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Article

Using Real Options to Estimate the Pre-commercialisation Value of a Drought Tolerant Wheat Trait

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ABSTRACT

Uncertainty, sunk investment costs and managerial flexibility means standard investment budgeting methods such as net present value are suboptimal tools for analysing risky investments. Real options can attain a more accurate and comprehensive assessment of investments. In this study, we apply a real options analytical framework to investment decisions during the research and development (R&D) process of a drought tolerant wheat trait. The results suggest the option value for investment is positive at each R&D stage and that investors should continue to invest. Biotechnology firms should consider using a real options analytical framework like the one applied in this paper for investment strategy development and for investment decisions involving uncertainty, sunk costs and decision flexibility.

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Keywords: Real options; Investment valuation; Commercialisation; Wheat; Drought tolerance

INTRODUCTION

Many studies on the economics of trait development in crops have focussed on social costs and benefits, such as agronomic benefit to producers and environmental costs (see for example Furtan et al. 2003 and Johnson et al. 2005), and have not explicitly considered private costs and benefits. Further, the scope of these studies is post-technology development, as opposed to ex ante. Few studies have examined investment in trait development from the perspective of the investor or developer or assessed the ex-ante, pre-commercialisation value of a new trait, see for example Shakya et al. (2013), Wilson et al. (2015), Wynn et al. (2017, 2018, 2019). To our knowledge, no study has estimated the ex-ante value of a wheat trait for specific producing country markets.

Investing in a new crop trait is risky and challenging. There is considerable uncertainty. Will the trait be a technical success and do what it is designed to do? Will farmers adopt the trait? Will the developer remain solvent with sufficient funds to complete the trait's development and commercialisation process? A new crop trait also involves considerable upfront investment or sunk cost, and although some of that cost may be salvageable, most of it is irreversible. In addition to these challenges, firms investing in a new crop trait exercise considerable decision flexibility and make decisions during the trait's development process to continue, adjust, postpone or abandon their investment.

Standard investment budgeting methods such as net present value and discounted cash flow analysis are often suboptimal tools for analysing risky investments. They incorrectly assume that many variables, e.g., prices, are known with certainty; that decision makers can reverse the investment without cost; and that once a development process is prescribed, it cannot be altered. To overcome these inadequacies, an alternative method for analysing investments is real options analysis. Real options allows decision makers to better incorporate uncertainty, irreversibility and decision flexibility into a budgeting framework and attain a more accurate and comprehensive assessment of their investment. In doing so, real options compels decision makers to explicitly

identify and consider assumptions underlying their investment budget. For these reasons, real options is increasingly used as an analytical tool for investment strategy development. A real option is the right, but not obligation, to undertake a certain business action. In this study, the action is to continue, abandon or postpone an investment in the development of a new crop trait. A new drought tolerant wheat trait being developed using gene technology for cultivation and importation in global markets is used as an example technology to demonstrate the real options budgeting framework.

The objectives in this study are to evaluate the potential investment returns a new crop trait has over conventional cropping, the potential revenues or returns of a successfully commercialised trait, and the pre-commercialised investment values of a new trait, using a drought tolerant wheat trait as the example technology. The study extends previous work of Shakya et al. (2013) and Wilson et al. (2015) and contributes to the evolving literature on trait valuation in a number of ways. It focuses on private costs and benefits and examines investment from the perspective of the investor or developer. It also captures the value of drought tolerance using empirical field trial data from Australia and multi-peril crop insurance premiums. Finally, it estimates the ex-ante value of a trait for multiple country markets and examines the impact of various global market entry strategies on the investment values.

METHOD

Investing in trait development under uncertainty

Using standard net present value or discounted cash flow methods, an investment's profitability is determined by comparing the present value of cash inflows and outflows, using a risk-adjusted discount rate. If cash inflows are greater than outflows, the investment is considered profitable and will proceed. These investment budgeting methods assume that the future cash inflows and outflows as well as other variables such as prices, are known with certainty. In reality, most of these variables are not known and are likely to change during the development and commercialisation stages of the technology. Standard budgeting methods also assume the investment can be reversed without cost (Dixit et al., 1994). While some investment in trait development might be able to be repurposed, such as laboratory facilities and scientists, much of the investment cannot be reversed, for example the cost of a field trial and trait-specific research and regulatory compliance work. Furthermore, standard budgeting methods assume that once a development process is designed, it remains unaltered for the remainder of the investment period and cannot be changed. In reality, considerable decision flexibility is exercised and various decisions are made over the investment period, including decisions to continue the investment if the science and trait technology looks promising, to abandon the investment if interim results are not so promising, or to postpone the investment and wait for further information before resuming or abandoning the project.

Investment under uncertainty and real options analysis

Real options is a valuation method that is better placed to account for uncertainty, irreversibility and decision flexibility than the more standard investment budgeting methods (Amram et al., 1999; Guthrie, 2009). Uncertainty arises here because a number of the input variables are stochastic, including trait efficiency, yield, trait prices, farm input costs, hectares to be planted with the trait and adoption by famers. Nevertheless, the stochastic nature of these variables can be incorporated in the model and the details of how they are incorporated are presented in subsequent sections. Irreversibility is also accounted for in the model. Although there is an option of abandoning the investment at each development stage, the value of this abandoning option is equal to a salvage value, from which only a proportion of the cumulative investment cost can be recovered. The remaining investment cost is considered unrecoverable.

Decision flexibility is also built into the real options model. The model explicitly includes 15 options in the trait development process, including continuing, abandoning or postponing the investment at each of the five development stages. Each combination of options or decision path chosen (such as continuing for three stages, then waiting, and then recommencing) has a distinct option value that can inform investment decisions. In addition to the explicit options, the real options analytical framework encourages decision makers to monitor conditions and update the model when conditions change or when new information becomes available. In doing so, decision makers can ensure their investment strategy and decisions are well informed and timely.

Our real options framework uses a binomial option tree and discrete event simulation with Monte Carlo techniques to model investment option values. Monte Carlo simulation was chosen because trait development is a complex problem and Monte Carlo simulation deals well with uncertainty and the many non-normal distributions in this study's model.

Table 1: Non-random variables

Variable	Source	Data
Historical yield (tonnes/hectare, 2004–13)	FAOSTAT (2013c)	ARG 2.74, CAN 2.82, CHI 4.70, IND 2.85, USA 2.94
Premium rate (%)	Various[a]	ARG 5.0, CAN 10.3, CHI 5.1, IND 1.5, USA 9.1
Government subsidy rate (%)	Various[b]	ARG 0, CAN 60, CHI 60, IND 6, USA 61
Yield coverage (%)	Assumption	75
Global price for wheat (US$/tonne)	Assumption	300
Risk premium kept by developers (%)	Demont et al. (2007); Price et al. (2003)	30
Weighted average cost of capital (%)	Assumption	10
Probability of success (single period probability, %)	Bell et al. (2006); McDougall (2011); Shakya et al. (2013); Wilson et al. (2015)	Discovery stage: 20; proof of concept stage: 50; early development stage: 67; advanced development stage: 83; regulatory submission state: 90.
Salvage value (% of cumulative investment value)	Assumption	40
Risk free government bond rate (%)	Bloomberg (2013)	2.5

[a]China (The World Bank, 2007); India and Russia (Mahul et al., 2011); USA, Canada, Kazakhstan, Poland, Argentina and Romania (Mahul et al., 2010); France, Germany, UK, Spain and Italy (European Commission, 2008); Pakistan (Thanvi, 2013); Ukraine (IFC Agri-Insurance Development Project, 2011); Turkey and Iran (in absence of data, a 5 per cent premium rate is assumed); Egypt (in absence of data, a 2 per cent premium rate is assumed).
[b]China, Ukraine, Iran, Kazakhstan and Romania (Mahul et al., 2010); India, Russia, France, Germany, Turkey and Argentina (Mahul et al., 2011), USA (Rain and Hail Insurance Society, 2013), Canada (Klak et al., 2013); Pakistan (FAO, 2011); UK, Spain and Italy (European Commission, 2008); Poland (Kaczala et al., 2013); Egypt (in absence of data, a 50 per cent subsidy rate is assumed).

Economic model

The model is an EXCEL-based workbook with simulation add-ins of Simetar (Richardson et al., 2005) and @Risk (Palisade Corporation, 2013). The model calculates the value of the trait to farmers across several risk aversion levels and in relevant regions of Australia by simulating sets of gross margins with and without the trait and, as gross margins are too difficult to estimate in global markets, the study simulates values of a substitute product, crop insurance. The value of the trait to farmers is used as the basis to calculating projected revenue after commercialisation and the real option value pre-commercialisation.

Case study

The example technology used in this study to demonstrate the real options framework is a wheat being developed in Australia using gene technology to increase its drought tolerance, sometimes referred as 'yield stability'. The drought tolerant trait uses delayed leaf senescence technology called "LXR™" that modifies levels of plant hormones (cytokinin) which influence growth and development, and inhibit leaf aging (senescence) and stress responses in plants (Kant et al., 2015). The performance of the drought tolerant trait was evaluated in an Australian field trial in the winter of 2014 with two treatments in Horsham, Victoria. The two treatments included rainfed and irrigated treatments so that the performance of the trait could be assessed under both drought (rainfed in what was a very dry year) and excess rainfall (irrigated) conditions. Results from the field trials were used to define the trait efficiency achieved by the drought tolerant wheat trait relative to conventional wheat and were a key input in the calculation of gross margins for Australian farmers (see Table 2 for further details).

Identifying markets to target for commercialisation

A market assessment was carried out to identify markets to target for trait commercialisation. The study uses multicriteria analysis to refine a list of target markets, with

key criteria including agronomic fit, regulation of and market readiness for GM products.

Agronomic fit was determined by assessing which countries are the largest wheat producers, whether they produce for domestic consumption or export, whether they suffer from drought and whether the drought affects wheat production in that country. Data was collected from the Food and Agriculture Organization on wheat production (FAOSTAT, 2013a), trade (FAOSTAT, 2013b), drought risk (Pardey et al., 2006) and impact of drought on wheat production.[i] A shortlist of countries with good agronomic fit was developed (see Table 3). Information on the regulatory systems in each shortlisted country was collected and analysed to assess the complexity of the regulations in each country for the cultivation (or importation in the case of key export markets) of GM products and the shortlist was refined based on this assessment.[ii]

Finally, the World Economic Forum's Global Competitiveness Report (Schwab et al., 2014) was used to rank the shortlisted countries according to a number of indicators we thought supportive of commercialisation of a GM product, including intellectual property protection, quality of infrastructure, goods market efficiency, technological readiness, business sophistication and innovation. Assessed on their agronomic fit, regulation and market readiness for GM products (with each criterion weighed equally), six countries with good results were scheduled for market entry and included in the model, including Argentina, Australia, Canada, China, India and the United States.

i China (Bradsher, 2011), India (Mukherji, 2014), USA (Worthington, 2014), Russia (Kramer, 2010), France (Reuters, 2011), Canada (Khakbazan et al., 2010), Germany (Reuters, 2011), Pakistan (Irin Asia, 2010), Australia (Barry, 2008), Ukraine (USDA, 2006), Turkey (Agrimoney, 2014), Iran (The Crop Site, 2014), Kazakhstan (Antoncheva, 2012), UK (Mason, 2011), Poland (USDA Joint Agricultural Weather Facility, 2006), Egypt (no information available), Argentina (Craze, 2009), Spain (Chillymanjaro, 2012), Romania (Savu, 2012), Italy (no information available).

ii The United States Department of Agriculture's country-specific Agricultural Biotechnology Annual reports were used as primary information sources for this assessment process. An extensive review of additional literature on the regulatory systems in each shortlisted country was undertaken, however, due to their volume, these details are not included here. These references and their treatment are available from the author on request.

Value of drought tolerant wheat to farmers in Australia

In addition to field trial results, conventional wheat yield data and farm budget data (ABARES, 2013) were collected to calculate and simulate gross margins for wheat with and without the drought tolerance trait (where the presence of the trait increases wheat yield, income and gross margin) for each relevant state of Australia. Gross margins were calculated as income less variable costs per hectare. The study assumes productivity gains will equal increases in inflation and gross margins per hectare will remain unchanged over the trait's lifetime. A yield gain of 0.5 per cent per annum is assumed. It is also conservatively assumed that the drought tolerant wheat will be sold at a five per cent discount compared to conventional wheat, based on current discounting practices in Australia for products derived from gene technology (Australian Wheat Board, 2014). Rainfall data (Bureau of Meteorology, 2013) was also collected to analyse the impact of rainfall on wheat yield and any statistically significant correlations were included in the model.

Stochastic dominance techniques analysed 10,000 outcomes and each outcome was ranked by farmers' absolute risk aversion measured using absolute risk aversion coefficients (ARAC) (Hardaker et al., 2004). Risk premiums were estimated for each region using Simitar (Richardson et al., 2005) and the second method outlined in McCarl (1989) for a scale of ARACs ranging from risk neutral to extremely risk averse. An Australia-wide risk premium was estimated by taking an average of the regional risk premiums.

Multi-peril crop insurance in global markets

Equivalent data to estimate gross margins was unavailable for global markets and so the value of a substitute product, multi-peril crop insurance, was calculated instead. Multi-peril crop insurance was identified as a substitute product to a drought tolerant wheat because it also protects farmers from yield and profit loss caused by drought, it is available in many countries, and it provides a good proxy for calculating farmers' willingness to pay for drought tolerant wheat.

Data was collected for the five target countries (excluding Australia) for their conventional wheat yield (FAOSTAT, 2013c), insurance premium rate (as a percentage of insured value) or average premium (in US dollars per hectare), and subsidy amount paid by government. The study assumes a flat rate of US$300 per tonne as the global price (and insured value) for wheat.

Table 2: Random variables

Variable	Source	Data
Australian risk premium	ABARES (2013); Bureau of Meteorology (2013); Spangenberg, G. (personal communication, 2014); and assumptions	Trait efficiencies in the field trials were widely distributed both within and between the rainfed and irrigated treatments and ranged from 7 to 68 per cent. Various distribution fitting techniques were tested and a triangular distribution of the minimum, maximum and mean trait efficiencies was chosen and used in the model across three possible ranges of rainfall. See also discussion in section entitled "Value of drought tolerant wheat to farmers in Australia"
Risk premium in other countries	See notes a and b in Table 1 above.	Triangular distribution used. The most likely value is the product of historic yield, yield coverage, global wheat price, premium rate and (1-government subsidy rate). The minimum and maximum values are 80% and 120% of the most likely value.
Hectares planted to wheat	FAOSTAT (2013a); USDA (2015)	Triangular distribution used. The most likely value is CHN24,100,000; IND 29,650,000; USA 18,274,206; RUS 23,371,401; FRA 5,323,000; CAN 10,441,500; GER 3,128,200; PAK 8,693,000; AUS 12,500,000; UKR 6,566,000; TUR 7,772,600; IRA 7,050,000; KAZ 12,953,500; UK 1,615,000; POL 2,137,600; EGY 1,418,700; ARG 3,162,138; SPA 2,121,900; ROM 2,097,490; ITA 1,888,500. The minimum and maximum values are 80% and 120% of the most likely value.
Adoption (percentage of planted hectares)	James (2008); Shakya et al. (2013); Wilson et al. (2015)	Triangular distribution used. The most likely value is Year 1: 10%; Year 2 18%; Year 3: 27%; Year 4: 37%; Year 5: 48%; Year 6: 60%; Year 7: 70%; Year 8: 69%; Year 9: 67%; Year 10: 65%; Year 11: 63%; Year 12: 58%; Year 13: 52%; Year 14: 45%; Year 15: 37%. The minimum and maximum values are 80% and 120% of the most likely value.
Investment duration (time in years)	Bell et al. (2006); McDougall (2011)	Uniform distribution used. Discovery stage: 2-4.5years; proof of concept stage: 2-2.3 years; early development stage: 2-2.5 years; advanced development stage: 2-3.1 years; regulatory submission stage: 2-7.17 years.
Investment cost (US$)	Spangenberg, G. (personal communication, 2013); Bell et al. (2006); McDougall (2011); assumptions	Triangular distribution used. Discovery stage: 150,000; 3,500,000; 31,000,000. Proof of concept stage: 250,000; 7,500,000; 28,300,000. Uniform distribution used. Early development stage: 12,500,000; 13,600,000. Advanced development stage: 22,500,000; 28,000,000. Regulatory submission stage: 30,000,000; 35,100,000.

The study also assumes that 75 per cent of historic yield (the measure typically used by insurers to limit claims) is covered by the multi-peril crop insurance because this roughly represents the protection provided by the drought tolerant wheat trait. Insurance premiums were calculated on a per-hectare basis.

Projected revenue after commercialisation

The risk premiums calculated separately for the Australian and global markets are the basis for the technology fee. We assume 30 per cent of the risk premium is kept as a technology fee by the developers and investors to cover the cost of developing the trait and reinvest in research and development (R&D), with the remaining 70 per cent kept by farmers. This assumption is broadly in line with public information on how biotechnology companies allocate value between farmers and themselves (Demont et al., 2007; Price et al., 2003).

The projected revenue after commercialisation is the potential return if the trait is successfully commercialised. It is calculated by multiplying the technology fee with the hectare projections for the new trait in each target country and involves consideration of projected adoption patterns and adjustment for risk

using a weighted average cost of capital (WACC). Planted hectares are modelled using a triangular distribution based on historic plantings (FAOSTAT, 2013a) and future projected plantings (USDA, 2015). The model uses a triangular distribution and assumes the 2013 planting in each target country is the most likely number of hectares planted in each year and minimum and maximum plantings are 80 and 120 per cent of the most likely. As GM wheat has not yet been commercialised, the adoption rate is based on adoption rates for other GM varieties (James, 2008; Shakya, Wilson, & Dhal, 2013; Wilson et al., 2015). The model assumes 10 per cent of wheat farmers adopt the new trait in the first year of its commercialisation in each target country increasing to 70 per cent in year seven before falling back down to 37 per cent of farmers adopting in year 15. This is a typical adoption trend in other crops with GM traits. The model also assumes there is a 10 per cent uplift on the adoption rate if a drought occurred in the previous year based on research that farmers' perception of climate risk depends on their recent experience (Tucker et al., 2010; Smit et al., 1997; Diggs, 1991). A WACC rate of 10% is used in the model to reflect the risk profile of a trait that has been successfully commercialised by a partnership between private and public sectors. The private sector tends to apply a higher WACC than the public sector so the 10% used in the model is in-between the rates likely to be used in each sector.

Real option value pre-commercialisation

The model calculates the option value at each node of the option tree, starting with the net present value of the projected revenue after commercialisation and then each phase of the R&D process using backward induction.

The binomial option tree represents the three options available to the firm at the end of each of the five project phases, including continue, postpone or abandon the investment. The 15 option values are based on estimates of the projected revenue after commercialisation, the duration of each project phase, the investment cost and the likelihood that the trait project will proceed successfully to the next phase (Bell et al., 2006; McDougall, 2011; Shakya, Wilson, & Dhal, 2013; Wilson et al., 2015). The investment costs assume cultivation approval for only 1-2 countries and import approval for 5-7 countries and so are likely to be low estimates. Higher costs have however been analysed in the sensitivity analysis. The developer can also exercise the option to abandon the investment at each stage. The value of abandoning is the salvage value and is calculated as 40 per cent of the cumulative value of the investment at each stage.

As introduced above, the option value is calculated starting with the net present value of the projected revenue after commercialisation and then each phase of the R&D process using backward induction. Each project stage has a likelihood of success where the project then moves to the next stage. This probability is converted into risk-neutral probabilities using a risk-free rate of interest equal to the rate of the U.S. Government 10 year bond (Bloomberg, 2013).

RESULTS AND DISCUSSION

Multi-criteria assessment results

Table 3 presents the 20 largest wheat-producing countries, producing between seven and 121 million tonnes of wheat per year. Of these countries, most produce for domestic consumption, with only five producing for export. Three countries have a low drought risk, five have a medium drought risk and 12 countries have a high drought risk. All countries had experiences where their wheat production suffered because of drought (except two countries for which no information could be found). For the data sources, please see section "Identifying markets to target for commercialisation".

The way in which the cultivation and/or importation of GM products is regulated varied considerably across countries. A few countries had relatively streamlined and transparent regulatory processes, including the United States, Canada, Australia and Argentina. The regulatory systems in China, Ukraine and to a lesser extent India, were somewhat accommodating of the cultivation and/or importation of GM products but the processes were less streamlined and transparent as the countries receiving higher scores. Several countries either had minimal or no regulatory process or had regulatory systems that were hostile towards the cultivation and/or importation of GM products, making commercialisation in those countries difficult or impossible.

Characteristics such as IP protection, infrastructure quality, goods market efficiency, technological readiness, business sophistication and innovation were characteristics of a market environment that were considered supportive of the commercialisation of the GM trait. These characteristics were selected (and their scores noted) from a list of characteristics presented in *The Global Competitiveness Report* (Schwab, 2013). Scores varied across countries, with the largest advanced economies scoring highest, except for Italy and Spain, which scored

slightly lower.

Table 3: Results of multicriteria analysis

Criterion 1: Agronomic fit					Criterion 2: Regulatory systems	Criterion 3: Market environment	Overall result
	Production size (metric tons in 2013)	% of production exported	Drought risk (low, medium, high)	Evidence that drought impacts canola production	Ease of navigating regulatory system (very low, low, medium, high)	Market support for GM trait commercialization (score out of 7)	Include or exclude from list of target markets
China	121 million	0	Low	Yes	Medium	4.2	Include
India	94 million	1	Medium	Yes	Low	3.6	Include
United States	58 million	60	High	Yes	High	5.5	Include
Russia	52 million	27	High	Yes	Very low	3.9	Exclude
France	39 million	57	Medium	Yes	Very low	5.3	Exclude
Canada	38 million	65	High	Yes	High	5.3	Include
Germany	25 million	27	Low	Yes	Very low	5.6	Exclude
Pakistan	24 million	8	High	Yes	Very low	3.3	Exclude
Australia	23 million	64	High	Yes	High	5.1	Include
Ukraine	23 million	18	High	Yes	Very low	3.6	Exclude
Turkey	22 million	0	Medium	Yes	Very low	4.2	Exclude
Iran	14 million	0	High	Yes	Very low	3.4	Exclude
Kazakhstan	14 million	13	High	Yes	Very low	3.9	Exclude
United Kingdom	12 million	15	Low	Yes	Very low	5.7	Exclude
Poland	10 million	9	Medium	Yes	Very low	4.1	Exclude
Egypt	9 million	0	High	No information	Very low	3.3	Exclude
Argentina	8 million	58	High	Yes	High	3.2	Include
Spain	8 million	8	High	Yes	Very low	4.6	Exclude
Romania	7 million	22	High	Yes	Very low	3.8	Exclude
Italy	7 million	9	Medium	No information	Very low	4.5	Exclude

Countries' scores against the three criteria were weighed equally to determine an overall score. Six countries scored relatively well and will be scheduled for potential market entry, starting with Australia in 2025.

Farm level values in Australian and global markets

The farm level value or risk premium is the amount farmers may be willing to pay, on a per hectare basis, to crop a new drought tolerant wheat and reduce their risk of profit loss caused by drought. The Australian value was calculated by comparing gross margins from cropping with conventional wheat and from cropping with the new wheat. The other countries' values were calculated by estimating multi-peril crop insurance premiums. As it would be expected, farm level values varied across the markets. Australia had the highest risk premium at almost US$34 per hectare, followed by Argentina, Canada, the United States and China (see Table 4). India had a relatively low risk premium at US$9 per hectare. Despite the different calculation methods, the Australian value is reasonably close to the highest of the other markets. The technology fees, calculated at 50 per cent of the risk premium, ranged from US$3 per hectare in India to US$10 per hectare in Australia.

Table 4: Risk premiums and technology fees (US$ per hectare)

Country	Risk premium	Technology fee
Canada	26.11	7.83
United States	23.46	7.04
China	21.57	6.47
India	9.04	2.71
Australia[a]	33.83	10.15
Argentina	30.82	9.25

[a]Australia's risk premium was converted to US$ using an exchange rate of US$1 = AU$0.76.

Projected revenue after commercialisation

The projected revenue is the potential return if the trait is successfully commercialised. Projected revenue totalled US$1.09 billion for the global commercialisation of the trait across the six target markets.

Real option value pre-commercialisation

The real option value is the investment's estimated worth at key stages along the R&D process and can be used by investors as a gauge for the financial merit of the project and a guide for their decision-making. Under the base case that includes six target countries, the value of the

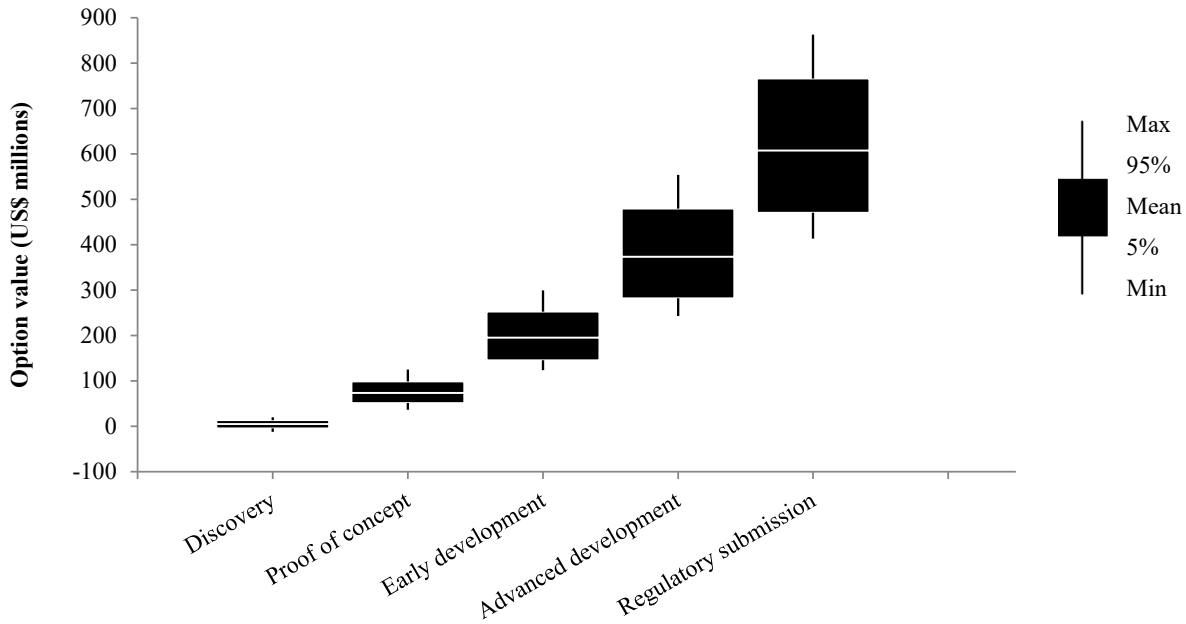

Figure 1: Real option values for drought tolerant wheat across development stages.

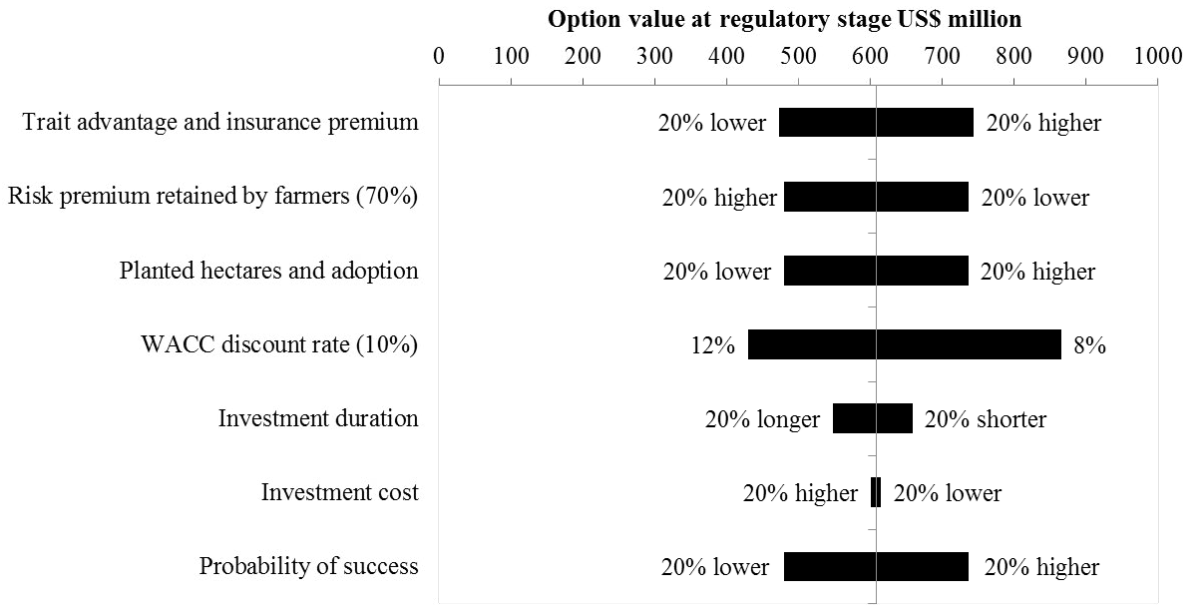

Figure 2: Results of sensitivity analysis on option value at the regulatory stage.

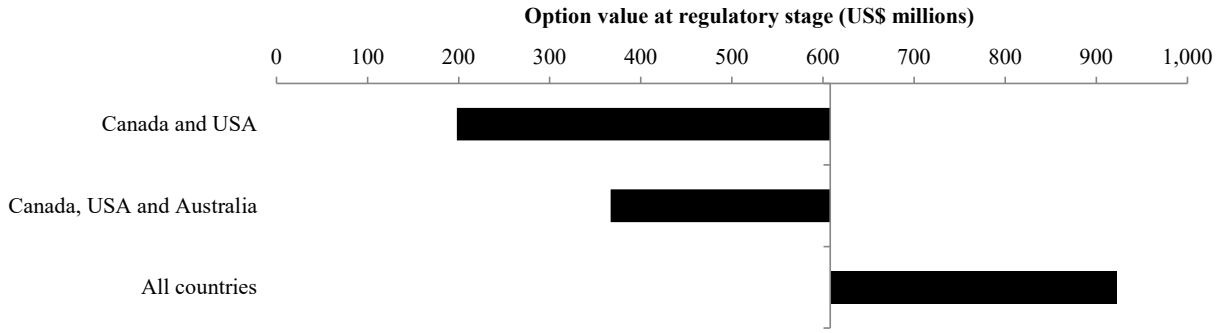

Figure 3: Results of scenario analysis on option value at regulatory stage.

option to continue investing started at US$5 million at the discovery stage and then increased to US$608 million at the final regulatory submission stage (see Figure 1). The values of the options to wait and to abandon were always lower than the option to continue investing. Guided by these results, investors would continue their investment.

Sensitivity analysis

Sensitivity analysis measures how sensitive the model is to certain inputs. This sensitivity analysis tested the sensitivity of the option value at the regulatory stage to seven key variables (see Figure 2). A number of variables had the same impact on the option value, including the trait efficiency and insurance premium, the risk premium, planted hectares and adoption, and probability of success, and the option value seemed to change relatively consistently with the change in each variable. However, the model and option value are particularly sensitive to changes in the WACC discount rate and so care should be taken when choosing which WACC rate is most appropriate for the model. The option value is not very sensitive to investment duration or cost.

Scenario analysis was also conducted to assess the impact of various market entry strategies on the option value (see Figure 3). The first scenario shows

that including only Canada and the United States reduces the option value at the regulatory stage from US$608 million to US$200 million while also including Australia produces a slightly higher option value of US$367 million. These two scenarios are relevant because Australia, Canada and the United States are likely to be the primary markets targeted for the new wheat trait. Including previously excluded countries (Russia, France, Germany, Pakistan, Ukraine, Turkey, Iran, Kazakhstan, United Kingdom, Poland, Egypt, Spain, Romania and Italy) increases the option value to US$922 million. This increase is not particularly large given the number of additional countries included in the scenario and it seems unlikely that cultivation of the new wheat trait would be approved by regulators in these countries.

CONCLUSION

Unlike most studies on the economics of trait development that focus on social costs and benefits, this study explicitly examines private costs and benefits from the perspective of the investor and assesses the ex-ante, pre-commercialisation value of a new trait for multiple country markets.

Investing in a new crop trait is risky and there are challenges, such as uncertainty and upfront investment costs, as well as opportunities for decision flexibility. Real options avoids some of the inadequacies of standard investment budgeting methods and allows decision makers to incorporate uncertainty, irreversibility and decision flexibility into a budgeting framework to attain a more accurate and comprehensive assessment of their investment.

This study evaluated the potential on-farm, per-hectare investment returns a new crop trait has over conventional cropping, the potential revenues of a successfully commercialised trait, and the pre-commercialised investment values of a new trait, using a drought tolerant wheat trait as an example technology. The study also examined the impact of various global market entry strategies on the investment values.

Based on multicriteria analysis, six countries were selected as having agronomic, regulatory and market conditions conducive to commercialising a new trait, including Argentina, Australia, Canada, China, India and the United States. An on-farm risk premium was calculated for Australia using farm budget data and for the other countries using multi-peril crop insurance data and these premiums were positive, suggesting farmers in these countries would value a drought tolerant wheat trait. The option values for the investment before commercialisation are positive throughout the R&D process, starting low and then increasing in later stages. Investors would likely invest in the trait based on these results.

Reducing the WACC rate considerably increases the option value. The impact on the model of changes in investment duration and cost on the other hand were small. The largest global markets for the new wheat trait were Australia, China and the United States. Commercialising only in Canada, the United States and Australia would still produce promising option values.

Results of this study raise important implications for biotechnology firms. For such firms, a real options analytical framework should be considered for investment decisions involving uncertainty, sunk costs and decision flexibility. The use of real options should also be considered as an analytical tool for investment strategy development. The framework developed in this study could be extended and applied to various other investments in agriculture, including other technologies and infrastructure.

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Article

Industry Drug Development Portfolio Forecasting: Productivity, Risk, Innovation, Sustainability

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ABSTRACT

Multiple factors may affect industry performance, risk, innovation and sustainability in coming years such as long-term economic trends, patents expiration, demographic shifts, and regulatory issues. Currently available industry-wide prediction frameworks have limited capabilities. They are based on: (1) analysts' consensus; (2) extrapolation of current trends; (3) financial performance of big pharma only; (4) empirical formulas, etc. Therefore, the need of robust forecasting methodology based on simulation modeling and covering the entire industry portfolio predictions could not be underestimated. The simulation model utilizes available data about each drug/indication in the industry R&D pipeline, and transforms it into a set of metrics characterizing future industry performance. Industry-wide portfolio simulation model was developed to address short- and long-term portfolio productivity forecasting challenges. The model is drug–centric, it simulates drug development workflow process. The model also incorporates multiple business rules related to drugs interdependence. The model predicted 2016 drop in NME approvals based on 2014 data. Other modeling experiments include analysis of industry sustainability and innovation strategy, impact of approval rates and likelihood on the variations of clinical trials cycle time, probabilities of success, and FDA approval cycle time.

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INTRODUCTION

One of key questions for biopharmaceutical industry is forecasting of R&D productivity. R&D productivity needs to be predicted at different hierarchical levels such as industry, therapeutic area, indication, company, and a drug with multiple indications. An informed industry-wide forecasting methodology can help to formulate government policy, company strategy, and investment allocations. It also can be used for planning resource allocation within regulatory agencies to reduce drugs application review delays, forecasting for clinical trials industry portfolio, and others. Risk is an integral component of the industry forecasting for the foreseeable future (3–10 years), because even at the approval stage there is a risk of a drug rejection – albeit smaller than at earlier stages of clinical testing.

Both external factors such as economic trends, demographic shifts, etc., and internal factors such as productivity of the industry discovery engine, complexity and outcome of clinical trials, likelihood of success, patent expirations, market competition, regulatory policies and others could add significant uncertainty to the prediction of industry performance.

Currently available industry R&D portfolio forecasting frameworks have limited capabilities and accuracy. These frameworks are based on analysts' surveys[1], extrapolation of big pharma company' performance trends[2], historical analysis[3, 4], empirical formulas[5, 6] , etc. These techniques are inaccurate and subjective, they lack flexibility and inability to incorporate many factors essential for the industry forecasting. Sometimes, they even generate contradictory results. For example, in a recent blog on Linkedin[7], it was predicted, based on Deloitte analysis[2] that the current industry business model is broken, and the industry is dying based on steady reduction of the Internal Rate of Return (IRR) for a cohort of selected big pharma companies.

According to[7], IRR for the industry would be close to zero around 2020.

In Deloitte study[2], the original cohort included 12 big pharma companies (Amgen, AZ, BMS, Eli Lilly, GSK,

J&J, Merck, Novartis, Pfizer, Roche, Sanofi, and Takeda). Despite significant market capitalization and resources, these companies contributed only to about 25%-30% of annual NME* approvals in last five years. For example, in 2016, above mentioned companies contributed only five NME approvals out of 22 NME industry approvals.

At the same time, Evaluate Pharma[1], CSDD (Tufts University)[8], IQVIA[9] and several other organizations predict industry robust growth up to 2024.

These predictions correlate withthe Deloitte cohort companies' substantial stock growth. E.g. Pfizer stock grew ~3.5 times in 2009-2019. It means that IRR based forecasting technique needs to be reviewed.

Another example of metrics misinterpretation is presented in[4]. The authors use the metric "number of approved drugs per billion US$ R&D spending". According to authors, R&D spending from 1950 to 2016 is growing substantially, and number of approved drugs is varied within a range. Therefore, "R&D efficiency" based on this metric is declining. However, according to[10] average R&D costs/Revenue ratio for most biopharmaceutical companies is about 20%. Therefore, increasing R&D costs per approved drug as evidenced in[4] is not caused by productivity decline over years, but increased industry R&D development portfolio size, investments and revenue as well as declining likelihood of success[11].

Given this uncertainty in predicting industry performance suggests that the industry-wide forecasting methodology needs to be improved by shifting from empirical techniques (industry surveys, subjective formulas, extrapolation of historic trends, etc.) to robust quantitative techniques based on detail modeling of the industry portfolio in order to reduce subjectivity in industry predictions and increase their accuracy.

PROBLEM STATEMENT

The goal is to develop a modeling methodology for life science industry R&D portfolio forecasting productivity. R&D portfolio includes drugs in Ph1-NDA. Industry R&D portfolio input could be presented as rate of investments volume or rate of drug candidates from discovery entering the pipeline. Portfolio output productivity could be measured as rate of cumulative sales revenue at the portfolio level, rate reduction of unmet needs, or rate of approved drugs. However, at the industry level, insufficient and unreliable[12] data about potential revenue for drug candidates across portfolio does not allow application of monetary metrics. Development costs at the portfolio level also have limited accuracy†. For example, in[13], "all other costs" (unidentified costs) as a cost component of a clinical trial is about 25-30% of total clinical costs across Ph1-Ph4.

Therefore, in this paper portfolio input could be presented as a rate of drug candidates entering the pipeline. Portfolio output is defined as risk based projected rate of drug approvals. Lag between input and output could be up to 12 years with significant attrition rate (up to 90+ %).

For the purpose of this paper, several other aspects of the industry portfolio forecasting, coupled with productivity metric, could be derived, such as:

i. Industry sustainability – could be defined as a rate of drug candidates entering portfolio to guarantee sustainable rate of drug approvals. If data is available, sustainable input could also be associated with size and rate of investments for early stage drugs (e.g. VC money, % of sales for companies with drugs on the market). Industry sustainability could be associated with certain level of the industry profitability‡
ii. Industry innovation index forecasting as a rate of ratio of New Molecular Entities (NME) approvals§ to total approvals.
iii. Approvals risk – probability that number of approvals could exceed certain target.

INDUSTRY R&D PORTFOLIO OVERVIEW AND INPUT DATA

Industry R&D portfolio structure presented in Figure 1. It was noted in[14] that number of drugs in Ph2 exceeds number of drugs in Ph1 (even taking into consideration attrition rate), because many companies test drugs for multiple indications simultaneously in Ph2, if Ph1 trials are successful.

* NME – New Molecular Entities

† Author hopes that quality accuracy of data, presented in industry databases will be increased, and more robust metrics characterizing industry R&D portfolio productivity, will be introduced in the nearest future.

‡ This topic needs further research

§ For example, FDA reports NME approvals

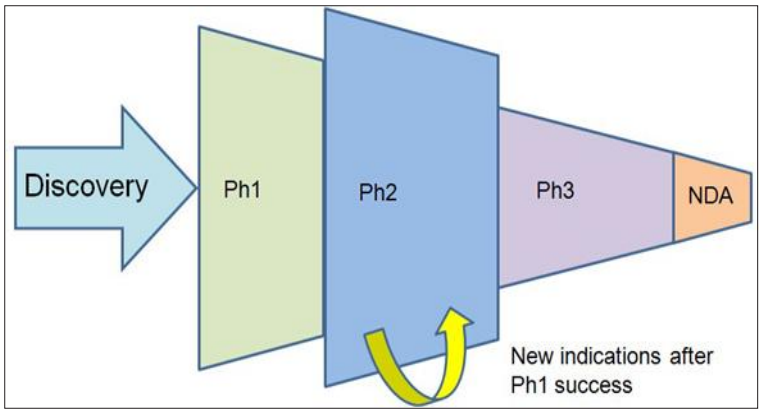

Figure 1: Industry portfolio structure.

Input data for the model

Industry R&D portfolio according to BioMedtracker[14] (January 2015) included about 5000+ drugs/indications in development.

Currently available techniques for portfolio modeling could potentially be applied to increase accuracy of predictions. However, their application is limited by data availability at the industry level. So far, available data relevant to the problem, obtained from BioMedtracker, includes:

1. List of drugs/indications
2. Phase of development for each drug indication – Ph1 –Ph3, NDA/BLA
3. Therapeutic areas (TA)
4. Drugs classification – chemicals, biologics, NME, mechanism of action, lead vs. non-lead indications.
5. Transitional probability of success (POS) for each TA and each phase obtained from[15]
6. POS adjustment for lead vs. non-lead indications[15]
7. Cycle time for drug/indication according to a development phase and TA
8. Planning horizon – 20 years
9. Planning interval – one month

As mentioned before, BioMedtracker and other industry databases such as EvaluatePharma[1], and Clarivate Analytis[16], do not contain systematic data of projected development costs and revenue, or any other value measures for each drug/indication in the development portfolio at the industry level. Therefore, it is assumed that that the industry productivity can be characterized by dynamic rate of approvals.

Methodology and the model

Decision analysis

Decision analysis methodology is a foundation for developing an effective modeling technique for the analysis of industry productivity and several derivative metrics like innovation index, sustainability and related risk.

Decision analysis is used to quantify and compare explicitly various strategies in terms of their effects and costs, thus providing decision makers with valuable information. It is useful especially in situations where there is uncertainty about the balance of potential benefits and risks associated with various development options. Decision analysis is coupled with advanced analytical techniques such as optimization[17,21] (e.g. linear, mixed – integer, and non-linear programming and many others) and Monte Carlo simulation[18,21]. It is also tempting to apply real options[19,20] used in financial industry for the analysis and forecasting of financial portfolios.

However, absence of robust economic/value data for each drug candidate across industry portfolio does not allow to apply both optimization techniques and real options. At the same time, Monte Carlo discrete event simulation could address industry forecasting challenges[18]. Discrete event simulation models for productivity analysis are widely used in many verticals at an enterprise[22], manufacturing plant[23], and assembly line levels[24]. Therefore, it seems natural to use Monte Carlo simulation for the industry productivity forecasting.

Often, graphical representation of decision analysis problems could be effectively presented with decision trees. Decision trees are used to characterize development workflows, the alternatives available to the decision maker, the uncertainty they involve, and evaluation

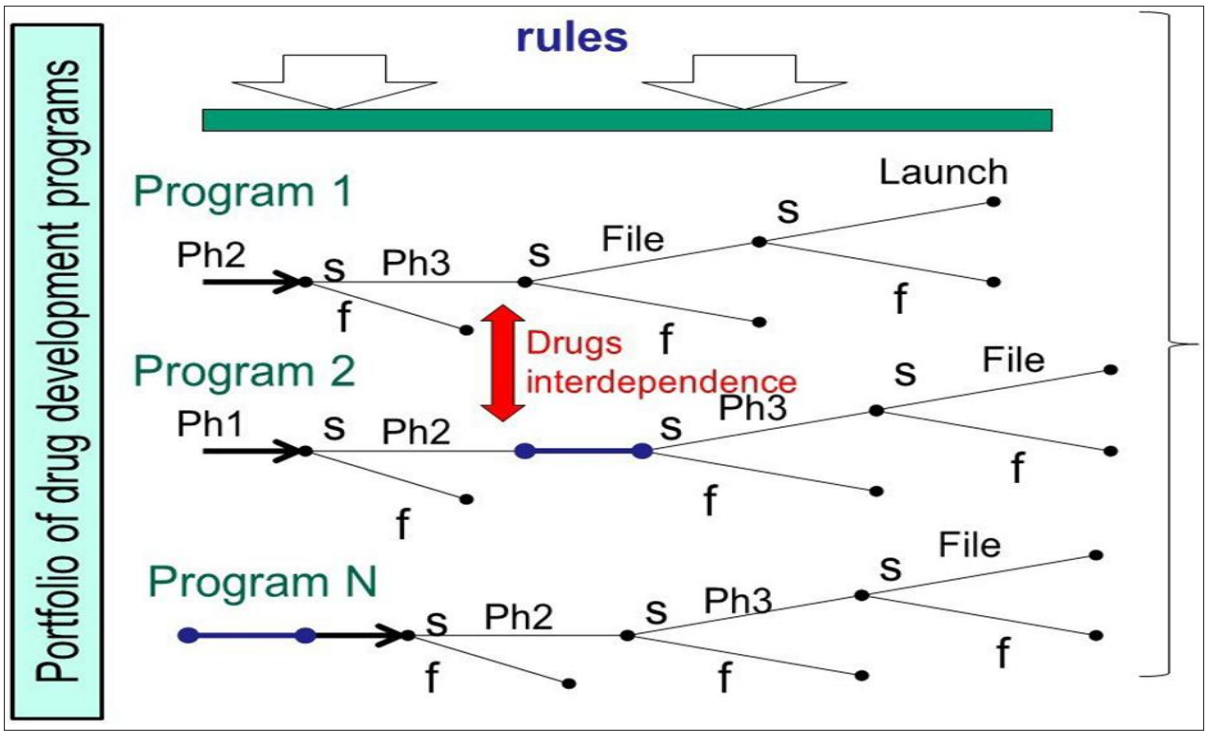

Figure 2: Decision "forest" containing multiple decision trees represents industry portfolio workflow.

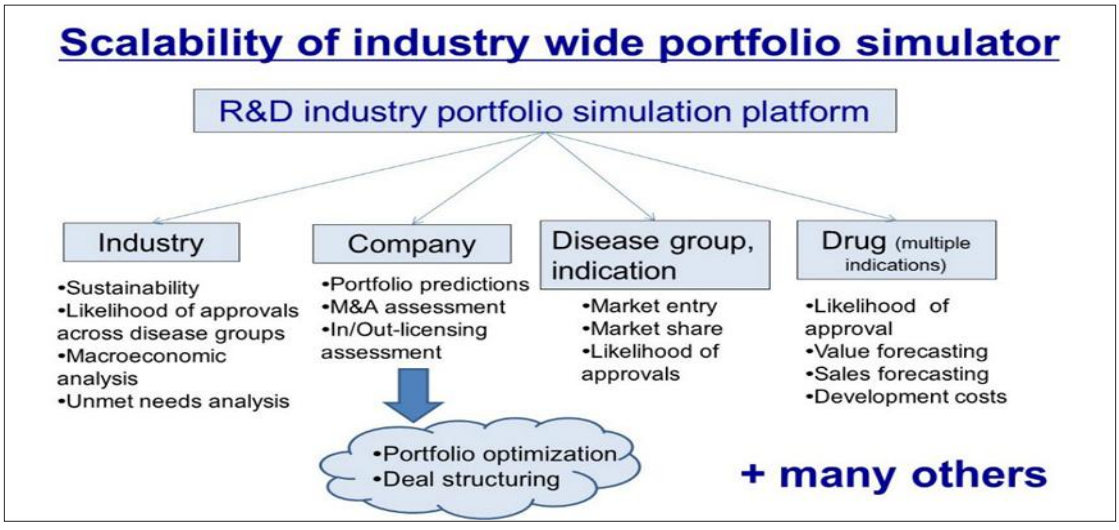

Figure 3: Scalability of the industry portfolio simulation platform.

measures representing how well objectives would be achieved in the final outcome.

Typical drug development process is characterized by high attrition rates, large capital expenditures, and long development timelines. This makes the valuation of such projects and portfolios a challenging task. Therefore, decision trees as graphical representation of drug development workflow coupled with Monte Carlo simulation algorithms provides powerful analytical engine for forecasting of the industry productivity. Industry wide databases such as Informa[14], Evaluate Pharma[1], Clarivate Analytics/Cortellis[16], and others can be used to populate the model.

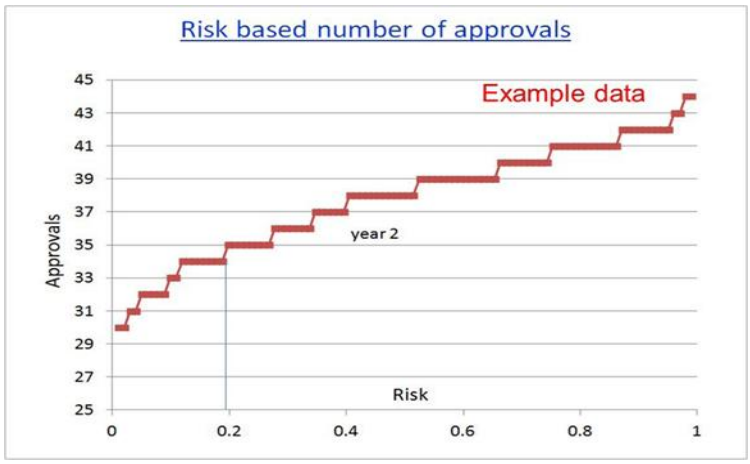

Figure 4: Risk based industry outcome predictions.

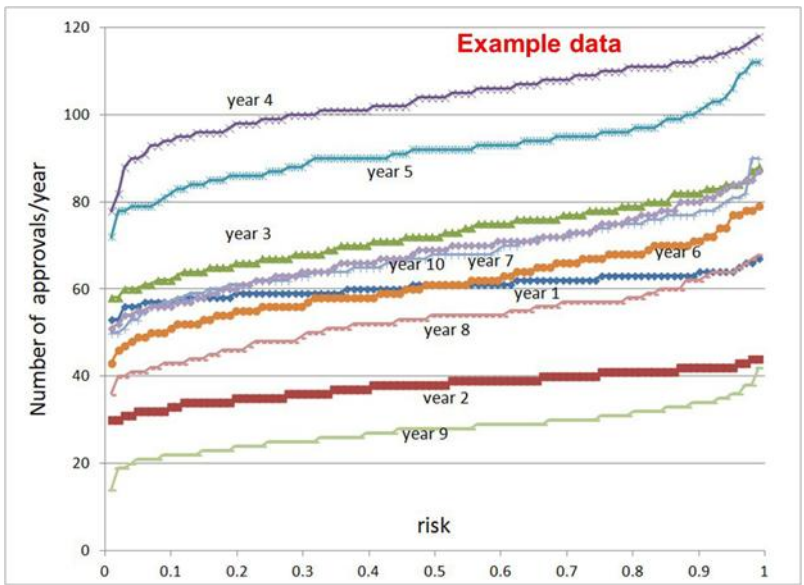

Figure 5: Risk based approvals for 10 years.

THE MODEL

The model is drug-centric. It is advantageous over an approach based on a biopharmaceutical company as modeling unit[2], because in case of M&A or in/out-licensing, the portfolio structure and data characterizing acquired or in/out-licensing drugs remains the same. The model is formally described as decision tree diagram with binary stochastic outcome (success, failure) after each phase of a clinical trial defined by corresponding probability of success at the therapeutic area level[11,15] and approval process. (Figure 2). In addition to simulating drug development workflow, algorithms characterizing interdependence between drug development programs need to be incorporated. Current version of the model includes the following rules: (1) if a lead indication fails in a clinical trial, then one of non-lead indications becomes a lead indication with higher POS[15]; (2) if, for example, the industry portfolio contains two drugs, A and B with the same mechanism of action, targeting the same disease. If drug A fails in a clinical trial, then development of drug B could be suspended, canceled, or its likelihood of success could be significantly reduced. Other algorithms also could be implemented.

The model utilizes available data about each drug/indication in the industry R&D pipeline, and transforms it using predictive simulation algorithms into a set of metrics characterizing future industry performance. The model is capable to run multiple "what-if" scenarios,

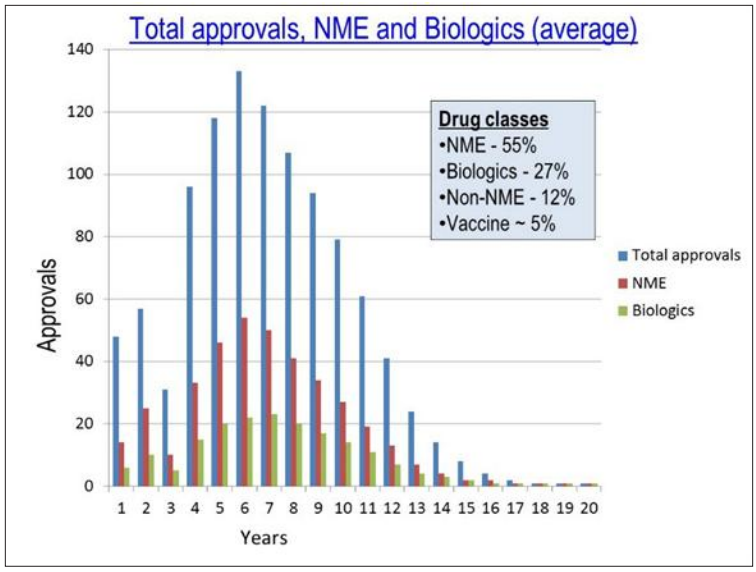

Figure 6: Dynamics of total, NME and biologics average approvals.

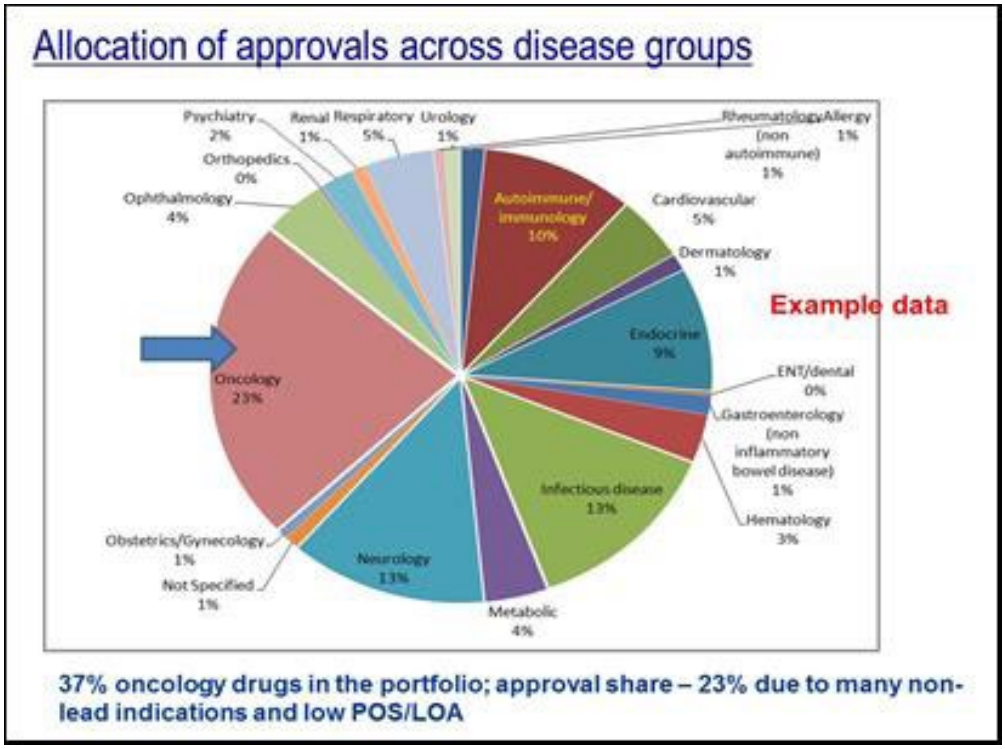

Figure 7: Allocation of approvals forecasting across therapeutic areas.

analyzing impact of major factors affecting industry performance.

The developed framework is scalable (Figure 3). It makes productivity predictions at the industry, TA (Therapeutic area), indication, and a company portfolio level. Likelihood of approval could also be predicted for each drug, including drugs with multiple indications. The developed simulation platform also allows to predict market risk for a drug with multiple indications.

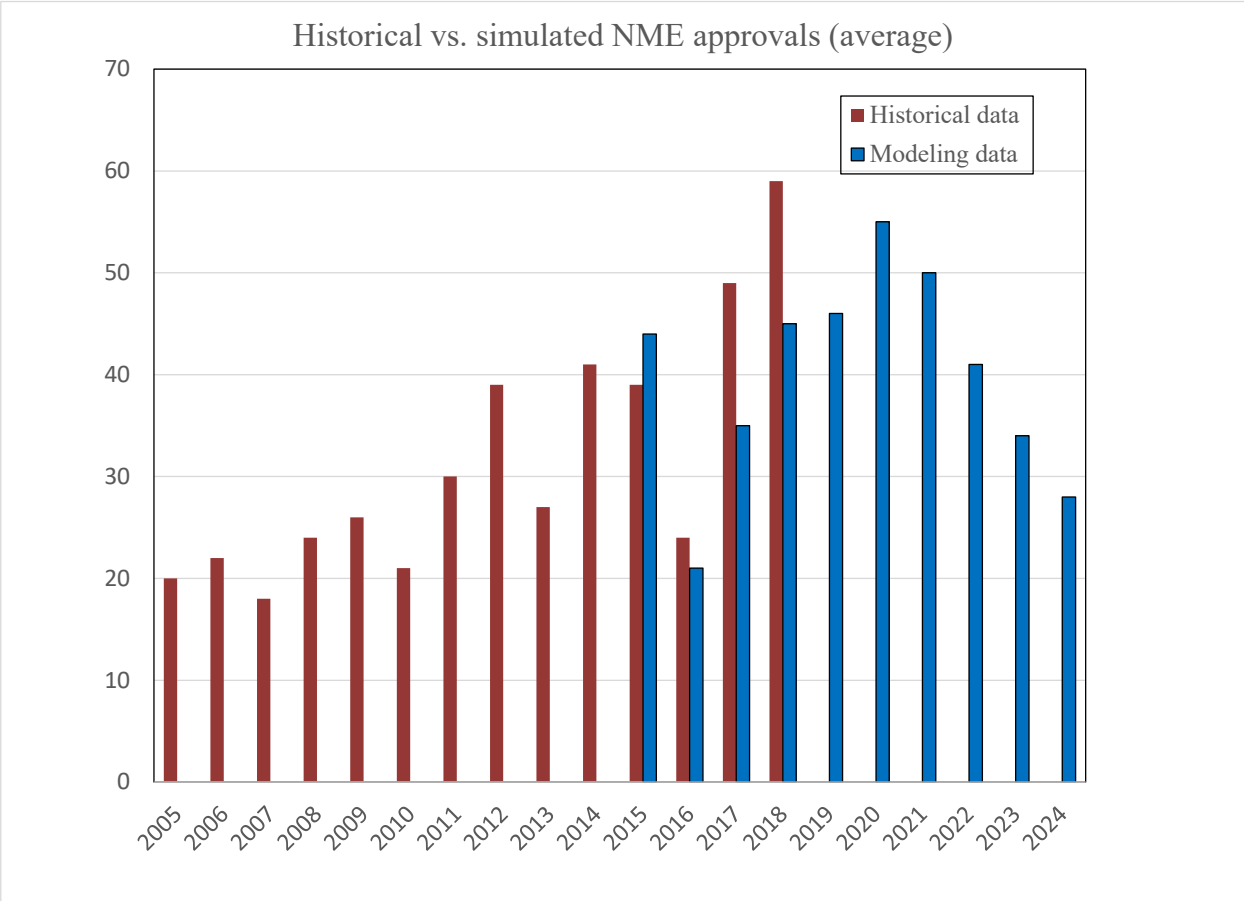

Figure 8: Dynamics of NME approvals (historical and modeling).

Simulation Experiments

1. Risk based industry portfolio productivity predictions. Baseline scenario

The model generates risk based industry outcome predictions. They are associated with portfolio risk (Figure 4). It means that, for example, for year 2 within 10 years planning horizon, the number of drug approvals ranges from 44 with highest risk to 30 with lowest risk. 20% risk is associated with more than 34 drug approvals. Results presented on Figure 4 could be interpreted as follows: If the goal is at least 34 drug approvals in year i, then the portfolio risk associated with this number is 20%.

Figure 5 illustrates risk based rate of total drug approvals for each year from ten years of planning horizon. More "horizontal" lines are for years 1 and 2 of planning horizon than for others due to lower uncertainty (drugs are in approval stage after successfully completed Ph3 trials).

Figure 6 represents dynamics of average total, NME, and biologics approvals for a snapshot of R&D portfolio. Number of drugs in approval stage relates to approvals forecasting in first two years of planning horizon. Number of drugs in Ph3 relates to approvals forecasting in years 3–4 of planning horizon. Ph2 trials correlate with approvals forecasting in years 5–6. Approvals forecasting in years 6-8 are associated with number of trials currently in Ph1 and remnants of Ph2 trials with significant cycle times. High number of approvals forecasting in years 4–7 correlates to a high number of compounds currently in early stages of development in the portfolio. Drop of approvals in year three (2016) is associated with low number of drugs in Ph3 as it was observed in January 2015.

Bell shape type curve related to the forecasting of approval dynamics, means that modeling experiments did not include new Ph1 drugs entering the pipeline outside of January 2015 database snapshot. Therefore, modeling results based on current data snapshot could not be validated effectively probably until 2020. Validation for years beyond 2020 requires data snapshots later than January 2015. Reasonable assumptions regarding rate of incoming new Ph1 drugs related to the portfolio sustainability will be discussed later in this paper.

Figure 9: Outcome sensitivity to the variations of probabilities of success in approval stage.

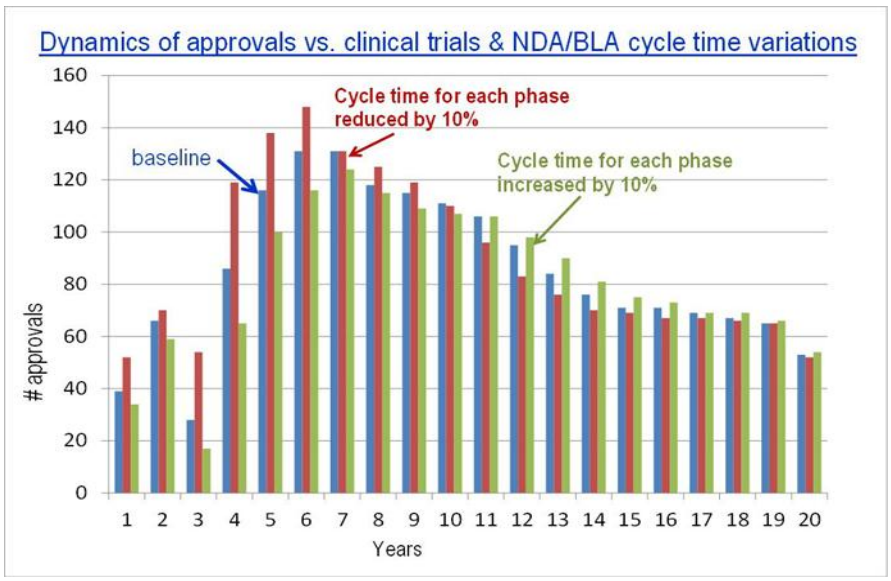

Figure 10: Cycle time variations.

2. Allocation of approvals across therapeutic areas

Figure 7 illustrates forecasting of average allocation of approvals across therapeutic areas (TA)/disease groups for 10 years planning horizon. Oncology will dominate share of approvals in foreseeable future (~23%), then neurology (13%) and infectious diseases (13%). Approval rate share of oncology drugs is un-proportionally low despite 37% of oncology drugs currently in the portfolio due to low likelihood of success (LOS) comparing to other groups[11,15].

3 Model validation

Multiple techniques could be used to validate modeling results[25]. Most common are:

a. Validation using historical data
b. Sensitivity analysis

a. Validation using historical data

Graph on Figure 8 shows several validation points (2015, 2016, 2017, and 2018) comparing rate of average NME approvals obtained from the model with actual FDA approvals statistics[26] based on January 2015 industry portfolio snapshot. They seem close enough to historical data. At the same time, equality of the model generated

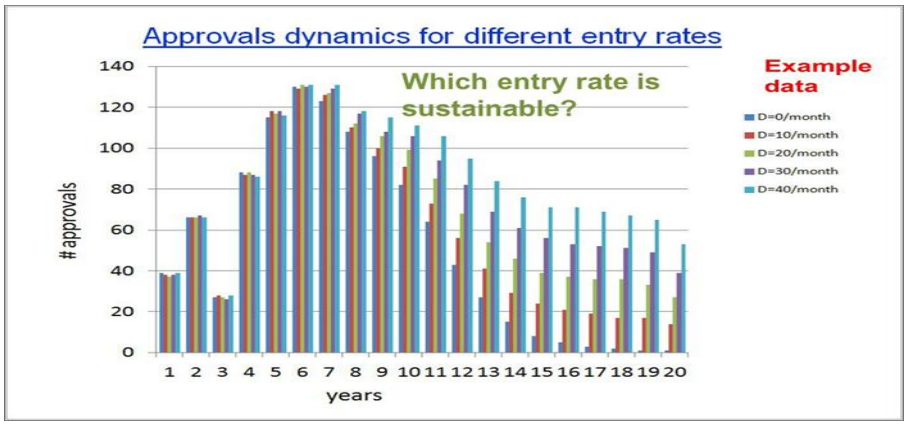

Figure 11: Approval dynamics for different Ph1 entry rates.

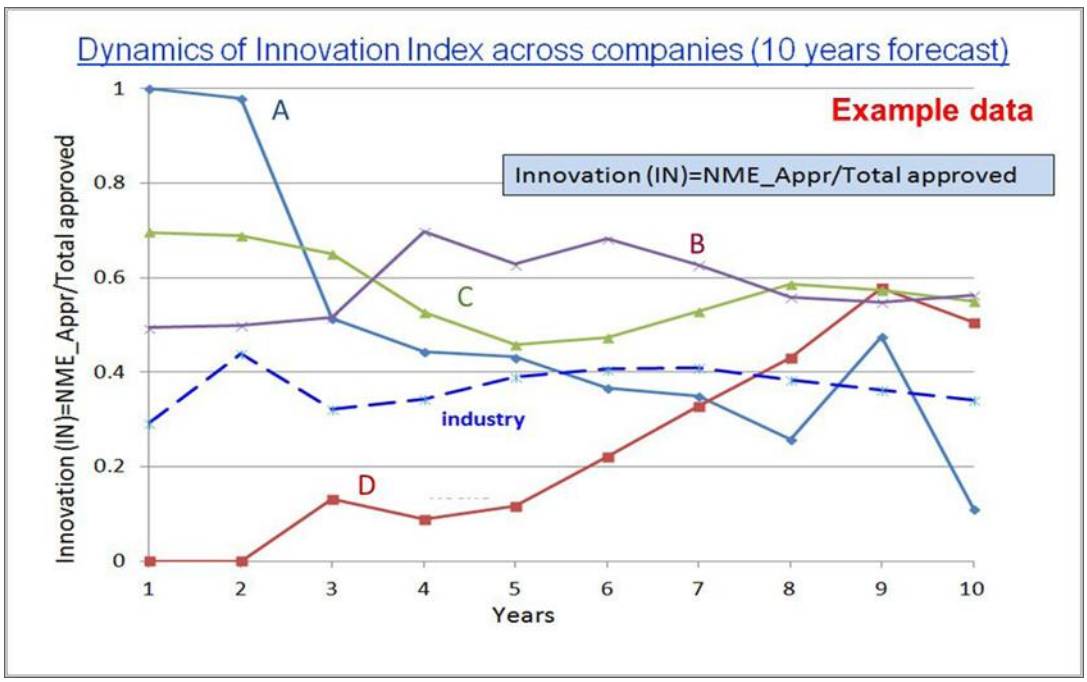

Figure 12: Innovation index for biopharmaceutical companies vs. industry.

and historical approvals may not be achieved due to probabilistic nature of the modeling outcome. Also, limitations of current model are related to limited knowledge of data flow related to FDA approval process (different review paths, multiple review rounds, their cycle time and probabilities). Modeling results highlight approval trend (number of the industry NME approvals dropped in 2016, and grew in last two years).

b. Model sensitivity analysis

Industry outcome sensitivity has been analyzed – variations of probabilities of success (Figure 9) and cycle times (Figure 10).

b1. Model sensitivity to probabilities of success

Model sensitivity was analyzed by variation of transitional POS by ±5% and ±10%. Rate of approvals for late stage drugs (years 1–3) is not sensitive enough to POS variations, because Likelihood of success (LOS) is defined as a product of POS(Ph3)*POS(NDA/BLA) for drugs in Ph3 or by POS(NDA/BLA) if drugs are in NDA. For Ph3 and NDA drugs LOS is relatively high[11,15].

For early stage drugs (years 4+) output is more sensitive to variations of transitional POS, because of multiplication of multiple transitional probabilities related to multiple phases of clinical trials.

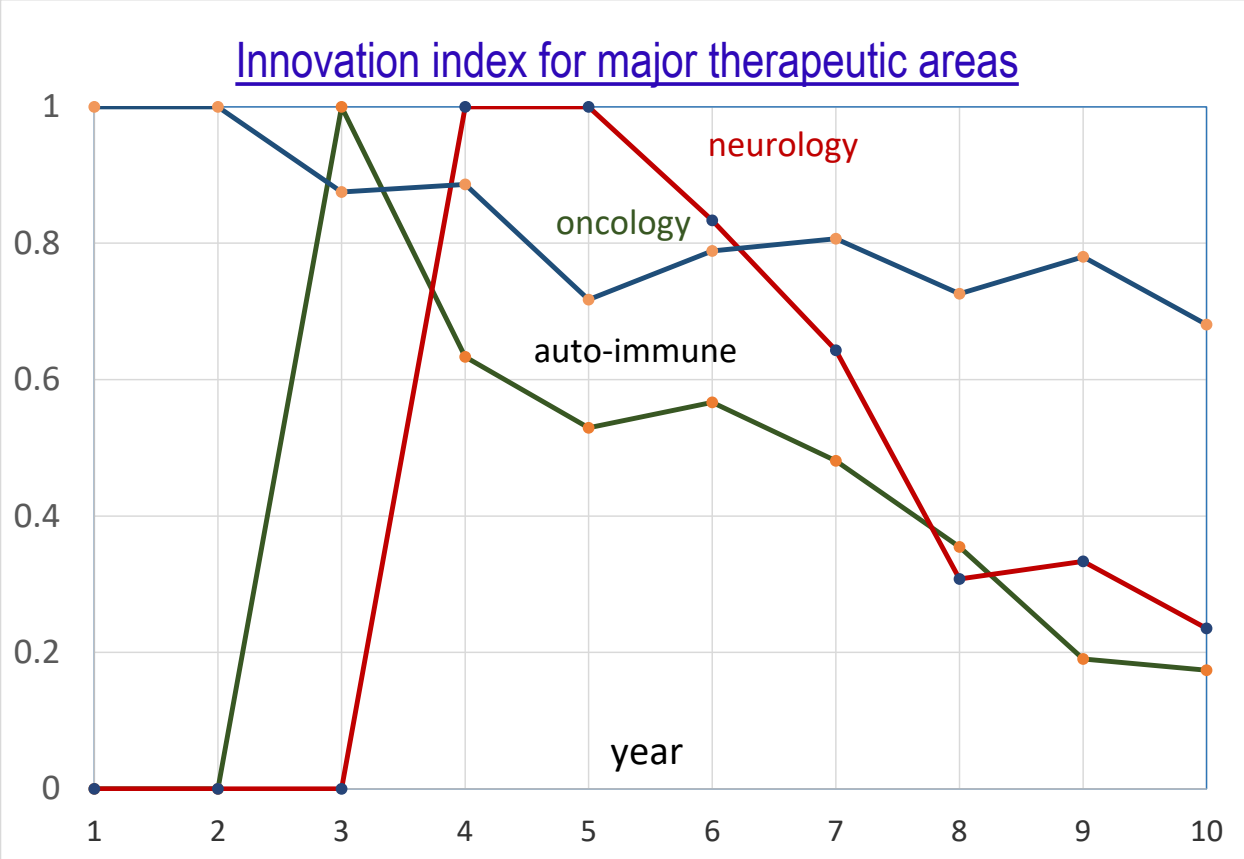

Figure 13: Innovation index for leading therapeutic areas (oncology, neurology, and auto-immunology).

b2. Cycle time variations.

Reducing or increasing cycle times significantly affect approvals predictions, especially in years 1–6 of planning horizon (Figure 10). Reduction of cycle time means shift to earlier approvals and vice versa. Therefore, main efforts need to be focused on reduction of cycle times for late stage development.

Industry strategy analysis

a. Industry R&D portfolio sustainability

Modeling experiments show that about 500 Ph1 drugs per year (~40 drugs/month) entering the pipeline could make the industry sustainable (Figure 11). It means that approval rate in about 20 years from now could be about the same as today. Could this rate be achievable?

b. Innovation index for major biopharmaceutical companies

Innovation is a key for the industry sustainability and growth. New molecular entities (NME) are backbone of the industry innovation. Therefore, ratio of NME approved/total approvals could be a relevant index characterizing innovation strategy for each company. The ratio could vary from zero (no NME) to one (all approved products are NME).

Figure 12 illustrates application of the innovation index for several big biopharmaceutical companies (A–D) as well as for the industry average. Average industry innovation index is predicted to be about ~0.3-0.4. It means that about 30%-40% of approved drugs are forecasted to be NMEs. Companies B and C have higher value of innovation index than the industry average (~0.6–0.7). Index value for both companies is relatively stable across 10 years. For company A value of innovation index is declining from 1 to 0.1. At the same time, innovation index for company D is climbing from zero to 0.6. It means that the best long-term strategy for company A would be to in-license innovative products, or to buy companies with innovative portfolios.

c. Innovation index for major therapeutic areas

Innovation index for several therapeutic areas is presented on Figure 13. For years 1–2 of planning horizon, oncology dominates innovation, then several years later, neurology will dominate innovation process due to very promising drugs in the pipeline. At the same time, oncology seems to be dominate innovator for the long run.

CONCLUSION

1. Industry simulator for productivity assessment was developed to make risk based approval rate predictions, their likelihood, and allocation across therapeutic areas.
2. Model sensitivity was analyzed to validate modeling algorithms.
3. The platform is effective to analyze industry strategy including industry sustainability and pipeline innovation.
4. Modeling capabilities can be enhanced by adding data as well as by development of more sophisticated algorithms describing drugs interdependence during development process.

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Article

Loss of Control of a Biosimilar Joint Venture and Remeasurement at Fair Value

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ABSTRACT

Samsung BioLogics recognized a big valuation gain when it lost control over a biosimilar joint venture. The investment community expressed concerns about the revaluation gain because the loss of control of the joint venture was attributable to potential voting rights held by the joint venture partner and Samsung BioLogics had incentives to present higher profitability prior to IPO. We suggest the following: (1) timely and full disclosure of the potential voting rights; (2) extensive disclosure about the fair value estimate; (3) a conservative recognition of valuation gains; and (4) a periodic assessment of potential impairment of fair value estimates.

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I. INTRODUCTION

In 2015, Samsung BioLogics reported a big profit of KRW 1.9 trillion (approximate $1.7 billion). The investment community took this as an important event because it could be a turning point for Samsung BioLogics that had not reported a profit since its inception. But, the press and the public also noted a huge valuation gain of KRW 4.5 trillion (US $ 4 billion) on the income statement.[i] Absent the gain, Samsung BioLogics would have reported a loss. Consistent with the concern, Samsung BioLogics returned to the unprofitable era in the following years, reporting a loss of KRW 177 billion in 2016 and a loss of KRW 97 billion in 2017.

The fortuitous handsome valuation gain arose from an investment in a biosimilar venture business that Samsung BioLogics jointly set up with a partner firm. When Samsung BioLogics disclosed loss of control of the joint venture in 2015, it changed the accounting method from "consolidation" to the "equity method" and remeasured its share of the joint venture business at fair value in accordance with relevant accounting rules. Losing control of the joint venture business would not be a joyful thing. But, if the loss of control is accompanied by a big valuation gain, it may not be that bad.

Accounting standards stipulate how a firm (the investor) accounts for its equity investment in other firm (the investee), depending on whether the investor controls or just is able to exert significant influence over the operational and financial decision makings of the investee. International Financial Reporting Standard (IFRS) 10 *Consolidated Financial Statements* requires management to consider all facts and circumstances and exercise professional judgement in assessing whether the investor has effective control over the investee. But, as a practical expedient, the investor with more than 50% of the voting rights is presumed to control the investee and consolidate the investee when they prepare financial statements. On the other hand, the investor is deemed to have significant influence over the investee when

i Samsung BioLogics also reported a loss of KRW 1.8 trillion on valuation of the related derivatives. Thus, the net gain associated with the remeasurement of the investment is KRW 2.7 trillion on a before tax basis.

the investor holds between 20% and 50% of the voting rights. International Accounting Standards (IAS) 28 *Investments in Associates and Joint Ventures* requires the investor firm with significant influence to apply the equity method of accounting. However, IFRS makes it clear that the investor firm shall consider all relevant facts and circumstances rather than a simple level of ownership interest when it assesses an effective control or a significant influence over the investee.

The case examines accounting and valuation issues of the equity investment in Samsung Bioepis, which Samsung BioLogics and Biogen set up as a joint venture in 2012. Samsung Bioepis specializes in the research and development of biosimilar drugs. Biosimilar drugs are a biological product that is highly similar to an existing reference biological medicine. Samsung BioLogics mainly operates as a biopharmaceutical Contract Manufacturing Organization (CMO) that provides drug manufacturing service through long-term contracts with other pharmaceutical firms. Biogen, the joint venture partner of Samsung BioLogics, is one of the leading biotechnology firms with expertise in engineering protein and manufacturing biologics to treat neurological diseases.

Samsung BioLogics held a majority of voting rights of Samsung Bioepis from the beginning so that Samsung BioLogics classified Samsung Bioepis as a subsidiary and consolidated Samsung Bioepis in its financial statements. But, in 2015 Samsung BioLogics ceased to classify Samsung Bioepis as a subsidiary, despite still maintaining 91.2% ownership interest. Samsung BioLogics disclosed that it no longer controlled Samsung Bioepis because the joint venture partner Biogen held "substantive" potential voting rights. According to the joint venture agreement, Biogen held an option to increase its ownership stake for Samsung Bioepis up to 49.9%. More importantly, with recent approvals of several high profile biosimilar products,[ii] Samsung BioLogics judged that the status of the call option changed from being "out of the money" to being deep "in the money." Thus, Samsung BioLogics disclosed that its ownership percentage would be insufficient to control Samsung Bioepis because Biogen is expected to exercise the call option.[iii] The loss of control led Samsung BioLogics to reclassify Samsung Bioepis as an associate and apply the equity method of accounting. As explained above, Samsung BioLogics recognized a big valuation gain from remeasuring its investment in Samsung Bioepis at fair value in accordance with IFRS.

The biosimilar industry is a high-tech industry segment in which the business process and technology are complex: a long time horizon for visibility of any revenues; substantial uncertainties regarding completing developing products, obtaining regulatory approvals, and commercializing the product. There is also a fierce competition among biosimilar developers.[iv] These characteristics of the biosimilar industry pose difficulties in gauging the probability of success and determining the business value. It is challenging to forecast expected future cash flows and assess inherent risks because historical financial and operating performance data do not project linearly to the future or there are scant past data to refer to. Thus, valuation of a biosimilar business is regarded quite speculative, relying heavily on a valuer's judgement and subjective assumptions [1]. Since valuation assumptions are often arbitrary and lacking in validity, the resulting value estimate is inevitably imprecise and is often subject to an optimistic bias about the probability of successful drug development and commercialization.

Furthermore, the case involves unlisted firms, both Samsung BioLogics (the investor) and Samsung Bioepis (the investee). Since private firms are not required to disclose value relevant data as extensively and on a timely basis as public firms, external parties have limited access

ii At the end of 2015, Samsung Bioepis received approval for two biosimilar products in Korea: an Etanercept biosimilar referencing Enbrel in September 2015 and an Infliximab biosimilar referencing Remicade in December 2015. Subsequently, these products are approved in Europe, Australia, and Canada. By the end of 2017, three more products got approval in Europe and one product was in its Phase III clinical trial stage.

iii When the call option is fully exercised, Samsung BioLogics would still have the majority voting right, that is, 50.1%. If a simple ownership interest threshold is used to assess whether Samsung BioLogics controls Samsung Bioepis, Samsung BioLogics should have continued to use the consolidation method and no gain would have been recognized. However, the joint venture agreement between Samsung BioLogics and Biogen requires a 52% majority ownership for key decision makings. Thus, 50.1% ownership interest would be insufficient for Samsung BioLogics to control Samsung Bioepis.

iv As of December, 2017, the Korean Ministry of Food and Drug Safety (MFDS) has approved 9 biosimilar products http://www.mfds.go.kr/eng/wpge/m_37/de011024l001.do). For certain active ingredients, multiple products got approved, resulting in a total of 11 different products. For example, Celltrion obtained an approval for its Infliximab biosimilar in September 2012 ahead of Samsung Bioepis. In addition, Hospira and Epirus have their own versions of approved Infliximab biosimilars, which are approved in Canada and US, and in India, respectively [2]. Hanwha Chemical got an approval for its Etanercept biosimilar Davictrel 10 months earlier than Samsung Bioepis, but retracted it from the Korean market in September 2015.

to detailed relevant information [3]. Thus, it would be difficult for outside investors and stakeholders to understand the effect of and rationales for changes in accounting policies and value estimates for unlisted firms.

Our case demonstrates difficulties and potential limitations of the fair value measurement and valuation of the equity investment in unlisted firms. Fair values under IFRS have a potential to provide a value relevant piece of information to stakeholders [4]. But, firms could exploit subjective and less reliable inputs or assumptions for fair value (referred to as "level 3" inputs) to manage and window dress earnings and to distort financial condition to their advantage. We suggest the following to enhance the value relevance of less reliable level 3 fair value estimates as in the case: (1) firms need to expand their disclosures of fair value estimates, for example, underlying assumptions of the fair value valuation model, changes in the assumptions, and eventual manifestation because these assumptions are often biased toward the investing firm's excessively optimistic views about the future and inherent risks; (2) firms shall defer the recognition of unrealized gains or at least conservatively measure unrealized valuation gains; and (3) the fair value estimates need to be rigorously reviewed for a potential impairment on a periodic basis.

The remainder of the paper proceeds as follows. The next section explains the biosimilar industry and introduces firms involved with the case. Section 3 presents the details of the case. Section 4 presents a valuation scenario and related issues. Finally, section 5 concludes the case.

II. BIOSIMILAR INDUSTRY AND BACKGROUND INFORMATION

(1) Biosimilar Industry

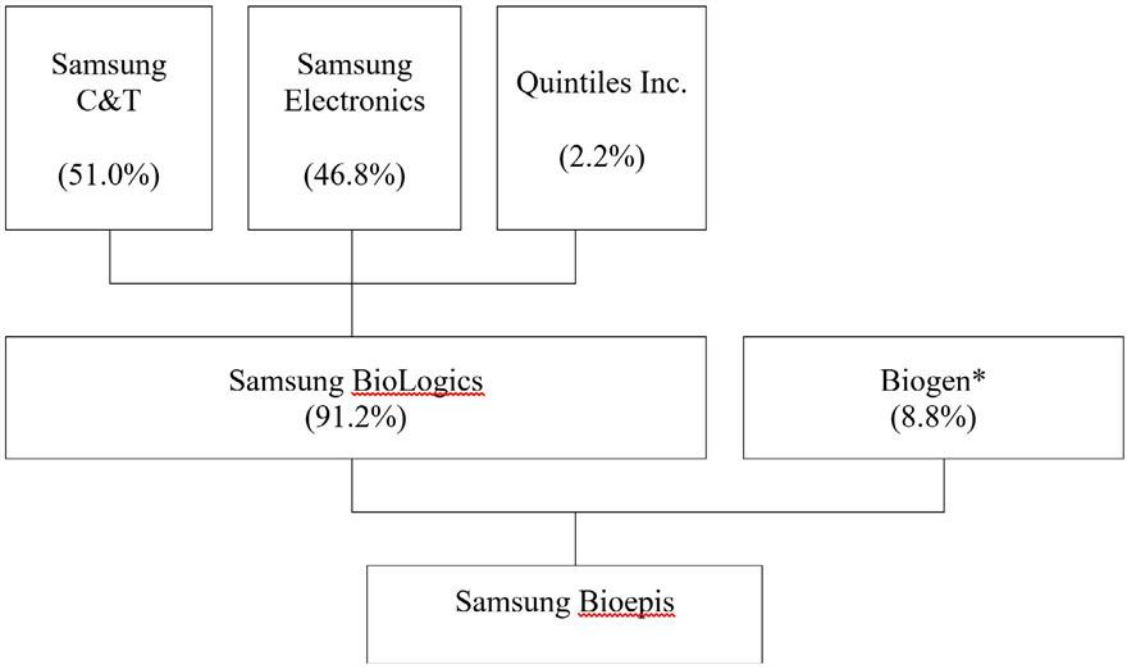
Conventional drugs are manufactured through synthesis of chemicals, whereas biological drugs are produced in living organisms through specialized biological process [5]. Similar biological medicinal products or biosimilars started to appear in 2006 with expiration of patents of several biological drugs in the European Union (EU) [6]. The European Medicines Agency (EMA) defines a biosimilar as "a biological medicinal product that contains a version of the active substance of an already authorized original biological medicinal product (reference medicinal product)." A biosimilar product exhibits similarity to the reference product in terms of quality characteristics such as biological activity, safety and efficacy. In other words, a biosimilar is a biological product that is very "similar" to, but not an "exact" copy of an existing reference or original biological drug.

It is relatively straightforward to replicate conventional chemical drugs or small molecules once chemical components and structure are analyzed. But, it is still difficult to replicate biological drugs or large molecules because breaking up and characterizing active components are complex and manufacturing technology influences the effectiveness of the drug [7]. The regulatory body does not approves a biosimilar drug unless the firm demonstrates similarity of the biosimilar drug to the reference drug in terms of safety and effectiveness [8]. Such an arduous due approval process takes long and requires a lot of efforts and resources. On the other hand, such stringent regulatory checks and monitoring for quality significantly reduce the costs and time it takes for approved drugs to be accepted by consumers [9].

In the European Union, EMA has pioneered the regulation of biosimilars by setting a regulatory framework for the approval process in 2005. In the US, the Food and Administration (FDA) established similar approval standards for biosimilars in 2009 [10]. As of May 2018, Europe has approved twenty-five biosimilars whereas the US has approved nine. But only three of those are on the market – Samsung BioLogics' biosimilar being one of them [11]. Thomson Reuters [12] reported that the global biosimilar sales are projected to reach $25 billion by 2020. This projected figure represents a quarter of the $100 billion sales of original biological drugs that have expired or would come off-patent. The cost of developing a biosimilar product ranges from $100 million to $250 million, which is lower than that of the originator drug, $800 million to $1.3 billion. In Europe, this cost advantage led biosimilar firms to offer their products at about 30% lower prices than original drug makers [13].

Anticipating high profitability and growth potential, many firms have jumped on the new wave of biosimilar business opportunities by forming a partnership with other companies. Unlike the conventional or generic drug market, the entry barriers of the biosimilar market are quite high in part due to the complexity of the manufacturing process and a long approval process. In addition, there are many regulations to abide by and powerful original drug makers attempt to thwart new comers' entry to the market by improving extant drugs and enhancing marketing efforts. The joint venture form helps diversify high risks of biosimilar business and enhance the probability of success by utilizing partner firms' technical expertise, financial resources, etc.

The business model of biopharmaceutical firms often differs depending on their size. Large global firms prefer having their key revenue generating products manufactured in-house whereas small-and-medium-sized firms



*Biogen has a call option to increase the ownership interest in Samsung Bioepis up to 49.9%.
Figure 1: Ownership Structure of Samsung BioLogics and Samsung Bioepis at the end of 2015.

often elect to outsource production to CMOs and focus on research, process development and marketing in their specialty drug business. Frequently, well-established firms choose to outsource production to ensure meeting a high demand or to secure contingent capacity [14].

(2) Samsung BioLogics

Samsung BioLogics was established on April 22, 2011 by Samsung Group's key member firms (Everland, Samsung C&T, and Samsung Electronics), and Quintiles, Inc. After a series of business portfolio restructuring by Samsung Group including the merger of Samsung C&T with Everland,[v] at the end of 2015, Samsung C&T, Samsung Electronics, Quintiles held 51.0%, 46.8%, and 2.2% of Samsung BioLogics, respectively (see Figure 1).

Samsung BioLogics is a biopharmaceutical CMO that earns revenues mainly from long-term outsourcing contracts with leading global pharmaceutical firms such as Bristol-Myers Squibb and Roche Holding. Samsung BioLogics makes extensive capital investments to maintain economically competitive production capacity, cutting-edge technology and quality control on a par with those of global top-tier competitors. At the end of 2017, two manufacturing plants were in operation, and the third plant was under construction. Once the third plant is completed, the production capacity will increase from 182,000 liters to 362,000 liters. Then, Samsung BioLogics will surpass the current market leader Lonza in the production capacity.

In 2012, Samsung BioLogics added biosimilar R&D business to its business portfolio by investing in Samsung Bioepis. On November 12, 2016, Samsung BioLogics successfully completed an initial public offering (IPO) and listed its shares on the Korea Exchange. In 2016, Samsung BioLogics reported sales revenue of KRW 295 billion (approximately $268 million), which represents a more than 300% sales growth from the preceding year. In 2017, sales revenue reached KRW 464 billion.

(3) Samsung Bioepis and Biogen

Samsung Bioepis was established on February 28, 2012 as a joint venture between Samsung BioLogics (85%) and Biogen (15%). Samsung Bioepis focuses on the research and development of biosimilar pharmaceuticals. Once biosimilar products are successfully developed and get approved, manufacturing, marketing, and distribution are delegated to its business partners. In 2015, Samsung

v As part of business succession of Samsung Group to the next generation, several affiliated firms underwent several phases of restructuring: 1) Everland acquired the fashion division of Cheil Industries (old) in 2013; 2) Everland changed its company name to Cheil Industries (new) after Cheil Industries (old) merged its chemical division with SDI in 2014; and 3) Samsung C&T (old) and Cheil Industries (new) merged and the new merged firm was named Samsung C&T (new) in 2015.

Table 1: Investment to Samsung Bioepis from 2012 to 2015

(Unit: KRW billion)

Year	Samsung BioLogics	Biogen	Total	Cumulative Total
2012	KRW 204.0	KRW 36.0	KRW 240.0	KRW 240.0
2013	76.5	13.5	90.0	330.0
2014	180.7	0.0	180.7	510.7
2015	117.2	6.3	123.5	634.2
Total	**KRW 578.4**	**KRW 55.8**	**KRW 634.2**	
Ownership Percentage at Year-end				
Year	Samsung BioLogics	Biogen		
2012	85.0%	15.0%		
2013	85.0%	15.0%		
2014	90.3%	9.7%		
2015	91.2%	8.8%		

Bioepis obtained approvals for two of its biosimilar products in Korea. In addition, six drugs in the pipeline were at least in the third-stage of their clinical trials so that the likelihood of commercializing more biosimilar products in the near future was quite high.

Biogen (the joint venture partner) was founded in 1978. As a global biopharmaceutical firm, Biogen focuses on discovering, developing and marketing medicine to treat neurological and neurodegenerative diseases. Biogen reports sales revenue of $12.3 billion in 2017 and $11.5 billion in 2016. The corresponding net profits are $2.7 billion and $3.7 billion, respectively.

III. CASE INTRODUCTION AND ANALYSIS

Classification of Samsung Bioepis: a subsidiary vs. an associate

Table 1 shows the amount of investment that Samsung BioLogics and Biogen had made to Bioepis over the period from 2012 to 2015. By the end of 2015, Samsung BioLogics and Biogen invested a total of KRW 578.4 billion and KRW 55.8 billion, respectively.[vi] Samsung BioLogics' ownership stake in Samsung Bioepis had been on the rise from 85% in 2012 to 91.2% at the end of 2015. Samsung BioLogics classified Samsung Bioepis as a subsidiary because it held a majority of voting rights of Samsung Bioepis.

In contrast, Biogen's ownership interest in Samsung Bioepis has been steadily decreasing from 15% in 2012 to 8.8% in 2015. Biogen has not fully participated in additional equity financing in the subsequent years. Biogen classified Samsung Bioepis as an associate because Biogen was maintaining a significant influence over Samsung Bioepis with its presence on Samsung Bioepis' Board of Directors and via a series of business contractual relationship such as a license agreement, technical development and manufacturing agreements. More importantly, Biogen possessed a call option to increase its ownership stake in Samsung Bioepis up to 49.9%.

IFRS requires a firm to consider all facts and circumstances when assessing whether it has power to control or has significant influence over other firms.[vii] A firm usually obtains controlling power by holding the majority ownership interest of the investee. The firm can further secure its controlling power over other firms through potential voting rights such as call options, forward contracts and convertible debt securities, either alone or in combination with existing current voting rights.

At the end of 2015, Samsung BioLogics [15] disclosed that it lost control over Samsung Bioepis because the call option held by the joint venture partner Biogen was substantive. That is, the option was deep in the money (i.e., the fair value of the underlying stock exceeding the exercise or

vi Samsung BioLogics further invested a total of KRW 400 billion to Samsung Bioepis in 2016 and 2017. Biogen did not participate in the equity financing by Samsung Bioepis after 2015. As a result, at the end of 2017, the ownership percentage of Samsung BioLogics increased to 94.6%.

vii An investor controls an investee when the investor has 1) power over the investee; 2) exposure, or rights, to variable returns from its involvement with the investee; and 3) the ability to use its power over the investee to affect the amount of the investor's returns (IFRS 10, para. 7)[17].

conversion price of the option by a large margin) and could be exercisable.[viii] With loss of control, Samsung BioLogics reclassified Samsung Bioepis as an associate, ceased to prepare consolidated financial statements, and started to apply the equity method of accounting. IFRS requires remeasurement of the investment at fair value when the status of the investee changes from a subsidiary to an associate.

Disclosure about the Call Option

The call option to allow Biogen to increase its ownership interest up to 49.9% is an important clause in the Samsung Bioepis joint venture agreement. Accordingly, Biogen [16] has disclosed the presence of the call option in the annual reports since 2012. The following is the disclosure made by Biogen.

> *"We [Biogen] have no obligation to provide any additional funding; however, we maintain an option to purchase additional stock in Samsung Bioepis in order to increase our ownership percentage up to 49.9 percent. The exercise of this option is within our control."*

In contrast, Samsung BioLogics has not disclosed the presence of the call option prior to 2014. In 2015, Samsung BioLogics disclosed the loss of control over Samsung Bioepis.

> *"The Company [Samsung BioLogics] lost the control over Samsung Bioepis Co., Ltd. during 2015 and excluded it from the Company's subsidiaries. The former subsidiary was accounted for as investments in associates at fair value from 2015."*

Fair value remeasurement of Samsung Bioepis

During 2015, Samsung BioLogics judged that Biogen is very likely to exercise the call option on the expiration date of June 29, 2018 because the fair value of Samsung Bioepis has substantially increased. However, it was unclear whether the joint venture partner Biogen had an intention to exercise the call option at the end of 2015.[ix]

The exercise of the call option requires Biogen to pay 49.9% of the total investment made by Samsung BioLogics into Samsung Bioepis in excess of what Biogen have already contributed plus interest for the invested capital by Samsung BioLogics at the 14% rate of return. Since Biogen held 8.8% ownership interest in Samsung Bioepis, Biogen could acquire additional 41.2% ownership interest by paying KRW 351.9 billion at the end of 2015.[x] If the call option expires unexercised, Samsung BioLogics could purchase all of Samsung Bioepis' shares then held by Biogen.

There were some controversies over the reclassification of Samsung Bioepis from a subsidiary to an associate and remeasurement of the former subsidiary at fair value. Furthermore, there was a rumor about Samsung BioLogics' imminent IPO and Samsung Group was amid controversies over the merger of Samsung C&T and Cheil Industry. Thus, the investment community was suspicious about Samsung BioLogics' intention to re-evaluate the equity investment in Samsung Bioepis.

Fair value measurement of an asset is vulnerable to subjectivity and bias if the measurement is not based on observed transaction prices of the identical or a similar asset in an active market. In the case of Samsung Bioepis, the fair value is not based on the observed transaction price, but is estimated using the discounted cash flow valuation method.

Table 2 shows assumptions underlying the fair value re-measurement of Samsung Bioepis as disclosed by Samsung BioLogics: a weighted average cost of capital (WACC) of 10.0%, revenue growth rates ranging from –1.0% to 105.3%, and operating profit margins ranging from – 24.1% to 57.1%. It is open to debate whether these valuation assumptions faithfully reflect the precarious nature of the biosimilar industry and whether they are reasonable considering the recent financial performance of Samsung Bioepis. Samsung BioLogics classified and disclosed these valuation assumptions as level 3 inputs, the least reliable one out of the three input categories for fair value.[xi]

viii Since Samsung Bioepis was less likely to pay dividends and the expiration date was more than two years away, an early exercise would not be optimal.

ix On April 24, 2018, Biogen announced its plan to exercise the call option in the Q1 2018 earnings presentation and eventually exercised the call option on the expiration date.

x Samsung BioLogics disclosed the amount in the media announcement on February 14, 2017, which was held to address issues regarding Samsung BioLogics' IPO. At the end of 2017, Biogen's ownership interest in Samsung Bioepis was 5.39%. Samsung BioLogics disclosed in the press release on May 18, 2018 that "As of June 29, 2018, the amount required [for Biogen] to acquire an additional approximately 44.6% stake in Samsung Bioepis is expected to be around KRW 700 billion."

xi There are three broad levels of fair value hierarchy in IFRS 13 *Fair Value Measurement*.[18] Level 1 is based on observable inputs such as quoted prices in active markets for identical assets. Level 2 uses observable inputs, but is based on more subjective inputs such as quoted prices of

Table 2: Valuation Method, Assumptions and Value Estimate for the investment in Samung Bioepis as Disclosed by Samsung BioLogics

Valuation Method	Discounted Cash Flow Model (Risk-adjusted NPV)
Valuation Assumptions	WACC: 10% Revenue Growth: – 1% ~ 105.3% Operating Profit Margin: – 24.1% ~ 57.4%
Valuation Result	KRW 4,808.58 billion (for 91.2% ownership interest)

Samsung BioLogics reported that the value of its share of Samsung Bioepis was KRW 4,808.6 billion at the end of 2015. We can infer the whole equity value of Samsung Bioepis at KRW 5,272.6 billion by grossing up KRW 4,808.6 billion (91.2% ownership interest held by Samsung BioLogics) to include 8.8% ownership interest held by Biogen. Samsung BioLogics also assessed the value of the call option held by Biogen at KRW 1,820.4 billion, which equals 41.2% of the whole value of Samsung Bioepis minus the exercise price KRW 351.9 billion at the end of 2015.

Total equity value of Samsung Bioepis (KRW 5,272.6 billion)
= Share of Samsung BioLogics (91.2%) + Share of Biogen (8.8%)
= KRW 4,808.6 billion + KRW 464.0 billion

Value of the call option held by Biogen (KRW 1,820.4 billion)
= 41.2% share interest of Samsung Bioepis (KRW 5,272.6 billion) – Exercise Price
= KRW 2,172.3 billion – KRW 351.9 billion

Fair Value Measurement Scenarios

We attempt to validate and illustrate the valuation of Samsung Bioepis by presenting valuation scenarios that are consistent with the valuation assumptions and the value estimate of Samsung Bioepis, KRW 5,273 billion.

To illustrate, we use the discounted cash flow model, the residual operating income model and the abnormal operating income growth model with a forecast horizon of 5 years ending in 2020.[xii] Since the three valuation models are equivalent in theory, the valuation results are identical [19]. With limited information, we have reversed engineered to review the assumptions Samsung BioLogics could have used to derive KRW 4,809 billion as the fair value estimate of its investment in Samsung Bioepis (91.2%).

Table 3 presents a valuation scenario consistent with the valuation result and assumptions in Table 1. Panel A of Table 3 shows selected information of Samsung Bioepis from 2012 to 2015. Net debts are defined as debts minus cash and cash equivalents. Samsung Bioepis does not have other short-term investments in financial assets. Net operating assets are calculated by adding the book value of equity and net debts. Samsung Bioepis had been reporting losses and negative operating cash flows since its incorporation. Capital expenditures are mainly financed through issuing new shares. As mentioned earlier, Samsung BioLogics' ownership percentage increased from 85% in 2012 to 91.2% in 2015. During 2014, Biogen did not participate in additional equity financing by Samsung Bioepis so that its ownership interest decreased below 10%. During 2015, Biogen contributed KRW 6.4 billion in the first quarter, but did not participate in the equity financing in the third quarter.

Panel B presents our own forecasts of revenues, operating profits, and net operating assets, which are used to determine key ingredients of the valuation models: free cash flows, residual operating income, and abnormal operating income growth. Below are the details of our own valuation assumptions for revenue growth, operating margin, and the net operating asset turnover over the forecast period.

First, sales are expected to grow substantially with the approval of drugs in the pipeline. Samsung BioLogics disclosed sales growth rates of – 1% to 105.3%. However, we could not come up with a valuation scenario when we assume a gradual increase of sales. Thus, we assume big increases of sales from the beginning over the forecast period: 510% in 2016, 150% in 2017, 100% in 2018, 60% in 2019 and 55% in 2020. We forecast a big hike of sales in 2016 because a plunge of sales in 2015 (from KRW 76 billion in 2014 to KRW 24 billion in 2015) was judged temporary. The forecasted sales growth of 510% in 2016 is, in fact, a 92% growth if we use 2014 as a reference year. Furthermore, the forecast sales revenue of KRW 146 billion in 2016 is close to the actual sales figure of KRW 147 billion.

Second, Samsung Bioepis had reported operating losses since its inception. We assume that the loss situation will continue in 2016, and the firm will be barely able to break even in 2017. With approval of several drugs in the pipeline, we assume that Samsung Bioepis would

similar assets or other than quoted prices such as interest rates, implied volatility, and credit spreads. In contrast, level 3 is based on unobservable inputs so that it is the most subjective and judgment is needed to utilize the information for valuation.

xii We also present a valuation scenario with a forecast horizon of 10 years.

Table 3: Valuation Scenario for Samsung Bioepis
Panel A: Figures from the Financial Statements of Samsung Bioepis from 2012 to 2015.

(Unit: KRW billion)

	2012	2013	2014	2015
Assets	236	257	477	654
Cash & Cash Equivalents (CE)	134	83	46	36
Liabilities	36	45	109	364
Debts	0	0	21	150
Equity	200	212	368	291
Retained Earnings	–39	–117	–141	–339
Sales	0	44	76	24
Operating Income	–44	–82	–25	–161
Net Profit	–39	–78	–24	–167
Comprehensive Income	–40	–79	–25	–169
Cash Flows from Operations	–32	-47	–91	–103
Net Debts: Debts minus Cash & CE	–134	–83	–26	115
Net Operating Assets (NOA)	66	129	342	406
Ownership %:				
Samsung BioLogics		85.0%	90.3%	91.2%
Biogen Idec Inc.		15.0%	9.7%	8.8%

Net operating assets are the sum of the book value of equity and net debts. Net debts are debts minus cash and cash equivalents.

Panel B: Forecasts of Operating Revenues, Operating Profits, and Net Operating Assets

(Unit: KRW billion)

	2015A	2016E	2017E	2018E	2019E	2020E
Revenue	24	146	366	732	1,171	1,815
Revenue Growth (%)		510%	150%	100%	60%	55%
Operating Income (OI)	–161	–37	–5	37	234	635
Op. Profit Margin (%)		–25%	–1.5%	5%	20%	35%
Operating Profit (after tax)		–28	–4	28	178	482
NOA (KRW billion)	406	732	915	1,301	1,815	1,924
NOA Turnover	0.37	0.50	0.8	0.9	1	1

be able to report a profit in 2018.[xiii] Consistent with the firm's assumed operating profit margins ranging from –24.1% to 57.4%, we predict operating profit margins of 5% in 2018, 20% in 2019, and 35% in 2020. The operating profit margin of 35% in 2020 is very optimistic even for the very lucrative pharmaceutical industry. The average operating profit margin of US pharmaceutical companies is around 24%.[xiv]

In the valuation scenario, we assume that Samsung Bioepis would be able to report a profit in the near future. Absent detailed disclosure, we do not know whether Samsung BioLogics assumed the break-even

xiii Samsung Bioepis reported a loss in 2018.

xiv http://pages.stern.nyu.edu/~adamodar/New_Home_Page/datafile/margin.html.

Table 4: Valuation Results using a Forecast Horizon of 5 Years
Panel A: Discounted Cash Flow Valuation Model

(Unit: %, KRW billion)

WACC	10%					
Perpetuity Growth	6%					
Tax Rate	24.2%					
	2015A	2016E	2017E	2018E	2019E	2020E
FCF		–354	–187	–359	–336	373
Discount factor (1.1^t)		0.909	0.826	0.751	0.683	0.621
PV of FCF		–322	–155	–269	–230	231
(a) Total PV of FCF	–745					
Continuing Value (CV)						9,876
(b) PV of CV	6,132					
Enterprise Value (a+b)	**5,388**					
Net Debt	115					
Value of Equity	5,273					
Ownership (%)	91.2%					
Share of Samsung BioLogics	**4,809**					

Free cash flows are calculated as $FCF_t = OI_t - \Delta NOA_t$.

timing similar to ours. But, if Samsung Bioepis cannot report a profit in the near future, a high value estimate of Samsung Bioepis would be possible only by a high perpetuity growth after the forecast horizon. To the extent that the perpetuity growth assumption is optimistic, the resulting fair value estimate would be optimistically biased.[xv]

Finally, net operating assets are estimated by dividing forecasted sales by the net operating asset turnover. We assume that the net operating asset turnover would be around 1 from 2019.[xvi] Additional investments in net operating assets are needed to support an increase in sales volume.

Valuation Results

Table 4 present valuation results when we employ the discounted cash flow model, the residual operating income model, and the abnormal operating income growth model (panels A, B, and C, respectively). We use a forecast horizon of 5 years and a perpetuity growth rate of 6% after the forecast horizon.

The valuation results are the same among the three valuation models because these models are equivalent. The enterprise value at the end of 2015 is estimated at KRW 5,388 billion. The value of equity is KRW 5,273 billion, which is determined by subtracting net debts of KRW 115 billion from the enterprise value. The value of Samsung BioLogics' share in Samsung Bioepis is KRW 4,809 billion, which is 91.2% of the value of total equity.

> Value of Samsung BioLogics' share in Samsung Bioepis (KRW 4,809)

xv Samsung Bioepis did not provide its own forecasts of future profitability, but we can catch a glimpse of its view from the disclosure of deferred tax assets (note 21 in the 2015 financial statements). Samsung Bioepis did not recognize deferred tax assets for incurred net operating losses because it would not be probable that taxable profits would be available for the next ten years (the tax loss carryforward period). It could be also argued that judgement for the recognition of deferred tax assets is based on different criteria, and Samsung BioLogics would differ from Samsung Bioepis in their judgment about the likelihood of future profits.

xvi The average (median) operating asset turnover is 0.96 (0.81) for the health care sector on the Korea Exchange in 2016 (the authors' own calculation for firms on the Korea Exchange).

Panel B: Residual Operating Income Valuation Model

(Unit: %, KRW billion)

	2015A	2016E	2017E	2018E	2019E	2020E
(a) Net Operating Assets	406	732	915	1,301	1,815	1,924
Residual Operating Income (ReOI)		–6.8%	–0.6%	3.0%	13.6%	26.5%
Discount factor (1.1^t)		–68	–77	–64	47	300
PV of ReOI		–62	–64	–48	32	186
(b) Total PV of ReOI	45					
Continuing Value (CV)						7,952
(c) PV of CV	4,938					
Enterprise Value (a+b+c)	**5,388**					
Net Debt	115					
Value of Equity	5,273					
Ownership (%)	91.2%					
Share of Samsung BioLogics	**4,809**					

Residual operating income is calculated as $ReOI_t = OI_t - r \times NOA_{t-1}$.

Panel C: Abnormal Operating Income Growth Valuation Model

(Unit: %, KRW billion)

	2015A	2016E	2017E	2018E	2019E	2020E	2021E
Abnormal OI Growth (AOIG)			–9	14	111	253	18
Discount factor (1.1^t)			0.909	0.826	0.751	0.683	0.621
PV of AOIG			–8.2	11.2	83.5	172.6	11.2
(a) Total PV of AOIG		270.3					
Continuing Value (CV)						6,695	477
(b) PV of CV		296.3					
(c) Forward OI for 2016E		–27.7					
(a) + (b) + (c)		538.8					
Capitalization rate		10%					
Enterprise Value	**5,388**						
Net Debt	115						
Value of Equity	5,273						
Ownership (%)	91.2%						
Share of Samsung BioLogics	**4,809**						

Abnormal operating income growth is calculated as $AOIG_t = ReOI_t - ReOI_{t-1}$.

Table 4A: Valuation Scenario of Samsung Bioepis with a Forecast Horizon of 10 Years
Panel A: Forecasts of Operating Revenues, Operating Profits, and Net Operating Assets

(Unit: KRW billion)

	2015A	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Revenue	24	146	366	732	1,318	2,108	3,057	4,127	4,952	5,546	5,990
Revenue Growth (%)	0	510%	150%	100%	70%	60%	50%	40%	30%	12%	8%
Operating Income (OI)	–161	–37	–92	–132	–211	–253	–122	83	594	1,387	2,097
Op. Profit Margin (%)		–25%	–25%	–18%	–16%	–12%	–4%	2%	12%	25%	35%
Operating Profit (after tax)		–28	–92	–100	–160	–192	–93	63	450	1,051	1,589
NOA (KRW billion)	406	732	915	1,464	2,108	3,057	4,127	4,952	5,546	5,990	6,170
NOA Turnover	0.37	0.50	0.8	0.9	1	1	1	1	1	1	1

Panel B: Discounted Cash Flow Valuation Model

(Unit: %, KRW billion)

WACC	**10%**										
Perpetuity Growth	**3%**										
Tax Rate	**24.2%**										
	2015A	**2016E**	**2017E**	**2018E**	**2019E**	**2020E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**
FCF		–354	–275	–649	–804	–1,140	–1,163	–763	–144	607	1,409
Discount factor (1.1^t)		0.909	0.826	0.751	0.683	0.621	0.564	0.513	0.467	0.424	0.386
PV of FCF		–322	–227	–488	–549	–708	–656	–391	–67	258	543
(a) Total PV of FCF	–2,607										
Continuing Value (CV)											20,739
(b) PV of CV	7,996										
Enterprise Value (a+b)	**5,388**										
Net Debt	115										
Value of Equity	5,273										
Ownership (%)	91.2%										
Share of Samsung BioLogics	**4,809**										

Free cash flows are calculated as $FCF_t = OI_t - \Delta NOA_t$

= 91.2% of total equity value of Samsung Bioepis (KRW 5,273)

Total equity value of Samsung Bioepis (KRW 5,273)
= Enterprise value – net debts
= KRW 5,388 billion – KRW 115billion

We note that the enterprise value estimate of Samsung Bioepis, KRW 5,388 billion, is 8.5 times of the cumulative investment of KRW 634 billion at the end of 2015 (see Table 1). Furthermore, the enterprise value estimate mainly stems from the continuing value (CV) estimate at the forecast horizon. In the discounted cash flow valuation model (panel A of Table 4), the present

Panel C: Residual Operating Income Valuation Model

(Unit: %, KRW billion)

	2015A	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
(a) Net Operating Assets	406	732	915	1,464	2,108	3,057	4,127	4,952	5,546	5,990	6,170
Residual Operating Income (ReOI)		−6.8%	−12.5%	−10.9%	−10.9%	−9.1%	−3.0%	1.5%	9.1%	19.0%	26.5%
Discount factor (1.1^t)		−68	−165	−191	−306	−403	−398	−350	−45	496	990
PV of ReOI		0.909	0.826	0.751	0.683	0.621	0.564	0.513	0.467	0.424	0.386
(b) Total PV of ReOI		−62	−136	−144	−209	−250	−225	−180	−21	211	382
Continuing Value (CV)	−634										
(c) PV of CV											14,569
Enterprise Value (a+b+c)	**5,388**										
Net Debt	115										
Value of Equity	5,273										
Ownership (%)	91.2%										
Share of Samsung BioLogics	**4,809**										

Residual operating income is calculated as $ReOI_t = OI_t - r \times NOA_{t-1}$

value of free cash flows over the forecast period is a negative KRW 745 billion whereas the present value of CV is KRW 6,132 billion. That is, the proportion of CV to the enterprise value exceeds 100% in the discounted cash flow valuation model. In the residual operating income model (panel B), the proportion of CV to the enterprise value is still quite high, about 92%. The continuing value estimate after the forecast horizon is inevitably more speculative than the value estimate for the forecast period [20]. Since the value estimate of Samsung Bioepis depends heavily on the continuing value, conservative and prudent investors would take the value estimate with a grain of salt.

In Table 4A, we present an equivalent valuation scenario with a longer forecast horizon of 10 years and a perpetuity growth rate of 3%. These modifications are made to ameliorate potential problems attributable to a short forecast horizon and a high perpetuity growth assumption. We calibrate our forecast assumptions such that the valuation result does not change with a longer forecast horizon. However, we do not see significant differences that would change our inferences on whether the value estimate asserted by Samsung BioLogics is reasonable.

Accounting Consequences of Loss of Control of Samsung Bioepis

Reclassification of Samsung Bioepis from a subsidiary to an associate affected Samsung BioLogics' financial statements as follows: (1) an increase in investments in associates and recognition of a gain from removing the subsidiary from the book; and (2) recognition of a derivative liability for the call option held by the joint venture partner and a related loss on the derivative.

(1) Investments in Associates and a Disposal Gain

Table 5 shows the calculation of a gain from removing Samsung Bioepis from Samsung BioLogics' subsidiaries. Samsung BioLogics assessed the fair value of its investment in Samsung Bioepis at KRW 4,809 billion. At the time of the measurement, the book value of the investment in Samsung Bioepis was KRW 265 billion, which equals 91.2% of the book value of equity or net assets of Samsung Bioepis. Biogen reports KRW 4,544 billion, the difference between the fair value and the book value of the investment in Biogen, as a gain on disposal of investment in subsidiary on the statement of income.

Panel D: Abnormal Operating Income Growth Valuation Model

(Unit: **%,** KRW billion)

	2015A	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E
Abnormal OI Growth (AOIG)			−96	−27	−115	−96	4	48	305	541	494	30
Discount factor (1.1^t)			0.909	0.826	0.751	0.683	0.621	0.564	0.513	0.467	0.424	0.386
PV of AOIG			−87.6	−22.0	−86.3	−65.8	2.6	27.2	156.7	252.5	209.4	11.5
(a) Total PV of AOIG		398.1										
Continuing Value (CV)												437
(b) PV of CV		168.5										
(c) Forward OI for 2016E		−27.7										
(a) + (b) + (c)		538.8										
Capitalization rate		10%										
Enterprise Value	**5,388**											
Net Debt	115											
Value of Equity	5,273											
Ownership (%)	91.2%											
Share of Samsung BioLogics	**4,809**											

Abnormal operating income growth is calculated as $AOIG_t = ReOI_t - ReOI_{t-1}$.

In 2015, Samsung BioLogics was able to report a profit of KRW 1,906 billion for the first time since its incorporation. It is a big jump in earnings compared to a loss of KRW 100 billion in 2014. But, in 2016 and 2017, Samsung BioLogics could not report a profit.

(2) Recognition of a Derivative Liability and a Loss on the Derivative for the Call Option Held by Biogen

At the end of 2015, Samsung BioLogics assessed that Biogen are very likely to exercises its option right before its expiry in 2018. When Biogen exercises the option to acquire additional stock in Samsung Bioepis up to 49.9%, it pays 49.9% of the total investments made by Samsung BioLogics into Samsung Bioepis in excess of what Biogen has already contributed plus 14% interest on the investment. At the end of 2015, Samsung BioLogics recognized a derivative liability of KRW 1,820 billion, which is the fair value of the option or expected losses when the option is exercised in the future (see Table 6). The same amount was reported as a loss on valuation of derivatives (as part of finance costs) on the statement of income in 2015. Samsung BioLogics disclosed that the derivative liability was determined using the binomial option pricing model.[xvii]

The derivative liability related to the call option further increased to KRW 1,874 billion at the end of 2016 and to KRW 1,934 billion at the end of 2017. Accordingly, Biogen recognized an additional loss of KRW 54 billion in 2016 and KRW 59 billion in 2017, respectively.

xvii The reported value of the derivative liability, KRW 1,820 billion, is not the value of the call option, but the intrinsic value of the call option: that is, the difference between the fair value of the 41.2% interest in Samsung Bioepis and the exercise price. Under the binomial option pricing model, the value of the call option would be higher than the intrinsic value. When we assume an intrinsic volatility of 30%, a maturity of 2.5 years, and the risk free interest rate of 3%, the value of the call option would be KRW 1,846 billion. The valuation result from DerivaGem (http://www-2.rotman.utoronto.ca/~hull/software/index.html) is presented in Figure 2.

Table 5: Gain on the fair value remeasurement of the investment in Samsung Bioepis

(Unit: KRW billion)

Fair value estimate of the investment in Samsung Bioepis	KRW 4,808.6
Less: book value of the investment in Samsung Bioepis (91.2% of the book value of Samsung Bioepis, KRW 290.5)	265.0
Gain on remeasurement of the investment in Samsung Bioepis	KRW 4,543.6

Table 6: Value of the call option held by Biogen

(Unit: KRW billion)

Fair value estimate of Samsung Bioepis (A)*	KRW 5,272.6
Value of the interest that can be obtained by the call option (B) (41.2% of A)	2,172.3
Exercise price (C)	351.9
Value of the call option (B – C)	KRW 1,820.4

* The value of the whole Samsung Bioepis is inferred by grossing up the fair value of the investment in Samsung Bioepis held by Samsung BioLogics (91.2%), KRW 4,808.6 billion, to include 8.8% ownership interest held by Biogen.

Discussion of the Fair Value Remeasurement of Samsung Bioepis

There are two issues in the fair value remeasurement of Samsung Bioepis.

(1) Whether Samsung BioLogics lost control over the Samsung Bioepis joint venture at the end of 2015.
(2) Whether the fair value estimate of the investment at the time of remeasurement is reasonable.

The first issue is regarding the likelihood that Biogen exercises its call option to acquire addition equity interest. If the option is already deep in the money, the likelihood would be very high. But, shares of Samsung Bioepis are not publicly traded so that it is not straightforward to judge whether the option is deep in the money or not. Thus, the first and second issues are closely related.

It is not easy to determine whether the value estimate of Samsung Biogen at the end of 2015, KRW 5,272.6 billion (approximate $4.6 billion), is reasonable or not. Those who criticize that the fair value estimate is excessive may point out that the ratio of the fair value estimate to the amount of cumulative investment (8.3 = 5,272.6/634.2 billion) is too high and that Samsung Bioepis has not shown profits since its inception. On the other hand, some may argue that the fair value estimate just reflects an expected high return on the speculative biosimilar business. At the end of 2015, Samsung Bioepis demonstrated its potential by successfully developing and obtaining approvals for two biosimilar drugs. Those who believe that the discounted cash flow model is not suitable to value a biosimilar firm may argue that the value of drugs in the pipeline cannot be estimated by short-term cash flow forecasts.

Then, how has Biogen, the joint venture partner, accounted for its investment in Samsung Bioepis? Biogen's investment in Samsung Bioepis totaled KRW 558 billion (about $50.7 million) by the end of 2015.[xviii] Biogen classified Samsung Bioepis as an associate from the beginning and had used the equity method of accounting. Samsung Bioepis had been suffering from losses since its inceptions. Thus, under the equity method of accounting, Biogen had recognized its share of the losses of Samsung Bioepis. At the end of 2014, the carrying amount of the investment in Samsung Bioepis was reduced to $8.6 million. By the end of 2015, the carrying amount of the investment in Samsung Bioepis is completely written down to zero.

At the end of 2015, the two joint venture partners, Samsung BioLogics and Biogens, use the same equity method of accounting for their investments in Samsung Bioepis. But, the two joint venture partners report quite differently for the investment in the joint venture business on the statement of the financial position: One reports KRW 4,809 billion and the other reports a zero. It is interesting that the huge disparity in the carrying amounts arises due to the fair value remeasurement of the investment in the joint venture when Samsung BioLogics adopted the equity method of accounting upon the loss of control. If Samsung BioLogics had classified Samsung Bioepis as an associate from the beginning, Samsung BioLogics would report the investment in Samsung Bioepis at KRW 265 billion rather than at KRW 4,809 billion.

V. SUMMARY AND CONCLUSION

Samsung BioLogics surprised the investment community by posting a big valuation gain when it disclosed loss of control of a biosimilar joint venture due to the in-the-money call option held by the joint venture partner. The financial press and activist investor groups such as Peoples' Solidary for Participatory Democracy alleged that, prior to IPO and amid the transfer of Samsung

xviii By the end of 2015, Samsung BioLogics' investment totaled KRW 578.4 billion.

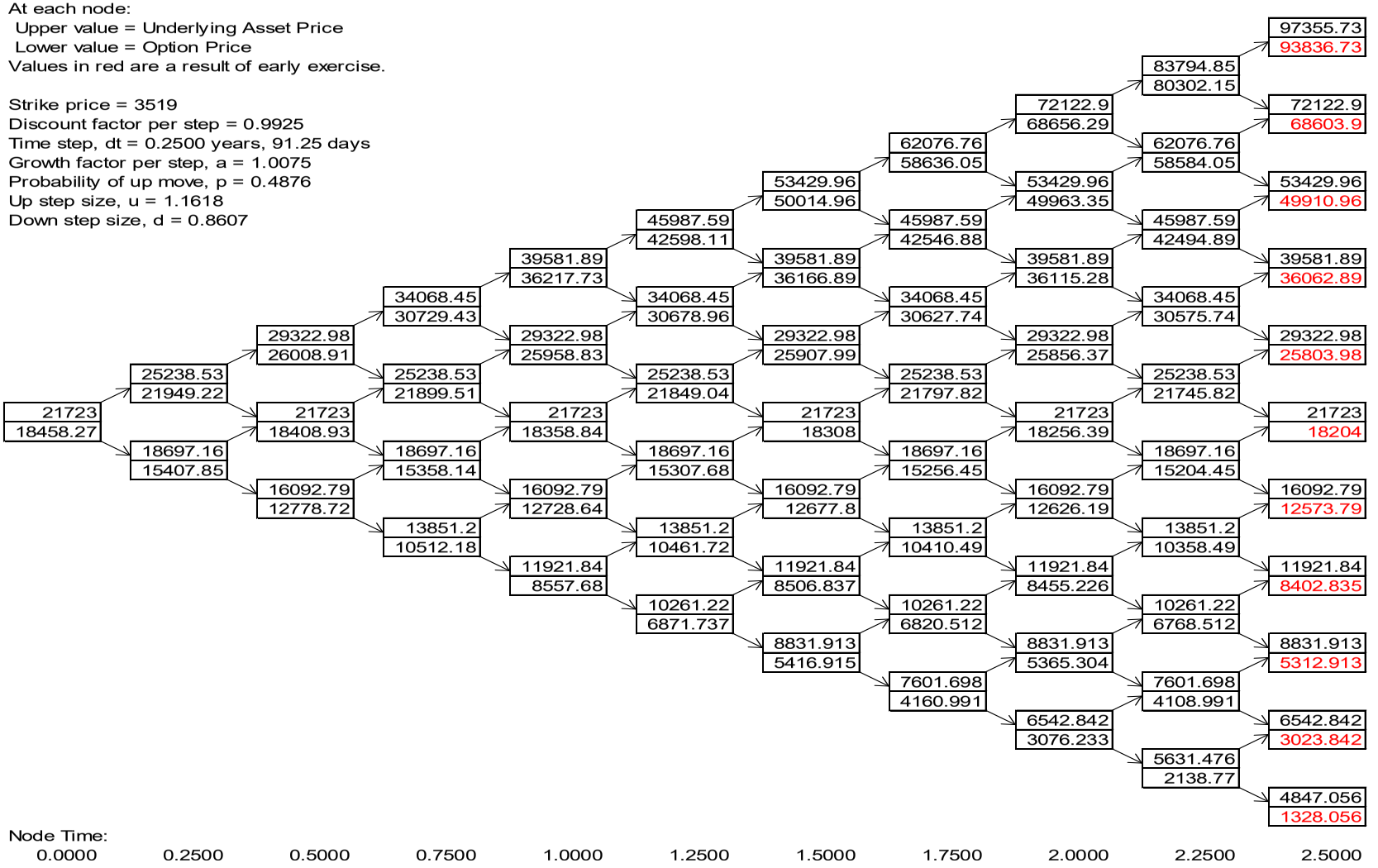


Figure 2: Valuation of the Call Option using a Binomial Tree.

Group's ownership to the next generation, Samsung BioLogics had an incentive to remeasure the investment in the former subsidiary at a higher fair value and report a gain on the investment in the joint venture business.

A series of subsequent allegations against Samsung BioLogics for a possible violation of accounting rules involve three issues: (1) whether Samsung BioLogics failed to disclose the existence and terms of the call option on a full and timely basis; (2) whether Samsung BioLogics lost control of Samsung Bioepis at the time of the recognition of the valuation gain; and (3) whether the fair value estimate of the joint venture business was reasonable.

The first issue is regarding the full disclosure of material information. In fact, the regulatory body subsequently ruled that Samsung BioLogics violated the full disclosure requirement. The second issue is about whether the call option was deep in the money (i.e., the value of the joint venture shares that the call option is entitled to acquire far exceeding the exercise price). If the call option was indeed deep in the money, one may conclude that Samsung BioLogics lost control of Samsung Bioepis. The third issue would critically depend on the valuation assumptions underlying the fair value estimate of the joint venture business. The antagonists may argue that Samsung BioLogics had incentives to overstate the fair value prior to an imminent IPO and amid controversies over the succession of Samsung Group's ownership to the next generation. They may also argue that the valuation failed to take into account the following: (1) the biosimilar industry is precarious and very competitive; (2) the joint venture partner fully wrote down its investment in the joint venture business; and (3) the joint venture business did not recognize deferred tax assets for incurred net operating losses.

Valuation is an art, not an exact science. It would be much more so for valuation of a biosimilar business. The presence of a call option in the case makes classification and valuation more difficult. We reviewed the assumptions of the valuation made by Samsung BioLogics, but did not carry out our own valuation. Thus, rather than giving our own definite answers for the above issues, we would like to leave the judgement for the violation of accounting standards to the readers.

Stakeholders benefit from fair value measurement and valuation if they provide timely and value relevant information. But, fair value estimates, in particular those that rely on subjective and less reliable level 3 inputs, could be abused by firms that had incentives to inflate reported earnings and to present a better looking financial condition. To the extent that disclosures of fair value inputs are ineffective in curbing management's incentives to bias the fair value measurement to their advantage, the regulatory body needs to reconsider allowing for the recognition of an unrealized gain by remeasuring equity investments at fair value and to mandate full and timely disclosures of all material information.

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Article

Bioenterprise Media Strategy 2020: Social Media, Mainstream Coverage, and a New Model of Trust

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ABSTRACT

In 2012 and 2016, the first two strategic science-business media models were published (SBBMM 1.0 and 2.0). Since that time, there have been significant changes both to the media landscape and to the usage and capability of online and social media platforms. This paper seeks to describe the current bioindustry-relevant media landscape, to introduce a new media model, the Strategic Bioenterprise Media Model 2020 (SBMM 2020), which reflects this new landscape, and to present a mainstream submodel to support the latest opportunity for biotechnology media coverage: Mainstream Media. Examples are drawn from media coverage following the FDA approvals of Zulresso from Sage Therapeutics, Aimovig from Novartis and Amgen, and AquAdvantage salmon from AquAdvantage Technologies. The overall goal of this paper is to equip bioenterprise professionals with an understanding of media dynamics and the strategic potential it brings, ultimately contributing to bioenterprise success.

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INTRODUCTION

Media strategy for any business is a two-part plan: elicit positive media, and counter negative media. While simple in concept, the media strategy for a bioenterprise is not. It starts with identifying the intrinsic risk of the organization, as media is inclined to cover risk – the risk that paid off, the risk that failed, and events of interest while waiting to see which one it will be. This is especially significant since for every biobusiness, the risk is constant and dynamic, and the proposition that the science will bear out and the technology will ultimately work is its driving impetus. As such, the bioenterprise was characterized in a 2013 Journal of Commercial Biotechnology article as follows:

> *"The unique nature of the life science industry has been aptly described as 'science-business'. As such, the endeavor carries innate risk. Simply stated, the bioenterprise must drive nascent science to stable, commercially-available and ultimately profitable products and services, an exercise for which success can neither be predicted from the outset, nor at numerous points along the way. Achieving commercial success requires a multi-disciplinary and creative entrepreneurial organization, which can operate within a continually challenging and unprecedented business context. This holds true across all biotechnology market sectors."* [1,2]

But the central question remains: how does risk and media coverage come together to contribute to the success or failure of a bioenterprise? The simplest answer is funding. Substantial and repeated tranches of funds are necessary to bring a product to market. Certainly, the biopharmaceuticals sector presents the greatest funding challenge. Expressed in 2013 dollars, the Tufts Center for the Study of Drug Development 2016 report combines "the cost of compounds abandoned during test … [with] the costs of compounds that obtained marketing approval" to estimate the cost for a single biopharmaceutical to be $1.3 Billion over 12-15 years[3]. This number rises to $2.6 Billion when the bioenterprise needs to

capitalize these costs with funds from external sources, the most typical scenario[3].

This paper seeks (1) to describe the current bioindustry-relevant media landscape, (2) to introduce a new media model, the Strategic Bioenterprise Media Model 2020 (SBMM 2020), which reflects this new landscape, and (3) to present a mainstream submodel to describe the latest opportunity for biotechnology media coverage: Mainstream Media. The overall goal of this paper is to equip bioenterprise professionals with an understanding of media dynamics and the strategic potential it brings, ultimately contributing to bioenterprise success.

THE EMERGENCE OF BIOSTRATEGIC MEDIA MODELS

The first strategic media model for the bioenterprise, now referenced as SSBMM 1.0, was published in this journal in 2012[4]. At that time, the biotechnology industry drew interest from bioindustry-only publications, perhaps best described as "trade press", and financial market coverage. The latter would be general financial market publications, business-oriented television and radio programming, and the finance sections of general audience media. Coverage focused primarily on publicly-traded stocks, mergers and acquisitions, and major capital funding events.

At that time, online-only media outlets of all types were beginning to emerge. In the bioindustry space, individuals began publishing without benefit of editors or editorial policies. This included independent industry analysts, biobusiness journalists, veteran biotechnology stock traders, consultants, and anyone with online access, since the tools to publish blogs, podcasts and materials from any venue had become plentiful and free.

Core to the 2012 media model was distinguishing between professional and non-professional media outlets, as well as the efforts needed to ensure the most accurate representation of the bioenterprise. The 2016 model (SSBMM 2.0) added the consideration of life science industry reports and databases that might improperly impact the perception of a bioenterprise, its product(s) and/or the geographic region(s) in which it operated[5].

Since that time, technology has evolved. Now, 24/7 access to media via smartphone is routinely expected, more and more biotechnology products have come to market, and more people in the general audience have felt their impact.

MEDIA OUTLET CATEGORIES AND AUDIENCE REACH

For the purposes of this paper, three media outlet categories will be considered. The first is BioIndustry Media, whether created by individuals or the product of substantive media enterprises. They exclusively cover the biotechnology industry.

The second media outlet category is Financial Markets Media. This category covers all financial markets, but are of interest when it covers the biotechnology industry. Financial Markets Media draws a larger audience than BioIndustry Media, given its wider scope. CNBC reports an hourly average of 177,000 viewers to its television programming during the business day, while its website reports 107 Million (non-unique) visitors during May, 2019[6]. While the fluctuations in usage throughout the day and business week are unknown, presuming website visits for 30 days each month and 24 hour website usage, this computes out 148,000 average visitors per hour. Changing assumptions to a five-day business week, and 12 hours each days of heavy website usage, the average access grows to over 400,000 visitors per hour. Here is the first instance where the impression of a media outlet being a television entity turns out to draw far more media consumers in its online presence.

Similarly, the Wall Street Journal publishes a print edition daily, Monday through Saturday. It has a print subscription base of 900,000, and a digital subscription base of 1.6 Million[7–9]. The Wall Street Journal site draws 42 Million visitors per month globally, while other parts of its Digital Network include MarketWatch with an average of 10 Million visitors online each month, and Barron's averaging 2.5 Million visitors monthly. Again, its online presence is far more significant than its traditional paper format.

Coverage in Financial Markets media has also extended beyond publicly-traded stock reports and other general financial information. For example, in the Wall Street Journal, Novartis and Amgen's Aimovig, a migraine preventative, was featured in a 900-word story in 2018, and Sage Therapeutics's Zulresso, a postpartum antidepressant treatment, was the subject of a 450-word story in 2019[10,11].

The third media outlet category covered in this paper is Mainstream Media. This is composed of news organizations with large mass audiences, to which they provide information relevant to their interests. While Mainstream Media has not generally covered the biotechnology industry, there are exceptions. On March 19-20, 2019, the mainstream coverage following the FDA approval of Zulresso from Sage Therapeutics was exceptional[12]. Coverage included a front-page story on the

New York Times, segments on ABC's "Good Morning America" and NBC's "Today Show", and an on-air feature on NPR's "All Things Considered". A detailed analysis of the total media coverage can be found in the article "When an FDA Drug Approval Makes Mainstream News".[13]

In terms of mainstream audience reach, the New York Times has 1 Million paid print subscribers and 3 million paid digital subscriptions. Its website draws 50 Million average visits monthly, providing yet another example of the growth of online media consumption[14,15]. ABC's "Good Morning America" and NBC's "Today Show" together are viewed by over 8 Million viewers, and "All Things Considered" from NPR has 14 Million weekly listeners via radio, and more in podcast form[16,17].

It should be noted that audience statistics for all media outlets, and programs within those outlets, often use different measures in terms of days, weeks and months. Also, many fail to distinguish between total visits versus the *unique* visits during that same time period. Still, the published statistics do serve as an indicator with regard to audience size.

Table 1 lists exemplar media outlets in each of the media outlet categories.

THE 2020 MEDIA LANDSCAPE

There are four essential differences between the media landscape in 2012 and today, which must be represented in any new media model.

Table 1: Media Outlet Categories

Media Outlet Category	Exemplar Media Outlets
BioIndustry	FiercePharma, Endpoints, Xconomy, Medscape, BioWorld, EvaluatePharma, BioPharma Dive
Financial Markets	CNBC, Wall Street Journal, MarketWatch, Barron's TheStreet.com, Business Insider, Yahoo!Finance, Investor's Business Daily
Mainstream Media	Washington Post, New York Times, National Public Radio, Good Morning America, The Today Show, USA Today, Newsweek, Fox News, PBS NewsHour

The Expansion of Traditional Media into Online and Social Media Venues

A television program once had viewers, newspapers and periodicals had readers, and radio programs had listeners, but no more. Now, for any program or media outlet, there are media consumers, and media may be consumed in many different forms. The PBS Newshour is a clear example of how traditional media has extended into the online space. Originating as a half-hour daily television newscast in 1985, it became a full-hour program in 1993. It continues to air on public television stations, with its audio track airing as well on public radio stations, both nationally and globally. The website for the PBS Newshour has 5.5 million unique visitors each month, but this does not fully describe the online and social media reach of this traditional, longstanding television program[20].

On Day 2 following the FDA's announcement of its approval of Sage Therapeutics' Zulresso, the PBS Newhour published a YouTube page covering its on-air seven-minute segment[21]. The page offered the video segment itself, links to its Facebook, Twitter, Instagram and Snapchat accounts, links to newsletters and podcasts, and, later, a link to a written transcript of the segment[22]. There was also the opportunity to join the 1.1 million YouTube subscribers already enrolled. No links were present connecting to schedules where you might watch the PBS Newshour on your local public broadcasting station, nor was there any suggestion that you could do so.

The extended list of online and social media options is emblematic of the "push" and "pull" of online media. Clicking on a link for a written transcript "pulls" the transcript to the media consumer on-demand. Signing up as a follower on Twitter, enables the PBS Newshour to "push" content out to the media consumer. While crowded, this menu fosters the pushing and pulling of content however the consumer wants, and in more forms than any one person would choose to consume. Still, this is the current signature of interconnected social media today, providing multiple online options at every online access point.

Also, what gets posted online is strategic. Whenever text is posted, search engines can "crawl" and index the content, making it word-for-word searchable. As yet, search engines do not transcribe the language content of audio or video, so until then, "tags" or the accompanying text are all that can alert search engines of the existence of online material. In this case, the transcript of the PBS Newshour Zulresso segment, may lead a media consumer (including journalists seeking background and quotes) to all the multiple online media options.

Online-Driven Publication Schedules

Another transformative aspect combines media consumer expectation with the available technologies needed to deliver the content. In the past, newspapers and periodicals needed to be printed and then physically distributed. Television and radio programs needed to be delivered to meet local broadcast schedules. Today, 24/7 ready readership online means that the posting of content cannot wait. If a media news outlet does not post in a timely fashion, another one may become a consumer's media outlet of choice.

It is this consumer-technology phenomenon which has led to a distinction between the digital and print editions of the same publication, and the posting of a vetted transcripts at a later time than the posting of a video [22]. In the Zulresso case, the FDA published its approval in a press release at 5:53PM on March 19, 2019, the New York Times published a previously-researched and polished 1,500-word article online just under two hours later at 7:45PM. This article appeared in print on the front page of the New York Times the following morning. While printed in the March 20, 2019 edition, the story continued to carry the March 19th dateline[23]. Instead of the print edition driving what is published online, it is now reversed. Online drives print.

Secondary & Tertiary Distribution of Bioenterprise-Driven Content

One solution many online sites have used to meet the demand for fast and accurate information in the minutes and hours after a news event is to immediately post press releases sent by paid distributors, such as PR Newswire and Business Wire. These two companies, for example, have been in business for some 70 years, and so clearly, the demand for the distribution of accurate information is not new.

In the case of the FDA's announcement of its approval of Zulresso, on March 19, 2019, the FDA itself issued a press release via PR Newswire at 5:53PM[12]. This was followed one hour later by Sage Therapeutics issuing its own press release at 7:00PM over Business Wire[24]. The media response started slowly with the FDA release, but within a 20-minute period of the Sage release, the Sage Therapeutics' own material was posted word-for-word by the Associated Press (AP), Barron's, MarketWatch, TheStreet.com and Yahoo!Finance. This Yahoo!Finance posting was in fact its second posting of the night, having previously posted the CNBC announcement earlier in the evening. Knowing who will repost information directly, and who prefers to create its own original source material, is essential strategic media relations information.

Another important distribution network is made up of the media consumers themselves. They can repost anything they choose on multiple online and social media platforms, providing the potential for significant tertiary distribution. While the bioenterprise cannot control this distribution, relevant information is presumably being moved through a large, interested audience.

Of course, when information can flow unedited over a volunteer network, information can be positive, negative or just plain incorrect. Thus, the bioenterprise must anticipate adverse information, as well as misinformation. Being prepared with effective materials, press releases, quotes from CEO's, experts willing to speak, media platform-ready copy reflecting a variety of scenarios, etc. is an essential part of delivering fresh information when it's needed, and improving the chances of driving all media toward a favorable perception of the bioenterprise.

Potential for Mainstream Media Interest

The FDA announcement of a drug approval is most often limited to Bioindustry and Financial Markets Media, but even this coverage requires effort on the part of the bioenterprise. Of the 59 novel drug approvals in 2018, the FDA only issued a press release announcing its approval in 24[25]. Whether with or without an FDA press release in play, corporations frequently issue their own via a paid distribution service. Still, a press release does not guarantee press, but it can often be the trigger.

When Mainstream Media has been given notification in advance of an FDA announcement, they can prepare. Such was the case with Zulresso. As a comparator, in 2018, Aimovig from Novartis and Amgen received mainstream attention, but to a somewhat lesser extent. The Bioindustry and Financial Markets media coverage were essentially comparable to Zulresso's, with Aimovig receiving a longer Wall Street Journal article in its Health section. However, its New York Times print story appeared on page A13. (Page A1 is the front page.) Dr. Sanjay Gupta did not cover Aimovig until the afternoon, reducing its replay potential, and NPR had an online entry in text, but no on-air coverage.

One major question is: How could the mainstream response be so different? Part of the mainstream success of the Zulresso story might be attributed to the fact that no substantive newsworthy events developed during the 24-hour cycle leading up to its FDA approval announcement, nor during Day 2. There were no competing top stories. In contrast, the day before Aimovig's FDA approval announcement, significant national news broke and remained newsworthy for several days. This

arguably reduced the level of mainstream attention even possible for all other stories. What is carried as "top of news" had the same space and time daily. Which stories fill the top slots is a daily competition.

These two recent examples, however, do demonstrate that bioindustry news can also be mainstream news, and thus, it is considered in the new media model. Proactive media preparation can lead to exposure in Mainstream Media, which can make the public aware of its products and complement its marketing efforts. It can also increase the perception of value with respect to its publicly-traded stock.

Of course, there are potential downsides. Mainstream audiences also view news in a social context, and this can evoke significant negative public response. Consider the public outcry after Martin Shkreli increased the price of the drug Daraprim by 5,000 percent in 2015[18]. Several years later this was followed by his conviction and sentencing on fraud concerning another pharmaceutical company[19]. It is unclear if the general public makes the distinction between an opportunistic act of greed with respect to pricing a half-century old drug, and pricing which reflects the cost of human endeavor and financial risk required to develop truly novel and breakthrough treatments. Regardless, mainstream coverage invites damage potential – to the biotechnology industry, to individual companies, and to bioprofessonals. And such issues as biopharmaceutical pricing will remain sensitive for as long as it is unfathomable to the average person.

BIOENTERPRISE MEDIA MODEL 2020 – TECHNOLOGY AND TRUST

In addition to the drivers of the new 2020 model described earlier, one more area has been explicitly added: Trust. When media fails – be it in the relationship between bioenterprise and the media outlets, or between the media outlets and their audiences, it is a failure of trust. Thus, the actions – and reactions – of the bioenterprise, must first build and maintain trust. Trust has been added as an explicit part of the strategic bioenterprise media model, and whenever it breaks down and in whatever way, the bioenterprise must be ready to act.

There are two areas in SBMM 2020 where trust is essential. First, the source information which all media outlets draws from must be trustworthy. The bioenterprise must be committed to the trustworthiness of its own information. This includes all information that it publishes, from press releases to the communications of its C-level officers and scientists, to peer-reviewed journal articles from its scientists, and more. Also, the bioenterprise must be trustworthy in terms of anything that it provides while undertaking public relations campaigns. A misstep by any of the above can label all information provided by the bioenterprise as unreliable. In the worst case, it can invite an unflattering story covered by media, in and of itself. Thus, trust starts with the bioenterprise, and then it is carried forward through the media model, and ultimately to the media consumers who choose the media outlets they trust. Even so, the bioenterprise cannot control the trustworthiness of other external information, nor can it control what media outlets produce. Every effort must be made to ensure that external sources are informed, and that media outlets have appropriate and timely information.

Figure 1 depicts the Strategic Bioenterprise Media Model 2020 (SBMM 2020).

SBMM 2020 – Mainstream Media Submodel

Given the importance of Mainstream Media coverage, a more detailed submodel has been developed. For one reason, Mainstream Media exposure is also challenged by the volume of what it must produce on a daily basis. In 2016, the Atlantic published an analysis of the daily output of several news media outlets[26]. The Washington Post, counting both original content and wire stories, "publishes an average of 1,200 stories, graphics and videos per day"[26].

The New York Times publishes some 150 original content pieces per day, save Sunday, when it publishes 250. Over 300 multimedia graphics also appear each month, in addition to blog posts, "interactives", and some 200 Associated Press and wire stories, which add to its online presence. The print edition of the New York Times remains unchanged in terms of physical size, which publishes almost entirely original content plus approximately 13 wire stories in every print edition. On its front page, the New York Times print edition carries six stories each day, four of which are "above the fold", and 12 abbreviated news stories at the bottom along with their location within the paper.

To frame the good fortune of the Zulresso coverage, in the past five years, only one other FDA approval received a front-page story in the print edition of the New York Times. On November 19, 2015, the headline read: "Genetically Engineered Salmon Declared Ready for U.S."[27] While its website does not have the size of the print edition, the priority in the print edition is an indicator of the positioning of the story as it is presented to online visitors.

Figure 2 depicts the submodel for bioenterprise media strategy as it relates to Mainstream Media. In print, the contact which is generally made regarding a story is a journalist. In radio and television, the contact often starts with a producer. This can vary through all

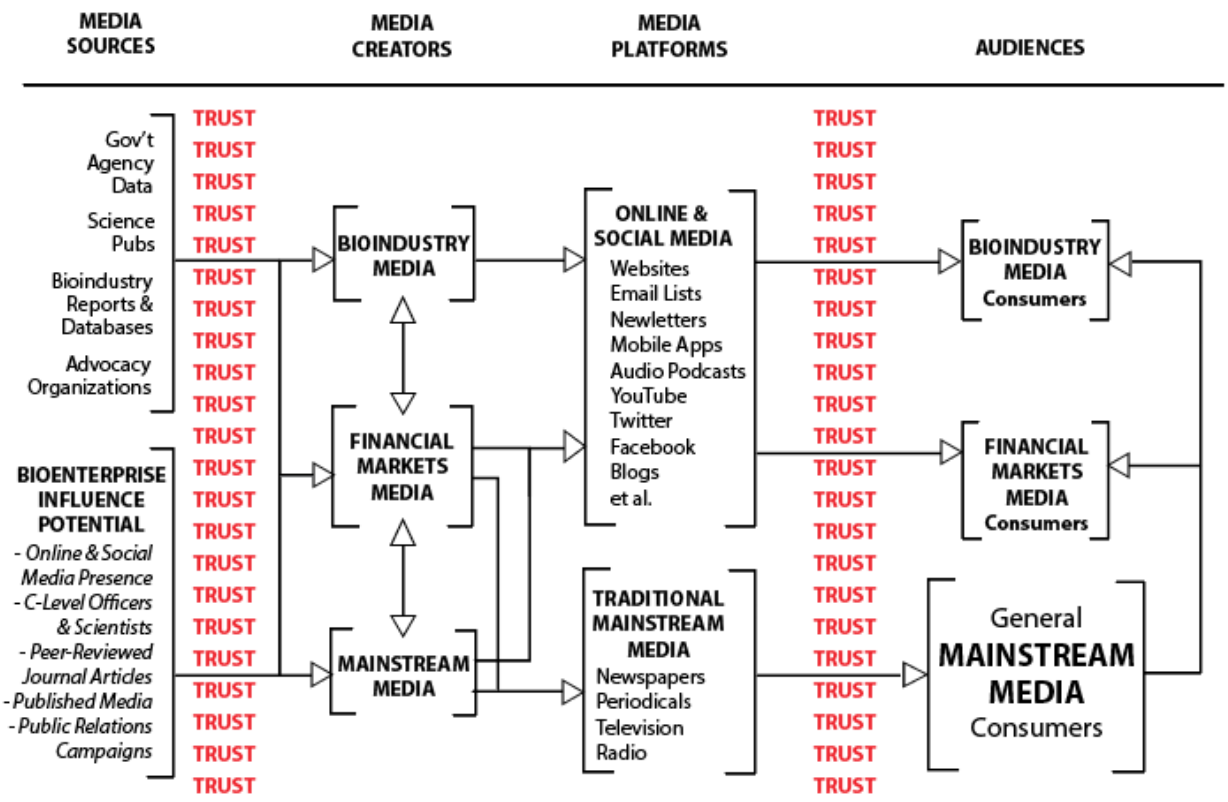

Figure 1: Strategic Bioenterprise Media Model 2020 (SBMM 2020).

media outlets. The media content contact and/or creator have been identified as journalists and producers for purposes of the model.

BIOENTERPRISE PREPAREDNESS

All of the elements described in Figures 1 and 2 can be put into play, and there can still be challenges to achieve successful outcomes in the Mainstream Media.

Use of Scientific and Technical Terms Relevant to the Mainstream Audience

Biopharmaceuticals are typically described as "biologics" which are "large molecules" which need to be "infused" at infusion centers or hospitals. Dr. Sanjay Gupta described the biopharmaceutical Zulresso as an "IV drug".[28] The language of the biotechnology industry is not the language of the mainstream audience. Every element of the story must be comprehensible by the mainstream audience.

Development of Media Relationships

Press releases and email pitches are the two primary ways that journalists and producers are communicated the potential for stories (and guests). The journalists and producers do not read every email or press release sent to them. They are most likely to respond to someone with whom they have a trusting relationship. These can be people within the bioenterprise and/or external public relations professionals.

Furthermore, the timing of an FDA approval is substantially anticipated following the input of any advisory panels. This gives public relations professionals time to work with journalists and producers well in advance of the approval. Once the approval is announced, there is no time to develop the story beyond what is immediately available. Shortly, it will no longer be news.

Identifying Media Outlets with Viral Reach

Aside from considering the audience reach of a target media outlet, assessing its viral reach is a complex undertaking. A number of organizations provide these analyses with respect to individual media outlets. Turbine

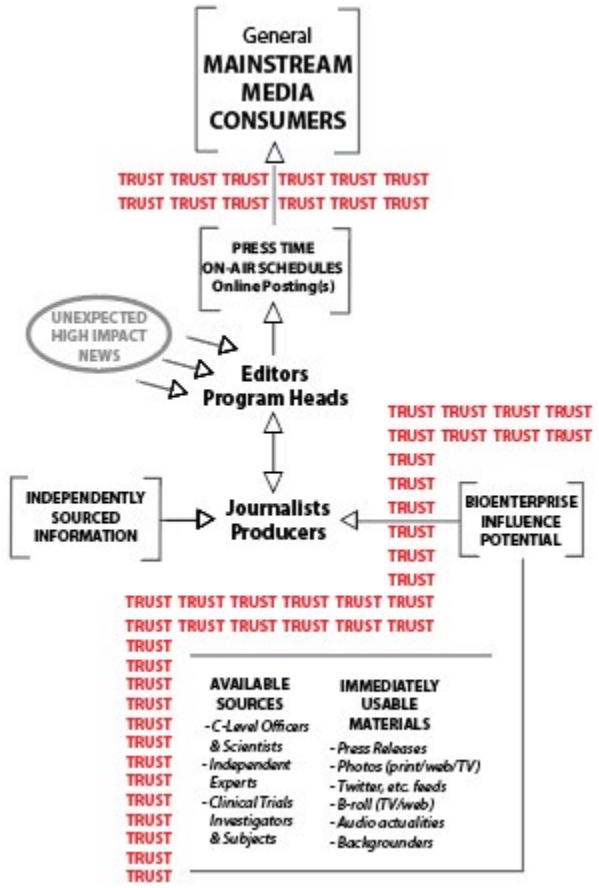

Figure 2: SBMM 2020 – Mainstream Media Submode.

Labs published its most recent "The Ten Most Viral News Sources" list on March 28, 2018[29]. The Zulresso story was covered in all seven of the top seven media outlets identified current; Aimovig was covered by five, although some in a less prominent position. See Table 2.

Building The Mainstream News Story

There are no guaranteed formulas for creating successful mainstream news stories, although searches of both the professional and academic literature reveal anywhere from five to eight essential elements. Common are Timing (happening today), Proximity (issue is important to the audience), Significance (percentage of audience affected), Prominence (inclusion of famous or known people), Human Interest (emotional reaction), Uniqueness (story different from others), Conflict (everything is not resolved), and more.

Still, the work of neuroeconomist Paul J. Zak is helpful to getting to the core of what makes a good story – newsworthy or otherwise. In his 2014 Harvard Business Review article, "Why Your Brain Loves Good Storytelling", he writes: "a story must first sustain attention by creating tension during the narrative".[30]

Table 2: Turbine Labs: Ten Most Viral News Sources

Rank	Media Outlet
#1	Yahoo!
#2	New York Times
#3	CNN
#4	Fox News
#5	National Public Radio
#6	Washington Post
#7	USA Today
#8	BuzzFeed
#9	The Guardian
#10	British Broadcasting Corporation

Source: Turbine Labs, "Ten Most Viral News Sources", March 22, 2018[29]

Consider the Zulresso story: There was finally an available drug for mothers with postpartum depression (first conflict – mothers, newborns, depression), and then there were still two more surprises: The IV treatment took 60 continuous hours, and it cost $34,000. That might count as two or even three more conflicts, since there was not yet time for insurance companies to say if they would cover it. There was at least one shock for everyone in this story, and sometimes three and four, which brings home the point that a story is not a recitation of facts. To borrow from Paul J. Zak, a story needs to create tension while it is being told. For the bioenterprise, the focus of the story they want to tell Mainstream Media now moves from the science, the funding, and their successes along the way … to the experience of being human.

CONCLUSION AND DISCUSSION

The commercial benefits of reaching the BioIndustry and Financial Markets media have been understood for some time; however, the extensive employment of online and social media in the current media landscape is unprecedented. As to the benefits to the bioenterprise as a result of Mainstream Media attention, there has been insufficient activity to enable general metrics. Even so, Mainstream Media attention is now a reality, and so it has been included the Strategic Bioenterprise Media Model (SBMM 2020) and a Mainstream Media Submodel.

Still, there are challenges. The task of communicating the scientific basis for a value proposition, and then the scientific differential from the previous available product, is not generally of interest to the mainstream audience. Recalling Dr. Gupta's use of the term "IV drug" instead of the cumbersome

large-molecule-biologic-needing-infusion suggests that bioenterprise must work to find a viable mainstream vocabulary, and one which relates to everyday experience.

Yet, while only a few bioenterprise stories have gained mainstream coverage, there is reason to believe that others can also be successful. Biopharmaceuticals, in particular, directly impacts the human condition, and where there is human impact, there is the likelihood for a human story, be it patients, scientists, the suffering or triumph of the vulnerable, and more. Furthermore, the biopharmaceutical pipeline is significant. As reported by Genia Long of the Analysis Group in the 2017 report "The Biopharmaceutical Pipeline", there are more than "6,300 products in clinical development globally" and "approximately three-quarters (74 percent) of clinical-phase projects were potentially first-in-class".[31] This suggests that there will be a steady influx of new products and new stories to be told, many of which can be made relevant to the Mainstream Media audience.

DISCLOSURE

In addition to being a professor of bioentrepreneurship at the University of San Francisco, the author is a professional journalist. She produces and hosts Tech Nation, and its regular segments in the areas of biotechnology and health, which airs on the NPR Channel on SiriusXM, among other venues. While Tech Nation examines the impact of breakthrough science and emergent technologies for the mainstream audience, it does not cover breaking news.

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Many thanks to the public relations professionals, who work in and with bioenterprise, to make scientific concepts understandable to the everyday person, to relate that science to value, and to create stories that are both newsworthy and mainstream.

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Article

Post Financial Crisis Transaction Trends of U.S. Biotechnology Firms

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ABSTRACT

Transactions announcements can signal the health of an industry. This article examines all biotechnology transaction announcements occurring in the U.S. between 2010 and 2017. A baseline comparison to the pre-financial crisis transaction announcements of 2002 through 2006 is provided. Our study finds a significant rebound in the number of transactions during the time of study and continuing shifts by those on both ends of the transactions.

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Keywords: Transaction announcements; Knowledge transfers; Post financial crisis

INTRODUCTION

The transfer of knowledge and technology in the biotechnology industry has been of interest to practitioners, governments, and scholars for decades [1]. This is due to the continued growth in need to access resources and capabilities in this industry from outside the firm [2–4]. These transfers have taken several different forms (i.e., collaborations, firm acquisitions, etc.)[5], and involved several sectors of society—from the university to the financial industry [6]. It has been noted that these transactions were affected by the financial crisis in the U.S. [7, 8], which lasted from December 2007 through mid-year 2009 [9]. For example, within the biotechnology industry there was a reduction in financing of firms via initial public offerings [10], venture capital investment [11], as well as out-licensing arrangements [12]. These and other financing issues led biotechnology firms in many cases to reduce or discontinue research and development programs during this time [7].

This article examines U.S. biotechnology transaction announcements after the recent financial crisis. The study compares post financial transactions to a five-year pre-financial crisis aggregate. It reviews inter-firm transaction announcement activity surrounding the location (e.g. U.S., foreign), type of firm (e.g. private, publicly-traded, non-profit), and form (e.g. collaboration, firm acquisition, license, etc.) of these transactions. This is important as the fluidity of transactions, in part, may positively affect the economic health of these firms and the biotechnology industry in the U.S. and abroad [13]. It focuses on biotechnology firms transferring knowledge because: 1) biotechnology represents a paradigm shift in drug discovery and development [14]; 2) there are few transactions from pharmaceutical firms to biotechnology firms; and 3) biotechnology firms typically lack the resources and leverage in transfer negotiations with larger pharmaceutical firms [15].

METHODS

This article is based on data derived from biotechnology transaction announcements from January 1, 2010 through December 31, 2017. It also at times (when data are available) shows a baseline comparison to pre-financial crisis transactions occurring from January 1, 2002 through December 31, 2006. It uses a database compiled by Levin and Associates. The primary sources for the announcements are from PR Newswire, PE Hub, and Seeking Alpha. The data reflect transactions where the originating firm is a biotechnology firm (i.e., pharmaceutical firms transferring technology or knowledge are excluded). The data reflect transactions only where either the transferor or transferee is a U.S. based firm. For our post financial crisis analyses, there were 897 separate announcements, of which 892 were usable. There

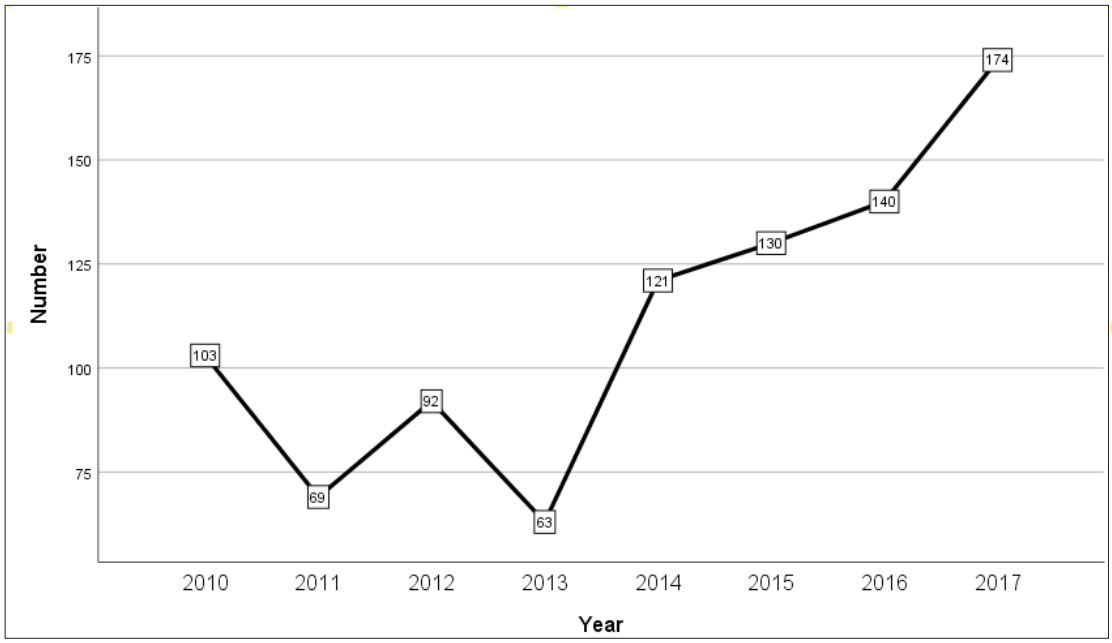

Figure 1: Transaction Announcements by Year.

are 370 announcements in the comparison data years (2002-2006).

The transactions differ from other sources in that it does not separate different transactions related to a given announcement. For example, if a biotechnology firm announces in one press release that it has entered into multiple licensing arrangements with another firm for multiple products, then this is considered one transaction. In a few cases, there were missing data for which the authors did an Internet search to complete the dataset. Based on a review of the announcement summary or an Internet search of the announcement, the authors categorized all transactions into the following groupings: collaboration agreements, collaboration and licensing agreements, product acquisitions, rights or licenses, merger or reverse merger, full or partial equity acquisition of the firm, spin-off, and sell of business line. Real numbers are presented in the figures. The narrative below uses both real numbers and percentages at times.

TRANSFERS BY YEAR, LOCATION, AND TYPE

Figure 1 shows the total number of transaction announcements by year. After swings up and down of up to 40 percent from 2010 to 2013, overall transactions steadily increase by 176 percent from 2013 through 2017 (Figure 1). Hence, the overall transaction market appears to have significantly rebounded from the financial crisis during the second half of the study. This compares with our baseline comparison years where from 2002 through 2006 there were 67, 89, 76, 68, and 70 transactions, respectively. Additionally, in the baseline pre-crisis years the average year had 74 transactions compared with 112 transactions on average post crisis—a 51 percent increase in transactions per year on average post crisis.

Figure 2A shows whether the transferring firm (transferor) was a U.S or foreign firm. Overall, 707 (or 79 percent) of the 892 transfer announcements were from U.S. firms transferring knowledge or technology to another firm. The percent of U.S. firms transferring knowledge or technology remained fairly constant at around 77 to 80 percent during this time. Figure 2B shows the transfer by country receiving (transferee) the transfer of knowledge or technology. Overall, U.S. firms received 673 (or 75 percent) of the transfers. This is the same as the baseline pre-crisis years (2002-2006) of 75 percent as well. Unlike U.S. firms transferring technology, there was greater variability in U.S. firms receiving knowledge or technology during the course of study—from 63 percent in 2010 to 86 percent in 2014. This similarly compares to our baseline pre-crisis years in which the U.S. firms saw a low of 66 percent in 2005 and a high of 83 percent in 2003. Additionally, overall, only 488 (or 58 percent) of the 892 post crisis transfer announcements involved U.S. firms both as transferor and transferee. This is to say that 42 percent of the time either the buyer or seller was a foreign firm. The year 2010 was the peak year at 57 percent for both the transferor and

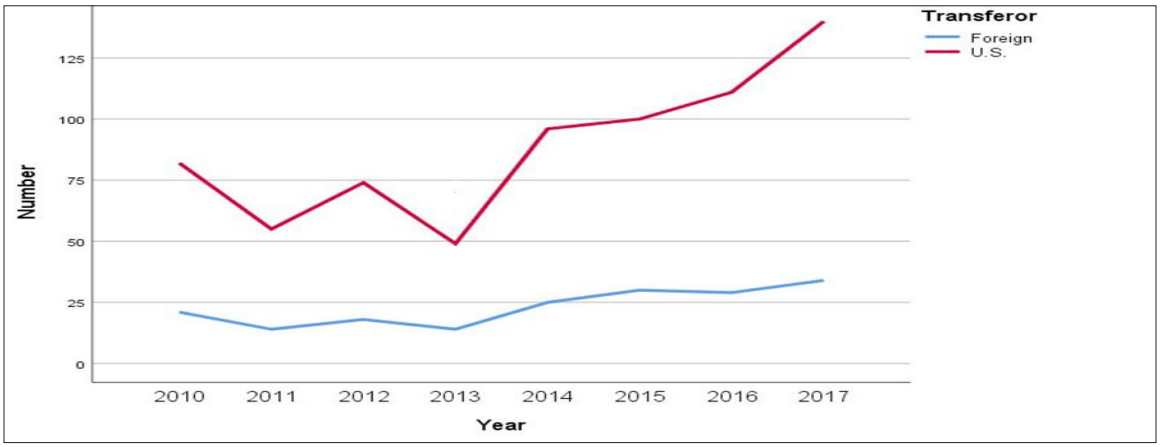

Figure 2A: Origin of Firm Generating Transaction.

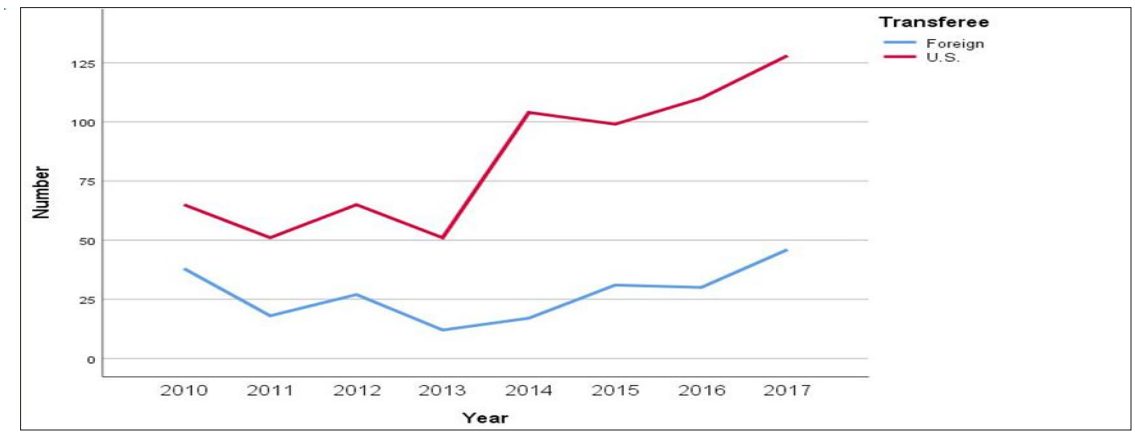

Figure 2B: Origin of Firm Receiving Transaction.

transferee to be a U.S. firm, with 2014 being the low year at 35 percent for both firms being a U.S. company.

It also is important to know which type of firm (e.g. private, publicly traded, or non-profit organization) is transferring knowledge or technology. Figure 3 illustrates these transactions by type of transferor. As one would expect, overall, 61 percent of the time the firm transferring was a private firm. This is similar as our baseline pre-crisis comparison years of 60 percent. Private firms typically transfer knowledge or technology in order to receive funding for other efforts. This compares with overall transfers of 34 percent and 4 percent for publicly traded firms and non-profit organizations, respectively. Our baseline pre-crisis transfers overall had 38 percent and 2 percent for publicly traded firms and non-profit organizations, respectively. However, there is great variation in transfers by type of firm over time. Private firms showed a low of 48 percent of transfers in 2017 and a high of 72 percent in 2012. This is similar to our baseline pre-crisis comparison of a low of 53 percent (2003) and a high of 71 percent (2004). In 2015 post crisis publicly traded firms saw a low of 27 percent. The high year was 2010 with 46 percent of transfers. Perhaps most interestingly, non-profit organization had two years (2010, 2012) of no announcements; yet in 2017 represent 13 percent of all announcements as transferors.

Figure 4 shows the type of firm receiving (transferee) the knowledge or technology. Overall, about 25 percent of the time, the firm receiving the transfer was a private firm. This compares with 74 percent of the time the transferee is a publicly traded firm and less than 1 percent of the time the transferee is a non-profit organization. Our baseline pre-crisis years show that 80 percent of the time the transferee is a publicly traded firm, 20 percent of the time the firm is a private firm, and less than 1 percent of the time the firm is a non-profit. For our post financial crisis years, the last three years of the study sees a shift in transferee on a percentage basis. At the expense

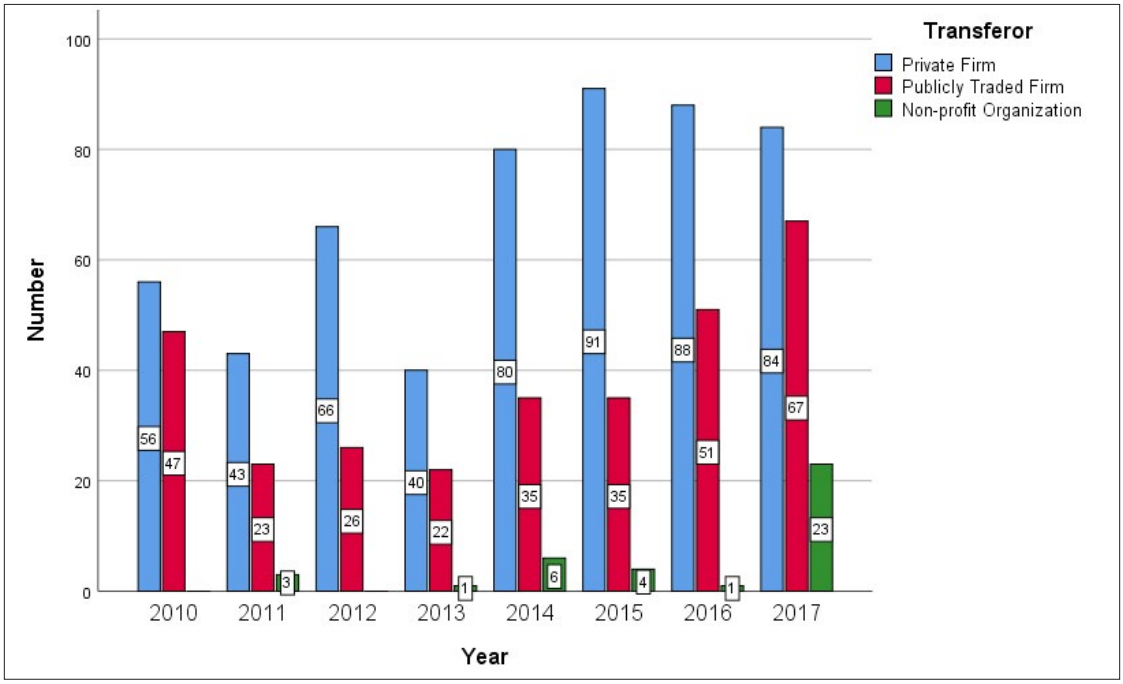

Figure 3: Type of Firm Transferring Technology or Knowledge.

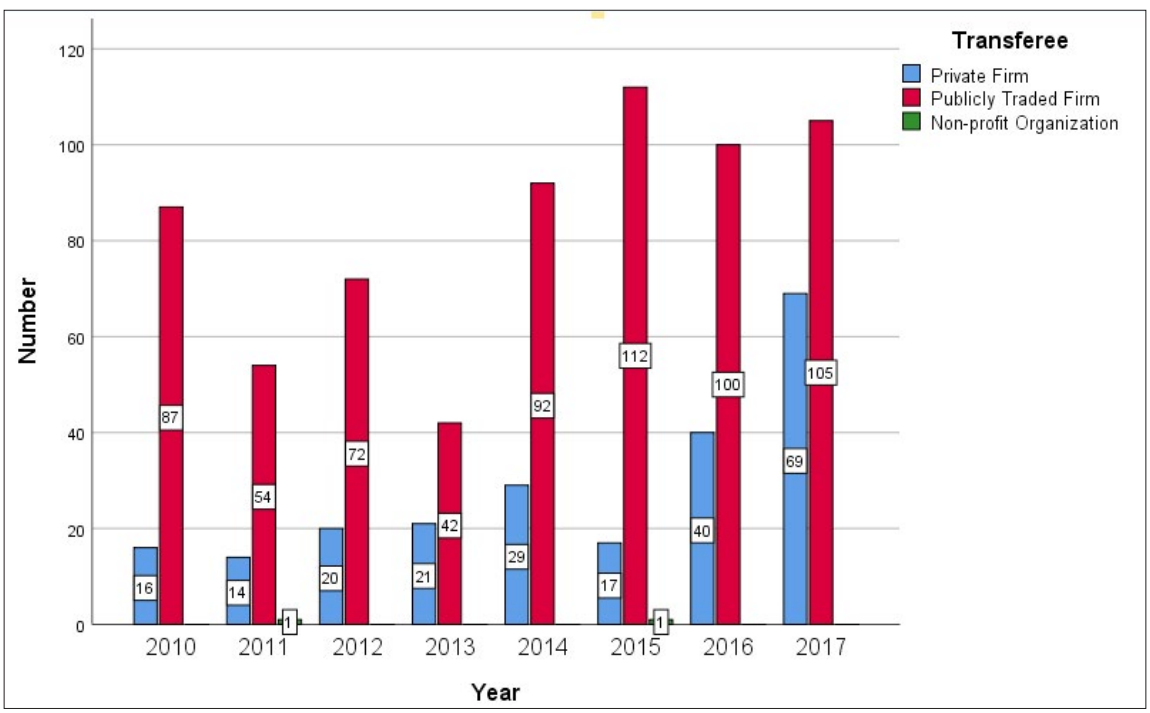

Figure 4: Type of Firm Receiving Technology or Knowledge.

of publicly traded firms, private firms increase from 13 percent in 2015 to 40 percent in 2017.

Figure 5 illustrates whether the firm receiving the knowledge or technology (transferee) was a biotechnology, pharmaceutical or other type of firm. Other types of

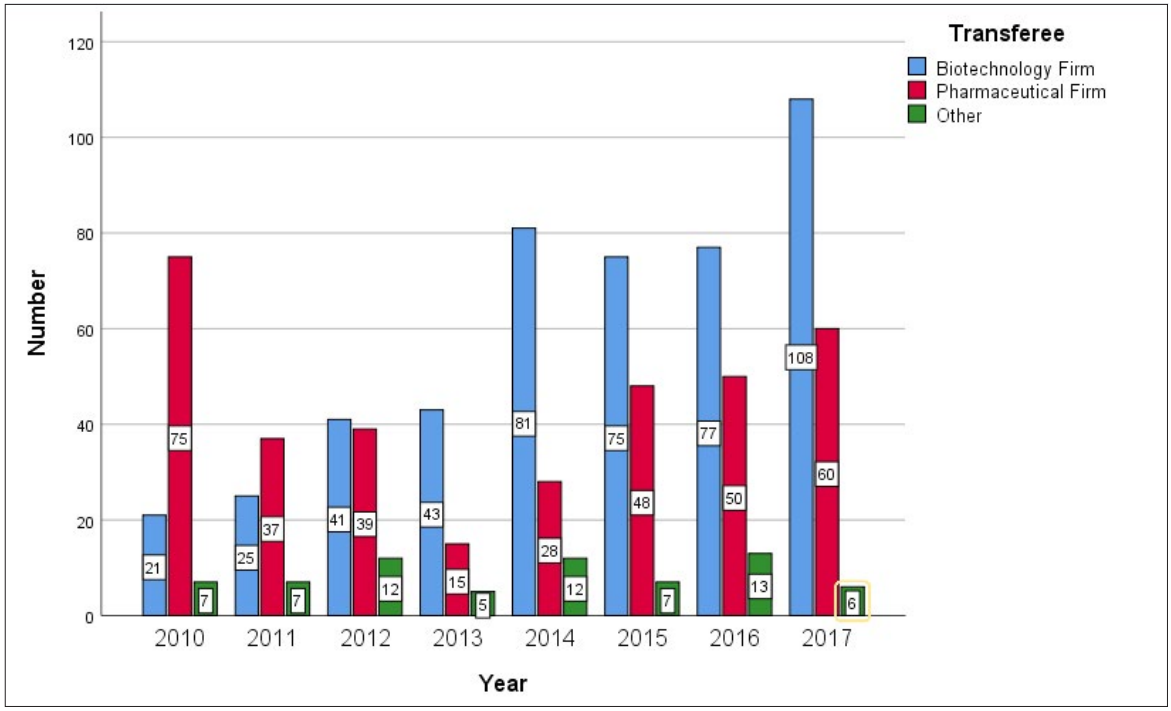

Figure 5: Biotechnology Firm or Pharmaceutical Firm Transferee.

firms include medical device makers, informatics firms, and private equity firms. These data are not provided in our baseline comparison years. Overall, biotechnology firms represented 53 percent of the firms, followed by pharmaceutical firms at 39 percent, and other firms at 8 percent. Interestingly, pharmaceutical firms in 2010 represented 73 percent of the transferee firms, but ended at 34 percent in 2017. It should be noted again that the study does not include pharmaceutical technology or knowledge being transferred. Nevertheless, the increase in real numbers and on a percentage basis of biotechnology firms transferring knowledge and technology to other biotechnology firms is significant and shows that the market for biotechnology is changing away from one dominated by pharmaceutical firms as the transferee. Thus, during this time period, there appears to be increasing development of an inter-industry market (i.e., biotechnology-biotechnology) as compared to an intersector market (i.e., biotechnology-pharmaceutical).

TRANSFERS BY FORM

Figure 6 illustrates the form of transaction overall and by year. Each transaction announcement summary was read and categorized. The largest category overall post crisis was rights or license agreement announcements. As it was difficult to distinguish at times between a transfer of rights and a license (i.e., non-exclusive), the two forms were combined. These represent almost 37 percent of all announcements during the eight-year period (2010-2017). An example of this is Halozyme's granting a license for rHuPH20 to Intrexon. This compares with our baseline pre-crisis years (2002-2006) of licensing arrangements representing only 19 percent. Full or partial equity acquisition was the second largest form post crisis. Here, firms typically are acquiring the equity of another firm to gain access to not only technology, but also the tacit (non-codified, know-how) knowledge that resides within individuals [16]. An example of this is Sanofi's acquisition of Genzyme. For our baseline pre-crisis years (2002-2006), acquisitions represent the largest form of transaction at 41 percent. The third highest percentage post crisis resides with collaborations, with this form representing almost 11 percent. An example of this is Isis Pharmaceuticals entering into a collaboration agreement with GlaxoSmithKline to develop and commercialize microRNA therapeutics for rare diseases. Mergers and reverse mergers represent over 4 percent. For our baseline pre-crisis years (2002-2006) mergers and reverse mergers represent 10 percent. The remainder represents collaborations and licensing arrangements, product acquisitions, and spin-offs. These last three areas represent about 7 percent of all transactions collectively post crisis.

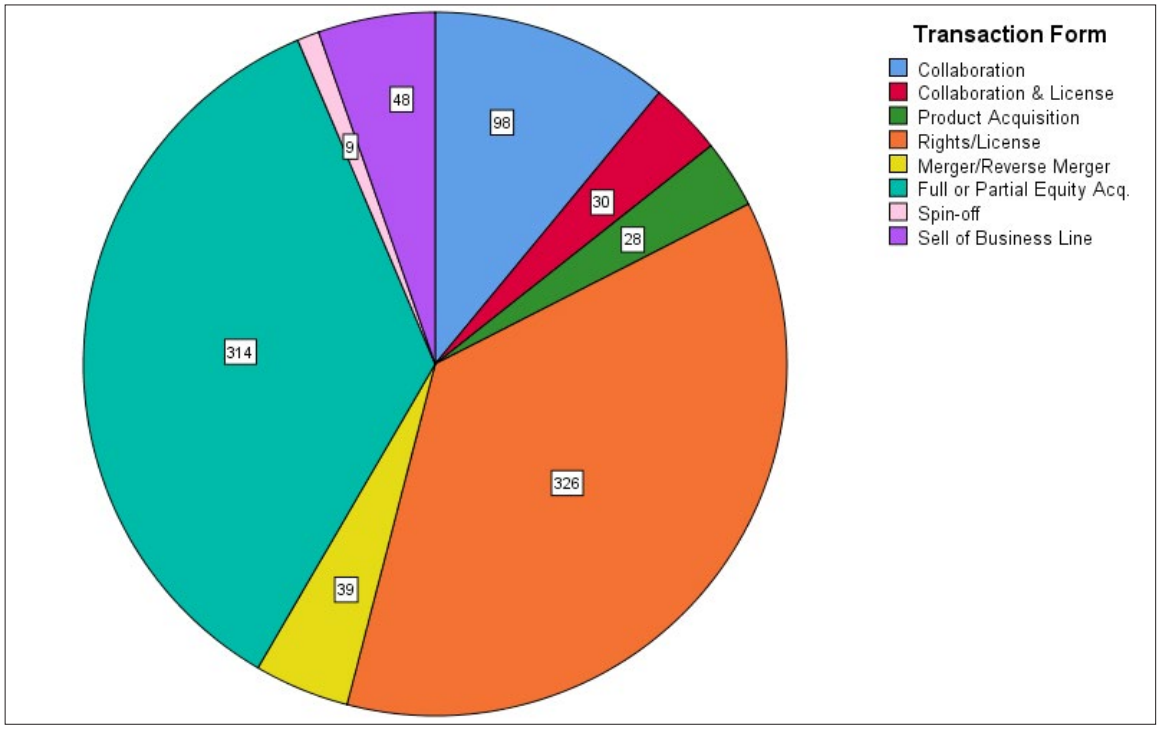

Figure 6: Form of Transaction (2010–2017).

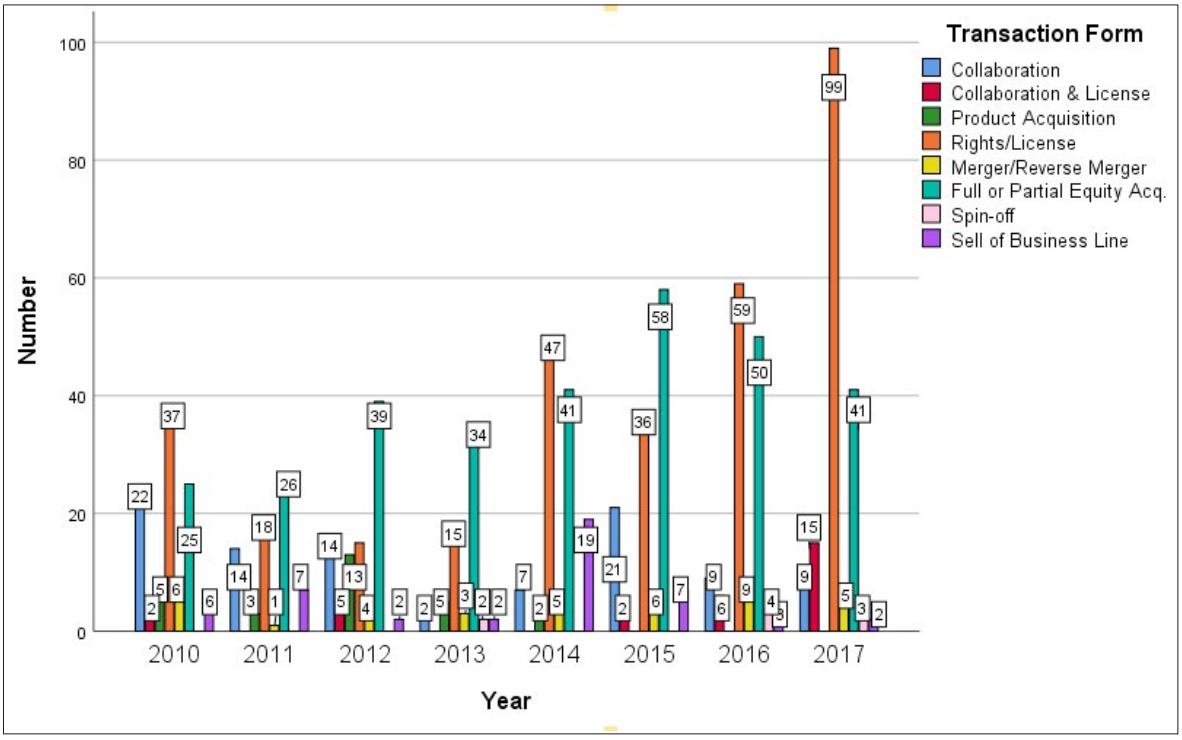

Figure 7: Form of Transaction Over Time.

In examining the form over time, one immediately sees the dramatic increase in licensing arrangements over the last few years of the study. This is shown in Figure 7. Indeed, licensing represents 28 percent, 42 percent, and 57 percent of total transactions per year in 2015, 2016, and 2017, respectively. Percentage-wise, this mainly comes at the expense of full and partial equity acquisitions during this same time period. Whereas, equity acquisitions increase from 24 percent to 54 percent of all transactions from 2010 to 2013, they decline to 24 percent by 2017. Yet, both licensing and equity acquisitions have greater numbers of transactions the last three years of the study than other years, collectively. Both the increase in overall numbers and the shift percentage-wise toward licensing during the later part of the study may be due to an improvement of financial markets (e.g. venture capital, IPO) that are available to biotechnology firms, with licensing typically a more preferred method of financing than equity acquisition.

CONCLUSION

Market activity at times can be an indicator of the health of an industry. Biotechnology firms have relied on markets in the various forms noted in this article to gain access to knowledge, technologies, and capital. The financial crisis of 2007-2009 in many regards stagnated these markets and thus the biotechnology industry. The present article has shown that to a large extent the market for biotechnology transfers has not only recovered, but also flourished with activity. It has also shown that post financial crisis there has been a recent shift within this market with respect to the growing global nature of these transfers.

Perhaps, the most important aspect relates to the increased activity of private firms and biotechnology firms receiving knowledge and technologies (i.e., being transferees) at a greater rate during the later stages of the study. This, combined with the recent increase in licensing agreements on a percentage basis, points to a more developed biotechnology transactions market and one lessening its reliance upon pharmaceutical firms for financing, with these firms, perhaps, being able to go further to bring products and technologies on their own than in years past [8]. Further research is needed to understand the scope of the apparent lessening of dependence of these firms.

The study is not without limitations. First, although the study is consistent in its method, it is not very fine grained as it examines transaction announcements and does not disaggregate the various elements in each announcement. Likewise, the study does not follow the different segments in the market due to the difficulty to at times categorize firms that pursue multiple diseases, treatment modalities, or applications. Nor does the study address potential distortions in the market via different segments movements (e.g. gene therapy and cancer immunotherapy). Additionally, the authors did not have access to data during the crisis. It would be interesting to compare these crisis (2007–2009) data to the pre – and post financial crisis results. The study only examines U.S. firms transferring knowledge and technologies and thus, does not study the amount, type, or effect of other countries' transfers on U.S. transfers. Nor did it study transfers originating from pharmaceutical firms. It would be insightful to compare pharmaceutical firm to biotechnology firm transfers over time. Further research is needed in these areas.

Nevertheless, the study verifies that the transaction market has rebounded and matured. It appears to have shifted away from one mainly reliant on established, publicly traded pharmaceutical firms to a transaction market with a more global reach and more driven by biotechnology firms themselves.

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