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Dynamic Mergers Effects on R&D Investments and Drug Development across Research Phases in the Pharmaceutical Industry

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Dynamic Mergers Effects on R&D Investments and Drug Development across Research Phases in the Pharmaceutical Industry

Abstract

Pharmaceutical firms spend increasing amounts in mergers and acquisitions (M&As), which raises the question of whether sufficient investment is left after mergers to further develop firms' internal drug development capability. We evaluate the effects of M&As on firms' post-merger R&D investments and drug development capabilities across drug development phases. This study builds on a novel database that enables us to evaluate the post-merger effect at the research project level and across development phases. A further novel feature of the study is allowing measurement errors to enter firms' R&D investments. Our study adopts a structural equation modeling approach, which is appropriate for evaluating a system of equations through which we examine the direct and indirect merger effects on R&D capabilities across development phases. We find that M&As have a strong effect on firms' drug development at the late development phases through economies of scope. At the early development phases, M&As serve to replenish firms' drug pipelines. The study shows that M&As have a direct and negative effect on firms' R&D investments. However, the overall effect on R&D investments accounting for enhanced post-merger R&D capabilities and product approvals turns out to be positive. M&As can be an effective instrument for firms to acquire drug development knowledge and technology in late stages of the development process (Phases 3 clinical testing and regulatory filing). Our study provide empirical evidence that investments in M&As in late stage of drug development help firms' growth and increase firms revenue.

JEL-Codes: L110, L130, L520, O310, O320, O380.

Keywords: drug development phases, dynamics, innovation management, merger and acquisition, pharmaceutical drug development, R&D capabilities.

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1. Introduction

Innovation in the pharmaceutical industry is associated with new drug development, a topic of fundamental importance to society, as it affects people's health and quality of life. Scholars, managers, and policy makers are deeply concerned with recent trends in declining drug approvals and increasing drug prices, both of which are related to the surge in drug development costs.¹ To overcome innovation challenges, pharmaceutical companies more frequently engage in mergers and acquisitions (M&As) and acquire drug development pipelines of innovative targets. In fact, the number of M&As and the associated money spent on acquiring firms took on drastic scale in recent years. In 2017, for example, pharmaceutical firms spent more than \$59 billion on M&A activities, which is close to the research and development (R&D) spending in the entire industry. This enormous M&A expense raised serious concerns as to whether merging firms would have sufficient funds left to further invest in post-merger R&D and to develop their research productivity. Competition authorities in the U.S. and Europe paid special attention to potential adverse effects of mergers on innovation (see Haucap (2017)). Until now, little is known about the post merger impact on innovation (see Gilbert (2002) and Katz and Shelanski (2007)).

This study addresses the research question of whether M&As serve as an appropriate instrument to boost the acquirer's post-merger drug development capabilities, or if M&As reduce post-merger investments in R&D and slow down the acquirer's development of its R&D capabilities. In answering this question, we put special emphasis on two aspects that relate to the measurement of post-merger drug development capabilities. These two aspects have not found much consideration in previous merger studies. First, we measure the post-merger effect on innovation while adopting a measure at a disaggregate research-phase specific level. This measure builds on an institutional R&D characteristic of the pharmaceutical industry, that is, a new molecule entity (NME) must successfully pass multiple drug development phases and the drug must be approved by the Food and Drug Administration before the NME (drug) can be launched on the market. In various drug development phases, NMEs undergo a series of pre-clinical and clinical tests, in which they are tested on animals and humans for safety (identification of possible adverse effects) and efficacy (relation between dose and effect).² Using data on firms' success rates of advancing drug development projects to subsequent research phases, we are able to identify differential merger effects on R&D capabilities across drug development phases.

More specifically, our model builds on the assumption that the successful passing of drug development phases depends on firms' internal R&D capabilities, (see Cohen and Levinthal, 1989;

¹ Drug development became more complex and uncertain, which resulted in increasing development costs (e.g. DiMasi et al., 2003). Pharmaceutical firms invested \$58.8 billion in research and development (see the industry profile report from the Pharmaceutical Research and Manufacturers of America (PhRMA, 2016)).

² Further information is provided in the industry description.

Pisano, 1990; Fleming, 2001). The R&D capabilities of a firm is its capacity to deploy resources for developing new technologies or new products. The internal R&D capability is determined by firms' research experience, research competency, and R&D intensity (see Wang et al., 2008). The demands on firms' internal R&D capabilities are phase-specific since every development phase is characterized by specific aims and objectives, which require specific capabilities (see Paul et al., 2010).³ Therefore, our study considers firms' phase-specific R&D capabilities as a measure for firms' innovative activities that determine the successful passing of drug development projects across research phases. Firms can invest individually in their internal phase-specific R&D capabilities to advance research projects across drug development phases and to increase the likelihood of developing new drugs. Firms obtain new R&D capabilities through internal development and external acquisition (Capron and Mitchell, 2009). One prominent form of acquiring external R&D capabilities is the engagement in M&A activities. In fact, Capron and Mitchell (2009) state that M&As can be an essential instrument for acquirers to overcome their R&D capability deficiencies. The acquisition of external R&D capabilities via M&As can serve multiple purposes that are not necessarily mutually exclusive: First, it allows acquirers to compensate and replenish R&D capability deficiencies. Second, it can provide the opportunity to benefit from complementarities since the integration of acquired R&D knowledge into the acquirer's own R&D processes can further improve the firm's internal drug development R&D capability.

The integration of the acquired R&D knowledge into existing organization consumes resources and disrupts R&D processes. Moreover, M&As can have different impacts on the acquirers' R&D capabilities since capabilities are research phase dependent. The main focus of our study is to empirically evaluate the impact of M&As on the acquirers' internal R&D capabilities across development phases; we also consider how the effect on R&D capabilities is dependent on post-merger research funds and resources. It should be noted that our post-merger measurement approach builds on phase-specific performance indicators, so it is different from most previous merger studies that measured merger effects on R&D capabilities at the aggregate firm level using overall firm-level patents.

Another novelty of our study relates to measuring the post-merger impact on R&D investments. In this regard, we adopt a structural equation modeling (SEM) approach that allows us to formulate R&D capabilities as latent variables and, therefore, explicitly allows measurement errors to enter measurement variables (R&D investments) and latent variables (R&D capabilities).⁴ The adaption of an SEM approach has the following advantages.

³ For further information on optimal R&D investment strategies across research phases and R&D capabilities, see Paul et al. (2010).

⁴ Structural equation modeling is used widely by social, behavioral, and educational scientists as well as by biologists, economists, and marketing and medical researchers.

First, it does not rely on firm-level R&D investments that are taken from financial disclosures of public companies as an innovation proxy, which can be problematic in our case. In the pharmaceutical industry, it is not uncommon to book R&D investments of a parent company as an expense of a subsidiary. Consequently, merging parent companies' R&D investment activity enters the merging parent firms' financial statements only partially. This can introduce measurement error into the R&D investments, and this can result in biased post-merger effects on innovation. The ignorance of measurement errors in these R&D investment variables can result in serious inaccuracies and misleading conclusions.⁵

Second, the SEM approach does not rely on the usage of overall firm-level patents to measure post-merger innovation; it can take more than 10 years to receive patent grants, which may cause potential truncation problems.⁶

Finally, the SEM approach can predict and evaluate complex relationships, such as those between mergers and firms' internal R&D capabilities. The complex relationship is enforced by firms' internal R&D capabilities being research phase specific, which also implies a distinction between direct and indirect merger effects across drug development phases. For example, while mergers exert direct effects on the instant success of research projects at current research stages, they can also have indirect effects on the future success of the same projects when advancing to consecutive research phase.

We established a novel and comprehensive database on the pharmaceutical industry that contains highly disaggregate information on firms' drug development projects throughout drug development phases, as well as M&A activities from 1990 to 2011. Our main empirical results show that firms' internal R&D capabilities across drug development phases are positively and directly related, having an effect on product approval and financial capabilities. The estimation results also provide evidence that firms' R&D capabilities in the late drug development phases are rather weak, which can become an innovation impediment, as it results in fewer late-stage research projects and fewer drug approvals. To overcome this innovation obstacle, firms engage in M&As to leverage their late-stage R&D and product approval capabilities via economies of scope. Hence, M&As are a promising and relevant instrument that enables firms to better advance their late-stage research projects to the drug approval stage. Our results also show that M&As serve to replenish their drug

⁵ The use of firm-level R&D expenditures as innovation proxies can also be conflicted by ambiguous effects on innovation. For example, a post-merger reduction in firm-level R&D expenditures can represent more efficient R&D spending, the elimination of research duplication, or a more efficient use of common R&D resources (such as R&D labs, R&D programs, and other equipment). Alternatively, a post-merger reduction in R&D investments can stand for adverse effects on innovation, possibly originated by less competition in technology and product markets or enormous M&A expenses and financial liquidity constraints.

⁶ More detailed information is provided later.

pipelines at early research stages. The study here provides evidence that mergers are an effective way for merging firms to benefit from a combination of direct and indirect innovation effects, which involve improvements in their R&D capabilities and their product approval capabilities. Finally, our estimation results show that mergers can have a direct effect on firms' financial capabilities and may result in lower post-merger R&D investments. Overall, however, mergers indirectly increase post-merger R&D productivity via improved post-merger R&D and product approval capabilities.

The remainder of the paper includes the following sections. The next section provides a literature review. Section 3 describes the industry. Section 4 defines R&D capabilities and the influences of M&A on firms' internal capabilities, and Section 5 introduces the data. Section 6 introduces the empirical model. Section 7 tests the model specification and discusses the estimation results. Section 8 concludes and suggests future research.

2. Literature Review

Mergers and acquisitions have attracted much attention among scholars. Many explanations for mergers have been proposed, ranging from the monopoly theory of mergers (Eckbo, 1992; Mueller, 1985; Ravenscraft and Scherer, 1987), to market power effects (Anand and Singh, 1997; Baker and Bresnahan, 1985; Barton and Sherman, 1984), to synergy and efficiency effects (Bradley et al., 1988; Houston et al., 2001; Ravenscraft and Scherer, 1987).⁷ Our study relates to the last stream of literature.

Policy makers, managers, and scholars have a long-standing interest in innovation since innovation is considered a relevant contributor to welfare. In this context, Gilbert (2002) and Katz and Shelanski (2007) devote special attention to the relation between market concentration, merger activities, and innovation incentives. Based on the Schumpeterian view, that most technological innovation would come from large corporations with high market power, an increase in concentration may be conducive to innovation (see also Mansfield, 1968; Scherer, 1992). In this context, several empirical studies evaluate the relationship between competition, concentration, and innovation. For example, Aghion et al. (2005) find an inverted-U relationship between product-market competition and innovation. Recent merger waves and increased post-merger market concentration levels attracted further attention by competition authorities to investigate postmerger effects on innovation. In the pharmaceutical market, Haucap (2017) reports that competition authorities were concerned about adverse innovation effects of mergers between Pfizer and Hospira, as well as Novartis and GlaxoSmithKline. Our study concentrates on M&A effects on firms' R&D capabilities. We are especially interested in evaluating the potential benefits and adverse merger effects on firms' R&D capabilities across product development phases.

⁷ See also Roeller et al. (2000), Cassiman et al. (2005), Gugler and Siebert (2007), and Ornaghi (2009).

Mergers can have several beneficial effects on R&D capabilities and innovation, as they allow firms to share R&D costs, pool resources, exploit scale and scope economies, and exchange knowledge and technologies. Mergers can create large synergies from scale and scope economies in R&D capability (Ahuja and Katila, 2001), attract talented scientists, and leverage financial investments to overcome financial constraints (see, e.g., DeBondt, 1997; Kamien and Schwartz, 1982; Jensen and Ruback, 1983; Jorde and Teece, 2003). Studies emphasize several other innovation-related arguments for engaging in M&As. For example, M&As can help acquirers replenish their drug development pipelines and commercialize technologies (see also Chesbrough, 2003; James, 2002; Pisano, 2003). Ahuja and Katila (2001) state that technological acquisitions provide technological inputs to the acquirers. Arora and Gambardella (1990) mention that large pharmaceutical firms acquire new technologies such as biotechnology through the collaboration with universities and small/medium sized research-intensive firms (NBFs), investments in the capital stock of NBFs, and acquisitions of NBFs.

In evaluating the success of M&As, Ahuja and Katila (2001) mention that the acquirers' innovative output increases in the size of the acquirer's knowledge base. Karim and Mitchell (2000) mention that M&As can add value to acquiring firms especially when they lack technological knowledge. Acquisitions allows firms to quickly reconfigure combined resources and to adjust their internal R&D capabilities. Ernst and Vitt (2000) find that the success of acquisition depends on the retention and performance of R&D personnel in the acquired firm. Further relevant determinants of success are the size of the acquired firm, cultural integration between the acquired firm and the buyer, and technological proximity between the two firms. Karim and Mitchell (2000) find that acquirers are more likely to retain targets' resources that are common to acquirers' own (synergy effect of merger). Karim and Mitchell (2000) also suggest that acquirers may retain resources that are distinct from their own and these resources may help the acquirer further develop its core competencies and dynamic capabilities through unique synergies with the acquirer's existing resources.

M&As can also have adverse effects on innovation, as mergers eliminate firms from the technology and product markets, which reduces competition. Furthermore, Cassiman et al. (2005) mention that large acquisitions financed by debt can harm innovation. Ahuja and Katila (2001) also state that the acquirers' innovative output decreases with the size of an acquired firm due to interruptions in the R&D operations. Paruchuri et al. (2006) find that pharmaceutical acquisitions can cause substantive disruption and negatively affects scientists' innovation productivity. Specifically, the acquisition can cause divergence from the acquirer's scientific expertise.

Many studies used patent information to evaluate the impact of M&A on innovation and productivity. Valentini (2012) focus on U.S. medical devices and photographic equipment industry from

1988 to 1996, and finds that M&As have a positive effect on patenting output but a negative effect on R&D quality. Ornaghi (2009) finds that the research output declines in drug discovery, and that research productivity (measured by ratio of patents to R&D expenditure) does not increase either. Ornaghi (2009) also finds that M&As have a negative impact on firms' financial performance (e.g., overall return for share-holders). Hitt et al. (1991) examine 191 acquisitions from 1970 to 1986, and they find that acquisitions have negative effects on the patent intensity of an acquiring firm (measured by the number of patents divided by sales). Hitt et al. (1996) remark that due to the transaction costs and absorption of managers' time and energy by acquisitions managers of acquiring and target firms may postpone major decisions regarding long-term R&D investments, which reduces the R&D capabilities of their firms. Kapoor and Lim (2007) find that the productivity of R&D staff from acquired firms declines. If a target firm and an acquiring firm have similar size, the R&D productivity of staff from the target firm does not decline much.

The previous studies show that acquisitions can have mixed effect on the acquiring firm's R&D output or productivity. Our study is one of a few studies that concentrate on research phase specific R&D capabilities, and our study may help understand why the previous studies found distinct M&A effects on R&D performance.

Whether M&As enhance acquiring firms' R&D capabilities depends on whether the external knowledge and technologies are complementary or substitutable to the acquiring firms' internal R&D knowledge. On one hand, firms may need internal knowledge to screen external collaboration projects. On the other hand, firms may need internal knowledge to use external knowledge effectively. Thus, complementarity between internal R&D capabilities and external knowledge is prevalent (Cassiman and Veugelers, 2006). The complementarity here refers to the marginal return of one activity increases as the intensity of the others increases (Cassiman and Veugelers, 2006). Cassiman and Veugelers (2006) suggest that the scientific and technological orientation of a firm's R&D may be a driver of the complementarity between internal R&D capabilities and external knowledge. Hagedoorn and Wang (2012) find that internal R&D activities and external R&D acquisitions are complementary innovation activities at higher levels of internal R&D investments, whereas internal R&D activities and external R&D acquisitions are substitutable at lower levels of internal R&D investments. Cassiman et al. (2005) conduct a qualitative analysis based on a questionnaire and find that R&D rises when the merging firms have complementary technologies but falls when they have substitutable technologies. Our study finds that R&D capabilities in Phases 1 and 2 have a positive effect on M&A activities, which confirms that internal early phase R&D capabilities are complementary to the externally acquired knowledge and technologies.

In general, the evaluation of mergers on innovation is complicated by the fact that innovation is a latent variable that is unobserved. Our study deals with the problem that innovation is a latent

(unobserved) variable by incorporating the concept of firms' internal R&D capabilities introduced by Cohen and Levinthal (1989) and Fleming (2001) into a structural equation model framework. More details follow later.

Empirical studies usually evaluate merger effects at the overall firm level using proxy variables for innovation, such as (innovation input-oriented) firm-level R&D investments and (innovation output-oriented) patents.⁸ While studies find mixed results (see Banerjee and Nayak, 2015; Comanor and Scherer, 2013; Haucap and Stiebale, 2016; Hitt et al., 1991; Ornaghi, 2009; Ravenscraft and Scherer, 1987), most empirical merger studies have shown that mergers reduce R&D investments (see Comanor and Scherer, 2013; Danzon et al., 2004, 2007; Haucap and Stiebale, 2016; Haucap, 2017; Hitt et al., 1991; Koenig and Elizabeth, 2004; Ornaghi, 2009). Other merger studies use output-oriented patents as innovation proxies and measure a rather short-term post-merger effect (see Ahuja and Katila, 2001; Banerjee and Nayak, 2015; Hitt et al., 1991; Ornaghi, 2009). For example, Ahuja and Katila (2001) examine the impact of M&A on innovation output up to four years after the acquisition. We adopt a different approach, instead of using innovation proxy measures (such as the number of patents) and aggregate input measures (such as R&D spending), we use information on the number of research projects in different phases to gauge acquiring firms' R&D capabilities and investigate the complex effects of M&As on acquiring firms' R&D capabilities.

3. The Pharmaceutical Industry

The industry is highly innovative, and the successful commercialization of new drugs is socially valuable, as they can promote longevity and treat diseases. To facilitate entry of new drugs, to enforce competition, and to make drugs more affordable, the 1984 Waxman-Hatch Act (also referred to as the Drug Price Competition and Patent Term Restoration Act) was designed. However, drastically increasing drug prices remained a serious concern. For example, from 2010 to 2014, prices for prescription drugs increased on average by more than 75% (see The Wall Street Journal, 2015). Pharmaceutical firms frequently blame exploding drug development costs and their implications on market structure for the surge in drug prices. Significant increases in development costs is one of the main reasons M&As became more popular among established pharmaceutical companies in recent decades.

The innovation process in the pharmaceutical industry is confronted by several challenges. First, the drug development process becomes increasingly costly. Pharmaceutical firms invest more than \$1.4 billion in R&D per year to develop new drugs (see DiMasi, 2002; DiMasi et al., 2016; Grabowski

⁸ Seminal contributions in this area are Blonigen and Taylor (2000), Comanor and Scherer (2013), Hall (1990), Hall (1999), Haucap (2017), Hitt et al. (1996), Hitt et al. (1991), Lichtenberg (1992), Ornaghi (2009), and Ravenscraft and Scherer (1987) and among others. A literature review on merger effects on innovation is provided later.

and Vernon, 1990; Paul et al., 2010). Grabowski et al. (2002) have shown that only 30% of new drugs earn revenues that are greater than their R&D costs. Second, the development process is uncertain and characterized by high failure or attrition rates such that only a few drugs are approved by the FDA. Many drugs drop out of the development process (see Grabowski and Vernon (1990)). Pharmaceutical firms face innovation challenges, such as high technological uncertainty and drastically increasing drug development costs that reduce firms' drug pipelines and the propensity to successfully develop drugs. In 2016, for example, only 22 drugs were approved by the FDA. Third, the industry suffers from major revenue losses due to patent expirations and increased competition from generic drugs, which reduce profits and slow down pharmaceutical innovation. Brand companies are experiencing losses of \$209 billion in revenues per year from fewer drugs marketed. Generic drugs are approaching 70% of all prescriptions written in the United States, such that \$113 billion is lost to competition arising from generics. Over the past decade, investors have exerted a lot of pressure on firms to discover and develop the next blockbuster drugs that generate significant profits. As a consequence of all these challenges, pharmaceutical firms are more inclined to engage in M&A activities.

The drug development process is inherently dynamic since new drugs have to successfully pass several research phases before they can be approved by the Food and Drug Administration (FDA). The research phases are characterized by specific aims, objectives, and requirements. Pre-clinical phase finds new chemical compounds that are tested on animals to determine the toxic levels for human trials. At this early drug development phase, the relevance of scope economies in finding a promising compound has frequently been stressed (see, e.g., Cockburn and Henderson, 1996, 2001; Nesta and Saviotti, 2005). For example, economies of scope in the form of internal as well as external knowledge spillovers are important aspects. Projects at the late drug development phases (or clinical phases) are more expensive, such that further access to financing enables firms to exploit scale economies. In the drug clinical development phases (clinical trials), companies test the drug on healthy individuals in Phase 1, test the drug on a group of 100 to 150 patients in Phase 2, and test the drug on a large group of patients in Phase 3. The number of projects that successfully pass these research phases is very low.

The Biotechnology Innovation Organization assessed the success or transition rates at each of the four phases of development: Phases 1, 2, 3, and regulatory filing. The overall likelihood of approval from Phase 1 for all developmental candidates is 9.6%. Phase 1 has the highest transition success rate, with 63.2% of projects successfully advancing to Phase 2. Phase 2 has the lowest transition success rate (30.7%), and Phase 3 has the second-lowest phase transition success rate (58.1%). Similar numbers are reported by DiMasi et al. (2016), who find an overall clinical success rate of 11.83%. The probability of moving from Phase 1 to 2 is 59.52%, from Phase 2 to 3 is 35.52%, and

from Phase 3 to regulatory filing is 61.95%. Recent industry trends suggest that Phase 2 and 3 attrition rates are increasing. For further information on optimal R&D investment strategies across different research phases that aim to increase R&D capabilities, see Paul et al. (2010).

To overcome the low success rates in drug development, firms acquire products in development from other firms or merge with other firms to enhance their product portfolio. From 1998 to 2011, 2,018 mergers and acquisitions occurred worldwide. Among the 2,018 M&A deals, 666 deals occurred in the U.S., and 120 M&As involved one of the top 20 pharmaceutical firms as an acquiring firm. The large number of M&As in the industry provides support that firms heavily rely on this form of acquisition. Whether M&As increase post-merger internal R&D capabilities across development phases will be the focus in our empirical analysis later.

4. Effects of M&A on R&D and Financial Capabilities

As Bettis and Hitt (1995) remark, a firm's internal R&D capability is one of the primary characteristics that determines R&D productivity and allows to differentiate successful from unsuccessful firms. The internal R&D capability is a firm's ability to develop new products or processes and to commercially exploit technological know-how (Pisano, 1990). Cohen and Levinthal (1989) and Fleming (2001) emphasize that the internal R&D capability enables a firm to recombine existing knowledge and to generate new, more advanced knowledge or innovations. Halfat (1997) suggests that R&D capability describes a firm's ability to integrate an R&D strategy with the firm's vision and mission.

Wang et al. (2008) assume that the internal R&D capability determines the success rate of R&D projects and the R&D intensity. R&D capability is often measured by R&D investments and the number of R&D employees (Kim et al., 2018). Moreover, Paul et al. (2010) highlight that firms' internal R&D capabilities in the pharmaceutical industry are dependent on the development phase since aims and objectives are different across drug development phases. For example, in Phase 1 clinical test projects (Phase 1 clinical trials), firms address the optimal dose strength and establish the appropriate application regime. In contrast, in Phase 2 and 3 projects (Phase 2 and 3 clinical trials), firms assess the efficacy and safety of a new drug. Our study adopts this definition of research-phase specific R&D capabilities and evaluates the effects of M&As on firms' internal R&D capabilities across drug development phases; this study also accounts for firms' product approval capability, and financial capability.

Firms can increase their productivity of developing new drugs by investing in their internal phase-specific R&D capabilities. Firms can also engage in M&A activities and integrate the acquired R&D knowledge and drug development projects into their own R&D processes, which may enhance their own internal R&D capabilities. The effects of M&As on firms' internal R&D capabilities is not only

relevant for drug development productivity but also for product approval and financial performance. If mergers can deliver economies of scale and knowledge synergies, M&As may increase firms' R&D capabilities, which can in turn enhance firms' product approval and financial capabilities. Finally, internal R&D capabilities and product approval capabilities also influence firms' M&A activities.

Our study investigates the effect of M&As on acquiring firms' research capabilities in clinical test phases including Phases 1, 2, and 3 and in drug approvals and the acquiring firms' financial capability. Our study also considers that firms' internal R&D capabilities and financial capabilities, in turn, determine their incentives to engage in mergers.

5. The Data

Our study examines the effect of M&As on firms' R&D capabilities using data on M&As, R&D projects, and financial information for publicly traded U.S. pharmaceutical and bio-pharmaceutical firms from 1998 to 2011. The dataset contains detailed firm-level M&As, research projects, and drug approvals. Firm-level information on finances, R&D, and workforces is taken from CompuStat. The R&D projects and M&A deals are taken from BioPharm Insight, which collects the information from U.S. Securities and Exchange commission filings, a global network of journalists, and industry research analysts.

Firms' M&A engagements are measured by the number of the mergers and deal values. Figure 1 displays the number of M&As and the total deal values. The number of M&As peaks in 2005, with 80 registered deals, while there were only 65 M&As performed in 2009. The total deal value reached its maximum of \$184 billion in 2009.

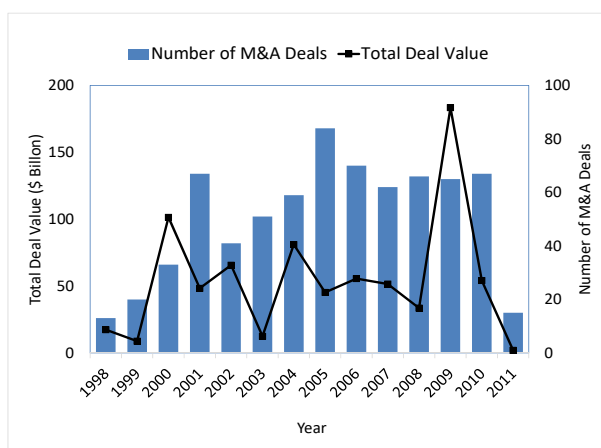


Figure 1 M&As from 1998 to 2011.

Figure 2 displays the number of M&As and the number of New Drug Application (NDA) or Biologics License Application (BLA) approvals from 1998 to 2011. In 2001 and 2007, sharp reductions

in drug approvals were registered, which coincided with larger numbers of M&A deals. This observation provides some supportive indication for firms engaging in M&As with the aim to replenish their drug pipelines.

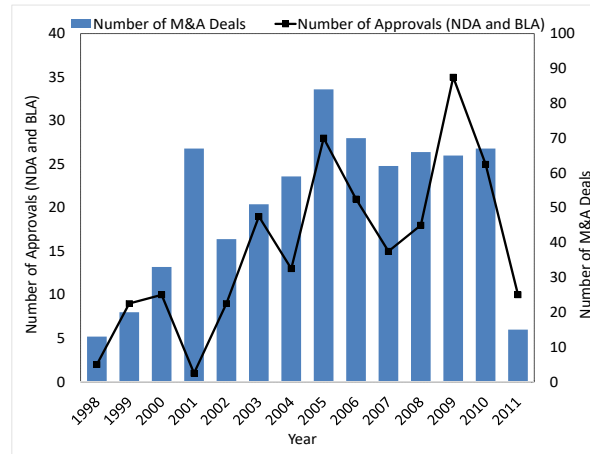


Figure 2 M&As and New Drug Approvals from 1998 to 2011.

Figure 3 displays the R&D spending and M&A deal values. It shows that R&D spending increased from 1998 to 2011; it monotonically increased from 1998 to 2008 and then hovered around \$70 billion from 2009 to 2011. Hence, R&D spending, number of M&As, and total merger deal values show increasing trends from 1998 to 2010.

Table 1 shows a summary of relevant variables used in our empirical model. The table lists the summary statistics for the merging and non-merging firms. The upper panel of Table 1 reports several firm-level financial variables that may be determinants of firms' product development capabilities and merger activities, such as firms' annual revenue, employees, R&D spending, market values, the number of M&A deals ($NDeals$), and the value of M&A deals ($DealValue$). In terms

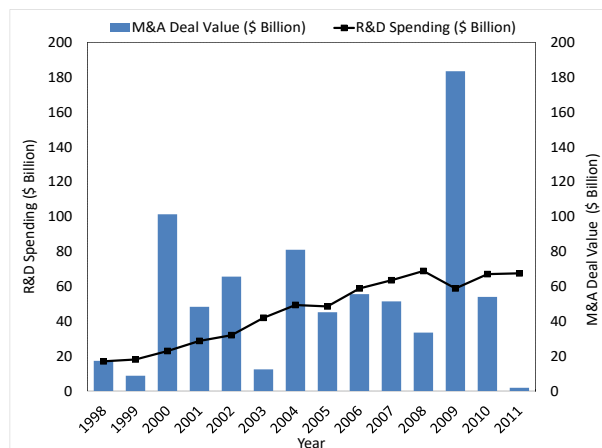


Figure 3 M&A Deal Value and R&D Spending from 1998 to 2011.

of revenues and employees, M&A firms are about 70 percent larger than firms without M&As. The market value of M&A firms is about three times higher than that of non-merging firms, an indication that M&A firms are more efficient in capitalizing their resources. M&A firms spend about twice as much in R&D as non-merging firms. M&A firms invest about 17% of their revenues, while firms without M&As invest only 15%.

Table 1 Summary Statistics (Annual) for Firms with and without M&As

	Merging Firms		Non-merging Firms	
	Average	Standard deviation	Average	Standard deviation
<i>Revenues</i> (\$ billion)	174.0	75.2	102.4	100.1
<i>Employees</i> ($\times 10^3$)	389.9	101.7	248.5	224.4
<i>R&DSpending</i> (\$ billion)	30.6	15.1	15.0	14.3
<i>MarketValue</i> (\$ billion)	732.7	150.5	229.3	252.2
<i>NDeals</i>	24	35		
<i>DealValue</i> (\$ billion)	174	75		
<i>NPhase1</i>	55	56	119	112
<i>NPhase2</i>	78	72	154	162
<i>NPhase3</i>	29	30	50	53
<i>NApprovals</i>	9	6	6	4

The lower panel of Table 1 shows the number of R&D projects in Phases 1, 2, 3 and the number of annually approved drugs (NDAs/BLAs) denoted by *NPhase1*, *NPhase2*, *NPhase3*, and *NApprovals*, respectively. Several aspects are worth mentioning. First, the number of research projects increases from Phase 1 to Phase 2, providing evidence that firms split research projects in Phase 2. Later, only one-third of the research projects in Phase 2 advance to Phase 3. It should also be noted that firms with M&As work on only half as many research projects as firms without M&As. This is somewhat surprising since M&A firms are significantly larger, spend more on R&D, and achieve a higher market value. This fact provides some indication that M&A activities improve firms' R&D capabilities. Finally, M&A-engaging firms have a higher success rate (31%) in advancing projects from Phase 3 to the approval rate compared to non-merging firms (12%). In the next section, we introduce our empirical model, which is used to investigate the impact of M&As on firms' internal R&D, product approval, and financial capabilities.

6. Research Methodology

Our study objective is to investigate the impact of mergers on firms' internal R&D capabilities across research phases and on firms' product approval and financial capabilities. For this purpose, we adopt a structural equation model (SEM) approach. SEM was also used in other studies. For instance, Liao et al. (2007) examine the influence of knowledge sharing and absorptive capacity on product innovation capability using SEM; Rothaermel and Deeds (2004) examine the influence of exploration alliance on firms' product development and exploitation alliance on firms' products on

the market using SEM; Capron and Mitchell (2009) examine how constraints from firms' stocks of capabilities and from their social contexts affect firms' capability sourcing modes using SEM.

SEM is particularly well suited in our case for the following two reasons. First, firms' internal R&D, product approval, and financial capabilities are unobserved to the econometrician and must be estimated. In the SEM approach, firms' capabilities are modeled as latent variables (also called constructs) that are represented by multiple measurement variables. Both types of variables—latent and measurement variables—are usually prone to measurement errors, and the consideration of these errors is one major advantage of the SEM approach (as opposed to traditional regression analysis). In the SEM approach, the measurement model represents how measurement variables together represent latent variables, and the structural model shows how constructs are related to each other. Second, merger analysis requires a complex system of measurement and latent variables, and the SEM approach enables us to statistically test the relationships between these variables. This system becomes even more complex once we account for direct and total (direct and indirect) merger effects on firms' R&D capabilities. For example, mergers can exert a direct effect on a firm's internal Phase 2 R&D capability, which increases the likelihood of advancing research projects from Phase 2 to Phase 3. Beyond this, mergers can also exert an indirect effect on advancing research projects to Phase 3 by improving a firm's capability in the earlier research stage (Phase 1), which increases the transition rate to Phase 2 and eventually improves the likelihood to advance projects to Phase 3.

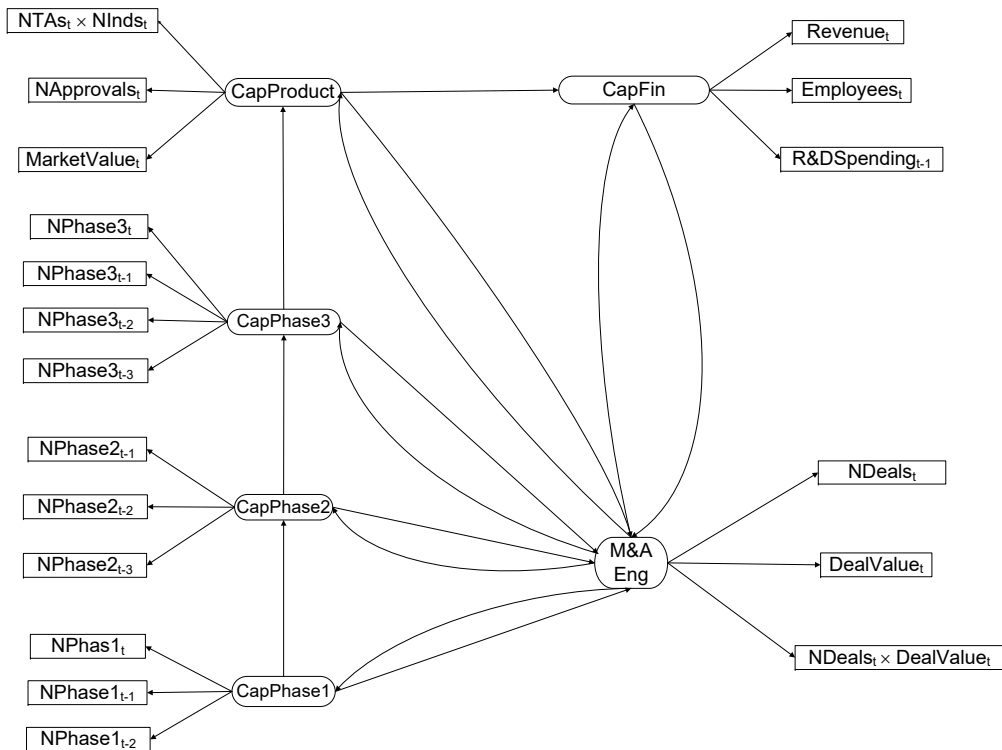
In the following, we introduce the SEM, which characterizes the relationships between measurement and latent variables based on theory, research objectives, and the literature on product innovation capability. Table 2 introduces the set of latent variables and the measurement variables that enter the structural model. The variables $NTAs_t$ and $NInds_t$ refer to the number of therapeutic areas and the number of indications of the approved drugs, and $NTAs_t \times NInds_t$ refers to the product of $NTAs_t$ and $NInds_t$. The variables $NDeals_t$ and $DealValue_t$ refer to number of M&A deals and total value of M&A deals in year t , and $NDeals_t \times DealValue_t$ refers to the product of $NDeals_t$ and $DealValue_t$.

The structural model is visually represented in the path diagram (see Figure 4), which portrays relations that are assumed to hold among the latent variables. The shapes with curved edges represent the latent variables, and the rectangles represent the measurement variables. As illustrated in the figure, the arrows represent the impact of the latent variables on the measurement variables.

Several aspects are important to recognize in this SEM specification. The proposed relationships translate into a series of structural equations in which the influence among latent variables is characterized. As mentioned earlier, we build on the concept by Cohen and Levinthal (1989) and Fleming (2001), that is, firms' internal R&D capabilities determine the successful passing of

Table 2 Latent Variables and Measurement Variables

Latent Variables	Measurement Variables	Description
<i>CapPhase1</i>	$NPhase1_t$	number of projects in Phase 1 in year t
	$NPhase1_{t-1}$	number of projects in Phase 1 in year $t-1$
	$NPhase1_{t-2}$	number of projects in Phase 1 in year $t-2$
<i>CapPhase2</i>	$NPhase2_{t-1}$	number of projects in Phase 2 in year $t-1$
	$NPhase2_{t-2}$	number of projects in Phase 2 in year $t-2$
	$NPhase2_{t-3}$	number of projects in Phase 2 in year $t-3$
<i>CapPhase3</i>	$NPhase3_t$	number of projects in Phase 3 in year t
	$NPhase3_{t-1}$	number of projects in Phase 3 in year $t-1$
	$NPhase3_{t-2}$	number of projects in Phase 3 in year $t-2$
	$NPhase3_{t-3}$	number of projects in Phase 3 in year $t-3$
<i>CapProduct</i>	$NApprovals_t$	number of approved drugs in year t
	$NTAs_t \times NInds_t$	product of number of approved TAs and indications in year t
	$MarketValue_t$	market value in t
<i>CapFin</i>	$Revenue_t$	revenue in year t
	$R\&DSpending_{t-1}$	R&D spending in year $t-1$
	$Employees_t$	number of employees in year t
<i>M\&AEng</i>	$NDeals_t$	number of M&A deals in year t
	$DealValue_t$	total value of M&A deals in year t
	$NDeals_t \times DealValue_t$	product of $NDeals_t$ and $DealValue_t$

**Figure 4 Merger and Acquisition Path Diagram.**

drug development projects. Firms' internal R&D capabilities serve as latent variables that are specific to the drug development phases (see also Paul et al., 2010). Firms' internal research phase-specific capabilities are formulated as latent variables ($CapPhaseX$, with $X = 1, 2, 3$), which have

a unidirectional successive effect and affect the product approval capability (*CapProduct*) and financial capability (*CapFin*). The latter relationship is explained by drug approvals presumably having a positive effect on a firm's market value.

R&D capabilities are measured by R&D investments and the number of R&D employees (Kim et al., 2018). The measurement variables for the product innovation capability (a construct) includes frequency of new product or service introduction, dependency of a firm's profit on new product or service development, and the speed of new product or service launch (Liao et al., 2007). However, firms usually do not report their R&D investment and the number of employees who work on phase specific drug development projects. Thus, the number of projects in each development phase (Phases 1, 2, and 3) is a good proxy of a firm's R&D investment and the number of employees for phase-specific projects. Other studies also use the number of approved products or patents as measurement variables in their structural equation models. For example, Rothaermel and Deeds (2004) use the number of patents as a measurement variable in their structural equation model. In our study, the R&D capabilities are measured by multiple project- and phase-related explanatory variables (such as research competency and experience), rather than using a single overall firm-level proxy variable. Similar to Liao et al. (2007) that examines firms' overall innovation capability and Rothaermel and Deeds (2004) that examines the effects of alliances on product development and products in the market, our study measures R&D and product approval capabilities using variables such as the number of research projects across research stages and at different time periods t ($NPhaseX_{t-y}$ for $X = 1, 2, 3$ and $y = 1, 2, 3$), new product approvals ($NApprovals_t$, $NTAs_t \times Nind_t$), and market value ($MarketValue_t$). A firm's financial capability is measured by a firm's revenue ($Revenue_t$), employees ($Employees_t$), and R&D expenditures ($R\&D\ Spending_{t-1}$). We assume that firms' internal capabilities have reciprocal relationships with firms' capability to acquire external knowledge and technologies ($M\&AEng$). Firms' M&A engagement itself is measured by the number and value of M&As ($NDeals_t$, $DealValue_t$, $NDeals_t \times DealValue_t$). Note that the bidirectional relationships in the structural model capture firms' incentives to increase their knowledge capabilities via M&A engagements depending on their research capabilities in various research phases and vice versa.

In summary, M&As can have an effect on firms' R&D capabilities and drug approvals via multiple channels. First, depending on the target firm's expertise, M&As can affect the acquiring firms' internal knowledge and firms' R&D capabilities specific to research phases, firms' product approval capabilities, and firms' financial capability. Mergers can exert direct and indirect effects on the likelihood that firms' research projects advance to successive research phases. Second, M&As have an effect on financial capability. A direct effect is explained by the fact that M&As are costly transactions that may diminish firms' ability to invest in R&D. An indirect effect is explained by

M&As having an effect on firms' product approval capability, which then influences firms' financial ability and R&D investments. Finally, M&As can be used to replenish firms' R&D project pipelines without having any effect on firms' capabilities other than acquiring a firm's research projects, which increases the likelihood of launching new drugs.

7. Model Specification and Estimation Results

Before testing the theory we introduced earlier, we evaluate the model (as illustrated in Figure 4) in two stages. In the first stage, we test the reliability of the measurement model, which employs the measurement variables to assess the latent variables. In the second stage, we test the structural model. We then test our theory through the structural model.

7.1. Examining the Overall Measurement Model

Measurement theory specifies a series of relationships that suggests how measurement variables represent a latent variable that is not measured directly. The measurement model represents the relationships among all latent variables.

7.1.1. Factor analysis. In the first stage, we use a confirmatory factor analysis (CFA) to determine the fit of the measurement model. The CFA is employed to statistically validate the measurement indicators while testing how well the measurement variables represent the latent variables (constructs). The CFA model nests all possible latent-variable structural models. We allow the measurement variables to be linked to only one latent variable and assume reciprocal relationships between any pair of latent variables. The measurement variables of a specific construct should converge or have a high proportion of the variance in common. High factor loadings indicate that the indicators converge to some common point. Adopting a common rule of thumb, we consider standardized factor loading estimates of at least 0.5 as being statistically significant. Table 3 lists the factor loadings.

The table shows that all factor loadings are greater than 0.5 except the ones for $NPhase2_{t-2}$, $NPhase3_{t-1}$, $NPhase3_{t-3}$, $MarketValue_t$, and $NDeals_t$. However, we keep those measurement variables with smaller load factors since they appropriately represent firms' R&D capabilities. More specifically, the removal of $NPhase3_{t-1}$ or $NPhase3_{t-3}$ would make the construct $CapPhase3$ less reliable. Similarly, the removal of $NPhase2_{t-2}$ would reduce the reliability of $CapPhase2$ (see Section 7.1.2). Therefore, they are kept in their respective constructs.

7.1.2. Reliability analysis. Reliability relates to the consistency of measurement variables for each construct (latent variable). Reliability is also an indicator of convergent validity. For its measurement, we use the Cronbach's alpha reliability measure and use a common rule of thumb that a measure of at least 0.7 is considered reliable. A reliability measure between 0.6 and 0.7

Table 3 Factor Analyses and Cronbach Alpha Coefficients

Variable	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Community	Cronbach Alpha Coefficient	Cronbach Alpha Coefficient with Deleted Variable
<i>NPhase1_t</i>	0.718	0.208	0.155	0.168	-0.002	0.647	0.877	0.858
<i>NPhase1_{t-1}</i>	0.745	0.142	0.333	0.183	0.130	0.736		0.803
<i>NPhase1_{t-2}</i>	0.774	0.097	0.251	0.227	0.168	0.753		0.817
<i>NPhase2_{t-1}</i>	0.517	0.148	0.631	0.248	0.058	0.785	0.854	0.766
<i>NPhase2_{t-2}</i>	0.663	0.143	0.411	0.053	0.181	0.673		0.831
<i>NPhase2_{t-3}</i>	0.403	0.151	0.642	0.085	-0.005	0.637		0.788
<i>NPhase3_t</i>	0.756	0.270	0.282	0.009	0.057	0.728	0.897	0.893
<i>NPhase3_{t-1}</i>	0.402	0.250	0.761	0.113	0.047	0.824		0.858
<i>NPhase3_{t-2}</i>	0.627	0.304	0.494	-0.048	0.051	0.739		0.848
<i>NPhase3_{t-3}</i>	0.333	0.296	0.738	-0.039	0.133	0.767	0.811	0.867
<i>Napprovals_t</i>	0.179	0.370	0.081	0.217	0.815	0.888		0.542
<i>NTAs_t × NInds_t</i>	0.117	0.197	0.084	0.519	0.801	0.973		0.684
<i>MarketValue_t</i>	0.106	0.899	0.115	0.101	0.153	0.867	0.974	0.932
<i>Revenue_t</i>	0.273	0.892	0.268	0.067	0.162	0.975		0.934
<i>R&DSpending_{t-1}</i>	0.297	0.792	0.382	0.083	0.160	0.931		0.981
<i>Employees_t</i>	0.184	0.932	0.157	0.152	0.133	0.970	0.783	0.968
<i>DealValue_t</i>	0.163	0.187	0.055	0.811	0.106	0.733		0.622
<i>NDeals_t</i>	0.249	0.422	0.076	0.319	0.148	0.537		0.881
<i>NDeals_t × DealValue_t</i>	0.127	0.040	0.084	0.865	0.389	0.933		0.573

may be acceptable if the other indicators of the model's construct are reliable. Table 3 reports the standardized alpha for each construct and also reports the standardized alpha after we removed one measurement variable from the construct. If the standardized alpha decreases after removing a variable from the construct, it suggests that this removed variable is strongly correlated with other variables in the construct. If the standardized alpha increases after removing a variable from the construct, then removing this variable makes the construct more reliable. The Cronbach's alpha coefficients are all above 0.78, which demonstrates that each construct explains a significant amount of variance of the measurement variables. While the removal of the variables *MarketValue_t*, *R&DSpending_{t-1}*, and *NDeals_t* from their constructs increases the Cronbach alpha coefficients, we still keep the three variables in their corresponding constructs for the following reasons: *MarketValue_t* measures the value of a firm, which is frequently used as a proxy for inventing new products. *R&DSpending_{t-1}* is described by a high factor loading of 0.792. Moreover, 63% of the variation in *R&DSpending_{t-1}* is explained by the latent variable *CapFin*.⁹ Finally, the number of deals that a firm engaged in in year *t* (*NDeals_t*) is an indispensable indicator variable for the latent variable *M&AEng*. In summary, the analysis shows that *MarketValue_t*, *R&DSpending_{t-1}*, and *NDeals_t* appropriately measure firms' internal R&D capabilities, M&A engagement, and financial capability, respectively.

⁹ The squared of a standardized factor loading represents how much variation in a measurement variable is explained by the latent variable.

7.1.3. Estimation and assessment validity measurement model. We estimate the measurement model along with the covariance matrix for all latent variables. The goodness-of-fit indices measure how well the theoretical covariance matrix matches the covariance matrix in the data. The measurement model is supported by the various fit indices as Column 1 in Table 4 shows.

Table 4 Overall Fit Indices

Index	Measurement Model (1)	Structural Model (2)
Chi-Square (χ^2)	1960.1	2007.7
Chi-Square (χ^2) Degree of Freedom	134	137
Standardized RMR (SRMR)	0.12	0.12
RMSEA	0.177	0.177
RMSEA Lower 90% Confidence Limit	0.170	0.170
RMSEA Upper 90% Confidence Limit	0.184	0.184
Goodness of Fit Index (GFI)	0.73	0.73
Adjusted GFI (AGFI)	0.62	0.62
Bentler Comparative Fit Index	0.81	0.81
Bentler-Bonett NFI	0.80	0.80
Bentler-Bonett Non-normed Index	0.76	0.76

The χ^2 test provides a statistical test of the difference between the covariance matrix of the data and the estimated covariance matrix. The smaller the χ^2 statistic, the better the measurement model. This statistic increases with the sample size and also increases with the number of measurement variables. The χ^2 is 1,960 with 134 degrees of freedom. A higher χ^2 might be due to a larger sample size and the larger number of measurement variables.

The root mean square residual is the square root of the squared residuals where the residuals are the prediction errors for the elements in the covariance matrix of the sample data. The standardized root mean square residual (SRMR) takes on a value of 0.12. The root mean square error of approximation (RMSEA) represents how well a model fits the population. The RMSEA here is 0.18. The 95 percent confidence interval of RMSEA is between 0.170 and 0.184. The SRMR and RMSEA along with the 95% confidence interval of RMSEA suggest a good model fit.

A Goodness-of-Fit Index (GFI) is less sensitive to sample size. The GFI ranges from 0 to 1, and a higher value of GFI indicates a better fit. The GFI takes on a value of 0.73 in our application. An Adjusted Goodness-of-Fit Index (AGFI) takes the complexity of the model into account. AGFI adjusts GFI by a ratio of the degrees of freedom used in a model to the total degrees of freedom available. The AGFI is 0.62. Both GFI and AGFI indicate good model fits given the large sample of data we used.

Incremental fit indices assess how well a specified model fits relative to a hypothesized model, in which all observed variables are assumed to be uncorrelated. The Normed Fit Index (NFI) is

the ratio of the difference in the χ^2 value for the fitted model and a null model to the χ^2 value of the null model. The model with perfect fit has an NFI of 1. The Bentler Comparative Fit Index, the Bentler-Bonett NFI, and the Bentler-Bonett Non-normed Index are 0.81, 0.80, and 0.76, respectively. These indices imply that the model fits the data well.

We list the factor loadings and t-statistics of the measurement variables in Table 5, Column 1. All the measurement variables are statistically significant at the 5% significance level. These statistics indicate that the measurement variables are significantly represented by their respective latent variables.

Table 5 Measurement and Structural Model Estimates

		Measurement Model (1)		Structural Model (2)	
Measurement variable	Latent variable	Estimate	t statistic	Estimate	t statistic
$NPhase1_t$	$CapPhase1$	1.000		1.000	
$NPhase1_{t-1}$	$CapPhase1$	1.097	19.701	1.098	19.700
$NPhase1_{t-2}$	$CapPhase1$	0.826	19.082	0.826	19.059
$NPhase2_{t-1}$	$CapPhase2$	1.000		1.000	
$NPhase2_{t-2}$	$CapPhase2$	0.763	20.986	0.763	20.988
$NPhase2_{t-3}$	$CapPhase2$	0.637	18.749	0.637	18.725
$NPhase3_t$	$CapPhase3$	1.000		1.000	
$NPhase3_{t-1}$	$CapPhase3$	0.941	19.745	0.937	19.736
$NPhase3_{t-2}$	$CapPhase3$	0.616	21.464	0.615	21.546
$NPhase3_{t-3}$	$CapPhase3$	0.458	18.417	0.455	18.376
$NApprovals_t$	$CapProduct$	1.000		1.000	
$NTAs_t \times NInds_t$	$CapProduct$	2.934	16.101	3.222	17.858
$MarketValue_t$	$CapProduct$	106.690	12.858	109.056	11.638
$Revenue_t$	$CapFin$	1.000		1.000	
$R\&DSpending_{t-1}$	$CapFin$	2.203	73.076	2.208	73.398
$Employees_t$	$CapFin$	0.144	54.167	0.144	53.672
$DealValue_t$	$M\&AEng$	1.000		1.000	
$NDeals_t$	$M\&AEng$	8.625	10.808	8.659	10.785
$NDeals_t \times DealValue_t$	$M\&AEng$	49.290	10.784	49.299	10.759

7.2. Assessment of the Overall Structural Model Validity

Based on the significant measurement model, we evaluate the fit and validity of the structural equation model. In the structural model, the covariance matrix of measurement variables is replicated by a smaller set of relationships between the latent variables as Figure 4 illustrates. The overall fit indices for the structural model are given in Table 4, Column 2. With the exception of the chi-square, all the other indices for the structural model are the same as those for the measurement model. Because we restrict some path coefficients to be zero in the structural model, the chi-square of the structural model is higher than the one of the measurement model. However, the ratio of the chi-square to the chi-square degrees of freedom for the structural model is roughly the same as that

for the measurement model. These indices demonstrate that the structural model represents all the relationships between latent variables, and the indices demonstrate that the structural model fits the data well.

The factor loading estimates are given in Table 5, Column 2. The factor loadings for the measurement variables in the structural model are roughly the same as those in the measurement model, even though we reestimate them along with the relationship paths in the structural model. Recall that the measurement model assumes an existing relationship between each latent variable pair. This consistency indicates that the overall structural model replicates the covariance of the measurement variables well and the possible improvement in the model fit is very small, so we have an appropriate specification for the structural model.

7.3. Estimation Results of the Structural Equation Model

After validating our structural equation model, which Figure 4 portrays, in Sections 7.1 and 7.2, we now turn to the estimation results. The main objective is to investigate the effect of mergers on firms' internal capabilities across drug development phases and on post-merger R&D investments (financial capability). If merging firms benefit from scope and learning effects in specific development phases, then we expect the phase-specific R&D capabilities to increase post merger. It should be noted, even if post-merger R&D capabilities remain unchanged, mergers may still exert a positive effect on R&D capabilities since the acquisition of additional research projects may increase the success of advancing research projects, also referred to as scale effects. M&As can also have an impact on firms' R&D investments. For example, a costly merger may limit a firm's financial capability and crowd out post-merger R&D investments. Alternatively, mergers can stimulate post-merger R&D investments through improved firms' internal R&D and product approval capabilities.

The features of the SEM enable us to evaluate direct and total (direct and indirect) post-merger effects on firms' internal R&D, product approval, and financial capabilities. We first present the results on successive effects of various firm capabilities such as research, product approval, and financial capabilities. We then discuss the merger formation incentives and the post-merger effects on various firm capabilities. Finally, we compare the transition rates across drug development phases between merging and non-merging firms.

7.3.1. Successive effects of firm capabilities. Table 6 reports the structural equation model estimation results of the direct effects and total (direct and indirect) effects among latent variables, and Figure 5 illustrates the direct effects.

The following relationships are noteworthy: First, all direct effects between firms' latent R&D, product approval, and financial capability variables are positive and significantly different from

Table 6 Total and Direct Effects

Path		Total		Direct	
From	To	Effect	t statistic	Effect	t statistic
CapPhase1	CapPhase2	1.063	16.641	1.070	13.098
CapPhase2	CapPhase3	0.416	7.488	0.401	3.911
CapPhase3	CapProduct	0.046	0.590	0.116	6.282
CapProduct	CapFin	38.207	9.227	35.976	11.156
CapPhase1	M&AEng	0.074	6.931	0.108	2.210
CapPhase2	M&AEng	0.012	0.304	0.277	2.404
CapPhase3	M&AEng	-0.358	-2.892	-0.724	-3.024
CapProduct	M&AEng	0.420	1.638	0.749	4.045
M&AEng	CapPhase2	-0.055	-0.155	-0.097	-0.145
M&AEng	CapPhase3	0.699	2.156	1.285	0.866
M&AEng	CapProduct	0.110	1.502	0.051	0.455
M&AEng	CapFin	2.977	0.965	-1.729	-2.199

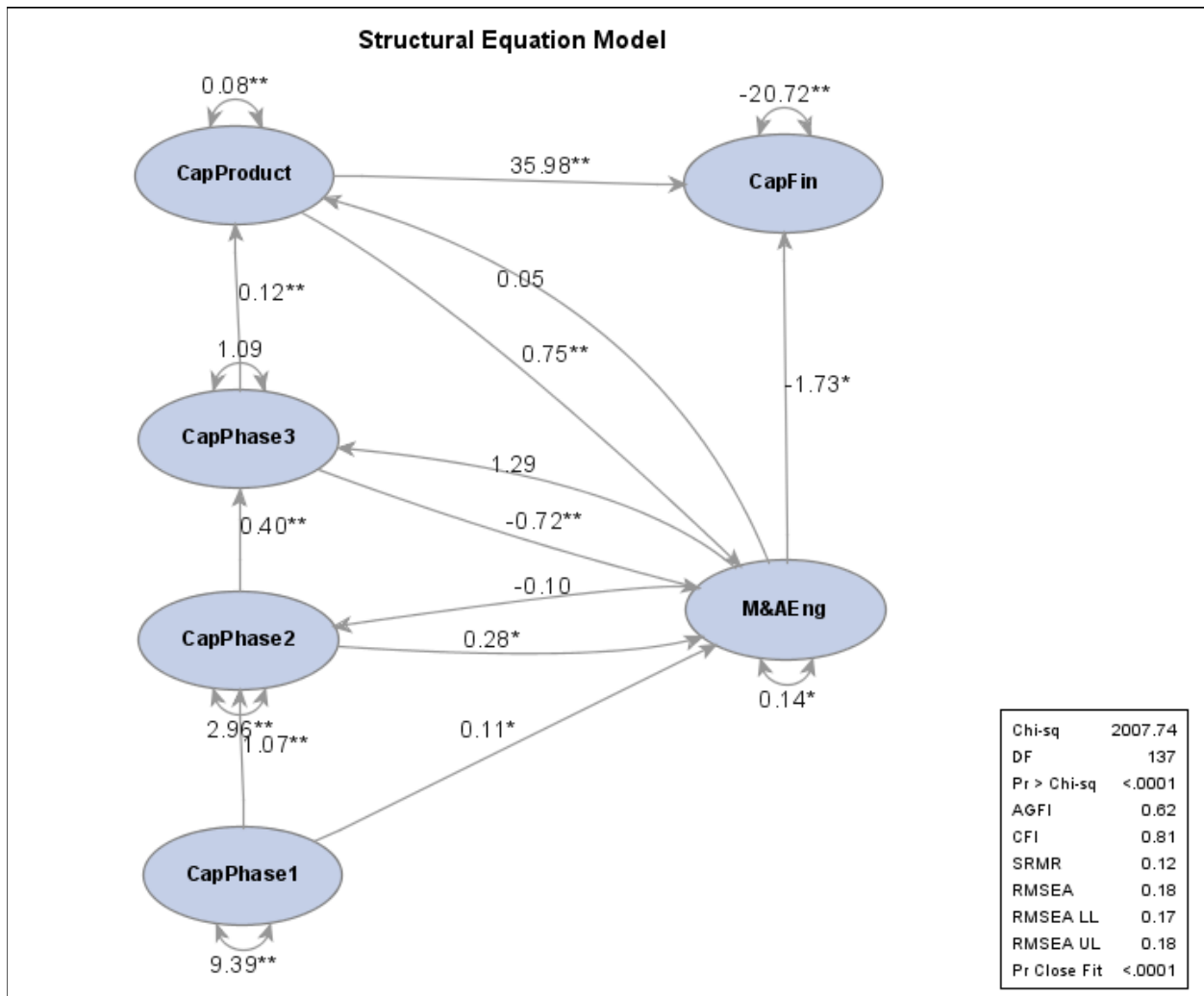


Figure 5 Estimates of the Structural Equation Model.

zero at a 1% significance level. More specifically, the effects of the R&D capability in Phase 1 (*CapPhase1*) on R&D capability in Phase 2 (*CapPhase2*), the R&D capability in Phase 2 (*CapPhase2*) on R&D capability in Phase 3 (*CapPhase3*), the R&D capability in Phase 3 (*CapPhase3*) on product approval capability (*CapProduct*), and the product approval capability (*CapProduct*) on financial capability (*CapFin*) are significant and positive. Thus, the drug development process is characterized by successive effects between firms' internal R&D, product approval, and financial capabilities. Thus, the success in gaining FDA approvals of new drugs depends on the internal R&D capabilities in Phases 1, 2, and 3.

7.3.2. Weak successive effects and incentives for merger formation. As Table 6 shows, the influence of *CapPhase3* on *CapProduct* is rather small, since only 11 percent of Phase 3 research projects successfully advance to the product approval phase. The low success rate of advancing research projects beyond Phase 3 has frequently been recognized in prior studies and referred to as innovation obstacles that can substantially increase development costs (see DiMasi et al., 2003; Grabowski et al., 2002; Paul et al., 2010). Firms recognize this innovation impediment (the low R&D capability in Phase 3) and respond by engaging in M&A activities (see the negative relation of -0.74 between *CapPhase3* and *M&AEng* in Table 6) with the intention to improve their Phase 3 capabilities. Our estimation results confirm that M&A engagements exert, in turn, a significant and positive total effect (0.69) on firms' Phase 3 capabilities. The positive post-merger effect on firms' Phase 3 capabilities eventually leads to a direct positive effect of the R&D capability in Phase 3 (*CapPhase3*) on the product approval capability (*CapProduct*), which improves the chances of gaining further product approvals. The positive effect of M&As on product approvals (*CapProduct*) is further supported by the estimated positive total effect (0.11) as Table 6 shows. Note that while the total effect of M&As on *CapProduct* is positive and significant, the direct effect is insignificant.¹⁰ This result highlights the relevance of adopting an SEM, which accounts for total effects (such as the effect of M&As on product approvals) as a combination of direct effects (M&As on product approval capability) and indirect effects (Phase 3 on product approvals). Hence, the complex relationship between mergers and firms' capabilities requires the consideration of total effects as a combination of direct and indirect effects.

The direct effects of R&D capabilities in Phases 1 and 2 and the product approval capability on M&A engagements are significantly positive. This result suggests that M&As are usually formed by firms with stronger research capabilities at the early drug development phases (Phases

¹⁰ Relatedly, while the direct effect of *CapPhase3* on *CapProduct* is significant, the corresponding total effect is not significant. The insignificance of the total effects is explained by the combination between a direct negative influence of *CapPhase3* on M&A and a direct positive effect of M&A on product approval, both of which work in opposite directions and result in insignificant total effects.

1 and 2). This observation supports that a firm's internal R&D capabilities (in Phases 1 and 2) are complementary with the external knowledge and technologies that the firm obtains through acquisition. M&A eventually enhances a firm's R&D capabilities in Phase 3 and product approval (total effects of M&A are both positive). In contrast, the R&D capability in Phase 3 (*CapPhase3*) is negatively related to M&A formation. The negative relationship further supports the fact that firms use M&As as an instrument to replenish their R&D projects in Phase 3 and to improve the drug approval success, as mentioned earlier. It is worth mentioning that the total effect of R&D capability in Phase 2 (*CapPhase2*) on M&A is positive, but not significant. This insignificant total effect is explained by a positive and significant direct effect from *CapPhase2* to *CapPhase3* in combination with a negative direct effect from *CapPhase3* to M&A. To summarize, our estimation results show that firms' internal R&D capabilities in Phase 3 of the development process are weak. Firms recognize this innovation impediment and use M&As as an effective instrument to overcome low (Phase 3) transition rates and to eventually increase the capability of gaining product approvals.

7.3.3. Impact of mergers on firm capabilities. Table 6 shows that the total effects of M&As on firms' Phase 3 and product approval capabilities are significant and positive. This result suggests that M&As are useful to exploit scope effects in the late development and the product approval stages. At this point, it is unclear, however, whether firms' improved post-merger capabilities in Phase 3 and the product approval stage effectively improve firms' success rates in advancing research projects to consecutive drug development phases, especially to the Phase 3 and product approval phases. We return to this aspect in the next subsection when we compare the transition rates between merging and non-merging firms across drug development phases.

Our results also show that the direct effect of M&As on firms' Phase 3 and product approval capabilities are insignificant. These discrepancies between the total and direct effects of M&As on Phase 3 and product approval capabilities are explained by the fact that indirect effects of M&As on firms' R&D and product approval capabilities are relevant factors that add significance to the total effects.

Turning to direct and total effects of M&As on Phase 2 (both turn out to be insignificant), we do not find supportive evidence for M&As generating scope effects. However, since the merging firm acquires research projects and replenishes its R&D pipeline, it may benefit from scale effects. We analyze this aspect in the next subsection.

Finally, we concentrate on the impact of M&As on firms' financial capability (*CapFin*). The results return a significantly negative direct effect (-1.73) of M&As on firms' financial capability, which implies that M&As crowd out successive R&D investments. Overall, however, the total effect

of M&As on firms' product approval capabilities is positive (0.11) and weakly significant, which will eventually result in an increase in R&D investments, as shown by the positive effect from *CapProduct* to *CapFin*. To summarize, M&As have a direct crowding out effect on post-merger R&D investments. However, their total effect on firms' financial capabilities, via increased R&D capabilities and new product approval capability, ultimately improves firms' financial capability and results in more resources invested in R&D.

7.3.4. Comparison of firms' capabilities and transition rates. We now turn to the question of whether firms' enhanced post-merger (Phase 3 and product approval) capabilities result in higher success rates in advancing research projects in late drug development phases. In this regard, we also relate to the insignificant effect of M&As on Phase 2 capabilities and investigate whether merging firms would benefit from scale effects. In order to answer these questions, we compare the firm capabilities and transition rates of merging and non-merging firms across drug development phases. The non-merging firms' capabilities are estimated from our structural equation model, as Appendix A describes.

Figure 6 displays the estimation results of the structural equation model for the non-merging firms in the Appendix A. It should be noted that the relationships between firms' internal capabilities are all significant. Figure 6 also shows that the successive effects of the internal R&D and product approval capabilities in an early phase on a later phase are smaller than those of the merging firms, see Figure 5. In a next step, we establish the merging and non-merging firms' R&D project transition rates, which measure the success rates of advancing R&D projects to successive drug development phases. The transition rates from an original phase to a successive phase is defined as the ratio of the number of R&D projects in the successive phase to the number of projects in the original phase. We evaluate the R&D project transition rates using the average duration for clinical trials in the original phase (that is, 1, 2, and 3 years for Phases 1, 2, and 3, respectively). Hence, the transition rates are calculated as follows:

$$\begin{aligned} TransRate_{1,2} &= \frac{NPhase2_t}{NPhase1_{t-1}}, \\ TransRate_{2,3} &= \frac{NPhase3_t}{NPhase2_{t-2}}, \\ TransRate_{3,Approval} &= \frac{NApprovals_t}{NPhase3_{t-3}}. \end{aligned}$$

Table 7 shows that the transition rate from Phase 1 to 2 is lower for merging firms than for non-merging firms. This result supports the earlier finding that mergers do not generate scope economies during the early drug development phases (Phases 1 and 2). Moreover, the results also suggest that M&As do not generate scale economies. In contrast, transition rates from Phase 2

to Phase 3 and from Phase 3 to product approval are higher for the merging firms. This result resembles the earlier findings that merging firms benefit from scope economies in the late drug development phases (Phase 3 to product approval). Because M&As enhance firms' Phase 3 R&D and product approval capabilities, merging firms enjoy a higher transition rate from Phase 3 to product approval than non-merging firms.

Table 7 R&D Project Transition Rate

Phases		R&D Project Transition Rate	
From	To	Merging Firms	Non-merging Firms
<i>Phase 1</i>	<i>Phase 2</i>	1.295	1.759
<i>Phase 2</i>	<i>Phase 3</i>	0.763	0.555
<i>Phase 3</i>	<i>Product Approval</i>	0.254	0.012

8. Conclusion

In the pharmaceutical industry, the number of M&As and the associated investment on acquiring firms continued to drastically increase in recent decades. The large investments in M&As raises concerns among scholars, managers, and policy makers who address the question of whether sufficient funds will be left for firms to further develop post-merger research capabilities. This study evaluates the influence of mergers and acquisitions on firms' internal R&D capabilities across drug development phases, as well as on their product approval capability and their post-merger R&D investments. The merger evaluation is complex, which arises from unobserved R&D capabilities and measurement errors in latent and measurement variables. For this reason, we adopt a SEM, which also enables us to evaluate direct and total (direct and indirect) post-merger effects on firms' internal R&D, product approval, and financial capabilities. Our results show that mergers can be an effective instrument for firms to improve their late-stage R&D and product approval capabilities. We also find mergers effectively increase revenues and R&D investments once indirect effects such as improved R&D capabilities and more product approvals are accounted for. To conclude, our study suggests that M&As are an important and useful instrument for firms in bringing new drugs to the market. Mergers also exert an overall positive effect on firms' R&D investments.

There are several other related aspects that would be interesting for future research, but they are beyond the scope of this study due to data constraints. One interesting future avenue would be to compare the impact of mergers versus alternative research collaborations, such as joint ventures.

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Table 8 Factor Analyses and Cronbach Alpha Coefficient for Non-merging Firms

Variable	Factor 1	Factor 2	Factor 3	Factor 4	Community	Cronbach Alpha Coefficient	Cronbach Alpha Coefficient with Deleted Variable
$NPhase1_t$	-0.032	-0.064	0.196	0.034	0.045	0.446	0.391
$NPhase1_{t-1}$	-0.008	-0.009	0.372	0.090	0.147		0.300
$NPhase1_{t-2}$	-0.014	-0.006	0.280	0.100	0.088		0.353
$NPhase2_{t-1}$	-0.005	0.013	0.539	0.177	0.322	0.599	0.518
$NPhase2_{t-2}$	0.045	0.026	0.516	0.191	0.305		0.447
$NPhase2_{t-3}$	0.068	0.006	0.443	0.054	0.204		0.530
$NPhase3_t$	0.034	-0.010	0.090	0.549	0.311	0.639	0.547
$NPhase3_{t-1}$	0.033	0.001	0.227	0.550	0.355		0.539
$NPhase3_{t-2}$	0.058	0.018	0.210	0.411	0.217		0.618
$NPhase3_{t-3}$	0.049	-0.007	0.146	0.511	0.285		0.573
$NApprovals_t$	0.068	0.880	-0.049	-0.001	0.782	0.615	0.161
$NTAs_t \times NInds_t$	0.042	0.879	-0.042	0.006	0.776		0.199
$MarketValue_t$	0.815	0.058	-0.068	0.018	0.673		0.915
$Revenue_t$	0.994	0.035	0.010	0.085	0.997	0.989	0.976
$R\&DSpending_{t-1}$	0.959	0.014	0.053	0.073	0.928		0.992
$Employees_t$	0.976	0.050	0.038	0.091	0.965		0.982

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Appendix A: Structural Equation Model for Non-merging Firms

We follow the same rationale as in Sections 5 and 6 while estimating a structural equation model of non-merging firms. Note that in this structural equation model specification, we do not have a latent variable that captures M&A engagement.

A.1. Examining the Overall Measurement Model

As before, we use confirmatory factor analysis (CFA) to determine the fit for the measurement model.

A.1.1. Factor Analysis The standardized factor loadings are shown in Table 8. All factor loadings are greater than 0.4 except $NPhase1_t$, $NPhase1_{t-1}$, $NPhase1_{t-2}$, and $MarketValue_t$. Similar to before, we keep these measurement variables since they properly indicate the R&D capabilities of the firms.

A.1.2. Reliability Analysis Table 8 lists the standardized Cronbach alpha for each latent variable and the standardized alpha once a measured variable has been removed from the construct. The reliability measurement alphas are all above 0.6, except for the alpha for Phase 1 capability ($CapPhase1$). For the latent variables $CapPhase1$, $CapPhase2$, and $CapPhase3$, the standardized alphas all decrease after we removed one measurement variable. This implies that the measurement variables for each of the above latent variables are closely correlated.

Table 9 Overall Fit Indices for Firms without M&As

Index	Measurement Model	Structural Model
Chi-Square (χ^2)	504.3	530.5
Chi-Square (χ^2) Degree of Freedom	89	94
Standardized RMR (SRMR)	0.0330	0.0333
RMSEA	0.0447	0.0446
RMSEA Lower 90% Confidence Limit	0.0410	0.0410
RMSEA Upper 90% Confidence Limit	0.0486	0.0483
Goodness of Fit Index (GFI)	0.9737	0.9724
Adjusted GFI (AGFI)	0.9597	0.9601
Bentler Comparative Fit Index	0.9821	0.9811
Bentler-Bonett NFI	0.9783	0.9772
Bentler-Bonett Non-normed Index	0.9758	0.9959

Note also that the standardized alpha increases for the latent variable *CapProduct* once *MarketValue_t* is removed. Moreover, the standardized alpha increases for the latent variable *CapFin* after *R&DSpending_{t-1}* is removed. However, we still keep these two measurement variables in their latent variables since they are indispensable indicator variables for their respective latent variables.

A.1.3. Measurement Model Estimation We estimate the parameters in the measurement model along with the covariance matrix for all latent variables. Table 9 lists the fit indices. The chi-square of the model is 504.3 and is based on 120 degrees of freedom. The ratio of χ^2 to the degrees of freedom is 4.2. The GFI and AGFI are 0.97 and 0.98, respectively. Both indices indicate good model fits given the large sample of data we used. The SRMR is 0.03, and the RMSEA is 0.04. The 95 percent confidence interval of RMSEA is between 0.041 and 0.049. The SRMR and RMSEA, along with the 95% confidence interval, suggest a good model fit. The Bentler-Bonett NFI and the Bentler-Bonett Non-normed Index are 0.98 and 0.98, respectively. These indices imply that the possible improvement in the fit of the model is limited.

We list the factor loadings and t-statistics of the measured variables in Table 10. All the measurement variables have statistically significant relationships with their latent variables and their t-values exceed the critical value of the 5% significance level. These t-statistics indicate that the measurement variables are significantly represented by their respective latent constructs.

A.2. Examining the Overall Structural Model

The overall fit indices are given in Table 9. These indices indicate that the overall structural model replicates the covariance of the measured variables well and the possible improvement in the fit of model is limited. The path weight estimates are given in Table 10. The factor loadings for the measurement variables in the structural models are roughly the same as those in the measurement model, even though we reestimate them along with the relationship paths in the structural model. This consistency implies that the specifications for the structural model are correct. Figure 6 displays the path coefficients. The coefficients are all different from zero at a 1% significance level.

Table 10 Measurement and Structural Model Estimates

Measurement variable	Latent variable	Measurement Model		Structural Model	
		Estimate	t statistic	Estimate	t statistic
<i>NPhase1_t</i>	<i>CapPhase1</i>	1.000		1.000	
<i>NPhase1_{t-1}</i>		0.984	8.894	1.268	6.758
<i>NPhase1_{t-2}</i>		0.526	9.142	0.525	8.724
<i>NPhase2_{t-1}</i>	<i>CapPhase2</i>	1.000		1.000	
<i>NPhase2_{t-2}</i>		0.629	13.083	0.615	13.474
<i>NPhase2_{t-3}</i>		0.362	11.068	0.353	11.257
<i>NPhase3_t</i>	<i>CapPhase3</i>	1.000		1.000	
<i>NPhase3_{t-1}</i>		0.567	18.126	0.567	18.113
<i>NPhase3_{t-2}</i>		0.313	15.331	0.311	15.329
<i>NPhase3_{t-3}</i>		0.287	16.984	0.282	16.895
<i>NApprovals_t</i>	<i>CapProduct</i>	1.000		1.000	
<i>NTAs_t × NInds_t</i>		1.579	7.873	1.387	4.282
<i>MarketValue_t</i>		632.174	4.506	861.902	3.373
<i>Revenue_t</i>	<i>CapFin</i>	1.000		1.000	
<i>R&DSpending_{t-1}</i>		2.138	204.800	2.138	204.600
<i>Employees_t</i>		0.124	137.000	0.124	136.500

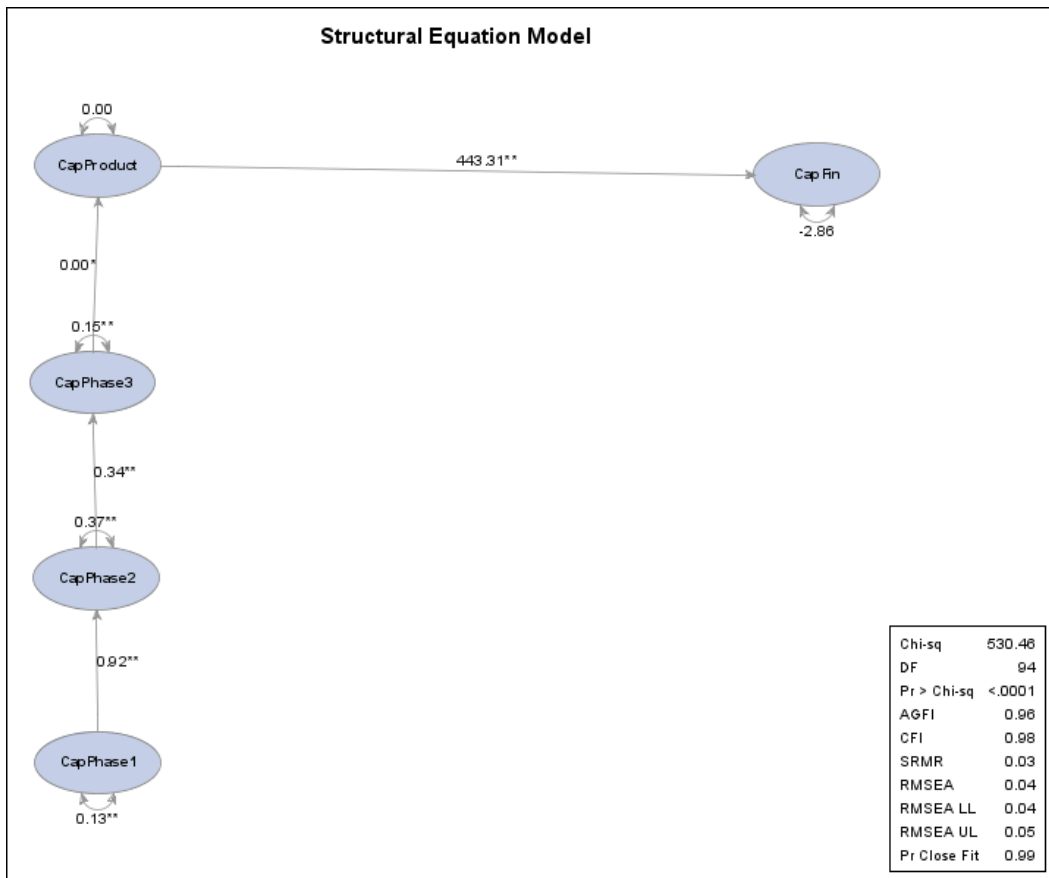


Figure 6 Estimates of the Structural Equation Model for Non-merging Firms.