compared to other European private firms.

In contrast to the enforcement for private firms, the enforcement of disclosure for *public* firms pre-2006 in Germany was much more stringent. Withholding financial statements can be advantageous due to the revelation of potentially sensitive information that can be used by competitors. For example, sales and profit information could induce market entry or penetration by competitors. Likewise, financial statements and notes disclosures can provide product profitability and investment (R&D) information to rivals that may lead to product mimicry or an increased risk of preemption through greater R&D spending by competitors. Therefore, prior to 2006, German private firms could evade disclosure and limit transparency by remaining private. In addition, mandating financial statement disclosure for private firms results in a relatively lower cost of going public, as private firms can no longer avoid the disclosure. Hence, this second setting is suitable to test our main hypothesis as the predicted channel operates in largely the same way as in our main specification.

Specifically, since the improvement in disclosure enforcement was specific to Germany, we predict an increase in IPO propensity for German private firms relative to other European private firms. To formally test for the effect in this setting, we use a difference-in-differences (DID) research design at the firm-year level similar to that of equation (1):

$$IPO_{i,t} = \alpha + \beta Treated_i \times Reform_t + \gamma' X_{i,t} + \mu_i + \eta_t + \varepsilon_{i,t}.$$
(3)

Regression (3) is run from 2003 to 2008. The dependent variable,  $IPO_{i,t}$ , is an indicator equal to one if private firm *i* went public in year *t*, and 0 otherwise.<sup>38</sup> Similarly, the variable

<sup>&</sup>lt;sup>38</sup>Unlike our first setting, we are unable to examine the effect of the IPO on subsequent project decisions in this setting. Hence, we drop firms the year following their IPO.

 $Reform_t$  is an indicator that takes the value of one if year t is 2006 or later, following the implementation of EHUG in 2006, and zero otherwise. We also consider a related specification where we drop observations from the transition year 2006 and define  $Reform_t$  to be equal to one if year t is 2007 or later, and zero otherwise. We discuss the reasoning for these specifications shortly.

Following Bernard et al. (2018), we use data for private firms from the following twelve EU member states: Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, Netherlands, Spain, Sweden, and the United Kingdom. As the law resulted in effective mandatory disclosure for German private companies, the variable *Treated<sub>i</sub>* is a dummy equal to one if firm *i* is a German private firm, and zero otherwise. Hence, our control group is comprised of non-German private firms in EU member states which had already enforced the EU accounting directives for mandatory disclosure and were unaffected by Germany's EHUG implementation. We include a vector of controls,  $X_{i,t}$ , as well as time and firm fixed effects, denoted by  $\eta_t$  and  $\mu_i$ , respectively. We drop any firms that went public prior to our sample period. We include controls for the logarithm of total assets, cash holdings scaled by total assets, and profitability (EBITDA over total assets).<sup>39</sup>

Our data come from the Bureau van Dijk Orbis database, which contains financial statement information for European private companies. The total sample includes 459,725 medium and large private firms and 1,050 IPOs, with 152 IPOs by German firms. We note that these counts exclude firms with missing controls in the database. We obtain consistent results if we run our specifications excluding controls (thus increasing the number of firms and IPOs) or if we use alternative controls (such as substituting profitability with asset growth).

In determining the appropriate post-period, we note that EHUG required disclosure of financial statements for fiscal years ending on or after December 31, 2006. As such, private firm financial statements for fiscal year 2006 would be publicly available in calendar year 2007. However, our research question focuses on a private firm's consideration of the costs and benefits of going public. We therefore use 2006 as the first year of treatment as firms rationally anticipated the expected proprietary disclosure costs and factored these costs into their going-public or staying-private decisions. We provide additional background to better elucidate this point. First, the EU passed a directive in July 2003 requiring that EU member states ensure that firms can file their financial statements electronically no later than January 1, 2007 (Directive 2003/58/EC). While Germany initially did not act in response to the directive, the federal government ultimately proposed the EHUG bill in April

 $<sup>^{39}{\</sup>rm Breuer}$  et al. (2018) note that Bureau van Dijk backfilled data for fiscal year 2005 using information that was disclosed in 2006.

2005. The Federal Chancellor sent the bill to the Federal Council (*Bundestrat*; analogous to the U.S. Senate) in December 2005, which indicates that the German federal government endorsed the law (Bernard (2016)), and a revised version of the bill was sent to the National Parliament (*Bundestag*; analogous to the U.S. House of Representatives) in March 2006, after incorporating the comments of the Federal Council. The law was passed by the National Parliament in September 2006.

Due to the EU directive's deadline of January 1, 2007, and since the law had been moving through different branches of government and parliament, it became increasingly clear that the law would pass in 2006. Moreover, unlike the 1985 law, EHUG specifically included provisions to enforce the (now long-existing) disclosure requirements through the creation of a new federal agency for monitoring and precise penalties for noncompliance. Consequently, private firms took into consideration the expected proprietary disclosure costs in their staying-private or going-public decisions as it became clear that the law would pass. We thus use 2006 as the first year of treatment in the research design as we seek to estimate the change in IPO propensity for treated firms when they rationally *anticipated* that they would have to incur proprietary disclosure costs.<sup>40</sup> This anticipation is also evidenced in Bernard (2016), as a substantial number of German private firms began disclosing prior to the law's passage. Moreover, our parallel trends graph indicates that the effect of the mandatory disclosure on firm IPO decisions first occurred in 2006. We also consider a specification where the transition year of 2006 is removed from the estimation, resulting in a post-period of two years.

Table 11, Panel A presents the results of this specification and Figure 4 presents the corresponding parallel trends. We see in Figure 4 that the propensity of going public for German private firms jumps in the first year of the post-period and remains significantly positive in all post years. Moreover, Figure 4 shows that German and non-German private firms largely did not have substantive differences in IPO propensity in the pre-EHUG period. These results are reinforced in column (1) of Table 11, Panel A, where the coefficient on the DID estimator,  $\beta$ , is positive and significant at the 1% level. As robustness to ensure that our results are not driven by the financial crisis, we exclude the crisis period (2007Q3 through 2008) from our sample in column (2), and we again get very similar results.

We next test a related specification where we drop the transition year 2006 from the sam-

 $<sup>^{40}</sup>$ We note that this is in contrast to related studies that employ the EHUG setting, such as Breuer et al. (2018) and Baik et al. (2020), which use 2007 as the first treatment year. However, these studies consider a learning channel, whereby capital market participants (banks and private equity/venture capital investors) can utilize the newly disclosed information for their lending and investment decisions. Hence, for these studies, 2007 is the most suitable treatment year, as the research designs consider the actual public *revelation* and accessibility of (previously private) financial statements.

ple, and consider a post-period of 2007–2008. The results of this specification are presented in Panel B of Table 11. The results are consistent with our previous specification.

A potential concern with the above test is that our control group of European firms is larger than our treatment group, and may not be comparable as a result. To address this, we re-run our tests, but construct balanced treatment and control groups using propensity score matching. We use one-to-one matching based on size, cash holdings, and profitability in the year before the reform, restricting our sample to firms on a common support. This results in a sample of 178 IPOs, with 81 IPOs in the treatment group and 97 IPOs in the control group over the entire sample.<sup>41</sup> These results are provided in columns (3) and (4) of Table 11, Panel A and column (2) of Panel B. For both the entire sample and our sample excluding the financial crisis, our results remain with very similar point estimates and significance.

#### 6.3 Extensions

We next run two additional specifications to provide further evidence. In the first specification, we restrict the sample to only German private firms, and exploit variation between German firms in terms of their exposure to the disclosure enforcement. Specifically, we re-run equation (3) for German firms, but re-define the variable *Treated<sub>i</sub>* as a continuous variable equal to the negative of the average Herfindahl for the industry firm *i* operates in, denoted as *Competitiveness<sub>i</sub>*. We calculate the sales-based Herfindahl-Hirschman Index (HHI) for each 3-digit NAICS code over the pre-period, and then define *Competitiveness<sub>i</sub>* as the negative value of firm *i*'s industry HHI, with a higher value therefore indicating less concentration. For robustness, we also define *Competitiveness<sub>i</sub>* using more granular 4-digit NAICS codes. (We note that our results are robust to defining this measure using 2-digit SIC codes.) In order to capture data about firm industries, we merge data from the Bureau van Dijk Amadeus database to our previously described Orbis data.<sup>42</sup> Hence, our treatment variable tracks German private firms who operate in relatively more competitive industries, comparing their IPO propensity to German private firms operating in less competitive indus-

<sup>&</sup>lt;sup>41</sup>We provide *t*-tests of the difference between the matching characteristics for the treatment and control groups in Table A5 of the Online Appendix. There is no significant difference between the groups in terms of size and profitability. The difference between cash holdings of the two groups is marginally significant; however, we control for cash in all of our regressions. We note that our matching is based on cash holdings winsorized at the 0.01 level in order to improve our match by reducing the influence of outliers; our results are robust to not doing this. Our results are also robust to performing our matching procedure within 1-digit SIC or 2-digit NAICS industry classifications. Furthermore, our results are robust to matching using asset growth instead of profitability, or matching just on size and cash holdings.

<sup>&</sup>lt;sup>42</sup>We drop foreign, non-profit, unlimited liability, financial, and utility firms, as well as firms not subject to the disclosure requirements. We control for size and cash holdings; our results are robust to also controlling for profitability, but we do not do so because these data are missing for many firms in Amadeus.

tries. The reasoning is similar to that of our main specification: firms in more competitive areas face greater proprietary costs of disclosure, and hence disclosure costs played a larger role in the decision to stay private for these firms. Consequently, firms in more competitive industries should experience a more pronounced increase in their IPO propensity following EHUG implementation. The results, presented in Table 12, are consistent with our main hypothesis. We see that German private companies that operated in more competitive areas are significantly more likely to go public following the enhanced enforcement.

Our setting also allows for a second distinct specification to test our main hypothesis (similar to the specification in Breuer et al. (2019)). In particular, we utilize the variation in size thresholds for required disclosure across firms in twelve EU member states: Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, Netherlands, Spain, Sweden, and the United Kingdom. In order to do so, we use data from the Bureau van Dijk Orbis database from 2002 to 2019, with a sample consisting of 1,421,334 firms and 1,949 IPOs. The idea is that a private firm that becomes subject to the disclosure requirements for its respective country will be more likely to go public, according to our argument. Further details of this specification are included in Section A of the Online Appendix.

The results are provided in Online Appendix Table A6, and the coefficient of interest is positive and significant. This indicates that, in this setting as well, private firms are more likely to go public once they are subject to increased disclosure requirements.

## 7 Conclusion

The determinants of what drive a private company to go public are of significant interest to lawmakers and researchers. In this paper, we show that increased mandatory disclosure requirements for private firms significantly increases their propensity of going public. We exploit a shock to disclosure requirements and utilize data regarding private firms in the U.S. Further analyses provide evidence that the mechanism underlying this increase is attributed to the proprietary costs of disclosure. Consistent findings in an alternative setting indicate that the effect we find is not limited to the specific setting, but rather holds more generally. This suggests that private firms' information environment and their ability (or lack thereof) to withhold proprietary information plays a significant role in the decision to transition to public equity markets.

The results are robust to a number of specifications and placebo tests, as well as a different setting involving enhanced disclosure requirements for German private firms. We additionally examine the project decisions of post-IPO firms, when the IPO is induced by the disclosure requirements. Our analysis using granular project-level shows the precise innovative effects due to the going-public decision. This contributes to our understanding of how firms' innovative focus changes after their IPO. In particular we find that, not only does innovation decline following the IPO, but firms shift their development efforts towards safer projects. These results have potentially important implications for laws that mandate additional disclosure requirements for private firms.

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#### Figure 1: Disclosures by Project Phase

The top figure shows the total number of disclosures per drug (the total number of disclosures scaled by the total number of drugs in each group) by private firms of drugs in Phase I compared to drugs in Phase II or above in the years around the enactment of the FDAAA. The bottom figure shows the differences in the scaled number of Phase I disclosures compared to Phase II disclosures by private firms over time.



#### Figure 2: Disclosures by Private and Public Companies

The top figure shows the total number of disclosures per drug (the total number of disclosures scaled by the total number of drugs in each group) by private firms compared to public firms in the years around the enactment of the FDAAA. The bottom figure shows the differences in the scaled number of disclosures by private compared to public firms over time.



### Figure 3: Parallel Trends for IPOs

This figure depicts parallel trends for the propensity to initiate an IPO surrounding the enactment of the FDAAA. In each year, the coefficient for the interaction between the treatment variable  $PropPhaseII_i$  and the corresponding year dummy is plotted. The bars represent 90% confidence intervals.



#### Figure 4: External Validity: Parallel Trends

This figure depicts parallel trends for the propensity to initiate an IPO for German limitedliability private firms compared to non-German limited-liability private firms surrounding enhanced disclosure enforcement in Germany (EHUG). The coefficient for each year of the interaction between an indicator variable for German firms and the corresponding year dummy is plotted. All coefficients are plotted relative to the effect in 2005 (i.e., the excluded year is 2005). Coefficient estimates are multiplied by 100 to ease interpretation. The dashed bands represent 90% confidence intervals.



#### Table 1: Summary Statistics

Panel A contains summary statistics for all variables for the period of our main specification, from 2004 to 2009.  $IPO_{i,t}$  is a dummy variable, which takes a value of 1 if the firm has undertaken an IPO, and 0 otherwise.  $PropPhaseII_i$  is the proportion of the firm's drug development portfolio in 2006 that is in Phase II or above.  $LOA_{i,t-1}$  is the lagged average likelihood of approval for all projects in a firm's drug development portfolio.  $NumDrugs_{i,t-1}$ is the lagged total number of drugs in a firm's development portfolio. Panel B provides the number of IPOs in each year of our sample.

Variable	Obs	Mean	Std. Dev.	Median
$PropPhaseII_i$	5,199	0.591	0.427	0.739
$IPO_{i,t}$	$5,\!199$	0.039	0.192	0.000
$LOA_{i,t-1}$	$4,\!295$	0.278	0.200	0.221
$NumDrugs_{i,t-1}$	4,295	5.488	16.250	2.000

Panel A: Summary Statistics

Year	Number of IPOs
2004	11
2005	10
2006	11
2007	14
2008	4
2009	3

# Table 2: IPO Propensity Following Increased Disclosure Requirements AfterFDAAA Enactment

This table provides results for the main specification, examining the propensity to do an IPO following the increased disclosure requirements introduced by the FDAAA. The dependent variable is  $IPO_{i,t}$ , which is a dummy variable that takes a value of 1 if the firm has undertaken an IPO, and 0 otherwise.  $PropPhaseII_i$  is the proportion of the firm's drug development portfolio in 2006 that is in Phase II or above.  $FDAAA_t$  is a dummy variable that takes a value of 1 if the time period is 2007 or later, and 0 otherwise. Control variables include  $LOA_{i,t-1}$ , which is the average lagged likelihood of approval for all projects in a firm's drug development portfolio. Drug portfolio therapeutic category indicators, year fixed effects, and firm fixed effects are included as indicated. The regressions are run from 2004 to 2009. Robust standard errors are in parentheses, and are clustered at the firm level. A constant term is included in all regressions, but not reported. \*\*\*, \*\*, and \* represent significance at the 1%, 5%, and 10% levels, respectively.

	Dependent	Variable:	$IPO_{i,t}$			
	(1)	(2)	(3)	(4)	(5)	(6)
$PropPhaseII_i \times FDAAA_t$	0.035***	0.035***	0.036***	0.025**	0.033**	0.030***
	(0.011)	(0.011)	(0.011)	(0.012)	(0.015)	(0.011)
$PropPhaseII_i$	0.006	0.012	0.012	0.012	0.007	
	(0.013)	(0.012)	(0.012)	(0.013)	(0.015)	
$FDAAA_t$	-0.004	-0.002				
	(0.008)	(0.008)				
Controls	Ν	Υ	Υ	Ν	Υ	Υ
Year FEs	Ν	Ν	Υ	Υ	Υ	Υ
Firm FEs	Ν	Ν	Ν	Ν	Ν	Υ
Project Portfolio Therapeutic	NT	N	N	V	V	V
Category Indicators	IN	IN	IN	Ŷ	Ŷ	Ŷ
Observations	$5,\!199$	4,295	4,295	$5,\!171$	4,295	4,295
$R^2$	0.006	0.009	0.010	0.332	0.362	0.903

# Table 3: IPOs Following the FDAAA, Partitioned by Pre-FDAAA Disclosures and Competitiveness

This table provides results examining the propensity to do an IPO following the increased disclosure requirements introduced by the FDAAA, split by the amount of disclosures by firms and competitiveness prior to the FDAAA. In columns (1) and (2), the sample is split based on whether a firm made a below-median or above-median annual number of disclosures per drug from 2000 to 2006. In columns (3) and (4), the sample is split based on whether a firm's drugs have a below-median or above-median number of competing drugs (in the same therapeutic class) in 2006. The dependent variable is  $IPO_{i,t}$ , which is a dummy variable that takes a value of 1 if the firm has undertaken an IPO, and 0 otherwise.  $PropPhaseII_i$  is the proportion of the firm's drug development portfolio in 2006 that is in Phase II or above.  $FDAAA_t$  is a dummy variable that takes a value of 1 if the time period is 2007 or later, and 0 otherwise. Control variables include  $LOA_{i,t-1}$ , which is the average likelihood of approval for all projects in a firm's drug development portfolio, and  $NumDrugs_{i,t-1}$ , which is the firm's total number of drug-indications currently under development. Drug portfolio therapeutic category indicators, year fixed effects, and firm fixed effects are included as indicated. The regressions are run from 2004 to 2009. Robust standard errors are in parentheses, and are clustered at the firm level. A constant term is included in all regressions, but not reported. \*\*\*, \*\*, and \* represent significance at the 1%, 5%, and 10% levels, respectively.

	Depende	v and $v$	t	
	Pre-FDAAA	Disclosures:	Pre-FDAAA C	ompetitiveness:
	Low #	High $\#$	Low # of	High $\#$ of
	Disclosures per	Disclosures per	Competing	Competing
	Drug	Drug	Drugs	Drugs
	(1)	(2)	(3)	(4)
$PropPhaseII_i \times$	0.045**	0.001	0.023	0.029**
$FDAAA_t$	(0.020)	(0.007)	(0.015)	(0.015)
Controls	V	V	V	V
Year FEs	Ý	Y	Y	Y
Firm FEs	Υ	Υ	Y	Υ
Project Portfolio				
Therapeutic Category	Υ	Υ	Y	Υ
Indicators				
Observations	1,962	1,876	2,195	2,070
$R^2$	0.853	0.968	0.888	0.923

Dependent Variable:  $IPO_{i,t}$ 

# Table 4:Robustness: Placebo Test for FDAAA

This table provides results for a placebo test, examining the propensity to do an IPO following falsely defining the passage of the FDAAA as 2004. The dependent variable is  $IPO_{i,t}$ , which is a dummy variable that takes a value of 1 if the firm has undertaken an IPO, and 0 otherwise.  $PropPhaseII_i'$  is the proportion of the firm's drug development portfolio in 2003 that is in Phase II or above.  $PlaceboTime'_t$  is a dummy variable that takes a value of 1 if the time period is 2004 or later, and 0 otherwise. Control variables include  $LOA_{i,t-1}$ , which is the average lagged likelihood of approval for all projects in a firm's drug development portfolio, and  $NumDrugs_{i,t-1}$ , which is the lagged total number of drugs in a firm's development portfolio. Drug portfolio therapeutic category indicators, year fixed effects, and firm fixed effects are included as indicated. The regressions are run from 2000 to 2006. Robust standard errors are in parentheses, and are clustered at the firm level. A constant term is included in all regressions, but not reported. \*\*\*, \*\*, and \* represent significance at the 1%, 5%, and 10% levels, respectively.

Del	pendent v	ariable: IP	$O_{i,t}$			
	(1)	(2)	(3)	(4)	(5)	(6)
$PropPhaseII_i' \times PlaceboTime_t$	-0.001	-0.040	-0.032	-0.029	-0.033	-0.003
	(0.021)	(0.025)	(0.026)	(0.021)	(0.026)	(0.022)
$PropPhaseII_i'$	-0.002	0.041	0.041	0.037	0.033	
	(0.028)	(0.026)	(0.026)	(0.023)	(0.029)	
$PlaceboTime_t$	0.015	$0.058^{***}$				
	(0.017)	(0.019)				
Controls	Ν	Υ	Υ	Ν	Υ	Υ
Year FEs	Ν	Ν	Υ	Υ	Υ	Υ
Firm FEs	Ν	Ν	Ν	Ν	Ν	Υ
Project Portfolio Therapeutic	N	N	N	V	V	V
Category Indicators	IN	IN	IN	ľ	ľ	ľ
Observations	3,229	2,311	2,311	$3,\!182$	2,311	$2,\!311$
$R^2$	0.001	0.008	0.010	0.314	0.387	0.944

Dependent Variable:  $IPO_{i,t}$ 

#### Table 5: **Robustness: Excluding the Financial Crisis**

This table provides robustness results for the main specification, examining the propensity to do an IPO following the increased disclosure requirements introduced by the FDAAA, but over various sub-samples surrounding the financial crisis. The dependent variable is  $IPO_{i,t}$ , which is a dummy variable that takes a value of 1 if the firm has undertaken an IPO, and 0 otherwise.  $PropPhaseII_i$  is the proportion of the firm's drug development portfolio in 2006 that is in Phase II or above.  $FDAAA_t$  is a dummy variable that takes a value of 1 if the time period is 2007 or later, and 0 otherwise. Control variables include  $LOA_{i,t-1}$ , which is the average lagged likelihood of approval for all projects in a firm's drug development portfolio, and  $NumDrugs_{i,t-1}$ , which is the lagged total number of drugs in a firm's development portfolio. Drug portfolio therapeutic category indicators, year fixed effects, and firm fixed effects are included as indicated. Robust standard errors are in parentheses, and are clustered at the firm level. A constant term is included in all regressions, but not reported. \*\*\*, \*\*, and \* represent significance at the 1%, 5%, and 10% levels, respectively.

Depende	ent Variable:	$IPO_{i,t}$	
			2004 - 2009,
Sample Period:	2003 - 2010	2004 - 2007	excluding
			2007Q3 - 2009Q2
	(1)	(2)	(3)
$PropPhaseII_i \times FDAAA_t$	0.025**	0.032***	0.028***
	(0.011)	(0.011)	(0.010)
Controls	Y	Y	Y
Year FEs	Y	Υ	Y
Firm FEs	Υ	Υ	Υ
Project Portfolio Therapeutic	V	V	V
Category Indicators	1	1	1
Observations	5,568	$2,\!196$	$2,\!184$
$R^2$	0.871	0.898	0.905

# Table 6:Robustness: Placebo Test for Portfolio Phase

This table provides robustness results for the main specification, examining the propensity to do an IPO following the increased disclosure requirements introduced by the FDAAA, but falsely defining the treatment phase threshold. The dependent variable is  $IPO_{i,t}$ , which is a dummy variable that takes a value of 1 if the firm has undertaken an IPO, and 0 otherwise.  $PropPhaseIII_i$  is the proportion of the firm's drug development portfolio in 2006 that is in Phase III or above; companies with drugs in Phase I are excluded in columns (1) to (6), and are included in column (7).  $FDAAA_t$  is a dummy variable that takes a value of 1 if the time period is 2007 or later, and 0 otherwise. Control variables include  $LOA_{i,t-1}$ , which is the average lagged likelihood of approval for all projects in a firm's drug development portfolio, and  $NumDrugs_{i,t-1}$ , which is the lagged total number of drugs in a firm's development portfolio. Drug portfolio therapeutic category indicators, year fixed effects, and firm fixed effects are included as indicated. The regressions are run from 2004 to 2009. Robust standard errors are in parentheses, and are clustered at the firm level. A constant term is included in all regressions, but not reported. \*\*\*, \*\*, and \* represent significance at the 1%, 5%, and 10% levels, respectively.

Dependent Variable:  $IPO_{i,t}$ 

	(1)	(2)	(3)	(4)	(5)	(6)	(7)
$PropPhaseIII_i \times FDAAA_t$	-0.010	-0.021	-0.022	-0.013	-0.020	-0.008	-0.001
	(0.012)	(0.014)	(0.014)	(0.014)	(0.018)	(0.017)	(0.015)
$PropPhaseII_i \times FDAAA_t$							$0.031^{**}$
							(0.013)
$PropPhaseIII_i$	0.003	0.008	0.010	0.009	0.032		
	(0.017)	(0.025)	(0.025)	(0.026)	(0.031)		
$FDAAA_t$	$0.025^{***}$	$0.027^{**}$					
	(0.010)	(0.011)					
Controls	Ν	Y	Y	Ν	Y	Y	Y
Year FEs	Ν	Ν	Υ	Υ	Υ	Υ	Υ
Firm FEs	Ν	Ν	Ν	Ν	Ν	Υ	Υ
Project Portfolio Therapeutic	Ν	Ν	Ν	V	V	V	V
Category Indicators	1	11	11	1	I	T	I
Observations	2,087	$1,\!848$	$1,\!848$	2,083	$1,\!848$	$1,\!848$	$4,\!295$
$R^2$	0.003	0.015	0.017	0.471	0.508	0.902	0.903

# Table 7: Robustness: Project Composition and IPOs pre-FDAAA

This table provides robustness results examining the propensity to go public based on portfolio composition prior to the enactment of the FDAAA. The dependent variable is  $IPO_{i,t}$ , which is a dummy variable that takes a value of 1 if the firm has undertaken an IPO, and 0 otherwise. *PropPhaseII*<sub>i</sub> is the proportion of the firm's drug development portfolio in 2000 that is in Phase II or above. *PropPhaseII*<sub>i,t-1</sub> is the proportion of the firm's drug development portfolio in the previous year that is in Phase II or above. Control variables include  $LOA_{i,t-1}$ , which is the average lagged likelihood of approval for all projects in a firm's drug development portfolio. Drug portfolio therapeutic category indicators and year fixed effects are included, as indicated. The regressions are run from 2000 to 2006. Robust standard errors are in parentheses, and are clustered at the firm level. A constant term is included in all regressions, but not reported. \*\*\*, \*\*, and \* represent significance at the 1%, 5%, and 10% levels, respectively.

Dependent	Variable	$: IPO_{i,t}$		
	(1)	(2)	(3)	(4)
$PropPhaseII_i$	0.013	0.030	0.044	0.047
	(0.031)	(0.033)	(0.034)	(0.039)
Controls	Ν	Y	Y	Y
Year FEs	Ν	Ν	Υ	Υ
Project Portfolio				
Therapeutic Category	Ν	Ν	Ν	Υ
Indicators				
Observations	$3,\!229$	2,311	$2,\!311$	2,311
$R^2$	0.0004	0.001	0.013	0.389

Panel A: Portfolio Composition at Beginning of Period Dependent Variable:  $IPO_{i,t}$ 

Depe	ndent Va	riable: <i>IF</i>	$PO_{i,t}$		
	(1)	(2)	(3)	(4)	(5)
$PropPhaseII_{i,t-1}$	0.010	0.015	0.012	0.010	0.004
,	(0.016)	(0.016)	(0.017)	(0.019)	(0.009)
Controls	Ν	Y	Y	Y	Y
Year FEs	Ν	Ν	Υ	Υ	Υ
Firm FEs	Ν	Ν	Ν	Ν	Y
Project Portfolio					
Therapeutic Category	Ν	Ν	Ν	Υ	Y
Indicators					
Observations	2,311	2,311	2,311	2,311	2,311
$R^2$	0.0003	0.001	0.009	0.387	0.944

Panel B: Portfolio Composition Over Time

# Table 8:Robustness: Autocorrelation

This table provides robustness results for the main specification, correcting for potential autocorrelation. The dependent variable is  $IPO_{i,t}$ , which is a dummy variable that takes a value of 1 if the firm has undertaken an IPO, and 0 otherwise.  $PropPhaseII_i$  is the proportion of the firm's drug development portfolio in 2006 that is in Phase II or above.  $FDAAA_t$  is a dummy variable that takes a value of 1 if the time period is 2007 or later, and 0 otherwise. Control variables include  $LOA_{i,t-1}$ , which is the average lagged likelihood of approval for all projects in a firm's drug development portfolio, and  $NumDrugs_{i,t-1}$ , which is the lagged total number of drugs in a firm's development portfolio. Drug portfolio therapeutic category indicators and year fixed effects are included, as indicated. The regressions are run from 2004 to 2009. Standard errors (in parentheses) are following Newey and West (1987), adjusting for heteroskedasticity and autocorrelation of up to 2 lags. A constant term is included in all regressions, but not reported. \*\*\*, \*\*, and \* represent significance at the 1%, 5%, and 10% levels, respectively.

	Depend	ent Variabl	e: $IPO_{i,t}$			
	(1)	(2)	(3)	(4)	(5)	(6)
$PropPhaseII_i \times FDAAA_t$	0.034**	0.035***	0.036***	0.025**	0.033**	0.030***
	(0.014)	(0.014)	(0.014)	(0.012)	(0.014)	(0.008)
$PropPhaseII_i$	0.006	0.012	0.012	0.012	0.007	
	(0.012)	(0.011)	(0.011)	(0.011)	(0.013)	
$FDAAA_t$	-0.004	-0.002				
	(0.010)	(0.009)				
Controls	Ν	Y	Y	Ν	Y	Υ
Firm FEs	Ν	Ν	Ν	Ν	Ν	Υ
Year FEs	Ν	Ν	Υ	Y	Y	Υ
Project Portfolio						
Therapeutic Category	Ν	Ν	Ν	Υ	Υ	Υ
Indicators						
Observations	$5,\!199$	4,295	4,295	$5,\!171$	$4,\!295$	$4,\!295$

ed in all regressions, but not report Dependent Variable:	$\frac{(1)}{NumDrugs_{i,t}}$	$\frac{(2)}{Initiation_{i,t}}$	$Suspension_{i,t}$	$\frac{(4)}{Acquisition_{i,t}}$	$\frac{(5)}{LOA_{i,t}}$
$\widetilde{IPO}_{i,t}$	$-3.748^{**}$	$-1.954^{**}$	$2.220^{**}$	$1.036^{*}$	$0.431^{**}$
	(1.764)	(0.976)	(1.124)	(0.573)	(0.202)
Controls	Y	Y	Y	Y	Х
Year FEs	Υ	Y	Υ	Υ	Y
Project Portfolio					
Therapeutic Category	Υ	Υ	Υ	Υ	Υ

 $4,295 \\ 0.719$ 

4,2950.239

4,2950.891

4,2950.809

 $4,295 \\ 0.997$ 

Indicators Observations  $R^2$ 

post-FDAAA
IPOs
and
Decisions
Project
9:
Table

52

L	able 10: Drug Proje	ct Acquisitions and IPOs	s post-FDAAA	
This table provides second-sti- IPOs induced by the disclosun to instrument for going publi more risky than the firm's cu are less risky than the firm's cu are less risky than the firm's II or above; and $Early Acquitelagged variables LOA_{i,t-1} andas indicated. The regressionsfirm level. A constant term isand 10% levels, respectively.$	age instrumental variablate requirements of the F. c. Outcome variables in trent development portfort current development potent positiom <sub>i,i</sub> , the number of $NumDrugs_{i,t-1}$ . Drug pare run from 2004 to 20 included in all regression	le (IV) results showing firms DAAA. $\widehat{IPO}_{i,t}$ is instrument nclude $Risky Acquisition_{i,t}$ , folio; $Less Risky Acquisition_{i,t}$ , artfolio; $Late Acquisition_{i,t}$ , acquisitions of preclinical or ortfolio therapeutic category 009. Robust standard errors ins, but not reported. ***, **	<sup>c'</sup> drug project acquis ed IPO, using regress the number of acqui $n_{i,t}$ , the number of ac the number of acquis Phase I drugs. Cont Phase I drugs. Cont indicators and year f are in parentheses, *, and * represent sig	ition decisions following ion (1) in the first-stage sitions of drugs that are equisitions of drugs in Phase rol variables include the ixed effects are included and are clustered at the nificance at the $1\%, 5\%$ ,
	(1)	(2)	(3)	(4)
Dependent Variable:	$Risky Acquisition_{i,t}$	Less Risky Acquisition $_{i,t}$	$Late Acquisition_{i,t}$	$Early Acquisition_{i,t}$
$\widehat{IPO}_{i,t}$	0.137	0.880*	$0.188^{*}$	0.245
×	(0.175)	(0.472)	(0.103)	(0.217)
Controls	Υ	Υ	Υ	Υ
Year FEs	Υ	Υ	Υ	Υ
Project Portfolio				
Therapeutic Category	Υ	Υ	Υ	Υ
$\operatorname{Indicators}$				
Observations	4,276	4,276	4,295	4,276
$R^2$	0.423	0.066	0.183	0.317

# Table 11: External Validity: IPO Propensity for German and other EuropeanPrivate Firms

This table provides results for German compared to non-German private firms surrounding enhanced disclosure enforcement in Germany. The dependent variable is  $IPO_{i,t}$ , which is a dummy variable that takes a value of 1 if the firm has undertaken an IPO in year t, and 0 otherwise.  $Treated_i$  is an indicator that takes a value of 1 if the firm is German, 0 otherwise.  $Reform_t$  is a dummy variable that takes a value of 1 if the year is 2006 or later, 0 otherwise. *Reform*' is a dummy variable that takes a value of 1 if the year is 2007 or later, 0 otherwise. Control variables include the log of total assets, cash holdings scaled by total assets, and profitability (EBITDA) scaled by total assets. In Panel A, the regressions are run from 2003 to 2008 in column (1), and exclude the financial crisis (2007Q3 through 2008) in column (2); Columns (3) and (4) present corresponding results for a propensity score matched sample, matched on size, cash, and profitability in the year prior to the reform. Robust standard errors are in parentheses, and are clustered at the firm level. In Panel B, the regressions are run from 2003 to 2008 excluding 2006 in column (1), and over the same period for a propensity score matched sample in column (2). Coefficient estimates are multiplied by 100 to ease interpretation. A constant term is included in all regressions, but not reported. \*\*\*, \*\*, and \* represent significance at the 1%, 5%, and 10% levels, respectively.

Panel	A:	Main	Specif	ication
Dener	nder	nt Var	iahle <sup>.</sup>	IPO:

	Dependent	variable. If $O_{i}$ ,	,t	
	Excluding Crisis			Excluding Crisis
	(1)	(2)	(3)	(4)
$Treated_i \times Reform_t$	0.228***	0.256***	0.204***	0.237***
	(0.038)	(0.043)	(0.046)	(0.051)
Controls	Y	Y	Y	Y
Firm FEs	Υ	Υ	Υ	Υ
Year FEs	Υ	Υ	Υ	Υ
Observations	$1,\!606,\!149$	$1,\!192,\!828$	109,067	$94,\!139$
$R^2$	0.405	0.415	0.569	0.399

	(1)	(2)
$Treated_i \times Reform'_t$	0.095***	0.111***
	(0.033)	(0.040)
Controls	Υ	Υ
Firm FEs	Υ	Υ
Year FEs	Υ	Υ
Observations	$1,\!288,\!061$	$83,\!396$
$R^2$	0.426	0.412

Panel B: Robustness: 2007 Treatment Year

#### Table 12: External Validity: Disclosure Enforcement Within Germany

This table provides the results for the impact of the enhanced disclosure enforcement within Germany. The dependent variable is  $IPO_{i,t}$ , which is a dummy variable that takes a value of 1 if the firm has undertaken an IPO in year t, and 0 otherwise. Competitiveness<sub>i,j</sub> is the negative of the average Herfindahl of firm i in industry j over the pre-period. Column (1) defines Competitiveness<sub>i,j</sub> using 3-digit NAICS industries, while column (2) defines Competitiveness<sub>i,j</sub> using 4-digit NAICS industries. Reform<sub>t</sub> is a dummy variable that takes a value of 1 if the year is 2006 or later, 0 otherwise. Control variables include the log of total assets and cash holdings scaled by total assets. Regressions are run from 2003 to 2008. Robust standard errors are in parentheses, and are clustered at the firm level. A constant term is included in all regressions, but not reported. \*\*\*, \*\*, and \* represent significance at the 1%, 5%, and 10% levels, respectively.

Dependent Variable: $IPO_{i,t}$				
	(1)	(2)		
$Competitiveness_{i,j} \times Reform_t$	0.004***	0.007***		
	(0.001)	(0.002)		
Controls	Y	Y		
Firm FEs	Y	Υ		
Year FEs	Y	Υ		
Observations	48,880	48,612		
$R^2$	0.436	0.436		

Online Appendix (For Online Publication)

## A Additional specification and results

In this appendix, we provide more detail regarding our second distinct specification to test our main hypothesis, discussed in Section . In particular, we utilize the variation in size thresholds for required disclosure across firms in twelve EU member states: Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, Netherlands, Spain, Sweden, and the United Kingdom. In order to do so, we use data from the Bureau van Dijk Orbis database from 2002 to 2019, and run the following regression:

$$IPO_{i,t} = \alpha + \beta Threshold_{j,i,t-1} + \gamma' X_{i,t} + \mu_i + \pi_j \times \eta_t + \varepsilon_{i,t}.$$
(4)

The above specification is similar to that of Breuer et al. (2019), which also utilizes variation in disclosure thresholds, however we consider the firm-year level and examine a different outcome.<sup>43</sup> In equation (4), Threshold<sub>j,i,t-1</sub> is an indicator variable that takes a value of 1 if firm *i* in country *j* crossed country *j*'s disclosure threshold in year *t*1 or if the firm stayed past the disclosure threshold for two or more consecutive years, and 0 otherwise. (The results are also consistent if we define this variable contemporaneously.) The idea is that a private firm that becomes subject to the disclosure requirements for its respective country will be more likely to go public, according to our argument. We use the same disclosure thresholds as in Bernard et al. (2018). We convert all non-euro currencies to euros, as in Bernard et al. (2018), using exchange rate data from the St. Louis Federal Reserve. We include the same control variables as in equation (3), and include firm fixed effects  $\mu_i$  as well as country-byyear fixed effects  $\pi_j \times \eta_t$ . Our sample consists of 1,421,334 firms and 1,949 IPOs. The results are provided in Table A6, and the coefficient for Threshold<sub>j,i,t-1</sub> is positive and significant. This indicates that, in this setting as well, private firms are more likely to go public once they are subject to increased disclosure requirements.

<sup>&</sup>lt;sup>43</sup>As disclosure requirements are very similar for medium and large firms, we focus on the thresholds for disclosure for firms to be designated as "medium" in size. The findings of Dedman and Lennox (2009), Minnis and Shroff (2017), and Bernard et al. (2018) indicate that small European private companies are concerned about proprietary disclosure costs.

#### Table A1: Probit and Logit Specifications

This table provides robustness results for the main results examining the propensity to do an IPO following the increased disclosure requirements introduced by the FDAAA, running as logit or probit specifications. The dependent variable is  $IPO_{i,t}$ , which is a dummy variable that takes a value of 1 if the firm has undertaken an IPO, and 0 otherwise.  $PropPhaseII_i$  is the proportion of the firm's drug development portfolio that is in Phase II or above.  $FDAAA_t$  is a dummy variable that takes a value of 1 if the takes a value of 1 if the time period is 2007 or later, and 0 otherwise. Robust standard errors are in parentheses, and are clustered at the firm level. \*\*\*, \*\*, and \* represent significance at the 1%, 5%, and 10% levels, respectively.

Dependent Varia	Dependent Variable: $IPO_{i,t}$					
	Probit	Logit				
	(1)	(2)				
$PropPhaseII_i \times FDAAA_t$	0.363**	$0.754^{**}$				
	(0.162)	(0.346)				
$Prop Phase II_i$	0.213	0.478				
	(0.215)	(0.474)				
$FDAAA_t$	-0.0003	$1.396^{**}$				
	(0.141)	(0.675)				
Controla	V	V				
Controls	Ŷ	Ŷ				
Observations	4,295	4,295				
Log pseudolikelihood	-696.832	-691.041				
Pseudo $R^2$	0.026	0.034				

#### Table A2: Project Composition and Project Decisions pre-FDAAA

This table provides robustness results examining the propensity to go public based on portfolio composition prior to the enactment of the FDAAA. *PropPhaseII*<sub>*i,t*-1</sub> is the proportion of the firm's drug development portfolio that is in Phase II or above. *NumDrugs*<sub>*i,t*</sub> is the total number of drugs in a firm's development portfolio. *Initiation*<sub>*i,t*</sub> is the number of new drug projects that a firm initiates. *Suspension*<sub>*i,t*</sub> is the number of drug projects in development that the firm suspends. *Acquisition*<sub>*i,t*</sub> is the number of drug projects that the firm acquires from other firms. Control variables include  $LOA_{i,t-1}$ , which is the lagged average likelihood of approval for all projects in a firm's drug development portfolio, and the lagged variable *NumDrugs*<sub>*i,t*-1</sub>. Drug portfolio therapeutic category indicators and year fixed effects are included, as indicated. The regressions are run from 2004 to 2006. Robust standard errors are in parentheses, and are clustered at the firm level. A constant term is included in all regressions, but not reported. \*\*\*, \*\*, and \* represent significance at the 1%, 5%, and 10% levels, respectively.

Dependent Variable:	$Num Drugs_{i,t}$	$Initiation_{i,t}$	$Suspension_{i,t}$	$Acquisition_{i,t}$
$PropPhaseII_{i,t-1}$	0.025	0.082	0.121	-0.016
	(0.086)	(0.099)	(0.093)	(0.040)
Controls	Y	Y	Y	Y
Year FEs	Υ	Υ	Υ	Y
Firm FEs	Υ	Υ	Υ	Υ
Project Portfolio				
Therapeutic Category	Υ	Υ	Y	Υ
Indicators				
Observations	1,570	$1,\!570$	1,570	1,570
$R^2$	0.9998	0.968	0.966	0.747

# Table A3: IPOs Following the FDAAA, Split by Pre-FDAAA Orphan Drug Designations

This table provides results examining the propensity to do an IPO following the increased disclosure requirements introduced by the FDAAA, split based on whether a firm has a drug in development designated as an orphan drug in 2006. The dependent variable is  $IPO_{i,t}$ , which is a dummy variable that takes a value of 1 if the firm has undertaken an IPO, and 0 otherwise.  $PropPhaseII_i$  is the proportion of the firm's drug development portfolio in 2006 that is in Phase II or above.  $FDAAA_t$  is a dummy variable that takes a value of 1 if the time period is 2007 or later, and 0 otherwise. Control variables include  $LOA_{i,t-1}$ , which is the average lagged likelihood of approval for all projects in a firm's drug development portfolio, and  $NumDrugs_{i,t-1}$ , which is the lagged total number of drugs in a firm's development portfolio. Drug portfolio therapeutic category indicators, year fixed effects, and firm fixed effects are included as indicated. The regressions are run from 2004 to 2009. Robust standard errors are in parentheses, and are clustered at the firm level. A constant term is included in all regressions, but not reported. \*\*\*, \*\*, and \* represent significance at the 1%, 5%, and 10% levels, respectively.

Dependent Variable:  $IPO_{i,t}$ 

Pre-FDAAA Disclosures: No Orphan Dr		an Drug	g Orphan Drug	
	(1)	(2)	(3)	(4)
$PropPhaseII_i \times FDAAA_t$	0.030**	0.024**	0.019	0.032
	(0.013)	(0.012)	(0.019)	(0.037)
$PropPhaseII_i$	-0.003		0.011	
	(0.015)		(0.030)	
$FDAAA_t$	-0.0004		$0.045^{**}$	
	(0.011)		(0.020)	
Controls	Ν	Y	Ν	Y
Year FEs	Ν	Υ	Ν	Υ
Firm FEs	Ν	Υ	Ν	Υ
Project Portfolio				
Therapeutic Category	Ν	Υ	Ν	Υ
Indicators				
Observations	$3,\!925$	$3,\!111$	$1,\!274$	$1,\!184$
$R^2$	0.004	0.926	0.009	0.925

# Table A4: Project Decisions for Firms that Remained Private Around FDAAAImplementation

This table provides DID results showing drug project decisions for private firms around the FDAAA.  $NumDrugs_{i,t}$ , the firm's total number of drug-indications currently under development;  $Initiation_{i,t}$ , which is the number of new drug projects that a firm initiates;  $Suspension_{i,t}$ , which is the number of drug projects in development that the firm suspends; and  $Acquisition_{i,t}$ , which is the number of drug projects that the firm acquires from other firms.  $PropPhaseII_i$  is the proportion of the firm's drug development portfolio in 2006 that is in Phase II or above.  $FDAAA_t$  is a dummy variable that takes a value of 1 if the time period is 2007 or later, and 0 otherwise. Control variables include  $LOA_{i,t-1}$ , the average likelihood of approval for all projects in a firm's drug development portfolio, and  $NumDrugs_{i,t-1}$ , the firm's total number of drug-indications currently under development. Drug portfolio therapeutic category indicators, year fixed effects, and firm fixed effects are included as indicated. The regressions are run from 2004 to 2009. Robust standard errors are in parentheses, and are clustered at the firm level. A constant term is included in all regressions, but not reported. \*\*\*, \*\*, and \* represent significance at the 1%, 5%, and 10% levels, respectively.

Dependent Variable:	$Num Drugs_{i,t}$	$Initiation_{i,t}$	$Suspension_{i,t}$	$Acquisition_{i,t}$
$PropPhaseII_i \times FDAAA_t$	0.087	0.052	0.045	0.045
	(0.059)	(0.074)	(0.069)	(0.038)
Controls	V	V	V	V
Year FEs	Ý	Y	Y	Y
Firm FEs	Υ	Y	Υ	Υ
Project Portfolio				
Therapeutic Category	Υ	Υ	Υ	Y
Indicators				
Observations	3,734	3,734	3,734	3,734
$R^2$	0.9997	0.937	0.963	0.635

### Table A5: T-test of Treated and Control Group Characteristics After Matching

This table provides *t*-tests for the means of the matching characteristics for treated and control firms in 2005 for the propensity score matched sample in Table 11. *Profitability* is EBITDA scaled by total assets.  $\log(TA)$  is the logarithm of total assets. *Cash* is winsorized cash holdings scaled by total assets. Standard errors are provided in parentheses. \*\*\*, \*\*, and \* represent significance at the 1%, 5%, and 10% levels, respectively.

	Num Firms	Profitability	$\log(TA)$	Cash
Treated	13,960	0.099	15.869	0.104
		(0.052)	(0.017)	(0.001)
Control	$13,\!960$	0.040	15.872	0.108
		(0.046)	(0.017)	(0.001)
Difference		-0.059	0.003	$0.004^{*}$
		(0.070)	(0.024)	(0.001)
<i>p</i> -value of difference:		0.401	0.902	0.083

#### Table A6: External Validity: Disclosure Requirements Across Europe

This table provides the results of the effect of disclosure requirements across Europe. The dependent variable is  $IPO_{i,t}$ , which is a dummy variable that takes a value of 1 if the firm has undertaken an IPO in year t, and 0 otherwise. Threshold<sub>j,i,t-1</sub> takes a value of 1 if firm i in country j crossed country j's disclosure threshold in year t - 1 (or if firm i stayed past the disclosure threshold for two or more consecutive years), and 0 otherwise. Control variables include the log of total assets, cash holdings scaled by total assets, and profitability (EBITDA) scaled by total assets. Regressions are run from 2002 to 2019. Robust standard errors are in parentheses, and are clustered at the firm level. Coefficient estimates are multiplied by 100 to ease interpretation. A constant term is included in all regressions, but not reported. \*\*\*, \*\*, and \* represent significance at the 1%, 5%, and 10% levels, respectively.

Dependent Variable: $IPO_{i,t}$					
	(1)	(2)			
$\overline{Threshold_{j,i,t-1}}$	0.032***	0.034***			
	(0.005)	(0.005)			
Controls	Y	Y			
Firm FEs	Υ	Υ			
Year FEs	Υ	Ν			
Country $\times$ Year FEs	Ν	Υ			
Observations	$9,\!261,\!662$	9,261,662			
$R^2$	0.186	0.311			

# **B** ClinicalTrials.gov disclosure example

In this appendix, we provide portions of a disclosure from ClinicalTrials.gov. We note that this does not include the entire disclosure for this particular entry but rather we present relevant portions in order to provide additional texture regarding the quality and nature of disclosures. This disclosure is by the private biopharma company Braintree Laboratories on November 17, 2009 regarding Phase III results of a clinical study examining the efficacy of nizatidine in treating infants with gastroesophageal reflux disease. The identifier for this disclosure in ClinicalTrials.gov is NCT00373334. The disclosure can be accessed through the following web address: https://clinicaltrials.gov/ct2/show/NCT00373334.

#### Figure B1: Sample disclosure: Participant flow and baseline characteristics

Participant Flow 1				Go to 💌
Recruitment Details Pre-assignment Details				
	Arm/Group Title	Nizatidine 2.5 mg/kg Twice Daily	Nizatidine 5.0 mg/kg Twice Daily	Placebo
	✓ Arm/Group Description	low dose nizatidine plus Conservative Measures	high dose nizatidine plus Conservative Measures	Placebo plus Conservative Measures Conservative Measures included: Hypoallergenic formula thickened with dry rice cereal Avoidance of seated and supine positioning Elimination of tobacco smoke exposure
Period Title: Overall Study				
	Started	43	50	45
	Completed	33	32	32
	Not Completed	10	18	13

#### Baseline Characteristics ()

Go to 👻

Arm/Group Title		Nizatidine 2.5 mg/kg b.i.d.		Nizatidine 5.0 mg/kg b.i.d.		Conservative Measures Only		Total	
▼ /	Arm/Group Description	[Not Specified]		[Not Specified]		[Not Specified]		Total of all reporting groups	
Overall Number of Baseline Participants		43		50		45		138	
<ul> <li>Baseline Analysis</li> </ul>	Population Description	[Not Specified]							
Age, Categorical Measure Type: Count of Participants									
Unit of measure: Participants	Number Analysis	40		50	_	AE anaticipanta		100	-1-
	Number Analyzed	43 participa	ants	50 participants	5	45 participants		138 рапісіра	nts
	<=18 years	43	100.0%	50	100.0%	45	100.0%	138	100.0%
	Between 18 and 65	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	years								
	>=65 years	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Sex: Female, Male Measure Type: Count of Participants Unit of measure: Participants									
	Number Analyzed	43 participa	ants	50 participants	5	45 participants		138 participa	nts
	Female	38	88.4%	44	88.0%	38	84.4%	120	87.0%
	Male	5	11.6%	6	12.0%	7	15.6%	18	13.0%
Region of Enrollment Measure Type: Number Unit of measure: Participants									
United States	Number Analyzed	43 participa	ants	50 participants	6	45 participants		138 participa	nts
United States		43		50		45		138	

## Figure B2: Sample disclosure: Outcome data and adverse events

tcome Measures					Go to 💌					
1. Primary Outcome										
	Title Infant Gastroe	sophageal Reflux Questionnaire Revised (I-GER	Q-R) Success							
▼ De	scription The I-GERQ-F indicates more treated for at le	he I-GERQ-R contains 12 questions assessing gastroesophageal reflux disease (GERD) frequency and severity. A low I-GERQ-R score (minimum = 0) indicates minimal symptoms and a high I-GERQ-R score (maximum = 42) indicates more frequent and/or severe symptoms. Success is defined as a reduction in I-GERQ-R score of at least 5 points from baseline, provided a subject did not discontinue due to lack of efficacy or adverse event, and had been eated for at least 4 weeks.								
Tim	e Frame 8 weeks									
<ul> <li>Outcome Measure Data</li> </ul>										
<ul> <li>Analysis Population Description</li> </ul>	n									
The analysis population includes a adverse events.	Il patients that took drug	and had any efficacy data reported. 5 patients that	at were lost to follow up (1 nizatidine 2	.5 group, 1 nizatidine 5.0 group, 3 placeb	o group) were not included because they had no efficacy data and had not reported an					
Arm/Gi	roup Title	Nizatidine 2.5 mg/kg b.i.d.		Nizatidine 5.0 mg/kg b.i.d.	Conservative Measures Only					
▼ Arm/Group Des	scription: [Not Specified		[Not Specified]		[Not Specified]					
Overall Number of Participants	Analyzed	42		49	42					
Measure Type: Unit of Measure: par	Number ticipants									
		27		32	31					
<ul> <li>Statistical Analysis 1</li> </ul>										
Statistical Analysis Overview	Comparison Group Selection	Nizatidine 5.0 mg/kg b.i.d., Conservative Measu	ures Only							
	Comments	[Not Specified]								
	Type of Statistical Test	Superiority or Other								
	Comments	[Not Specified]								
Statistical Test of	P-Value	0.528								
Hypothesis	Comments	[Not Specified]								
	Method	Cochran-Mantel-Haenszel								
	Comments	[Not Specified]								

#### Serious Adverse Events ()

	Nizatidine 2.5 mg/kg b.i.d.		Nizatidine 5.0 mg/kg b.i.d.		Conservative Measures Only	
	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	0/43 (0.00%)		0/50 (0.00%)		1/45 (2.22%)	
Respiratory, thoracic and mediastinal disorders						
Respiratory distress * 1	0/43 (0.00%)	0	0/50 (0.00%)	0	1/45 (2.22%)	1
* Indicates events were collected by non-systematic assessment						

1 Term from vocabulary, MedDRA 9.1

#### Other (Not Including Serious) Adverse Events ()

Frequency Threshold for Reporting Other Adverse Events	5%

	Nizatidine 2.5 mg/kg b.i.d.		Nizatidine 5.0 mg/kg b.i.d.		Conservative Measures Only	
	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	27/43 (62.79%)		31/50 (62.00%)		31/45 (68.89%)	
Eye disorders						
conjunctivitis * 1	0/43 (0.00%)		3/50 (6.00%)		0/45 (0.00%)	
Gastrointestinal disorders						
Diarrhea * 1	4/43 (9.30%)		4/50 (8.00%)		5/45 (11.11%)	
Teething * 1	4/43 (9.30%)		3/50 (6.00%)		3/45 (6.67%)	
gastroesophageal reflux disease † 1	2/43 (4.65%)		10/50 (20.00%)		4/45 (8.89%)	
vomiting * 1	2/43 (4.65%)		3/50 (6.00%)		1/45 (2.22%)	
General disorders						
Pyrexia * 1	6/43 (13.95%)		1/50 (2.00%)		3/45 (6.67%)	
Infections and infestations						
bronchiolitis * 1	3/43 (6.98%)		6/50 (12.00%)		2/45 (4.44%)	
gastroenteritis * 1	0/43 (0.00%)		3/50 (6.00%)		2/45 (4.44%)	
otitis media * 1	8/43 (18.60%)		13/50 (26.00%)		7/45 (15.56%)	
Respiratory, thoracic and mediastinal disorders						
nasal congestion * 1	3/43 (6.98%)		1/50 (2.00%)		4/45 (8.89%)	
upper respiratory tract infection * 1	13/43 (30.23%)		6/50 (12.00%)		15/45 (33.33%)	