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Abstract

Besides R&D spending, performance in terms of NDA and patent approval has been a key surrogate marker of R&D efforts of pharmaceutical firms. The results show that Korean firms are more responsive to patent approval, whereas non-Korean firms are more responsive to NDA approval. Although many recently approved patents of Korean firms are related to innovative discovery of novel drug candidates, the commercial value of NDA approvals accomplished by non-Korean firms is remarkably high. The annual quantitative accomplishment of NDA approval is small, considering the long development process. However, its commercial value is quite big and the drug receives worldwide acceptance. This is the reason that investors react quite positively to NDA approval news of non-Korean firms. The findings in this study imply that it would be advantageous for both Korean and non-Korean firms to persist with their R&D efforts, in accordance to their respective strategy. This would help in maintaining and upgrading their firm value as well as developing new drivers of potential growth for corporate sustainability management, besides managing the financial capacity well through firm-specific execution.

Key Words: R&D; NDA; patent; firm value; pharmaceutical firms

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Introduction

The pharmaceutical industry is currently undergoing a phase of significant transformation. Pharmaceutical firms have been investing in R&D more than ever to come up with new inventions that have the potential to drive revenues and profits, provide new treatment options of incurable diseases, and improve patients' quality of life. However, there is no guarantee of success of the R&D projects due to several uncertainties associated with them. The R&D process for new drug development takes several years (10–15) and requires significant investments, but its probability of success remains quite low.

DiMasi, Hansen, and Grabowski (2003) examined that a typical new compound first goes through the initial stages of research, following which it is tested on animal models before moving forward with clinical testing on humans. Clinical testing in humans consists of three phases that assess the investigational drugs' effectiveness and safety. If the tests are successful, the drugs are approved by regulatory authorities for marketing. Since only one in 5,000–10,000 compounds tested eventually reach consumers after several years of capital-intensive work on it, each individual company is required to develop its firm-specific R&D platform or distinctive set of activities in accordance with the desired strategic positioning. The innovations in health sciences have brought in new therapies to treat incurable diseases. These therapies are superior to their predecessors in terms of efficacy, safety, and economics. Despite this innovative advantage, the discovery and development of new drugs is a very protracted and expensive process. Capitalizing out-of-pocket costs per new drug up to the point of marketing approval exceeded USD802 million in 2000 (DiMasi, Hansen, and Grabowski 2003). Furthermore, R&D expenditure in the US expanded from USD26 billion in 2000 to USD50 billion by the end of 2011. Conversely, the average new drug approvals during the same period dropped.

Amid the turbulent industry dynamics and uncertainty of R&D, pharmaceutical firms may be required to strike a balance between their investments and financial soundness. Successful R&D has the potential to enhance a firm's value through more revenue and profit. On the other hand, unsuccessful R&D has led to liquidity crisis and even bankruptcy. The Korean Ministry of Health implemented and announced a new regulation to cut prices of all pharmaceutical prescription drugs by 14% on average with effect from April 2012. As many as 7,500 items out of the 14,000 available in the market were chosen for price cut. This price cut has had the most groundbreaking impact on the Korean pharmaceutical industry in the last couple of decades. However, innovative drugs whose patents are still valid, drugs manufactured by fewer than three companies, and drugs used to fight rare diseases were treated as exceptional cases, with some government favors to go with them. There are some common features in the three exceptional cases mentioned above. These drugs are outcomes of recent R&D efforts with no or fewer competitors, and with higher value to society than commodity drugs. In today's tough market scenario and regulatory environment, Korean firms are feeling

pressurized to reconsider their strategic approach. These firms are apparently finding it difficult to manage their financial aspects, having been indifferent to them for decades. One way to stage a turnaround and sustain in the industry is to reinforce aggressive R&D efforts and come up with a valuable product. However, if firms invest in R&D without a well-designed strategic plan, it may cause irrecoverable damage. Thus, it can be said that Korean firms are currently finding themselves in a dilemma. Meanwhile, global top-tier pharmaceutical firms have been suffering from lack or absence of new breakthrough launches, among other issues. As part of efforts to plug the product gap, they have been persistently seeking M&As. The productivity from R&D has been declining. The firms are also facing fast erosion of generic drugs since the expiration of their innovative blockbusters. Furthermore, spiraling healthcare costs and pressures on price reduction of drugs is another global issue faced by the pharmaceutical sector. Moreover, the marketing cost to consumers has been exceeding the costs of conducting R&D. This puts companies at risk of not directing enough resources toward developing drugs, and lesser number of new drugs being launched in the market.

In view of the above, a study on relationship between pharmaceutical firms' R&D efforts and firm value in the recent decades may offer some guidance and implication to firms, and help them devise a future-oriented strategy accordingly. As R&D spending is considered to be one of the key indices to assess the degree of R&D efforts in the pharmaceutical sector, several prior research have found a positive association between R&D spending and firm value. Besides, qualitative and quantitative performance of the new drug application (NDA) approval could also be an indicator of R&D efforts in the pharmaceutical sector. An NDA approval before a new product is introduced in the market is the final assessment of the exhaustive and expensive R&D that firms have conducted. Therefore, a count of NDA approvals could be a reliable measure of success in the pharmaceutical industry (Shortridge 2004). Moreover, cumulative abnormal returns (CAR) at NDA approval dates can be a good proxy variable to measure the changes in firm value after controlling the market movements. Korean pharmaceutical firms have been traditionally more dependent on patent-expired, economical generic drugs, and some slightly modified drugs rather than new innovative drugs due to their strong reverse engineering technology. This late-mover advantage has driven the continuing growth of Korean firms for decades. However, since 2000, many of these firms have been making efforts to develop more value-added and innovative products even as global top multinational firms have been engaged for decades in the development of new innovative breakthrough drugs that dominate the global market. Another possible way of measuring R&D performance is through the number of patents obtained. As a patent is the first materialized intellectual capital of a firm's innovative idea, it gives inventors the exclusive right to sell an invention for up to 20 years. This substantial duration has proved to be a fundamental incentive for boosting costly R&D activities in the pharmaceutical and biotechnology sectors. Mansfield (1986) observed that 65% of pharmaceutical inventions would not

have been introduced if patent protection could not have been obtained; this statistic is only 8% in 11 other industries that he studied. These findings show that patent approval significantly matters as one of key motivating drivers and measurement of R&D efforts in the pharmaceutical industry.

This study examines whether there is a close relationship between R&D-related intangible assets (R&D spending, NDA approval, patent approval) and firm value in the pharmaceutical industry. The study also attempts to determine whether the observations differ among different groups of firms with diverse characteristics, origins, and strategies. For a specific comparison, top Korean firms and top-tier global non-Korean firms have been investigated. The investigation assumes that Korean firms are heavily dependent on less breakthrough products and most firms are managed by the founder's family as majority shareholders even though many of them went public and most of the revenue is still limited to Korea. Meanwhile, a larger portion of revenue of global top-tier firms comes from several parts of the world, and is not restricted to their origin country. Besides, many global firms are managed by professional CEOs and founders, and their family members retain quite less shares of stocks compared to Korean firms. This study also tried to discover whether there is any difference situation in biotech firms, which are typically R&D dedicated with extremely high R&D spending but low revenue. Since 2000, there have been very few articles on the relationship between R&D efforts and firm value in the pharmaceutical sector. Since there have been no specific articles on the comparative analysis between Korean firms and non-Korean firms, this study investigates, through a couple of hypotheses, whether prior studies indeed apply to pharmaceutical firms after 2000 in a similar manner. The hypotheses are: R&D efforts (R&D spending, NDA approval, patent approval) are positively associated with the market cap of firms, and the associated pattern between market value and R&D efforts is likely presented in a different manner depending on the group of sample firms (between top-tier Korean firms, top-tier non-Korean firms, and top-tier biotech firms). To test the robustness of the regression results based on the annual dataset, event study results based on the daily CAR around the NDA and patent approval dates are provided as well. For the multivariate regressions of market value on R&D expenses, NDA, and patent approval, the experimental model proposed by Ohlson (1995) and applied by other researchers was used.

Literature Review and Hypothesis Development

Of late, several empirical studies have analyzed the market reaction to announcements of R&D spending, and their results indicate that, in general, R&D investments enhance the market value of firms. Chauvin and Hirschey (1993) investigated the market reaction to R&D expenditure using a large sample of Compustat firms. They observed that R&D has a positive influence on the market value of firms. This result is in accordance with Cockburn and Griliches (1988), who indicate that the market valuation of R&D investment is

quite high. Bae and Kim (2003) examine this relationship by comparing the effect of R&D investment on market value across US, German, and Japanese firms. Their findings confirm that R&D positively affected firm value in these countries (Pindado, Queiroz, and Torre 2010).

Shores and Bowen (2002) examined the impact of R&D on residual income. Following their study, a number of accounting researchers attempted to measure the benefit of R&D investment by testing whether it leads to creation of intangible assets. Hirschey and Weygandt (1985) examined the impact of intangible assets on market value. Dedman et al. (2009) consider practices with respect to the measurement and disclosure of intangible assets, focusing on R&D activities. Much of intangibles have concentrated on R&D as the most important source of firm's intangible assets. Thus, the study had mainly proceeded by regressing firm market value on various accounting variables, including R&D expenditure. The outcomes confirm the results with respect to the value relevance of research and development as propagated by previous studies. The coefficients for R&D were significantly positive.

The factor that new product innovations are essential to the continued existence of firms is also supported by several approaches to developing a business strategy. The well-known growth-share matrix, popularized by the Boston Consulting Group in the 1970s, postulated that a balanced portfolio of products, some relatively mature to provide a stable current cash flow and some new to generate cash flow in the future, is needed for the long-term profitability of the firm (Chaney, Devinney, and Winer 1991). On the other side, the authors also found that many cases of new product failures that cost the sponsoring companies a significant amount of money can be documented. According to DiMasi (2001), the drug development process is known to be complex, costly, and time-consuming. Besides, it is also risky since most compounds that undergo clinical testing are abandoned without obtaining marketing approval. The author found approval success rate of new drugs under clinical testing being only 19–30%. A recent analysis by the Centre for Medicines Research in the UK has concluded that since 2008, the failure rate for drugs in phase II and III clinical trials has been rising. Particularly, phase II success rates currently stand at 18%, lower than at any other phase of drug development (MedCity News, June 2, 2011). [1] In short, R&D spending for new product development in the pharmaceutical industry could be either a growth driver of enhancing market value or non-systemic risk that may reduce firm value, based on the R&D strategy and product.

Some prior studies show that ownership structure can substantially influence the efficiency of pharmaceutical firms. Thomsen and Pedersen (2000) said that different types of owners may also indicate different attitudes toward R&D investment strategy. You, Chenb, and Holder (2010) invoked Drucker (1986) who revisited the argument that type of ownership can influence the firm's R&D investment. Yoon and Kim (2008) investigated the

[1]Medcitynews(2011), New drug failure rates rising in Phase II and III clinical trials, Retrieved Dec. 22, 2012, from http://medcitynews.com/2011/06/new-drug-failure-rates-rising-in-phase-ii-and-iii-clinical-trials

impact of ownership structure on the value-relevance of R&D investment in KOSDAQ firms and found the equity ratio of foreign investors to be positively associated with the value-relevance of R&D investment. The result of this analysis implies that the market values R&D investment differently, according to the ownership structure. Korean pharmaceutical firms (one of the sample groups in this study) are generally characterized by strong family ownership. A strong family ownership may promote firm efficiency for two reasons. First, as indicated by Shleifer and Vishny (1997), strong ownership gives the family owners a particular incentive to monitor the managers, thereby reducing agency costs (You, Chenb, and Holder 2010). Second, as emphasized by Pollack (1985), attributes of family business can promote operational flexibility, ease decision-making, and reduce shirking, all of which may have favorable effects on the efficiency of the firm. Durand and Vargas (2003) also find evidence that owner-controlled private firms are more efficient than agent-led private enterprises. Based on these discussions, we derive the following hypotheses that different types of ownership may lead to different findings in the relationship between R&D efforts and investor response. Here, we have assumed that Korean firms are more likely run by family-led ownership than non-Korean firms. Furthermore, the size of Korean firms is comparatively quite small, as reflected in the statistics table below. As a result, cash inflow for R&D investment is quite less compared to top-ranking non-Korean firms. The fact that new drug development of a high market value product costs billions of dollars and takes around 10–15 years confirms that the pharmaceutical industry is capital intensive in R&D. Considering that, it's possible that Korean firms are not investing an adequate amount in R&D to reach the scale of economy for developing new innovative drugs and attracting investor attention.

Based on prior researches explained above, a couple of hypotheses have been made in this study to confirm whether the findings of these prior researches were similarly or differently presented in case of Korean firms, non-Korean firms, or biotech firms, particularly amid the recent dynamic decade for the pharmaceutical industry. Although numerous studies have reported the relationship between R&D efforts and firm value, there have been no specific articles on the comparative analysis between Korean firms and non-Korean firms, including biotech firms, particularly in the recent decade (since 2001) during which the pharmaceutical sector has experienced turbulent market dynamics worldwide as well as in Korea. Based on this factor, few hypotheses have been made to investigate how R&D affects creation of firm value and whether there are some distinctive findings among different sample groups.

H1: R&D spending as potential engine of future growth is positively associated with the market cap of sample firms.

Investors react positively to R&D spending as they perceive it as an intangible asset that may drive the firm toward financial growth through its contribution to the firm's performance. Thus, the more the spending, the higher the firm value could be.

H2: More number of NDAs and patents are assumed to increase the market cap of firms.

Investors react positively to the key milestones of R&D performance (NDA, patent approval) as well as R&D spending. Thus, more quantitative accomplishment is likely to increase the firm value.

H3: The associated pattern between market value and R&D efforts differs, depending on different groups of sample firms (top-tier Korean firms, top-tier non-Korean firms, and top-tier biotech firms).

Firm-specifics originating from different ownerships, organizational structures, strategies, firm size, profitability, cultures, profiles of new product values, geographical business territories and R&D pipeline portfolio among Korean firms, non-Korean firms, and biotech firms are known to be quite different.

Data and Methodology

Data

We surveyed 46 sample firms from Korea and other countries for the period 2001–2011 in terms of revenue ranking. The top 20 (by revenue) Korean pharmaceutical firms were considered as samples for empirical analysis, assuming that they could act as representative since they belong to the top-tier group in terms of revenue, income, and R&D spending. Besides, all of them went public at some point of time, and thus the market value can be measured. Of the top 20 Korean firms, SK's business unit included the non-pharmaceutical (energy and chemical) as well as pharmaceutical sectors. Hence, it was excluded due to ambiguous qualitative performance of NDAs and patent approval of drugs. We were thus left with 19 Korean pharmaceutical firms. Based on the same criteria, 27 global top-tier non-Korean pharmaceutical firms, including top-tier biotechnology firms, were selected as they had been heavily influencing the worldwide pharmaceutical industry and its dynamics as representative leaders. Table 1 shows information on sample firms in the latest year at a glance and each quantitative measurement of R&D efforts as well as key financial indicators that have been utilized into empirical formula in this study. The top-tier Korean (panel A) and non-Korean global firms, including top-tier biotechnology firms (panel B), are listed in terms of average revenue during the sample period from top to bottom. The size of book value, market cap, and net income also similarly coincide with the ranking in revenue while a few exceptions were found. The market cap of Yuhan is particularly high, which is presumably attributed to its high book value and net income.

We obtained the year-end market value, annual R&D spending, and key financial information (total asset, revenue, net income, book value of equity, ROE, ROA) of 46 sample firms for the period between 2001 and 2011 from Datastream. Data on daily returns for event study and stock market indices in which each firm's economic activity takes place was also sourced from

Datastream. Data on NDA approval (count for the year and approval dates) was obtained from the website of Korean Food & Drug Administration for Korean firms' and FDA (www.fda.gov) for non-Korean firms.[1] Data on patent approval count was obtained from Korea Intellectual Property Right Information Service (KIPRIS). The number of NDAs and patents per year for multiple regressions were counted, and NDAs and patent approval dates for event study were collected for each sample firm from 2001 to 2011. Many top-tier non-Korean firms are US-based. All of these have US operations as their main revenue source. Furthermore, many of them operate at the global level.

Table 1 : Lists of sample firms and key financial indicators in the latest year

This table reports the lists of sample firms and their key financial indicators in the latest year. The sample includes the biggest 19 Korean and 27 global (non-Korean) top-tier pharmaceutical firms, including 12 biotechnology firms. They are selected based on their revenue within each group. Panel A reports the list and key financial indicators of 19 Korean sample firms (SK Chemical was excluded because there was no NDA or patent approval during the sample period 2001~2011), while panel B reports the list and key financial indicators of 27 non-Korean globals, including 12 biotechnology firms. All stock and financial data (in USD million) have been obtained from DATASTREAM. New drug application (NDA) information is from Korean FDA (Ezdrug: http://ezdrug.kfda.go.kr/index.jsp) for Korean firms and FDA (www.fda.gov) for non-Korean firms. Patent approval data are from Korea Intellectual Property Right Information Service (KIPRIS).

Panel A : Korean Pharmaceutical Firms

Firms	Latest fiscal year	Market Cap	Revenue	R&D spending	Book value	Net income	NDA completed	Patent approval
Donga	2011	903	1,056	74	862	75	19	16
Yuhan	2011	1,315	679	50	1,116	94	10	8
Hanmi	2011	452	606	84	378	5	33	9
Daewoong	2011	294	710	74	362	50	11	7
Greencross	2011	1,223	768	59	630	58	6	3
Joongwae	2011	165	431	28	170	-10	15	4
Chongkundang	2011	241	569	45	359	57	21	0
Jeil	2011	233	463	18	231	27	4	2
Handok	2011	145	333	16	278	17	2	0
Ildong	2011	186	348	28	310	27	14	7
Kwangdong	2011	211	314	5	250	30	16	10
Boryung	2011	95	308	26	138	6	9	3
Shin poong	2011	197	230	12	180	25	23	3
Dongwha	2011	126	235	14	230	18	0	6
Bukwang	2011	361	101	9	191	6	5	0
Samjin	2011	114	202	10	120	7	7	0
Samil	2011	24	95	4	67	-7	5	3
Korea United	2011	87	146	19	113	20	14	8
Hanall	2011	334	88	11	51	-15	3	7

Panel A of Table 2 shows descriptive statistics on the key characteristics of the sample pharmaceutical firms. Data on 46 firms for the 11-year period

[1]Ezdrug: http://ezdrug.kfda.go.kr/index.jsp for Korean firms, and www.fda.gov for non-Korean firms

(2001–11) was collected to come up with 486 firm years. Firm years are further allocated into sub-analysis firm groups in order to compare specifics.

The mean market capitalization value is USD289.6 million for Korean firms and USD52,983.5 million for non-Korean firms. The mean R&D spending is USD14.7 million for Korean firms and USD2,425.0 million for non-Korean firms. NDA and patent approvals show some characteristic features. The NDA approval count obtained per year varies widely across firm-years, as the mean is 10.1 with standard deviation of 6.7 for Korean firms, while it is only 1.1 with standard deviation of 1.5 for non-Korean firms. In other words, Korean firms obtained more NDAs and non-Korean firms obtained less. On the other hand, the mean number of patent approvals for Korean firms obtained from 2001 to 2011 is only four with standard deviation of five, while it is much higher at 14 with standard deviation of 27 for non-Korean firms. Patent count of non-Korean firms is quite bigger than that of Korean firms.

Table 2 : Summary statistics and pairwise correlation

This table shows the summary statistics and pairwise correlation between main variables to be used in the regression analysis within each group. Panel A reports means and standard deviations (in USD millions), panel B reports full sample correlation, and panels C, D, and E report pairwise correlation of main variables within each group. ***, ** and, * in panels B to E indicate statistical significance at the 1, 5, and 10% levels, respectively.

Panel A : Means and Standard Deviations of Main Variables

Variables	All firms		Korean		Global (non-korean)		Biotech	
	mean	(s.d)	mean	(s.d)	mean	(s.d)	mean	(s.d)
MV	30,323	(49,350)	290	(369)	52,983	(55,507)	12,434	(20,374)
R&D	1,388	(2,221)	15	(16)	2,425	(2,482)	470	(762)
NDA	5	(6)	10	(7)	1	(2)	0	(0)
Patent	10	(21)	4	(5)	14	(27)	2	(3)
Revenue	9,705	(15,628)	264	(187)	16,828	(17,628)	2,057	(3,777)
Net Income	1,666	(3,040)	21	(25)	2,907	(3,555)	423	(1,103)
Book Value	8,729	(16,410)	193	(183)	15,169	(19,401)	3,069	(5,659)

Panel B : Full Sample Correlations

	MV	R&D	NDA	Patent	Revenue	Net Income	Book Value
R&D	0.900***	1					
NDA	-0.288***	-0.299***	1				
Patent	0.403***	0.449***	-0.088**	1			
Revenue	0.891***	0.965***	-0.289***	0.507***	1		
Net Income	0.871***	0.896***	-0.255***	0.368***	0.882***	1	
Book Value	0.813***	0.899***	-0.242***	0.434***	0.885***	0.804***	1

Panel C : Correlations in Korean Pharmaceutical Firms

	MV	R&D	NDA	Patent	Revenue	Net Income	Book Value
R&D	0.714***	1					
NDA	0.193***	0.159***	1				
Patent	0.478***	0.420***	0.242***	1			
Revenue	0.726***	0.885***	0.175***	0.380***	1		
Net Income	0.824***	0.624***	0.126**	0.368***	0.682***	1	
Book Value	0.834***	0.716***	0.113	0.360***	0.797***	0.802***	1

Panel D : Correlations in Global Pharmaceutical Firms

	MV	R&D	NDA	Patent	Revenue	Net Income	Book Value
R&D	0.861***	1					
NDA	0.540***	0.514***	1				
Patent	0.342***	0.398***	0.295***	1			
Revenue	0.849***	0.952***	0.511***	0.470***	1		
Net Income	0.831***	0.865***	0.474***	0.304***	0.845***	1	
Book Value	0.758***	0.872***	0.465***	0.382***	0.853***	0.751***	1

Panel E : Correlations in Biotech Pharmaceutical Firms

	MV	R&D	NDA	Patent	Revenue	Net Income	Book Value
R&D	0.838***	1					
NDA	0.386***	0.271***	1				
Patent	0.408***	0.492***	0.155*	1			
Revenue	0.869***	0.975***	0.307***	0.457***	1		
Net Income	0.739***	0.854***	0.231***	0.320***	0.910***	1	
Book Value	0.895***	0.936***	0.291***	0.471***	0.945***	0.806***	1

The major difference of R&D spending between Korean and non-Korean firms is attributed to the following distinctive features of firms' R&D strategy. Of the 27 firms, 12 are NASDAQ-listed biotech companies. Most of biotech's R&D spending is extremely high due to their new innovative drugs. Furthermore, non-Korean firms have traditionally spent quite higher on R&D than Korean firms because most of non-Korean firms spend on innovative new drugs while Korean firms spend more on less-innovative generic or modified product development, which costs less than innovative drug development. This explains why Korean firms obtain more NDAs and less patent approvals.

However, this pattern has been changing recently as more Korean firms are now spending on innovative drug development than ever, and therefore R&D spending of these firms has continued to grow fast since the past decade. Even though not reported, the sample Korean firms obtained more NDAs around 2008 and 2009 than in other sample years. This could be probably because many innovative drug patents expired during that period, and hence Korean firms tried to penetrate the market with generics. Moreover, Korean as well as non-Korean firms obtained more patents around 2006, implying more R&D spending during the late development stages of research when patents are created. In the same vein, mean R&D spending of Korean sample firms increased from 4.9 to 30.8 USD million during the 11-year period. This trend implies Korean firms changed their R&D strategy dynamically, moving from less innovative products, which demanded low R&D spending, to higher value innovative products, which demanded higher spending and long development period. Similarly, it may also imply lower R&D efficiency. The first scenario seems more authentic, considering the recent R&D pipeline of Korean firms.

We also investigate the correlation between market capitalization value as a main dependent variable and the proxy variables of R&D efforts (R&D spending, and count of NDA and patent approvals each year) as main explanatory variables prior to various multiple regressions to validate hypotheses 1 to 3. Revenue, net income, and book value of each year are also considered as key financial performance indicators affecting firm value. Panels B to E of Table 2 above show the results. In panel B of full sample correlation, the market value and R&D spending of sample firms expectedly show a high and significant correlation of 0.9. The correlation between market value and NDA count of each year presents an unexpectedly low but significantly negative value of -0.29, while the correlation with patents shows higher and significantly positive value of 0.4. For the unexpected result of NDA correlation with market value, we need to consider a more detailed look at the subgroup correlation results from panel C to E. In panel C of the correlation table for Korean sample firms, the correlation of market value with NDA count is low but significantly positive at 0.19. Further, the correlations within the non-Korean global sample firms and biotech firms have higher and significant values at 0.54 and 0.39, respectively, indicating the increased efforts of non-Korean pharmaceutical firms in innovative new drugs and higher market reactive results. On the other hand, the correlation results between market value and count of patent approvals are contrary to the result of NDA count. In panel C for Korean sample firms, the correlation of 0.48 is higher than those in non-Korean or biotech sample firms, which are 0.34 and 0.41, respectively. This means the Korean market is more reactive to patent approvals than NDA approval. The correlations between market value and control variables of revenue, net income, and book value are highly significant in the full sample and all of the subgroup correlations.

Methodology

Calculating CAR

We provide event study results based on the daily returns at the NDA and patent approval dates to investigate robustness of the results based on annual accounting data. Changes in market reaction around the NDA and patent approval dates of each sample firm during the period 2001 to 2011 can be measured by the CAR at each approval dates. For the calculation of abnormal return (AR), the below market model is used:

$$R_{i,\tau} = \alpha_i + \beta_i \cdot R_{m,\tau} + \epsilon_{i,\tau} \qquad \forall \tau \in [-250, \cdots, -11]$$

where $R_{i,\tau}$ is the daily return for the firm i, and $R_{m,\tau}$ is the (value weighted) market index corresponding to each sample firm. Following the standard practice, the residual $\epsilon_{i,\tau}$ calculated from the market model is the daily AR. We estimate the market model over the 240-day period starting 250 days before the event and ending 11 days before the event to capture stock run-ups. We measure CAR using the market model adjusted for market risk for the [-2,+2], [-5,+5], and [-10,+10] windows around the each approval date as follows:

$CAR_{i,t}[\pm d] \equiv \left\{\prod_{\tau=-d}^{+d}\left(1 + \widehat{AR_{i,\tau}}\right)\right\} - 1 \quad \forall d \in \{2, 5, 10\}$ for approval date *t*

Multiple Regressions

The positive association of market value creation with various R&D efforts presented in the correlation results is investigated in greater depth in the multivariate regressions of the experimental model proposed by Ohlson (1995) and applied by other researchers. To validate hypotheses 1–3 proposed in section 2, the multiple regression model mentioned below is tested for the full sample and the various subgroups (Korean, non-Korean global, and biotech groups). Besides R&D efforts as main explanatory variables, key financial performance indicators reflecting the firm's size, stability, and profitability such as revenue, book value, and net income too probably affect the firm value.

$$MV_{i,y} = \alpha + \beta_1 \cdot R\&D_{i,y} + \beta_2 \cdot NDA\ Count_{i,y} + \beta_3 \cdot Patent\ Count_{i,y} + \beta_4 \cdot Revenue_{i,y} + \beta_5 \cdot Net\ Income_{i,y} + \beta_6 \cdot Book\ Value_{i,y}$$

where $MV_{i,y}$ is the market capitalization value for firm i at the end of the first quarter following the fiscal year end t, $R\&D_{i,y}$ is research and development spending for firm i incurred during fiscal year t, $NDA\ Count_{i,y}$ is the number of new drug applications approved by the Korean Food and Drug Administration for firm i during fiscal year t, $Patent\ Count_{i,y}$ is the number

of patents approved by the patent authority for firm i during fiscal year t. $Revenue_{i,y}$, $Net\ Income_{i,y}$ (net income from continuing operations), and $Book\ Value_{i,y}$ (total shareholder's equity) follow their respective definitions of accounting terms for firm i at the fiscal year end t. In the next section, we mainly investigate the signs and significance of coefficients β_1, β_2, and β_3 to test the hypotheses.

We also test whether CARs at NDA and patent approval dates show significant differences among sub-sample groups. The regression model is as follows:

$$CAR_i[\pm d] = \alpha + \beta_1 \cdot Global(Dummy)_i + \beta_2 \cdot Biotech(Dummy)_{i,y} + \beta_3 \cdot Revenue_{i,y} + \beta_4 \cdot Net\ Income_{i,y} + \beta_5 \cdot Book\ Value_{i,y} \qquad \forall d \in \{2, 5, 10\}$$

where CAR_i is the cumulative abnormal return for the [-2,+2], [-5,+5], and [-10,+10] windows around the approval date of each firm i, and $Global(Dummy)_i$ and $Biotech(Dummy)_{i,y}$ are the dummy variables set to one if the firm i belongs to each subgroup of non-Korean global and biotech pharmaceutical sample firms, and zero otherwise.

Empirical Results

As hypothesized in the introduction, if R&D spending is reflected in investors' valuation decisions, R&Ds will be positively associated with market cap. Both NDA and patent counts also could be good indicators of innovation in the pharmaceutical industry if they are positively associated with market cap. As proposed in 3.2.2, the multiple regression method is applied by locating market cap as a dependent variable reflecting the market value of a firm, and R&D spending, NDAs, and patents as key explanatory variables. A couple of key financial performance indices are set as control variables. Standard errors are adjusted for clustering at the sub group level, and the corresponding t-statistics are presented in parentheses; ***, **, and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

In table 3, we present the test results of the positive association between market value and R&D efforts. The results for full sample firms provided in panel A are not very supportive, especially for the NDA and patent counts from Model 3 to Model 7. The coefficients of NDAs and patents are not significant but negative. However, when the full sample is investigated separately by sub groups, it turns out that each market responses differently depending on the kind of R&D efforts. We report the results by subgroups in the next three panels: Panel B reports the results for Korean sample firms, while panels C and

D report results for non-Korean global firms and separately for biotech firms. As expected in hypothesis 1 and reported by prior researches, R&D spending turned out to be positively associated with the market cap quite significantly across the investigated subgroups of firms as the coefficient β_1 of R&D is positive and statistically significant, even though it may negatively affect the financial statement of certain firms. In panel B of Korean pharmaceutical firms, all the coefficients from model 1 to model 7 are positive and statistically significant. In the case of biotech pharmaceutical firms in panel D, the coefficients of models 2, 4, and 6 are negative, but statistically insignificant. This finding is explained with a couple of assumptions. First, the financial data on those biotech firms shows that the firms invest quite heavily on R&D spending compared to their revenue or income. This implies that many biotech firms have gone beyond their financial control and investment capacity, and investors may perceive this unbalanced financial management as a kind of operational risk that may frequently put the firms into capital impairment. In fact, many biotech firms historically went insolvent mainly due to the failure of their R&D projects, which were heavily funded. Thus, more informative investors may evaluate these points from a negative context. Second, this negative association of biotech firms' R&D spending and firm value may be attributed to the inconsistency of market valuation. This is in line with the evaluation of Chan, Lakonishok, and Sougiannis (2001) that investors overestimate the benefits from R&D, and hence valuations attached to R&D-intensive technology stocks are excessive. Thus, the market may be overly optimistic about the technological breakthroughs that are publicized by R&D-intensive firms, such as a biotechnology firm's promise to deliver a cure for cancer. Chan, Lakonishok, and Sougiannis (2001) also examined that large distortions can arise from expensing rather than capitalizing R&D costs in case of high level of R&D spending, and if investors fail to adjust standard valuation measures such as price-to-earnings or price-to book ratios for the long-term benefits of R&D, potentially severe mispricing can arise. The insignificance of the coefficient in models 2, 4, and 6 of panel C, which depicts the case results of global pharmaceutical firms including biotech firms, is likely due to the effect of these characteristics of biotech firms.

As the main result of table 3 suggests, the positive association of R&D spending with the market cap implies R&D spending in most firms plays a significant role as an engine to drive firms to retain higher firm value. This is because R&D spending is the key material source of new products that drives firms to fuel their business sustainability in the market, though it may negatively affect the financial statement of certain biotech firms due to excess amount of cash outflow. This finding proves that R&D spending of the pharmaceutical industry is not pure cost but some investment converted into an intangible asset once it is paid. Investors are also likely to rely on its positive influence instead of looking at its negative context.

In addition to R&D spending, we measured the quantitative performance of NDA[1] and patents as additional key marker of R&D efforts to know whether they are associated with firm value. Therefore, hypothesis 2 of how NDAs and patents, which are also the key outcome of R&D efforts of firms, are associated with market firm value, and hypothesis 3 that probes whether there are any group-specific differences also can be validated through panel B to D of table 3. One of the remarkable findings is the distinctive difference between Korean firms and non-Korean firms. Korean firms are more responsive to patents than NDAs and non-Korean global firms are more responsive to NDAs than patents. As panel B of table 3 shows, a patent is positively associated with the firm value of Korean firms; the coefficient of NDA is also positive but not significant. A patent is the first milestone of R&D performance and NDA approval is the final frontier of R&D efforts. As explained, Korean firms are more dependent on less innovative generics, and their annual quantitative accomplishment of NDA approval is quite high due to its simpler process and lower cost compared with innovative drug development. Many NDAs that Korean firms attain used to be generic products. One single generic NDA approval usually did not impact the business performance as profoundly as that of a new innovative drug because generics are typically limited to a geographical location of sales territory and have many identical competitors, thus making the firm less competitive in the market. Thus, investors may not regard NDA approval as the key success outcome of R&D efforts of Korean firms. Meanwhile, owing to technological advancement, several patents approved by Korean firms in the recent decade are related to innovative discovery on higher value-added novel drug candidates. This may possibly lead firms to more growth and profit, which investors may consider as a measure of the firm's potential. This may be the reason why Korean investors react to accomplishment of patents positively. On the other hand, NDA approval is positively and statistically significantly associated with the firm value of non-Korean global firms and biotech firms, as seen in each of panels C and D, whereas patents are not associated with firm value. Non-Korean firms generally obtain NDA approval of innovative drugs; however, annual quantitative accomplishment is small. As panel A of table 2 shows, annual NDA approval is around 1.0 on average as it requires long-time development efforts in order to pass through its full course of works to ultimately succeed as explained in the R&D process part of the "Introduction" section. However, its commercial value is quite big and the product is available worldwide, and

[1]It would be ideal to count the accumulated NDA approvals for a certain period of years rather than counting the approvals in one particular year, because the market cap reflects the total firm value at a single point in time. However, it is not sufficient to assess accumulated years based on how long each drug is actually effectively used. For example, a truly creative product is likely to be valuable for a long period of time, while some products become less valuable or obsolete in a few years as better replacements are developed. This may be also applied when patent counts are included as independent variables in a valuation model. Shortridge (2004) stated that this methodology was used in Hirschey et al. (1998), where the authors included annual patent counts as an independent variable in the valuation model versus the sum of patents over several years.

hence investors react quite positively to NDA approval news of non-Korean firms, which ultimately enhances firm value.

Control variables, net income, and book value are positively associated with contemporaneous market cap for Korean firms at the 0.01 level; however, revenue is not significantly associated with market cap for Korean firms, as panel B shows. This implies that firm size does not matter in investors' valuation of Korean firms. Instead, they consider the profitability and tangible assets to be important. On the other hand, in panel C, net income is positively associated with market cap for non-Korean firms, but book value is not significantly associated with market cap. This implies that investors do not consider tangible assets but do consider the firm's profitability in their valuation. On the other hand, net income of biotech firms is not positively associated with market cap.

Table 3 : Market value and R&D efforts, including the performance of NDA approval and patent approval counts, as key proxies of R&D efforts

This table presents the OLS estimates of panel regressions of each firm's market value on R&D, and NDA and patents as additional key proxies of R&D efforts. R&D is the research and development spending for firm i incurred during fiscal year t. NDA is the number of new drug applications approved by the (Korean) Food and Drug Administration, and patent is the number of patents approved by the patent authority for firm i during fiscal year t. All the financial variables, including market value, R&D, and other financial control variables (revenue, net income, and book value), are obtained from DATASTREAM, and the values are expressed in USD million. Panel A reports the regression results for the full panel set, and each of panels B, C, and D report those for the sub-panel groups (Korean, global, and biotech pharmaceutical firms). Within each panel, the first two columns, Models 1 and 2, are constructed to show the results mainly being driven by R&D effect on market value. Models 3 and 4 are to see the effect of R&D and NDA on market value. Models 5 and 6 are to see the effect of R&D and patents on market value. Finally, Model 7 reports the result of the combined effects of R&D, NDA, and patents on market value. Every second column includes additional control variables. Standard errors are adjusted for clustering at the firm level, and the corresponding t-statistics are presented in parentheses. ***, ** and, * indicate statistical significance at the 1, 5, and 10% levels, respectively.

Panel A : Full Sample

	Model1	Model2	Model3	Model4	Model5	Model6	Model7
R&D	20.001***	8.608	19.861***	8.365	20.011***	8.482	8.262
	(15.551)	(1.666)	(14.712)	(1.591)	(13.722)	(1.665)	(1.595)
NDA			-163.429	-197.205			-192.731
			(-1.188)	(-1.552)			(-1.487)
Patent					-2.251	-28.940	-24.865
					(-0.019)	(-0.243)	(-0.204)
Revenue		0.781		0.775		0.825	0.814
		(0.988)		(0.977)		(1.121)	(1.102)
Net Income		4.976***		5.007***		4.922***	4.960***
		(3.882)		(3.908)		(4.371)	(4.426)
Book Value		-0.002		0.009		0.000	0.011
		(-0.009)		(0.043)		(0.001)	(0.049)
Constant	2551.3**	2521.1**	3554.0*	3739.1**	2560.5**	2625.6**	3801.3**
	(2.067)	(2.400)	(1.781)	(2.151)	(2.207)	(2.392)	(2.182)
R^2	0.810	0.836	0.811	0.836	0.810	0.836	0.836
N	486	486	486	486	486	486	486

Panel B : 19-Korean Pharmaceutical Firms

	Model1	Model2	Model3	Model4	Model5	Model6	Model7
R&D	16.736***	6.313**	16.433***	6.275**	14.608***	5.116**	5.187**
	(5.506)	(2.412)	(5.215)	(2.495)	(4.557)	(2.162)	(2.201)
NDA			4.453	4.128			2.877
			(1.568)	(1.470)			(1.294)
Patent					15.880**	10.172**	9.343**
					(2.229)	(2.309)	(2.291)
Revenue		-0.219		-0.249		-0.196	-0.219
		(-0.920)		(-1.050)		(-0.955)	(-1.075)
Net Income		6.194***		6.115***		5.819***	5.794***
		(3.064)		(3.141)		(3.113)	(3.119)
Book Value		0.805***		0.823***		0.799***	0.813***
		(3.601)		(3.797)		(4.054)	(4.138)
Constant	42.584	-31.200	2.210	-66.127	6.060	-54.245	-76.709
	(1.311)	(-0.968)	(0.057)	(-1.457)	(0.195)	(-1.579)	(-1.641)
R^2	0.509	0.784	0.516	0.789	0.548	0.799	0.802
N	209	209	209	209	209	209	209

Panel C : 27-Grobal Pharmaceutical Firms

	Model1	Model2	Model3	Model4	Model5	Model6	Model7
R&D	19.244***	7.695	17.718***	7.199	19.250***	7.582	6.971
	(12.965)	(1.419)	(13.347)	(1.329)	(11.378)	(1.420)	(1.317)
NDA			4893.2**	4193.2**			4288.1**
			(2.423)	(2.304)			(2.326)
Patent					-1.456	-26.806	-51.465
					(-0.011)	(-0.204)	(-0.364)
Revenue		0.749		0.680		0.790	0.757
		(0.920)		(0.803)		(1.045)	(0.975)
Net Income		5.055***		4.877***		5.005***	4.776***
		(3.892)		(3.459)		(4.466)	(4.032)
Book Value		0.034		0.015		0.035	0.018
		(0.155)		(0.071)		(0.161)	(0.082)
Constant	6316.9**	6520.6**	4734.2	5152.9*	6322.6**	6603.5**	5281.1069*
	(2.09)	(2.54)	(1.58)	(1.94)	(2.19)	(2.58)	(1.99)
R^2	0.741	0.776	0.754	0.785	0.741	0.776	0.786
N	277	277	277	277	277	277	277

Panel D : 12-Biotech Pharmaceutical Firms

	Model1	Model2	Model3	Model4	Model5	Model6	Model7
R&D	22.384***	-14.876	21.144***	-12.267	22.452***	-14.652	-12.005
	(21.703)	(-1.090)	(21.834)	(-0.986)	(38.356)	(-1.040)	(-0.939)
NDA			7482.2***	4687.1**			4696.9**
			(3.502)	(2.592)			(2.575)
Patent					-35.862	-90.141	-103.404
					(-0.077)	(-0.219)	(-0.292)
Revenue		5.334		4.309		5.344	4.319
		(1.461)		(1.483)		(1.457)	(1.476)
Net Income		-3.938**		-2.936*		-4.038**	-3.048*
		(-2.368)		(-2.165)		(-2.520)	(-2.046)
Book Value		2.355**		2.401**		2.358**	2.405**
		(2.396)		(2.797)		(2.378)	(2.787)
Constant	1923.1	2890.8	714.8	2082.7	1957.8	2965.0	2166.2
	(0.949)	(1.530)	(0.484)	(1.288)	(0.923)	(1.588)	(1.303)
R^2	0.702	0.821	0.729	0.831	0.702	0.821	0.831
N	117	117	117	117	117	117	117

This finding may be attributed to the fact that many biotech firms have been experiencing net loss (negative income), and investors do not care much about current income in their valuation of firms. Surprisingly, biotech firms have likely been overestimated by high-risk investors who have low risk aversion. Moreover, they are more dependent on the biotech firm's future potential reflecting intangible assets that are not recorded on the financial statement rather than current profitability.

While the results of table 3 are based on annual financial variables and qualitative counts of R&D efforts, tables 4 and 5 provide the supportive evidence based on daily cumulative abnormal return (CAR) at the NDA and patent approval dates of each firm. Table 4 presents test results of CAR around the NDA and patent approval dates of full sample firms and each sub group. Consistent with hypotheses 2 and 3, NDA CARs of global pharmaceutical firms, referring to the average cumulative abnormal returns at NDA approval dates, are significantly positive at 0.7%, 0.7%, and 1% over the event windows [-2, 2], [-5, +5], and [-10, +10], respectively, with significance at 1% calculated using the Wilcoxon p-value. The NDA CARs of biotech pharmaceutical firms are even higher at 2.9%, 2.2%, and 1.8% over the event windows [-2, +2], [-5, +5], and [-10, +10], respectively, even though CAR over [-10, +10] window is not statistically significant. On the other hand, patent CARs of Korean pharmaceutical firms, referring to the average cumulative abnormal returns surrounding patent approval dates, are significantly positive at 0.4% and 0.6%

over the event windows [-2, +2] and [-5, +5], respectively. Patent CARs of global or biotech pharmaceutical firms are not statistically significant or positive. These results with CAR support the robustness of the key findings in table 3: Korean firms are more responsive to patents than NDAs, and non-Korean global firms are more responsive to NDAs than patents.

Table 5 presents the test results of panel regression with CAR as the dependent variable and sub group category dummies as the key explanatory variables controlling for key financial variables. The results are quite similar to the results of table 4. For NDA CAR in panel A, all global and biotech dummies show positive coefficients over all event windows [-2, +2], [-5, +5], and [-10, +10] no matter what the existence of financial control variables, even though the coefficients are strongly positive over [-2, +2] event window. Consistent with the results of tables 3 and 4, panel B of table 5 does not show any significantly positive coefficients of patent CARs on the global or biotech dummy. This means that global and biotech groups are not more responsive to patent approval events than Korean firms, as shown in table 4.

Table 4 : Cumulative abnormal returns around NDA and patent approval date

This table presents average cumulative abnormal returns (CAR) around the NDA and patent approval dates of full sample firms and sub-groups. CAR (NDA) is for cumulative abnormal return around NDA approval dates and CAR (Patent) is for patent approval dates of each sample firm, and [±d] indicates the company's 5-day ([±2]), 11-day ([±5]), and 21-day ([±10]) cumulative abnormal return around the announcement date. CAR average of each category is reported in the column, and the standard deviations are presented in parentheses. ***, ** and, * indicate statistical significance at the 1, 5, and 10% levels, respectively.

	CAR (NDA)				CAR (Patent)			
	N	[-2,+2]	[-5,+5]	[-10,+10]	N	[-2,+2]	[-5,+5]	[-10,+10]
Full Sample	2,234	-0.001 (0.060)	-0.001 (0.091)	0.001 (0.130)	4,163	0.001 (0.040)	0.000 (0.058)	-0.001 (0.080)
Korean	1,935	-0.003 ** (0.062)	-0.002 (0.095)	0.000 (0.137)	790	0.004 ** (0.063)	0.006 ** (0.089)	0.000 (0.123)
Grobal	299	0.007 *** (0.040)	0.007 *** (0.055)	0.010 *** (0.071)	3,373	0.000 (0.032)	-0.001 (0.048)	-0.001 (0.067)
Biotech	28	0.029 ** (0.054)	0.022 *** (0.059)	0.018 (0.067)	217	0.000 (0.055)	-0.003 (0.077)	-0.004 (0.108)

Table 5 : Panel regressions of cumulative abnormal returns

This table presents the results of panel regressions of cumulative abnormal returns on group dummy. The dependent variable is the company's 5-day ([±2]), 11-day ([±5]), and 21-day ([± 10]) cumulative abnormal return (CAR[±d]) around the announcement date. The independent variables are dummy for global and biotech pharmaceutical firms. Every second column includes additional control variables (revenue, net income, and book value (in UDS million)) as in Table 3. Panel A reports the results of NDA CAR regression, and Panel B is for patent CAR regression. Standard errors are adjusted for clustering at the country level, and the corresponding t-statistics are presented in parentheses. Finally, ***, **, and * correspond to statistical significance at the 1, 5, and 10% levels, respectively.

Panel A : NDA

	CAR [-2,+2]		CAR [-5,+5]		CAR [-10,+10]	
	(1)	(2)	(3)	(4)	(5)	(6)
Global (dummy)	678.9**	1438.8**	847.1**	1007.8	1188.6**	564.5
	(2.355)	(2.672)	(2.249)	(1.147)	(2.052)	(0.446)
Biotech (dummy)	2421.1***	1715.0*	1921.7*	1727.2	1229.7	1615.2
	(2.938)	(1.925)	(1.909)	(1.374)	(1.180)	(1.092)
Revenue		-0.034*		-0.007		-0.028
		(-1.806)		(-0.253)		(-0.685)
Net Income		-0.048		-0.175*		-0.132
		(-0.697)		(-1.787)		(-0.755)
Book Value		0.02		0.037*		0.081**
		(1.357)		(1.691)		(2.186)
Constant	-373.1	-366.9	-638.0**	-639.6**	-606.7*	-612.3*
	(-1.684)	(-1.648)	(-2.643)	(-2.639)	(-1.739)	(-1.749)
R^2	0.063	0.07	0.03	0.038	0.017	0.034
N	355	355	355	355	355	355

Panel B : Patent

	CAR [-2,+2]		CAR [-5,+5]		CAR [-10,+10]	
	(1)	(2)	(3)	(4)	(5)	(6)
Global (dummy)	-59.4	-264.2	-192.7	-472.0	79.4	-617.9
	(-0.134)	(-0.486)	(-0.454)	(-0.809)	-0.163	(-0.772)
Biotech (dummy)	-283.8	-107.7	-598.1	-357.4	-1276.8	-697.9
	(-0.417)	(-0.157)	(-0.660)	(-0.386)	(-0.909)	(-0.494)
Revenue		0.003		0.005		0.001
		(0.244)		(0.288)		(0.033)
Net Income		0.024		0.028		0.089
		(0.713)		(0.579)		(0.996)
Book Value		0.000		0.000		0.010
		(0.025)		(0.068)		(1.065)
Constant	181.33	180.01	214.67	212.75	-182.00	-185.77
	(0.422)	(0.417)	(0.526)	(0.519)	(-0.422)	(-0.429)
R^2	0.001	0.002	0.004	0.005	0.006	0.009
N	368	368	368	368	368	368

Discussion and Conclusion

This study examined the effect of R&D efforts on firm value in the pharmaceutical industry with respect to changes in market capitalization value and, more specifically, CARs surrounding the NDA and patent approval dates in the recent decade from 2001 to 2011. Besides the value relevance between R&D efforts and firm value as reported by prior studies, it is also validated that R&D efforts have played a key role in enhancing firm value in the pharmaceutical industry in the recent decade. The empirical result verifies the hypothesis that the relationship between R&D efforts and market value of firms is positively associated in a statistically significant manner. Particularly, R&D spending affects firm value enhancement quite positively in most of the sample firm groups investigated (all sample firms, top-tier Korean firms, top-tier non-Korean firms). This supports hypothesis 1 in this study. On the other hand, as a remarkable point, R&D spending is negatively associated with biotech firms' value creation. This finding is well attributable to technology-oriented biotech firms' specific goal of its establishment and the firm behavior that the entrepreneurs pursue prompt jumping to big success depending on its innovative platform technology. Thus, they tend to invest rather heavily beyond their financial control and the reasonable consideration of sustainability management. This frequently results in excessive R&D spending without increase in firm value, in line with investor's overestimation of benefits from the technological breakthroughs that R&D-intensive firms promise to deliver.

As previously implied, two more performance milestones of R&D efforts, namely count of NDA and patent approvals, generally provide a positive effect on the value enhancement of pharmaceutical firms (supportive evidence of hypothesis 2). However, the result also shows some difference in case of different sample groups. For Korean firms, it appears that patent approval has a more positive impact on firm value, while NDA approval fails to show a positive association with firm value creation. On the other hand, for non-Korean firms, NDA approval is quite positively related with firm value. These findings imply that R&D efforts need to be diversified depending on the country of origin, business strategy, and other specifics (this evidence supports hypothesis 3).

Korean firms face the biggest financial hardship they have ever experienced due to the government's tough policy implementation on price cut and uncertain market dynamics. Therefore, many Korean pharmaceutical firms are likely to go into reorganization and business reset, including R&D strategy toward their R&D spending cut. This phenomenon is similar to the Clinton Administration's Health Security Act 1993, which regulated drug prices by setting an upper limit. This had significant negative effects on stock prices and firm-level R&D spending. The HSA reduced R&D spending by about USD1 billion even though it was not legislated (Golec, Hegde, and Vernon 2010). However, based on the finding in this study, it is advisable for Korean firms to continue spending on R&D efforts not only in order to maintain or upgrade firm value but also develop new drivers for potential growth and corporate sustainability amid the recent turbulent business environment. R&D spending is enormously high and should be carried out for long years to move one single project from the beginning to the commercial launch. Moreover, annual R&D spending is comparable to or higher than the annual income of firms. Therefore, as part of efforts to minimize sunk cost and failure rate, managers may be required to design a more sophisticated resource planning system in order to select and focus on more valued projects through pre-screening efforts which are undertaken prior to entering money-intensive stages.

Not only Korean firms, even non-Korean firms are recommended to pursue continuing R&D innovation and find better ways to improve efficiency. Particularly, biotech firms may need to restructure R&D resource planning in order to strike a financial balance between internal capacity and R&D spending, and in turn avoid the negative impact of financial deterioration on firm value caused by excessive spending.

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