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Success Factors in Product Licensing in the Pharmaceuticals Industry

Identification and evaluation of factors influencing likelihood and financial value of a licensing deal

Master's Thesis in the Master's Programme
Entrepreneurship and Business Design

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Abstract

The pharmaceutical industry is facing a challenging situation with decreasing financial performance and declining R&D productivity. In the latest decade there has been a large increase in the number of externally sourced pharmaceutical programs and biotech-pharmaceutical collaborations as a way to increase the R&D productivity. Thus, licensing has become a crucial element of the business model in the pharmaceutical industry and a key activity for biotech companies. There exist gaps in the academic research regarding licensing in the pharmaceutical industry especially in relation to what drives the likelihood of a deal. This thesis has therefore focused on identifying and evaluating success factors in product licensing by conducting three in-depth interviews with biotech professionals and a questionnaire with 19 responders from biotech, mid-size and large pharmaceutical companies. The results from this thesis shows that qualitative success factors such as the *strategic fit*, *relationship* and the quantitative factor *scientific attractiveness* have the largest influence on the deal likelihood. Whereas quantitative success factors such as the *commercial attractiveness* is the main financial value driver, confirming the limited research that has previously been done in the field. In addition, *intellectual property* has been singled out as the main absolute requirement, or what we would define as a deal-breaker, in licensing negotiations. These results can assist biotech companies to develop and excel with their licensing activities and thus help them to grow in the industry.

Key Words: **Licensing, Success Factors, Value, Pharmaceutical, Biopharmaceutical, Biotech**

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Jimmie Hofman & Adam Niklasson

Gothenburg, May 23rd, 2016

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1. Introduction

This thesis will describe and evaluate success factors in pharmaceutical licensing activities and how these factors relate to increasing the likelihood of deal completion, driving the financial value and deal-breakers.

1.1 Background

The pharmaceutical industry has in the recent decade struggled with its financial performance and maintaining its former stellar R&D productivity. An analysis of the 15 largest pharmaceutical companies showed that the companies lost around $850 billion in shareholder value, from 2000 until 2008, and that the average share price fell from 32 to 13 times earnings (Garnier, 2008). Several challenges have had an impact on the industry's financial performance, e.g. patent expiration of several blockbuster drugs[1] shorter exclusivity periods, declining R&D productivity, higher cost of commercialization and increasing payer influence (Garnier, 2008).

Jean-Pierre Garnier (2008), former CEO of GlaxoSmithKline, among other industry experts argues that it is the declining in R&D productivity that is the main challenge for the pharmaceutical industry. Several scholars argue that the traditional business model in the pharmaceutical industry needs to evolve to solve the grand problem of a declining R&D productivity (Booth, et al., 2004; Paul, et al., 2010). The total R&D expenditure in the pharmaceutical industry has increased for several years all while the number of new approved drugs has been flat and according to a report from Bain & Company (O'Hagen, et al., 2009) the total R&D the cost to develop and launch a new drug have increased from $1.1 billion in the late 90's to the double $2.2 billion in 2009. While the actual cost of developing a drug is highly contested the trend of increasing cost is quite clear.

Traditionally mergers and acquisitions (M&A) have been the usual response as an effort to fuel the internal R&D pipeline. However, the results of M&A activities have not been able to increase the R&D productivity. On the contrary, a review of Ornaghi (2009) showed that companies that are very active with M&As actually perform worse.

An analysis of over 28 000 compounds, being investigated for use as therapeutic agents since 1990, by Pammolli (et al., 2011) showed that one of the reasons behind the decline in R&D productivity may be the fact that there has been an increase in riskier R&D projects. Targeting diseases where the likelihood of approval is lower but also where the market potential is larger. Another reason that has further facilitated the decline in R&D productivity according to Pammolli (et al., 2011) is the increase of new biotech tools, e.g. the genomics revolution. The new tools have increased the number of potential technologies that can create viable therapeutics.

The dramatic increase in availability of new inventions and technologies has made it impossible for a pharmaceutical company to have all technologies available for R&D activities in-house. A pharmaceutical company is therefore required to use external innovation to stay competitive. Chesbrough (2003) introduced the concept open innovation as a new paradigm where a firm can and should use both external and internal knowledge and ideas to accelerate internal innovation.

[1] Blockbuster drugs: Drugs having annual peak sales over $ 1 billion.

In the last decade the number of externally sourced drug programs in big pharma's pipeline have increased significantly. It is safe to say that drug development has transformed into an open innovation ecosystem where small biotech companies are the innovators and where the large pharmaceutical companies act as their commercialization partner.

For a small biotech company working in partnership with big pharma, licensing of drug programs is an essential part of the business model and thus also the industry ecosystem. Therefore, it is key for biotech companies to excel at licensing activities in order to achieve growth and become successful in the industry. This thesis aims to provide a better understanding of the nature of licensing in the pharmaceutical industry and to provide insights that can assist biotech companies in their licensing activities.

1.2 Purpose

The purpose of this master thesis is to identify critical success factors in a program out-licensing[2] activity in the pharmaceutical industry. Furthermore, the purpose is to categorize these success factors and evaluate the effect on a proposed licensing deal. The aim is to provide a better understanding of which success factors increase the likelihood of a licensing deal being put in place, and which factors drive the value of the licensing deal. In addition, the impact of the success factors will be evaluated in regards to each other in an effort to provide biotech companies with knowledge to better focus their licensing activities.

1.3 Problem Introduction

As mentioned in the background, excelling at licensing is key for the growth of a biotech company. Today there does not exist any theoretical frameworks for how licensing activities should be managed to be successful as a biotech company. It would therefore be of interest to know what the success factors are and how they influence licensing deals.

Licensing as a business phenomenon is by its nature a very secretive and non-transparent activity. Thus it is difficult for academics to gain a good insight into the industry and licensing activities. This might be one of the reasons why success factors for licensing in the pharmaceutical industry has not been extensively researched. Despite this, one area that has been explored is key factors for inflation of the financial value of a licensing deal.

However, the financial value is only one of many parts of a licensing deal. The likelihood of deal execution and factors that are absolute requirements are other aspects that would be of great interest for a biotech company to get a better understanding of, in addition to financial value drivers.

In line with the purpose of this thesis, the aim with this thesis is to expand on the current research and frameworks to identify success factors in licensing.

[2] Program out-licensing: Company A is transacting the rights of an internally development therapeutic pharmaceutical product (e.g. a small molecule or an antibody) to Company B for financial compensation (e.sg. royalties and smilestone payments) for further development and commercialization.

These success factors in a licensing deal can be divided into three subcategories: 1) success factors for increasing the likelihood of deal execution (both sparking initial interest and reaching a concrete offer e.g. a term sheet), 2) success factors that drives the financial premium value[3] of a deal, 3) success factors that are an absolute requirement for the deal (deal-breakers).

1.3.1 Success Factors for Increasing the Likelihood of Deal Execution

To set up a licensing deal is a complex and time-consuming task. The first obstacle is to get potential partners interested in the drug program. After having gained interest from a potential partner the next obstacle is to maintain the interest and to finally convince the partner that they need the program. In other words, that it is an attractive investment. If the partner wants the program it becomes a question at what value they want it but the decision that they want the program is to some extent independent of the valuation. For a biotech company it is important to know which success factors increase the likelihood of a deal execution by making potential partners interested and maintaining interest in the program and eventually reaching a concrete offer.

1.3.2 Success Factors that Drive the Financial Value of a Deal

The licensor must produce a convincing commercial case or "story" that supports a high valuation of the asset. There are several components of a commercial case and there are even more factors that influence the value of an asset. This can however be difficult to communicate.

At present however, there is no consensus on how to apply valuation in life sciences (Bogdan, 2007). Bogdan (2007) argues that is due to inconsistent description and application of valuation methods and input parameters. One framework for success factors in relation to deal value that this thesis is based on is an analysis from Kellogg School of Management, Northwestern University, in 2002 (Arnold et al., 2002). Arnold and her team has done one of the most comprehensive analysis of licensing deals in the pharmaceutical industry and what factors influence the deal value. They have shown that various financial valuation methods, e.g. discounted cash flow (DCF), do not explain the valuation of many licensing deals. Indicating that there are other qualitative success factors that a biotech company needs to be aware of to drive up the value of the deal.

1.3.3 Success Factors that are an Absolute Requirement for the Deal

The third type of success factors are factors that are considered absolute requirements for the deal. These factors are of a binary nature, as if these are not presence the deal would be non-existent. In contrast to value drivers and inherent to their binary nature, the presence of these factors does however not drive the value of the deal or increase the likelihood of deal completion. However, the presence of these factors creates a situation where deal completion is possible. Due to their binary status as deal enabler or disabler, they will hereby be defined as "deal-breakers". To know which factors are deal-breakers is arguably key to a biotech company to even have a chance of starting serious discussions. In addition, it is also important for the biotech company to know where to prioritize its resources and time

[3] Premium value: An additional cost above the normal cost (WebFinance, Inc., 2016).

1.4 Delimitations

When it comes to success factors in licensing in the pharmaceutical industry, factors such as the *development phase of the molecule* and other factors that cannot be controlled have been excluded. For example, if a company has decided to out-license an asset because they cannot afford to develop it further then it is not interesting to know how the phase of the asset influences the licensing deal since this cannot be changed. However, if the company have a choice to either out-license or continue to developed it in-house then the timing becomes an important factor to consider but this has not been investigated in this thesis.

The thesis has specifically looked at product licensing and not licensing of a platform technology[4]. Therefore, it is not possible to say if the results are transferrable. This thesis has looked at success factors in licensing from the perspective of biotech companies. Factors that determines if a large pharmaceutical company is successful in its in-licensing activities has not been review but their perspective has been taken into account. The success factors are only evaluated in relation to each other and not how they quantitatively affect a licensing deal, e.g. the financial value.

1.5 Research Questions

The pharmaceutical industry has transformed into an open innovation ecosystem where licensing is the core business model for biotech companies. To further explore licensing activities in the pharmaceutical industry and to answer the questions raised in 1.3 Problem Introduction exploratory open ended research questions have been constructed.

The research questions are the following:

- What are the factors that influence a product licensing process from a small biotech company to a large pharmaceutical company?
    - Which are the most important factors, in other words *success factors*, of a potential product out-license?
    - What type of influence does the success factors have on the licensing deal?

[4] Platform technology: Examples of platform technologies in the pharmaceutical industry are proprietary technologies to develop mRNA, RNAi and CRISPR/Cas9 based therapeutics. An example of licensing of a platform technology would be “company A will discover and develop multiple programs by using their platform technology for company B”.

2. Theory

First in this chapter the concept of open innovation will be presented in-depth. Second a general process of licensing in the pharmaceutical industry will be presented. Third a theoretical framework for financial value drivers will be presented before moving on to theory regarding strategic fit.

2.1 Open Innovation in the Pharmaceutical Industry

The open innovation concept was defined by Chesbrough as "the antithesis" of the traditional pharmaceutical R&D process, i.e. the blockbuster model. This closed model of innovation consists of a vertically integrated internal process that generate innovations or so called blockbusters within the firm, which in turn are then distributed by the firm (Chesbrough, 2006). The traditional blockbuster model of pharmaceuticals would in its heyday generate substantial revenue streams with strong intellectual property protection ensuring market dominance for decades. Chesbrough defines the blockbuster model as part of the closed model of innovation, where all the key activities are performed inside the walls of the company. A model to which its credit succeeded in generating a high and stable return on investments for its stakeholders (Chesbrough, 2011).

The conundrum of the matter would be that the pharmaceutical companies employed the closed model of innovation homogeneously throughout the industry, soaking up all the risk of pharmaceutical development. The pharmaceutical companies would reach a breaking point once the so called "low hanging fruit" molecules had been exploited. Forcing the pharmaceutical industry to focus on more complex diseases and molecular interactions. An instance that occurred in conjunction with the expiration of major blockbuster patents, which in turn led to the introduction of generic drugs and thus a plummeting of blockbuster sales. The patent expiration of drugs between 2010 and 2014 has estimated to have put around 209 billion US dollar in drugs sales at risk (Evaluate Pharma Alpha World Preview 2014, Evaluate pharma Report 2009).

As internal projects fail to perform in clinical trials or to establish market presence, the attrition rates and the fixed costs of the close model of innovation increases (Kola, 2004). Together with increasingly long development times, this has translated into increasingly higher R&D costs per New Molecular Entity (NME) approved. The cost of developing a NME has increased to as high as within the billion-dollar range, as each "blockbuster" must cover the cost of all failed ventures (Munos, 2009). According to the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA, 2011) the R&D based pharmaceutical industry invests annually over $ 100 billion on R&D to develop NME's. However, the industry only manages to produce around 21.8 NME's annually, a number that is insufficient to provide growth for the industry (Hughes, 2009). Without a dramatic increase in R&D productivity, today's pharmaceutical industry cannot sustain sufficient innovation to replace the loss of revenues due to patent expirations for successful products (Paul, 2011). A decreasing R&D productivity and devastating costs of failure put the future of the sector in a grim light.

Chesbrough (2006) questions the closed model of innovation when introducing the concept of open innovation, a shift in the innovation paradigm, where firms could and should use external ideas as well as internal ideas, and internal and external paths to market, as to advance their own technology and generate wealth to the firm.

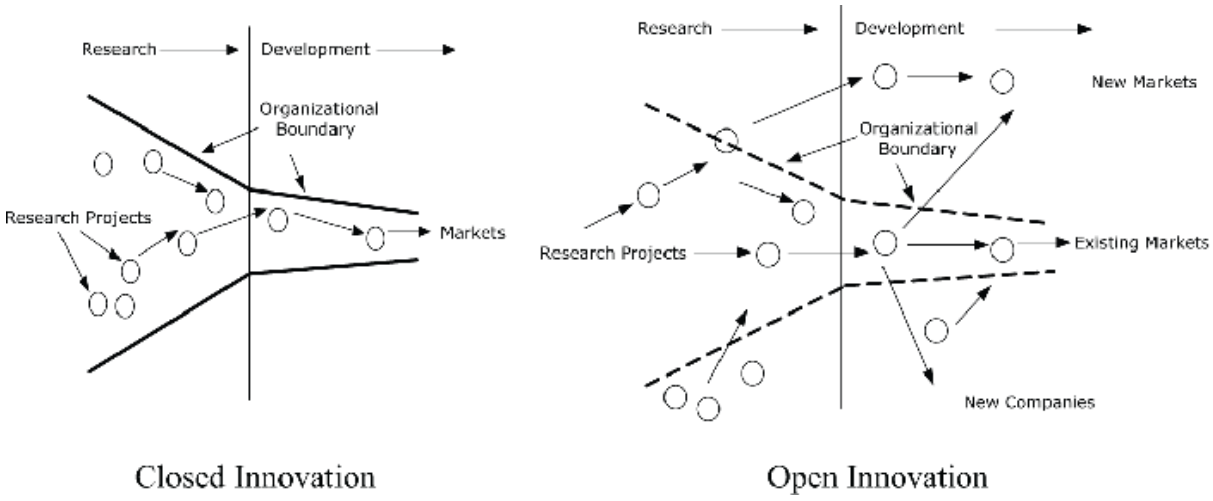

Figure 1. *Comparing closed innovation and Open innovation. The closed innovation model with its organizational boundaries can be observed on the left, where all the generation of innovation occurs within the firm. The concept of open innovation can be observed on the right side with an influx and out-flux of knowledge crossing organizational boundaries. Source: Chesbrough 2006.*

Chesbrough (2006) argues that useful and significant knowledge is widely distributed and to prosper even the most competent R&D organizations must identify and leverage external knowledge sources as part of the core innovation process. As the pharmaceutical industry faced increased complexity, new technologies, demand and availability of highly qualified experts outside the firm's traditional expertise and together with an increased pressure on time and cost, it eventually adapted the open innovation model (Schuhmacher, et al., 2013).

In the open innovation model, companies fill the gap of their internal product portfolio through licensing and acquisition of drug candidates. These candidates are identified through external scanning of the academic and business environment in order to find candidates that fit the company's expertise and business model. In-licensing compound from a biotech company or a university allows the pharmaceutical companies to avoid the full cost of development, decrease the early risk and selectively choose products that fit the firm's business model. Companies can out-license abundant projects or technologies to cover cost and to focus their efforts on a specific indication or technology (Chesbrough, 2011). Pharmaceutical companies gain access to external know-how through outsourcing and joint endeavors, further expanding upon the internal knowledge base (Schuhmacher, et al., 2013).

2.2 Licensing in the Pharmaceutical Industry

The complex activity of out-licensing is the sum of several sub-activities which include strategic planning, preparation of supporting material, targeting of potential opportunities, evaluation of the product and partner, contact with potential partners, due diligence, negotiation and the maintaining and management of the deal once it is set in place (Reepmeyer, 2006). Figure 1, gives an overview of how a general out-licensing process in the pharmaceutical industry is structured. The main responsible of the licensing activity usually belongs to members of the business development and licensing department. This does however shift to the alliance management team, project team and scientists or clinicians once the collaboration is executed and ongoing development of a product phase with the licensee has initiated (IBM, 2003).

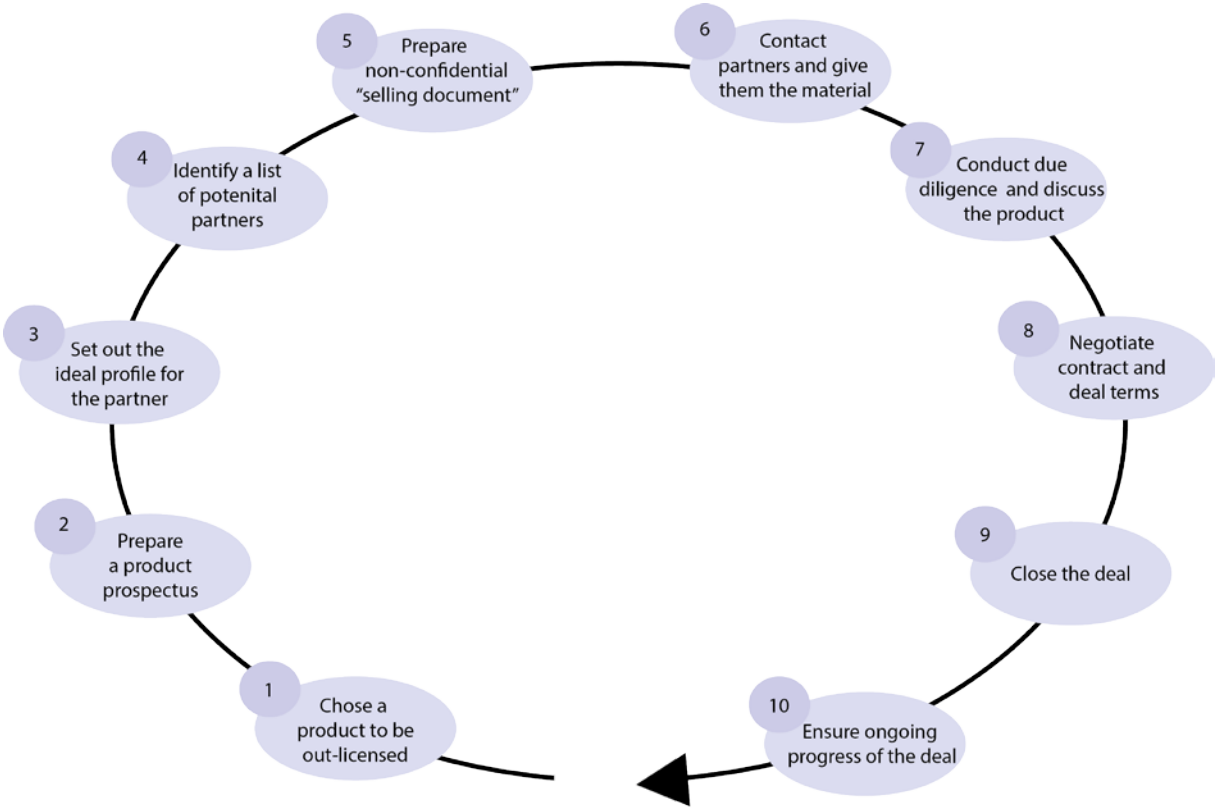

Figure 2. *General out-licensing process in the pharmaceutical industry adapted from Reepmeyer (et al., 2006).*

The first action of an out-licensing process is the decision of which product to potentially license out, see figure 1. Among the factors that are taken into account are the intellectual property status, potential commercial positioning and unique characteristics of the product. The data gathered during this phase is what makes up the prospectus, a document that is reviewed internally to access and evaluate the opportunity (Reepmeyer, 2006).

After the prospectus document has been set up, the identification of the optimal partner profile is constructed. Smaller biotech companies do not have access to all the necessary skills and organizational capabilities to commercialize the product. Drug development is changing rapidly, the sources of knowledge are dispersed across many companies, requires regulatory savviness and is financially demanding. Biotech firms will have strong incentives to enter into an array of alliances (Powell et al., 1996). Once the characteristics of the optimal partner has been constructed, it is up the business development and licensing department to set a list of potential partners.

In parallel to the partner process and before the construction of non-confidential presentations is the process of gathering accurate and reliable market information. Megantz (2002) argues that this the most important factor in developing a successful strategy and will allow the licensor to evaluate its product's value properly. The data will be utilized in the construction of a non-confidential selling document or out-reach document which will be distributed to the potential partners identified. The material will describe the market and scientific potential of the product. Powel (2006) argues that the quality and format of data supplied to the partners are key in any out-licensing activity.

Once the interest of partner firm has peeked and a non-disclosure agreement has been signed, the biotech company can choose to share additional sensitive and confidential material. This is the initiation of the due diligence process and this often includes close communication and the exchange of critical information and knowledge between the firms. Not unusual in this phase is providing the product for test trials at the partner's own research locations enabled by a material-transfer agreement and site visits as an effort to convince the partner to acquire the license.

Once the due diligence process has been completed, the two actors need to define the contractual detail and negotiate the deal terms and structure. Term sheets are exchanged in the start of negations as a suggestion of deal structure, scope and financial terms of the deal. Once an agreement has been reached and a licensing agreement has been signed the deal is completed. What remains is to maintain and support the partner during the remainder of the agreement (Powell, 1996).

An example of a licensing deal is a deal between Roche and Actelion. In figure 2 a timeline of the licensing deal between Roche and Actelion in relation to the drug development process is presented. In this case Roche decided that the development of the asset was best suited for out-licensing. Actelion in-licensed the phase II asset and was thereafter responsible for further development and commercialization of the asset.

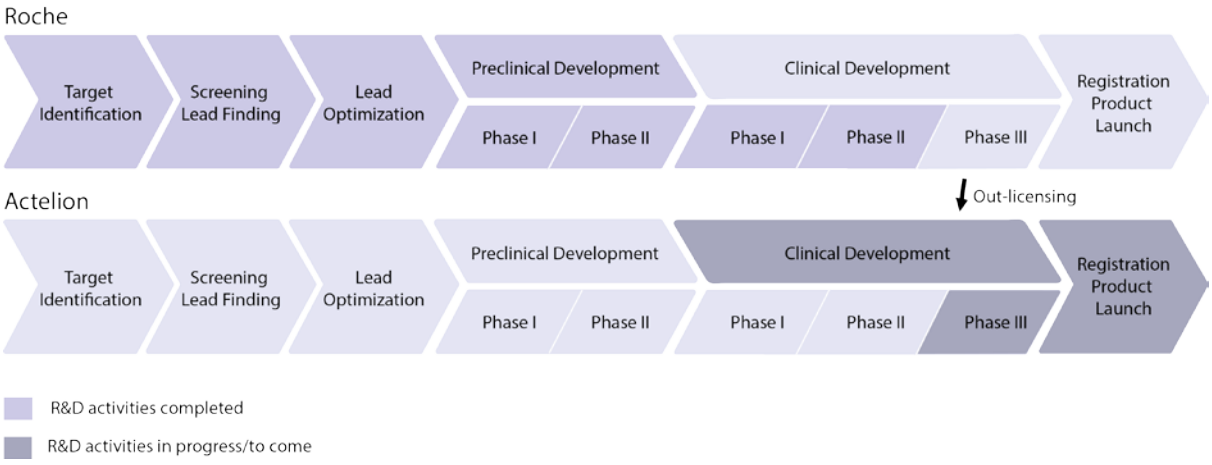

Figure 3. *Licensing deal between Roche and Actelion. In this deal Roche out-licensed a phase II asset to Actelion for further development and commercialization. Adapted from Reepmeyer (et al., 2006).*

2.3 Theoretical Framework of Financial Value Drivers by Arnold (et al., 2002)

This thesis sets out to explore what the main factors are for getting a licensing deal in place. One assumption is that there is a correlation between financial value drivers and factors that increase likelihood of completing a licensing deal. However, this may or may not show the complete picture of a complex licensing deal. Therefore, it comes naturally to start in the research regarding financial value drivers and further expand it into success factors for the entire licensing deal. In other words, why a licensing opportunity is acted on or not.

A framework developed in 2002 at Kellogg School of Management, Northwestern University, in collaboration with several industry actors identifies key factors for inflation of the financial value of a licensing deal (Arnold, et al., 2002). This framework and its applicability in explaining success factors for licensing in the pharmaceutical industry will be examined in this thesis.

A key insight from the work performed by Arnold and her group is that various financial valuation methods do not explain the valuation of many licensing deals. Thus suggesting that the total value of a deal cannot be defined by only looking at a financial valuation.

The framework is built on an analysis where 16 biotechnology leaders were tasked, through a survey, to rank which factors influence the deal value (Table 1) and assess the importance of certain value drivers (Table 2).

Table 1. *Ranking of factors that influence the financial deal value*

Ranking	Factor
1	Phase of molecule
2	Therapeutic area
3	Type of agreement
4	Scope of agreement
5	Type and reputation of partner
6	Type of molecule

Table 2. *Perception about the Importance of value drivers*

Factor Mentioned Most Times as a Value Driver (in descending order)
Market, including market size, market potential and patient population
Stage, phase or stage in development, e.g. phase I-III
Strategy, the strategic fit with the company's pipeline and potential synergies
Competition, competition from other companies on the same target or other substitute products
Reputation of the licensee or licensor, including management or scientific talent
Investments, the financial need to develop the product
Intellectual property, access to key patents or other IP
Novelty, the inventiveness level of the product
Control of development and commercialization
Comparable deal values, similar target or technology
Reimbursement, willingness of payer to pay for the treatment

Arnold (et al., 2002) also assessed the relationship between deal value and different quantitative[5] parameters of 77 deals over a 10-year period of time. The results of the multivariate regression did not align with the perception of the biotechnology leaders.

[5] Quantitative parameters or factors: A factor that can be measured with number e.g. market potential or stage of an asset.

According to the analysis the following parameters had a significant impact on the deal value: 1) Partner type (pharmaceutical company versus biotechnology), 2) Novelty of product (revolutionary versus evolutionary), 3) Type of molecule (small molecule versus biologics), 4) Type of license (marketing vs non-marketing), 5) Scope of deal (global versus US) and 6) Development stage (from phase IV to discovery).

However, the most interesting results from Arnold's (et al., 2002) analysis is that 46-68 % of the deal value cannot be accounted for by defined quantitative parameters. Meaning that qualitative[6] factors such as negotiation skills most likely play an important role and constitutes the remaining 32-54 % of deal values.

It is logical to assume that the perceived value drivers in table 2 will also have an impact on the likelihood of getting a licensing deal in place. Therefore, a part of the focus in this thesis will be to investigate, test and further expand on the factors in table 2.

2.4 Theory about Strategic Fit

The concept of *strategic fit* is nothing new in business research and several different aspects and themes of strategic fit have been debated and researched extensively (Venkatraman, et al, 1984). According to A Dictionary of Business and Management from Oxford University Press (Law, J., 2016) strategic fit is defined as:

"The extent to which diversification into another field fits with the future scope of a firm. To evaluate whether or not the proposed action would fit strategically with a firm's plans requires the strategic logic to be examined in detail and the extent to which integration could be achieved to be evaluated."

Most of the research regarding strategic fit in the interplay between biotech companies and large pharmaceutical companies focuses on how their business models, both the biotech and pharmaceutical companies, should be adapted to fit with a changing environment e.g. in research done by Carsrud (et al., 2008).

Hess (et al, 2011) researched strategic fit in relation to the value chain in the pharmaceutical industry and defines a fit or that an asset is complementary as when upstream (discovery research) and downstream (marketing) process are matched. A part of the research in this thesis will be to investigate how strategic fit is defined and used in the pharmaceutical industry. Beside research made by Hess (et al, 2011) there has not been a lot of research done on how an asset can complement a pharmaceutical company.

[6] Qualitative factors: factors that are difficult to measure e.g. the strength of a social relationship

3. Method

3.1 Research Strategy

The research field, licensing in the pharmaceutical industry, is at the time of writing not a matured research field, an effect of a non-transparent industry with high levels of business and scientific secrecy. When it comes to success factors in licensing, the existing theory is even more scattered. The research strategy and the role of theory in this thesis were adapted to the scattered and lack of theory within the research field. The role of theory describes the relationship between theory and research. There are two main roles of theory that can be taken on either a deductive or an inductive approach. Bryman and Bell (2007) describe a deductive approach as when a researcher assumes a hypothesis that will be observed in empirical analysis. In contrast, an inductive approach is when the researcher uses their observations to create a theory (Bryman, et al., 2007).

As a result of the scattered theory, the role of theory in this thesis took on both a deductive and an inductive approach in different stages of the thesis. Therefore, the role of theory when the stages were combined was abductive in other words what is most probable. As a start, a deductive role of theory was applied to test existing theoretical framework and see how well they describe success factors in licensing in the pharmaceutical industry. In addition, an inductive role of theory was used to both expand upon the existing theoretical framework and to identify other characteristics of success factors, see figure 4. However, despite the fact that both a deductive and an inductive approach were used in this thesis an interpretivism purpose of theory was mainly applied. Interpretivism is a view where the subject matter of social science is viewed to be different from that of the natural science (Bryman, et al., 2007).

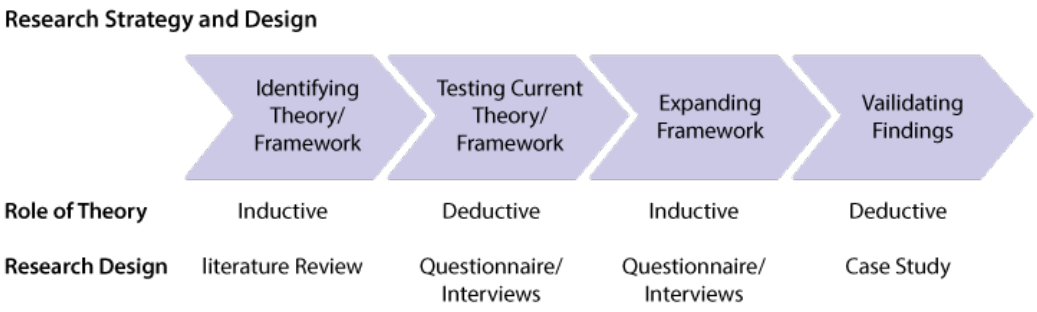

Figure 4*. Graph illustrating the research strategy and design for each part of the thesis.*

This thesis concerns success factors in licensing deals, in other words, a business or social phenomenon. As a result, the ontological considerations of these business phenomenon should be considered. Ontological considerations concern the question whether social entities should be regarded as objective entities, meaning that its existence have a reality external to social factors, or if it should be regarded as a social construction based on the perception of social actors (Bryman, et al., 2007). From an ontological standpoint a business phenomenon such as a licensing deal is ontological subjective, a licensing deal is merely a social construction whose mode of existence is subjective, it does not exist if it is not experienced by any subjects.

Furthermore, the epistemological aspects of success factors in licensing deals should be considered. Epistemological considerations concern the question of what knowledge is and how it should be viewed (Bryman, et al., 2007). What success is and the level of success a factors has is from an epistemological standpoint subjective and individual i.e. epistemological subjective.

An interesting aspect of ontological and epistemological consideration handled in this thesis is how despite the ontological subjective fact that a licensing deal is ontological subjective the social construction itself is handled and seen as ontological objective within the industry. The same argumentation can be used for success factors and how it is handled as being epistemological objective despite being epistemological subjective. A licensing deal as an institutional fact has in this thesis to a large extent been regarded as a brute fact. In other words, what this thesis has tried to answer is how well anchored different success factors are and are they so anchored that they function as epistemological objective in the pharmaceutical industry.

The final aspect to consider for the research strategy is if it should be a quantitative or qualitative research. When it comes to epistemological considerations quantitative research usually has a positivism purpose and an objectivist in nature when it comes to ontology (Bryman, et al., 2007). Quantitative research is mostly used in deductive approaches. Qualitative research on the other hand, is often used in inductive approaches and has an interpretivism purpose (Bryman, et al., 2007). Since this thesis is of an interpretivism nature, a qualitative research method will be applied. This will have an effect on how much the result can be generalized and the replicability of the research. Furthermore, qualitative research is less generalizable and has a low level of replicability (Bryman, et al., 2007).

3.2 Research Design

The concept of research design is defined by Bryman and Bell (2007) as a framework for which the collection and analysis of data is conducted within. The framework takes in consideration a number of important aspects to establish a valid and legitimate research procedure when conducting the study. Additionally, a proper research design is an indication of that the research will be performed in a coherent and explicit way. It is a way to ensure that the data gathered can effectively address the research question.

In order to evaluate the quality of the research conducted, Bryman and Bell (2007) have suggested and introduced four criterions to assess the research design: *validity, reliability, trustworthiness* and *authenticity*.

Validity is concerned with the integrity of the drawn conclusion based on the gathered results or data set. The measurement of research validity takes into consideration both internal and external aspects of conducted research. This thesis will strive to measure and compare success factors in licensing and in doing so constructing a relative measurement between the factors. The question arises then of the *validity of the measurement* itself, does it really describe and measure the concept in a coherent and valid way. Another aspect of validity that is of significant importance is the issue of causality between variables or rather the *internal validity* of data gathered and constructed conclusions. Which creates the question if a causal relation between the variables can confidently be established. On the other side of the spectrum is the consideration of *external validity*, which incorporates the concept of generalization. Can the selection of data points or in the case of interviews, the interviewees, truly represent the whole industry or field. The external validity puts a strong emphasis on the selection process of the data gathered. In an effort to describe a social phenomenon, the validity of accurately describing it in a social

research setting must be put into question, which is what *ecological validity* takes into consideration. Does the data gathered from the research accurately represent the real world or not.

Reliability has similarly to validity several sub aspects. The internal reliability takes into account if observations in the gathered data is translated in the same sense. Strong internal reliability translates into the perception of result unity, as several observers see the same conclusions or patterns when observing the data. External reliability is the representation of research replication or rather to which degree the study can be replicated. External reliability is particularly difficult to establish within social sciences as the natural world seldom is constant (Bryman, et al. 2007).

Trustworthiness was further divided into four aspects by Bryman and Bell (2007). *Credibility, transferability, dependability* and finally *confirmability.*

Credibility is established by conducting and carrying out the research in good practice and accordance with the scientific norm. The decision of which research method should be employed must therefore be in accordance what is considered proper. Additionally, the sources of the data extracted must be credible and reliable from the perspective of general scientific community and the research must conduct crucial and critical thinking when deciding the sources of information. If the conclusions and correlations drawn in this thesis can be applied in another sector outside of the pharma and biotech field, the thesis has achieved good transferability. The greater the transferability of the thesis, the broader conclusions of the phenomena can be drawn. If the instance and situation of the study can be replicated or repeated, this would indicate that the research has high dependability. This is most often such as with the case of external reliability difficult to conduct. An effort to manage this was done by offering a compressive description of the research methodology and how it was conducted as this can create and establish dependability. Confirmability takes into consideration the complete objectivity or prior bias of the researchers. To establish confirmability, it is even further important to motivate and provide a good scientific reasoning behind the choice of research methodology and actively manage inherent bias through acknowledgment of aforementioned bias.

The final parameter to evaluate the quality of the research is the aspect of *authenticity*, which concerns the wider political impact of the research. The considerations for different viewpoints and the understanding of others perspectives.

The research conducted in this thesis will be of a mixed design. The literature analysis will be conducted as an inductive exploratory review with the main objective to gather a compressive understanding of the research that has previously been performed.

The interviews and questionnaire in turn will build upon the gathered data and use this with a deductive role of theory to test established frameworks and in an inductive combinational study. The interviews were conducted as a semi-structured study whilst the questionnaire was carried out as a cross sectional study. Each with their own weaknesses and strengths. Integration of the data strands will be conducted to triangulate the results. Following this, a case study will validate and compare the results gained and achieved from the interviews and questionnaire. The concept of triangulation, to use several methods to gather data, is a method to ensure validity in qualitative research (Bryman, et al., 2007). See figure 4 for an overview of applied research strategy and design. The main intention for applying several methods for data gathering is to achieve a comprehensive picture of the field and fill the gaps that exist in current research.

3.2.1 Literature Review

The literature review was conducted to evaluate and integrate previous research and to further expand upon it. The main objective was to identify success factors in product licensing and important aspect of deal making process. Their relation to the value proposition of a product out-licensing in pharma was also mapped and investigated. The literature review was done by focusing on different aspects such as improved likelihood of a deal, value drivers, deal-breakers and impact on licensing deals. The results from the literature review was used as a base for the qualitative interviews, e.g. narrowing down what aspects and factors to focus on. The literature review was the main method used to get a direction on the answer to each research question. The literature has been identified through public databases such as PubMed.

As the data gathered under this phase was focusing on the licensing within the biotech sector, it must be taken into consideration that there might be lack of transferability into other industries and only be representative of the biotech/pharma field. This focus in the literature review does ebb throughout the study, so the same transferability aspect can be said for the following activities.

3.2.2 Qualitative Interviews and Questionnaire

The qualitative interviews were conducted as semi-structured manner, to confined the conversations within the field but still allow the participants to openly express their thoughts and ideas.

The qualitative interviews were employed to identify success factors in relation to all three subcategories; increasing the likelihood of deal execution, drive the financial value of a deal and absolute requirement for the deal. Additionally, the interviews were also used to verify existence of these categories. The interviews were a key method for data gathering in this thesis since the lack of transparency in licensing is reflected in the lack of available literature and data on the subject. The interviews had a starting point in the framework created by Arnold (et al., 2002) and her team.

The interviews were done in two steps. The first step were initial interviews to identify success factors, in these interviews a qualitative methodology of investigation was applied. For the second round of interviews a questionnaire was created that included the factors identified in the initial interviews. The questionnaire performed as a cross sectional study, an observational study that involves the analyses of data collected from a group of individuals at one specific point or period in time. The questionnaire was designed so that semi-quantitative data could be gathered, see Appendix 8.1. for questionnaire questions. This allowed analysis of what success factors are most important.

3.2.2.1 Selection of Interviewees

The main purpose of this thesis has been to provide a better understanding of success factors in product licensing and especially which of these factors are most important for a biotech company to have successful licensing activities. Three biotech professionals were therefore chosen for the in-depth interviews to achieve an adequate understanding of biotech companies needs and capabilities. These results will then be tested on the industry in general, including large pharmaceutical companies, through a questionnaire. Thus, no larger pharmaceutical professionals were interviewed in this part of the thesis.

The three interviewees were:

- Chief Executive Officer of a public US biotech company

- Head of Business Development of a public US biotech company
- Director, Business Development of a public German biotech company

The selection of interviewees creates the difficulty of representing the whole field with a small of individuals. Whilst the selection includes knowledgeable and experienced individuals within the field, the lack of representation of the big pharma could put into the question the external validity of the research. In an effort the manage this, the thesis and its conclusions represent success factors mainly from the perspective of biotech companies while still including input from pharma executive. The success of a licensing deal is most often a success for both parties involved, which in turn would constitute that the results do in fact represent both biotech and the pharma sector. However, it is important to take into account this issue of lack of generalization, throughout the thesis, as each data set builds upon each other and thus ebb through the following activities and eventual triangulation. Another aspect of weakness when conducting interviews with as few induvial as three, is the aspect of scientific credibility. In order to retain scientific credibility, it is therefore important to narrow the scope even further of the drawn conclusions so that the number of involved individual can in fact be a reasonable amount to describe the specific instance.

3.1.2.2 Selection of Questionnaire Participants

With the main purpose of validating data for the whole industry, the decision was to expand the participant segment and especially include employees of larger pharmaceutical companies in the questionnaire.

The intention was to obtain answers from participants within the following data ranges:

- Varied market cap of businesses,
    - Ranging from: $ 50 million - $ 100 million as the lowest interval up to $ 5 billion +
    - Multiple responses from different companies of similar size
- Both privately and public held companies
- Professionals with a wide range of licensing experience

In an effort to establish measurement validity, the data gathered from the questionnaire was only examined in relations to the other data points in the set. Not quantitative conclusion can therefore be drawn without relating the data points to each other which in turn also limit the external validity of the research as without allowing the individuals answering the questionnaire with an unlimited amount of answers, they were confined within boundaries of the research design. Additionally, the unnaturalness of answering a questionnaire might put into question the ecological validity of the research, as the setting is considerably different from the natural setting for which the answers are experienced.

External reliability is in a sense establish as all individuals and those who would take part in a replicated study would observes the same choices and question presented to the original group. However external aspects could however still influence the induvial and create a situation where the opinion if asked today might differ to when they are participating in the study. Another difficulty of a cross sectional design is the lack correlation of cause and effect resulting in confounding factors. In order to manage this, the participants were encouraged to offer comments on their answers as a way to identify these aspects.

3.2.3 Case Study

The main purpose of the case study was to validate the results and findings obtained in the literature review, qualitative interviews and the questionnaire. The case was selected based on advice from industry experts as a case that exemplified an ideal licensing deal from a biotech company perspective.

The case study was analyzed by reviewing several sources: 10-K filings and other SEC filings, the redacted licensing contracts, company websites, press releases, new articles, interviews with industry experts, financial analysis, scientific publications and the use of a competitive intelligence software, BioMedTracker (Sagient Research Systems, San Diego).

The selection process of an event or case, to compared the extracted data to, will put into the question the external validity of the research conducted. Can a singular case chosen be generalized to that degree where it is enough to validate the findings of the thesis. With the chaotic characteristics of the natural world, this is must certainty not the case and is therefore a consideration that must be held in mindset when the conclusions are drawn. It is therefore important to narrow the scope of the conclusions to instead of a brute description of the importance of success factors in licensing to rather a hint of the true nature of the phenomena.

4. Results and Analysis

This chapter includes an analysis of the theoretical framework developed by Arnold (et al., 2002), results from the interviews and results from the questionnaire.

4.1 Analysis of Theoretical Framework

This section will analyze the application and validity of Arnold's (et al., 2002) framework in regards to the whole pharmaceutical industry.

4.1.1 Application of Theoretical Framework in the Pharmaceutical Industry

The correlation between several of the factors in table 2 (see section 2.2. Theoretical Framework of Financial Value Drivers by Arnold (et al., 2002)) and their independent effect on the value of a deal comes natural, e.g. global marketing rights will cost more than regional rights. However, regarding the factors impact on likelihood of completing a deal the relationship is not as straightforward. It is likely that qualitative factors such as relationships will have an even larger impact on the likelihood of completing a deal compared to the impact on deal value.

One theory that will be evaluated is that several of the factors in table 2 have a binary nature, e.g. if an asset does not have any IP (or other exclusivity, such as market and data exclusivity) the value may be non-existing but the value would perhaps not be increased just because the IP is extra broad or strong. This may also be the case for the impact on the likelihood of deal completion. If this is the case a factor as such can be regarded as a deal-breaker.

4.1.2 Analysis of Validity

In Arnold (et al., 2002) the research and its corresponding analysis was based on the evaluation of 105 biotechnology drug deals signed during the timespan from 1992 to 2001. Complete information regarding upfront and follow-on payments was only available for 77 of 105 deals, therefore the team chose to discard the uncertain data points for most of the analysis. Of these discarded data points were deals that were atypical of the industry as whole. Questionable was the decision to base the analysis on not more than one deal per company. An argument could be made that this will lead to misrepresentative data, since one deal might facilitate more deals and thus is an important factor. This exclusion questions the validity of the research team's intentions to describe the industry as whole.

4.1.2.1 Validity of Multivariate Regression

The largest problem with a multivariate regression on deal values by using a DCF or a net present value (NPV) model is the assumptions going into the model. This will be illustrated by an example below.

Valuation example

Company X values asset A to $ Y at the time of the deal. Let us say that the value split will be 30-70, meaning that company X will get 70 % of the value and the originator will get 30 %. Now this will further be split up to: up-front, milestones and royalties. The split could for example be 20 %, 30 % and 50 %. This will mean that company X will pay the following value in up-front and milestones (royalties are not included in Arnold and her team's model):

Company X value of asset A in up-front and milestones = 0.3*(0.2+0.3)*Z = 0.15Y

Let us assume that Arnold and her team use actual market data for the asset A. And let us for the sake of the example say that this market data has a lower market penetration and slower uptake than what company X had assumed in their valuation at the time of the deal. This will make Arnold and her team's valuation of asset A lower, e.g. $ 0.5Y.

This will lead to the following equation for up-front and milestones:

Arnold's calculation of value of asset A in up-front and milestones
= 0.3*(0.2+0.3)*0.5Y = 0.075Y

0.15Y>0.075Y

This result in the example above shows that company X paid too much for the asset A and that the 15 % of the value Y paid in up-front and milestones cannot be explained by quantitative factors such as market potential. But is that really the case? We would argue that if company X really believed in their assumptions at the time of the deal than their valuation was explained by the market potential. The fact that this turned out to be wrong in reality is not relevant to the valuation.

Arnold (et al., 2002) argues that the type of partner, pharmaceutical company vs biotechnology company, has the largest effect on the deal value. Arnold provides the definition of value as the sum of up-front and total milestone payments. However, excluded are royalties. It is reasonable to argue that most of the value comes from royalties so to exclude this can potentially lead to misrepresentative data. Moreover, the exclusion of royalties has a large effect on the result in co-development and co-commercialization deals where an increased royalty rate is common. This would likely be the case when a biotech company licenses to another biotech company since it would be unreasonable to expect the same amount of up-front financials as it would be with a larger pharmaceutical company. It is also logical to think that only less prioritized products, with lower potential, would be licensed to other biotech companies of similar size since they cannot compete with financials from a pharmaceutical company. Therefore, the result that the type of partner has the largest effect on the deal value might not necessarily be true since the deals cannot be directly compared.

4.1.2.1 Exclusion of Large Pharmaceutical Leaders

As part of the perception analysis of the research, a panel of 16 biotechnology leaders (three chief executives, two chief operating officers, four vice presidents, four directors, three managers, and one industry consultant) were tasked to provide their own list of value drivers in licensing deals. The samples size is diverse and covers many aspect of the deal making structure.

However, to draw conclusions without investigating aspects of the pharmaceutical in-licensing side of the affair give a biased sample. It does not represent the industry as a whole merely a part of it. One could argue that when it comes to the likelihood of a deal the less important part of the industry was looked into.

The data used in Arnold (et al., 2002) was gathered from data between 1992 and 2001 which arguably can be considered valid today since the pharmaceutical industry has long technology cycles. Licensing deals have become more and more common and are now a major part of the industry. Thus, it is logical that business processes around licensing, especially in the large pharmaceutical companies, have become more defined and structured. This will have an impact on the negotiation game played between biotech and pharmaceutical companies. Therefore, it is important to also include pharmaceutical companies' perspective on the topic.

4.1.2.1 Usefulness of Financial Value Drivers

The intention of the framework is to assess what factors drive the value in a licensing deal and more specifically what are the main factors that drive a premium value. In essence Arnold (et al., 2002) is trying to answer the question why the deal value of some licensing deals are higher than the value obtained by using various financial valuation methods.

The framework is designed to assess which factors drive the value of a licensing deal. However, what would be more interesting to know is what drives a premium value since this is the financial component that a biotech wants to influence during licensing activities of an asset.

4.2 In-depth Interviews with Industry Professional

Three in-depth interviews were conducted as described in section 3.1.2. Qualitative Interviews and Questionnaire. The results have been divided into four topics: *Success Factors, Strategic Fit, Deal-breakers and Value Drivers and Likelihood of Completion.* These topics were chosen based on the result of both the literature review and the interviews.

4.2.1 Success Factors

As an entry point into the discussion of success factors, the interviewees were given open ended and exploratory questions regarding their perceived success factors in licensing activities. From these discussion, several categories of success factors were brought up and discussed in further detail. These factors have been categorized into broader categories below.

4.2.1.1 Scientific Attractiveness and Quality of Data Package

The first factor mentioned by all the industry professionals as the main critical success factor was *scientific attractiveness*. As one of the interviewees put it:

"It's the science that drives the deal".

A difficulty is to define what *scientific attractiveness* constitutes and how it can be measured. According to the industry professionals, *scientific attractiveness* is determined by *the quality of the data package*. The data package needs to be convincing and as stated by the interviewees it is key that it represents the stage of the asset.

For example, as one of the interviewees explained, a phase II asset should have a data package that represents that stage and supports further clinical development without having to build up data that already should have been gathered since this will negatively affect timelines, labeling possibilities[7] and increase risk. An aspect that was mentioned as an important factor in relation to the scientific attractiveness and data package was a transparent communication about what data you have and what data you lack and how and when you will generate it.

Moreover, the data set is also highly linked to the concept of best-in-class[8] and first-in-class[9]. For a potential first-in-class asset, a less comprehensive data set can be offset with the opportunity to be first to market with a new mechanism of action (MoA). On the contrary, for a best-in-class asset more data needs to be shown to prove that the asset is superior to what already is or will be on the market.

4.2.1.2 Strategic Fit

During the conversations the topic of *strategic fit* was raised and the factor was deemed significant during all aspect of the deal making process. The interviewees definition of *strategic fit* did however include several pharmaceutical business aspects which were not found in the current literature definition of *strategic fit*. Specific components of *strategic fit* that were mentioned by the interviewees were e.g. *established sales force within the indication, complementing to existing product portfolio* and *aligned with overall strategy*. Essential factors mentioned were focusing on the characteristics of the partner and aspects of scientific and business synergy.

4.2.1.3 Commercial Attractiveness

All the industry professionals mentioned *commercial attractiveness* as an important factor. The *commercial attractiveness* goes hand in hand with an unmet medical need and a clearly defined patient population. When it comes to valuation of the asset a rNPV (risk-adjusted net present value) model is standard in the industry when it comes to clinical stage assets. The rNPV model of the asset is however rarely shared. What was regarded as important, is to be transparent with assumptions in relation to the commercial case.

4.2.1.4 Differentiation from Competition

A success factor that was mentioned by all of the biotech experts and is highly linked to both *scientific* and *commercial attractiveness* is *differentiation*. If you have an asset that is not differentiated from competition, then the scientific attractiveness is likely lower and the commercial case not as good. In a sense the concept of *differentiation* overlaps with competition. However, *differentiation* can also include a novelty aspect which in itself can be regarded as a success factors, as one of the interviewees brought up.

[7] The label of an approved drug determines for what indication and for what patient population it can be used for and it is decided by the authorities in the specific region (e.g. FDA in the US and EMA in EU).
[8] Best-in-class: A drug program that is superior to all other programs or products in the same category (e.g The best compound that target a specific target X).
[9] First-in-class: A drug program that is first in its category (e.g first to target a specific target Y)

4.2.1.5 Timing and Momentum

Timing was mentioned as a success factor. An interesting aspect of timing is that the professionals talked about it as an "element of luck" or "serendipity". If you have good *timing* and starting to gain traction within the partner organization, keeping the *momentum* up is a key according to the interviewees. As one of the interviewees put it:

"There are thousands of reasons not to do a deal, so move fast when you have reached a term sheet"

A factor with strong ties to both *timing* and *momentum* is the effect of market trends or an increased interest in a specific indication or MoA at the time. As an example immuno-oncology and CRISPR/Cas9 are two "hot fields" at the moment where a lot of investments are made. A "hot indication" comes with increased likelihood of more licensing deals being made but it also increases the amount of competition.

4.2.1.6 Competition or the Perception of Competition

The perception of *competing actors* interested in the product was mentioned as an important factor of product licensing and particularly relevant to the likelihood of deal completion and as an important value driver. The factor was deemed particularly important as it incentivizes the potential actors to advance more quickly in the deal process.

4.2.1.7 Relationship

A success factor that was mentioned by all of the experts was *relationships* and especially what *entry point* you have into the potential partner's organization. As an example one of the interviewees talked about how personal *relationships between the executive management* at both companies can prioritize the review of an opportunity. This factor can further give an additional indication on what some of the qualitative factors are that Arnold (et al., 2002) has shown make up for a lot of the value in a licensing deal.

4.2.1.8 Internal Project Champions

Individuals characterized as *internal project champions* within the potential partner's organization was identified by all interviewees as a highly influential success factor. Additionally, the correlation between the necessity of a driven project champion and how early in the development process the asset was drawn by some of the interviewees. The interviewees differentiate between scientific and business connected champions but were not unanimous in their differentiation. The importance of an *internal champion* was increased if the evaluation process at the partner company is rigorous and takes a long time. The product licensing deal might in an initial process be declined but remain in the potential deal making sphere thanks to the persistence of a *project champion* and eventually find a better footing in the conversation and results in a deal completion.

4.2.1.9 The Lack of Mention of IP and the Non-necessity of Freedom to Operate

From a knowledge based economy perspective intellectual property rights are key to profit financially from a valuable asset (Petrusson, et al. 2009). The value of one single patent, a composition of matter patent, in the pharmaceutical industry has a very high value in comparison to what a single patent in many other industries e.g. information and communications technology (ICT) has. In the ICT industry the value of a patent portfolio is more relevant than the value of a single patent. *IP* was not mentioned as a success factor it the interviews initially. However, when the subject was brought up it was a consensus among the professionals that it is important to have *IP* protection and that regulatory exclusivity is not enough but that it is more of a requirement that is checked off and not something that has a large impact on a potential deal.

Interesting is the question of *freedom-to-operate (FTO)*. One of the experts stated that the industry in general has become more and more relaxed when it comes to *IP* and *FTO* and that companies are prepared to launch at risk despite the fact that there might be dominant *IP* out there. The interviewee brought up the ongoing patent dispute between Bristol-Myers Squibb/Ono Pharmaceuticals and Merck & Co regarding PD-1 antibodies arising in 2014 and another lawsuit from 2016 between Morphosys and Johnson & Johnson regarding CD38 antibodies. Yet another good example is the large investments made in and large IPOs by companies working on CRISPR/Cas9 despite the fact that the patent landscape is uncertain and is currently being battle out through an interference proceeding.

As one of the biotech experts said during the interview, this can be due to the fact that there are so many things that can go wrong during drug development and to take the patent landscape into account for a preclinical asset, when the likelihood of even reaching the market already is low, does not make too much sense.

4.2.1.10 "Perfect storm" - The Sum of Many Necessary Effects

Several success factors for licensing in the pharmaceutical industry have been presented above. One important aspect of these success factors is that they on its own do not facilitate a deal, you need a "perfect storm" of multiple factors in order to be successful.

4.2.2 Strategic Fit

The importance of a strong *strategic fit* was strongly stressed by the interviewees and the literature research as critical success factors that heavily influences the deal outcome. Several components of *strategic fit* that were highlighted during conversations with the interviewees were; *existing salesforce or clinical program in the therapeutic area, complementary to existing product portfolio, complementary capabilities e.g. development, technology and regulatory expertise, executive management relationships and management credibility.* However, *strategic fit* is not always something that is apparent to an external actor and therefore needs to be communicated.

One interesting aspect and potential downside of having an *existing salesforce or clinical program within the same therapeutic area* is that it increases the risk of cannibalization of the partner's internal programs.

4.2.3 Deal-breakers

Deal-breakers have been defined as factors that are an absolute requirement but do not necessarily increase the value or likelihood of the deal. Several factors have been mentioned but response has not been as clear cut. However, one factor that stood out was *IP*. It is essential that the drug program is protected but in relation the strength of the *IP* is not as important and does not affect the deal to a larger extent. Another factor that was mentioned throughout the interviews was *conflicting data* and *scientific reputation of the licensor*. This leads back to the fact that it is the *scientific attractiveness* that is the key success factor.

An interesting aspect of deal-breakers are "must-haves". A must-have is an individual deal-breaker for one of the parties involved in the negotiation e.g. "we need to have a co-development structure for this asset". When it comes to negotiations, a communicated must-have really needs to be an absolute requirement. All interviewees said that you need to be prepared to be called on your must-have, in other words you need to be prepared to walk away from the deal. Otherwise you lose credibility and your bargaining position.

4.2.4 Value Drivers and Likelihood of Completion

An interesting aspect of the success factors is how they relate to the deal value and the likelihood of completing the deal. Is the factor a value driver or does it increase the likelihood of deal completion? According to Arnold (et al., 2002) 46-68 % of the deal value cannot be accounted for by quantitative criterions such as market potential instead they argue that it comes from qualitative factors such as *negotiation skills*.
The interviewees thought that *negotiation skills* would be beneficial in getting a desired deal (e.g. scope, structure and financial terms) in place but it will not enable getting a deal in place independent on the asset. In that sense they saw *negotiation skills* as a value driver. However, the most important value driver was *competition* or the perception of competition on an asset, meaning that several are interested in the same deal. This is an important aspect that Arnold's (et al., 2002) framework lack. According to the interviewees you can be more aggressive regarding timelines in negotiations and the deal structure and push up the value if you have competition.

Another interesting aspect of value drivers are individual people's need. As one of the interviewees said there might be a case where the organization has as a goal to make one certain type of deal and that the responsible person for the transaction has bonuses tied to reaching this goal. In this case they might overpay since the individuals at the partner company have a personal gain on getting the deal in place.

Having an *internal champion* at a potential partner is the key success factor for increasing the likelihood of completing the deal according to the biotech professionals. At larger pharmaceutical companies there are a lot of processes and obstacles to overcome to successfully set up a licensing deal. One of the interviewees said that it is therefore key to have an *internal champion* who convinces the organization to buy in to your program.

4.3 Questionnaire with Industry Professionals

In order to validate the results from the in-depth interviews, a questionnaire was constructed and sent out to industry professionals within the pharmaceutical industry. The participants in the questionnaire were selected to create a representative group of the industry as a whole according to section 3.1.2.2 Selection of Questionnaire Participants. The distribution of market cap of the companies where the responders are employed and their years of experience within licensing can be seen in table 3 and 4. In total there were 19 responders to the questionnaire.

Table 3. *Distribution of market cap of the companies where the responders are employed.*

Market Cap	Percentage of Responders
$50MM-$100MM	11 %
$100MM-$200MM	6 %

$200MM-$500MM	11 %
$500MM-$1BM	6 %
$1BM-$5BM	17 %
$5BM+	17 %
Privately held	33 %

Table 4. *Distribution of years of business development/licensing experience in the pharmaceutical industry of the responders in the questionnaire.*

Year of Experience	Percentage of Responders
0-5 Year	17 %
6-10 Year	22 %
11-15 Year	33 %
15+ Year	28 %

4.3.1 Success Factors

Table 5. *Top success factors mentioned by participants in the questionnaire.*

Top Mentioned Success Factors	Percentage of participants mentioned it as part of top 5 most important factors
Strategic fit (including complementary with existing portfolio, overall strategy, need of technology access and partner capabilities)	69 %

Internal alignment (including executive management support)	50 %
Negotiations (including negotiation skills, aim for a win-win and negotiations preparations)	50 %
Relationship (including personal relationships and respect and trust for partner)	44 %
Commercial attractiveness	38 %
Financials (including aligned financial deal-terms with value of asset, financial structure)	38 %
Scientific attractiveness (including quality of data)	31 %
Momentum and timing	19 %
Preparations and Coordination	19 %
Communication (transparency and honesty)	19 %

The success factor that was mentioned the most by the responders in the questionnaire was *strategic fit* closely followed by *internal alignment* and *negotiation aspects.* All of these factors were mentioned by more than 50 % of the responders, see table 5. Following the top three success factors were *relationship, commercial attractiveness, financials* and *scientific attractiveness* and all of these success factors were mentioned by more than 30 % of the responders.

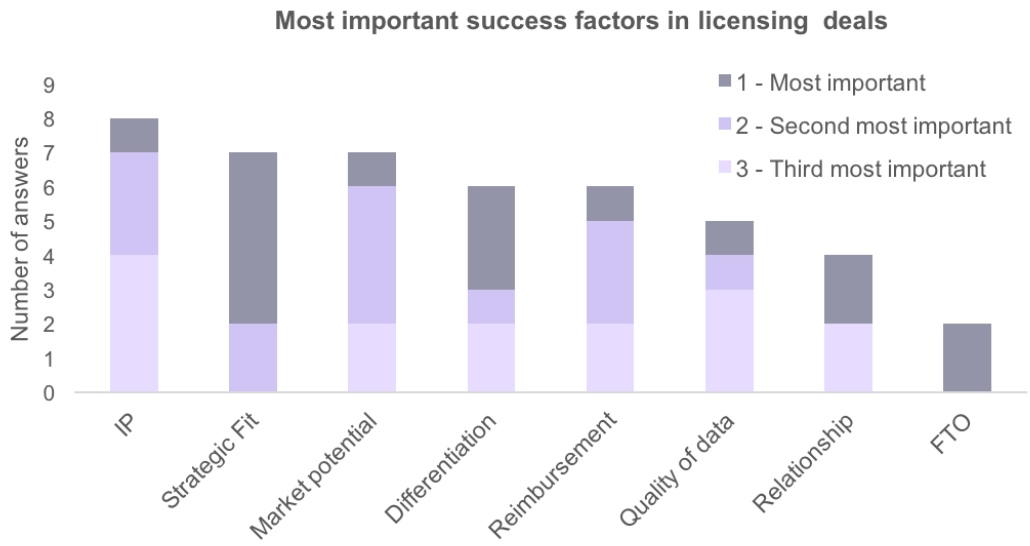

Figure 5. *Most important success factors. Stacked column chart showing number of Most important, Second most important, Third most important and total responses for different success factors; IP, Strategic fit, Market potential, Differentiation, Reimbursement, Quality of data, Relationship and FTO.*

When offered the choice to rank which success factors the participants considered as most important, they clearly favored *strategic fit* as the single most significant factor. Factors related to the commercial case of the product such as *market potential, differentiation* and *reimbursement* system did also perform well in the rankings.

It is clear from the results in figure 3 that *IP* is considered important by more industry professionals than *FTO*. Interestingly *IP* and *FTO* are not one of the top mentioned success factors (see table 5) but when given the option to rank they are among the top factors. Qualitative or subjective factors such as quality of data set and relationships were also ranked among the top factors.

4.3.2. Strategic Fit

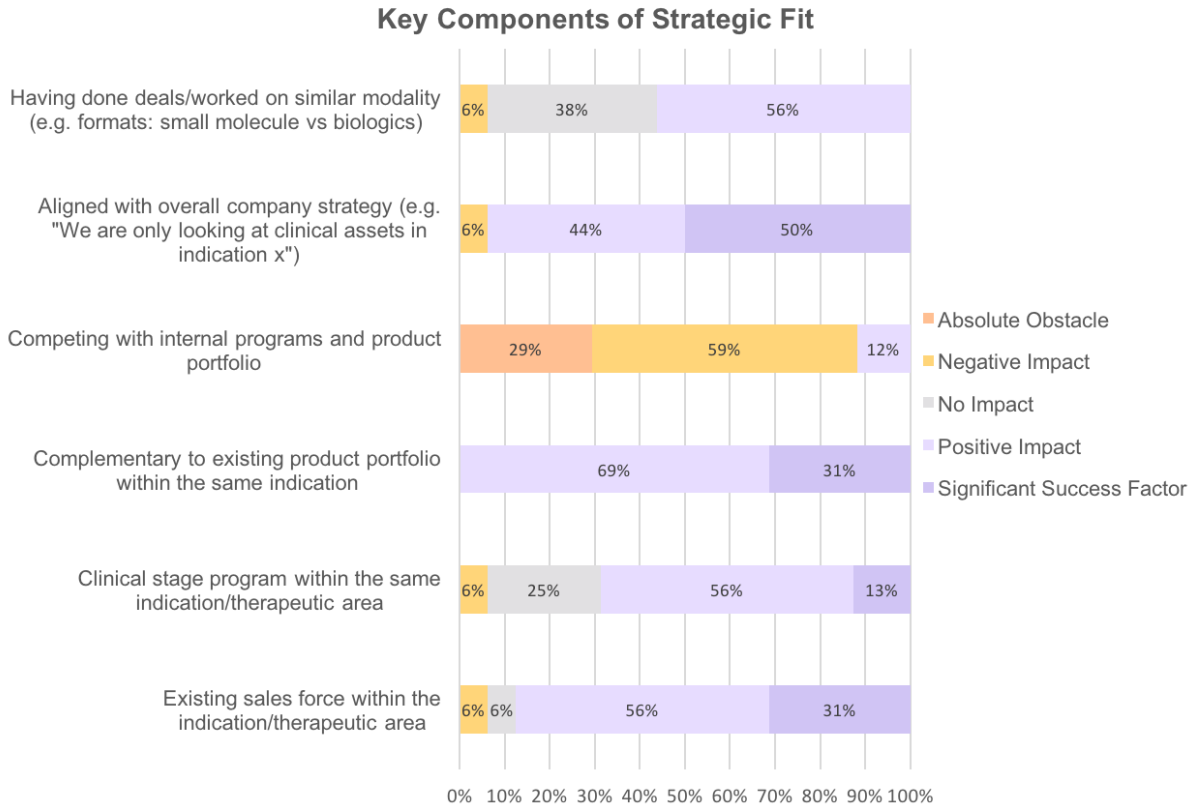

Figure 6*. Key components of Strategic fit. The figure shows the percentage of responders who considered a success factor as an absolute obstacle or having a negative impact, no impact, positive impact or being a significant success factor in relation to deal likelihood.*

The results from the questionnaire point towards two key components of strategic fit: 1) *Aligned with overall company strategy* (e.g. "We are only looking at clinical asset in indication X") and 2) *Complementary to existing product portfolio within the same indication.* The first factor *Aligned with overall company strategy (e.g. "We are only looking at clinical asset in indication X")* has the highest percentage of "Significant Success Factor" as can be seen in figure 4.

The results further indicate that approaching a partner that either has an *existing salesforce or a clinical stage program within the same indication/therapeutic area* as the asset to be licensed increases the chance of a good *strategic fit.* It is however skewed towards a "positive impact" and not "significant impact factor". This is what could be defined as a "nice-to-have" but not a "must-have".

To have an asset that is *competing with internal programs within the same indication* is either an "absolute obstacle" or has a "negative impact" besides a few percent that say it has a "positive impact". One potential explanation of the dual impact of the factor comes from one of the participants:

"A competing program may be positive if it's better than the internal one. Otherwise, it won't be."

For the factor *having done deals/worked on similar modalities (e.g. formats small molecule vs. biologics)* the results are mixed in regards to if it has a positive effect or if it does not have any impact at all.

4.3.3 Deal-breakers

Table 6*. Top success factors, in percent, mentioned as deal-breakers by the participants in the questionnaire.*

Top Mentioned Deal-breakers	Percentage of participants mentioned it as a part of top 3 deal-breakers
Intellectual property (IP protection and FTO)	56 %
Financial terms (Unreasonable price compared to value of asset)	31 %
Scientific attractiveness (Quality of data)	31 %
Available Rights (Including sub-licenses, scope, exclusivity etc.)	31 %
Commercial case (including differentiation, change in competition)	25 %
Negotiation (including unwillingness to negotiatie and change in key terms)	19 %
Strategic fit (including cannibalization of internal pipeline, overall company strategy)	19 %
Relationship (including trust, respect and executive management relationship)	19 %

Table 6 shows a summary of the top eight deal-breakers that the participants in the questionnaire highlighted. The participants were asked what they consider to be the top three deal-breakers. The results show that *intellectual property* including both *IP* protection and *FTO* is considered to be a deal-breaker by more than half of the participants. *Financial terms*, in relation to unreasonable price compared to the value of the asset, is also consider a deal-breaker by around one third of the participants. At the same percentage as *financial terms* the participants also considered *available rights (including sub-licenses, scope and exclusivity) and scientific attractiveness (quality of data)* to be deal-breakers. Other factors mentioned were: *commercial case, negotiation, strategic fit and relationship.*

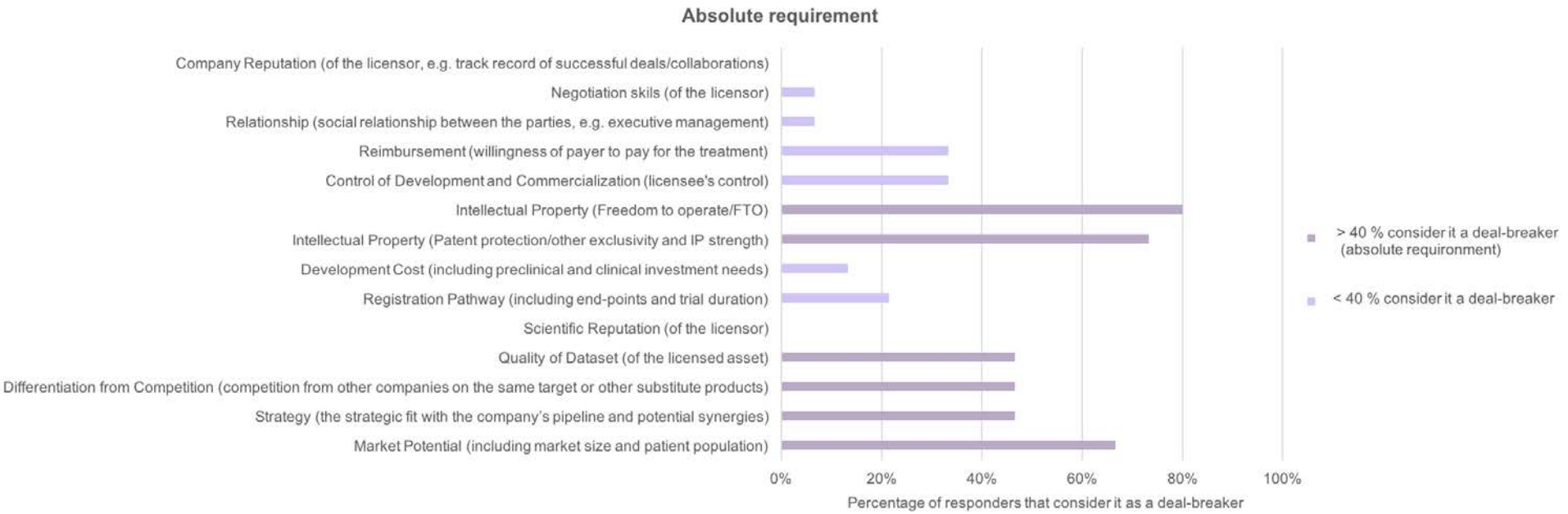

Figure 7. *Absolute requirement. Graph showing the percentage of responders in the questionnaire considering specific success factors as deal-breakers. The color scheme indicates for each factors if more or less than 40 % of the responders considered the specific success factors as a deal-breaker.*

When the participants were asked to define if they consider a specific factor an absolute requirement for a deal, the results (see figure 5) align with the results in table 6 to a large extent. *IP* and *FTO* are the factors that are considered an absolute requirement by most of the participants. When asked about the *market potential*, which relates to the *commercial attractiveness*, the majority considered it to be an absolute requirement. Only *IP* and *FTO* surpassed *commercial attractiveness* as an absolute. This is however not the case in table 6 where only 25 % mention it as a deal-breaker. However, contractual aspects such as *scope of license* (*rights*) and *financial terms* were not taken into consideration in figure 5. *Differentiation, Strategic fit, and Quality of data* are also considered an absolute requirement by more than 40 % of the participants.

4.3.4 Value Drivers and Likelihood of Completion

The results from the questionnaire show that factors related to the *commercial attractiveness* had the largest impact on additional financial value, as can be seen in figure 6 (p. 24). *Market potential, differentiation* and *reimbursement* are the main aspects of the commercial case and these are the factors that have the highest response rate for adding moderate or significant additional financial value. Qualitative factors such as *scientific and company reputation, relationship and negotiation skills* do not seem to add additional financial value to a deal.

When observing the data, it becomes clear that *strategic fit* is once again an important component of the deal process and particularly in this case of deal likelihood, see figure 7 (p. 25). Additionally, *relationship* arises as an important aspect of increasing deal likelihood, contrasting its lack of relevance as a value driver. Another interesting aspect comes in the form of a *clear registration pathway*, which adds twice as much impact on increasing deal likelihood compared to increasing the financial value. Aspects of *reputation* are contested and opinions differ on its influence. *IP* apparently does not influence the financial value nor does it increase the likelihood but is a requirement, for a deal process, which would potentially indicate a binary requirement i.e. a deal-breaker.

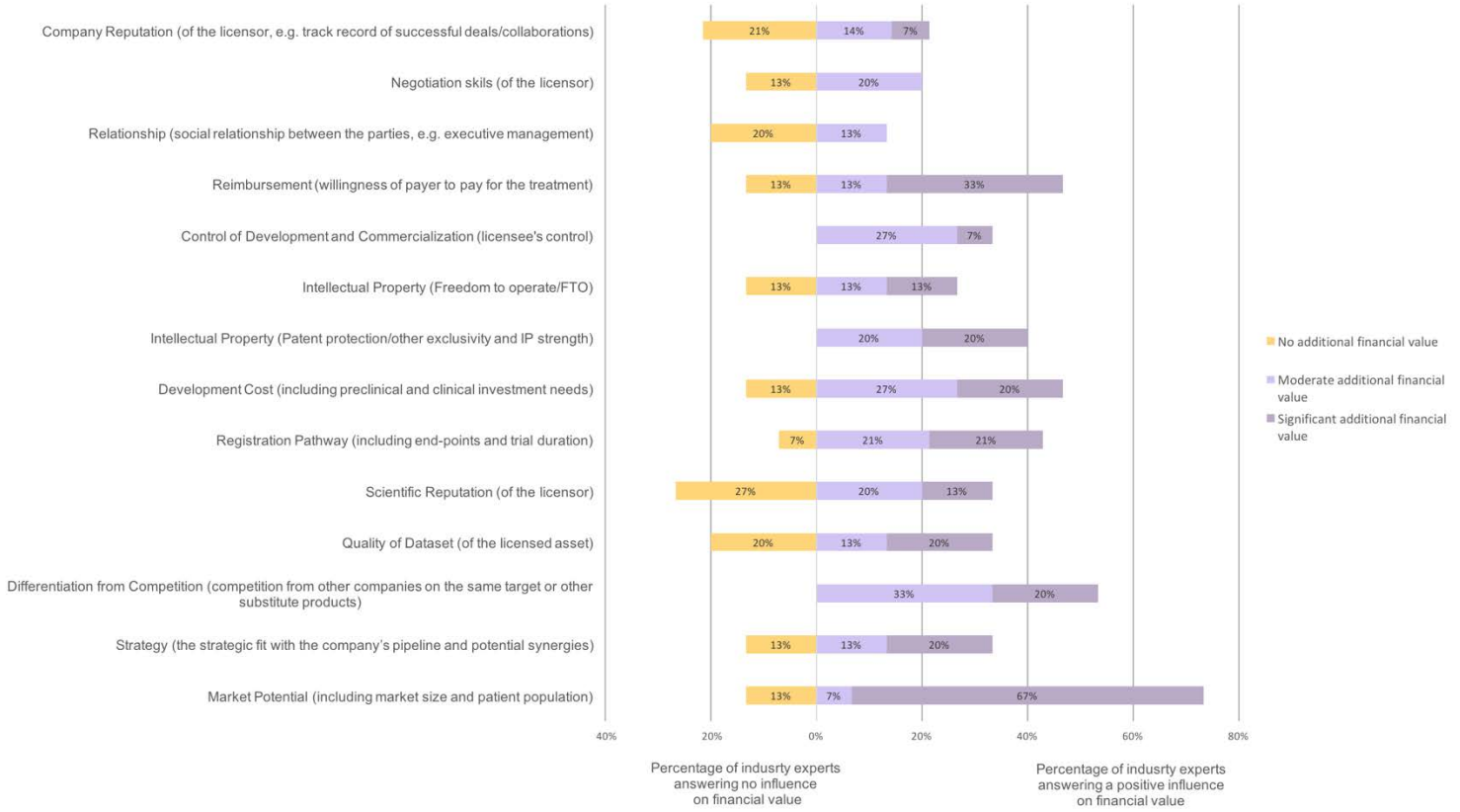

Figure 8. *Financial value. Graph of responder's perception of additional financial value added by different success factors. No additional financial value and moderate/significant additional financial value responses are stacked in opposite directions.*

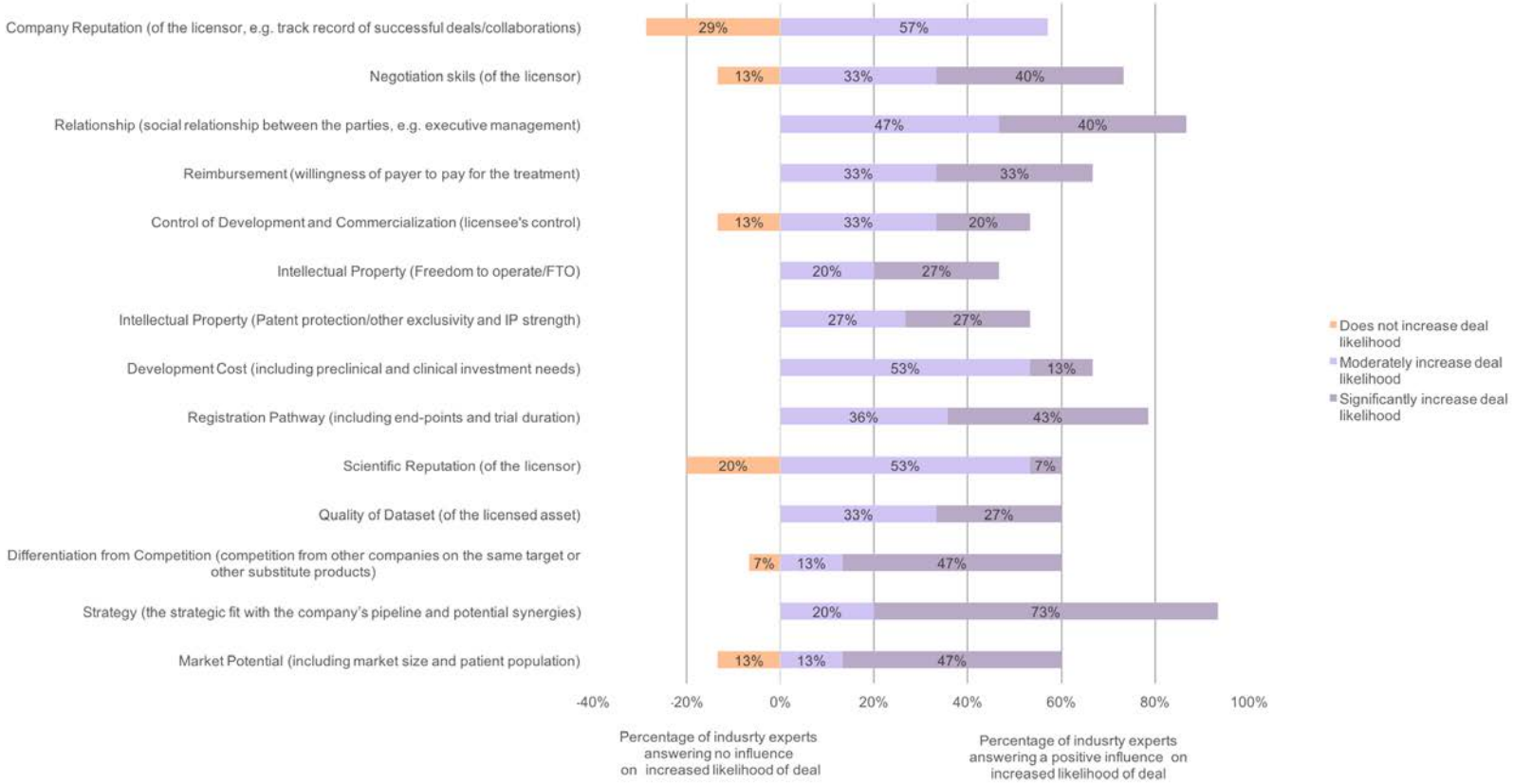

Figure 9*. Likelihood of a deal. Graph of responder's perception of success factors impact on the likelihood of a deal. No increases in deal likelihood is stacked in the opposite direction of moderate/significantly increasing likelihood.*

4.4 Case Study

In research and interviews, the deal between Genentech and NewLink Genetics, regarding NewLink's indoleamine-2,3-dioxygenase (IDO) inhibitor (NLG919, GDC-0919), has come up as a deal were strategic fit is exemplified in a good way and the influence it has on the deal structure and the financials. In this section a brief description of the involved companies background and analysis of their pipelines and the licensing deals will be presented.

4.4.1 Genentech and NewLink Genetics IDO-inhibitor Deal

In october of 2014 NewLink Genetics announced that they have entered into a worldwide exclusive license with Genentech for the development of NLG919 a phase I stage indoleamine-2,3-dioxygenase (IDO)-pathway inhibitor (NewLink Genetics Corporation, 2014). In addition to NLG919, the parties also entered into an agreement for discovery and development of next generation IDO and TDO inhibitors (NewLink Genetics Corporation, 2014).

Genentech paid $ 150 million upfront and NewLink Genetics is eligible to receive over $ 1 billion in potential milestones as well as double-digit royalties while retaining an option to co-promote NLG919 and potential next generation IDO/TDO inhibitors in the US, see figure 8 (NewLink Genetics Corporation, 2014).

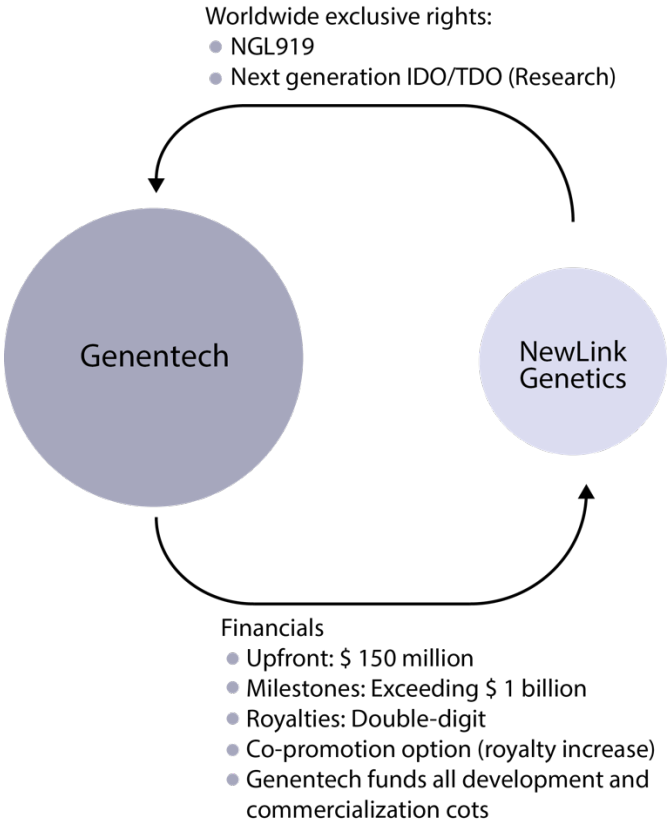

Figure 10. *Overview of Genentech - NewLink Genetics deal. The figure shows the rights for NGL919 and next generation IDO/TDO inhibitors transferred to Genentech in exchange for the disclosed financial terms and co-promotion rights.*

4.4.1.1 Genentech: Background and Pipeline Analysis

Genentech was founded in South San Francisco as the world's first biotech company in 1976 by Herbert Boyer, a biochemist from the University of California, San Francisco, and Robert Swanson, a venture-capitalist (Russo, et al., 2003; Genentech, 2016). The company was founded on the discoveries of recombinant DNA made by Boyer and Stanley Cohen, a medical professor at Stanford (Russo, et al., 2003; Genentech, 2016).

In 1980 the first recombinant protein, human insulin, was approved by the FDA (Genentech, 2016). The recombinant insulin was licensed from Genentech to Eli Lilly & Company, which was also the first licensed biopharmaceutical ever (Genentech, 2016). In March of 2009 Genentech became a part of the Roche Group and Genentech Research and Early Development acts as an independent center within Roche (Genentech, 2016). In October of 2014 Genentech had a large oncology pipeline and several approved drugs on the market, see figure 9.

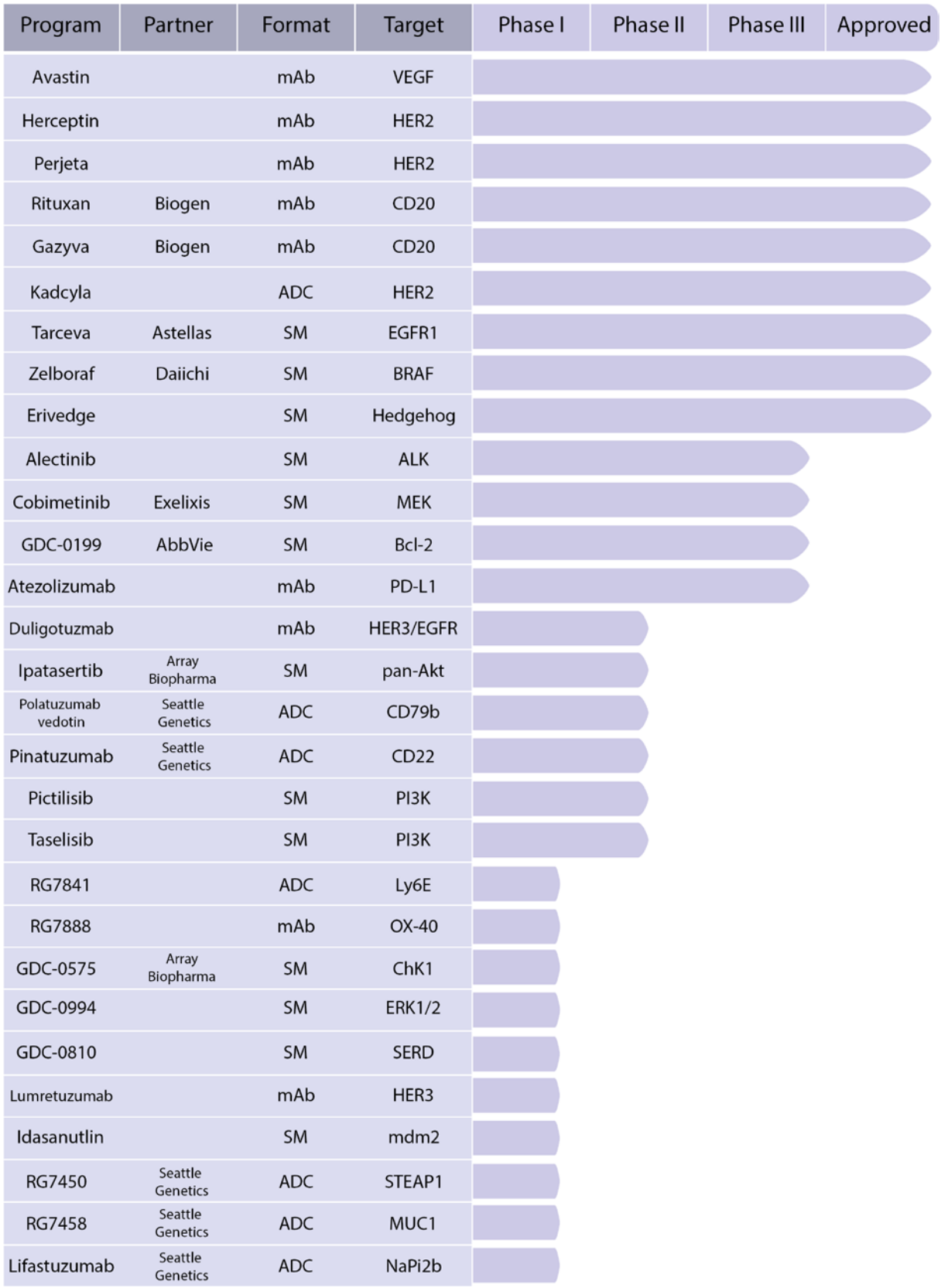

Figure 11. *Genentech's clinical oncology pipeline and approved oncology drugs in October 2014. The figure shows disclosed programs. SM = Small Molecule, mAb = Monoclonal Antibody, ADC = Antibody-drug Conjugate. Source: Biomedtracker (2016) and Genentech (2016).*

Genentech had four blockbuster oncology drugs in 2014; Avastin, Herceptin, Rituxan and Tarceva (Biomedtracker, 2016). Rituxan was the sixth best-selling drug in the world in 2014 with total sales of $ 7.55 billion worldwide (FirstWordPharma, 2015). Avastin was the seventh best-selling drug with total sales of $ 7.021 billion and Herceptin was the ninth best with sales of $ 6.866 billion (FirstWordPharma, 2015). In addition, both Perjeta and Kadcyla, Genentech's two other drugs in their HER2 franchise, were forecasted to reach blockbuster status in the future by several analysts (Biomedtracker, 2016).

4.4.1.2 Genentech's immuno-oncology pipeline

One of the most interesting and promising late stage assets in Genentech's pipeline in October of 2014 was their PD-L1 inhibitor Atezolizumab. In the first half of 2014 Genentech had published promising results from both a phase I and top-line results from a phase II trial of Atezolizumab (Powles, et al., 2014).

Atezolizumab targets PD-L1 or Programmed death-ligand 1 and is a so called checkpoint inhibitor. Checkpoint inhibitors belong to a sub-field of oncology called immuno-oncology which is an approach where the patient's own immune-system is used to fight cancer. The first approved checkpoint inhibitor, Yervoy, targeting cytotoxic T-lymphocyte antigen 4 or CTLA-4, was approved in March of 2011 (FDA, 2011). In Addition to Genentech's promising PD-L1 results, monoclonal antibodies targeting PD-1 or programmed death-1 receptor had already been approved in 2014 (biomedtracker, 2016). Opdivo, marketed by Bristol-Myers Squibb was the first approved PD-1 inhibitor when it received approval in Japan, July 2014 (Ono Pharmaceuticals Co, 2014). The first PD-1 inhibitor to be approved in the USA by FDA was Merck & Co's Keytruda in September 2014 (FDA, 2014).

Atezolizumab works as mentioned by inhibiting PD-L1 which is one of the ligands to PD-1 (Freeman, et al., 2000). PD-1 is a cell surface membrane protein of the immunoglobulin superfamily and is expressed on activated T-cells, B-cells and macrophages (Pruitt, et ak., 2013; Agata, et al., 1996). Cancer cells utilize several pathways, by up-regulating expression of certain proteins, to escape the immune-system (Zou, et al., 2005). The PD-1/PD-L1 pathway down-regulate T cell response by inhibiting T cell activation (He, et al., 2015). PD-L1 expression is up-regulated in various cancers including non-small cell lung cancer, melanoma, renal cell carcinoma, gastric cancer, hepatocellular, several leukemias and multiple myeloma to name a few (Velcheti, et al., 2013; Boland, et al., 2013; Spranger, et al., 2013; Thompson, et al., 2005; Bernstein, et al., 2014). The MoA for a PD-L1 antibody is outlined in figure 10 and 11.

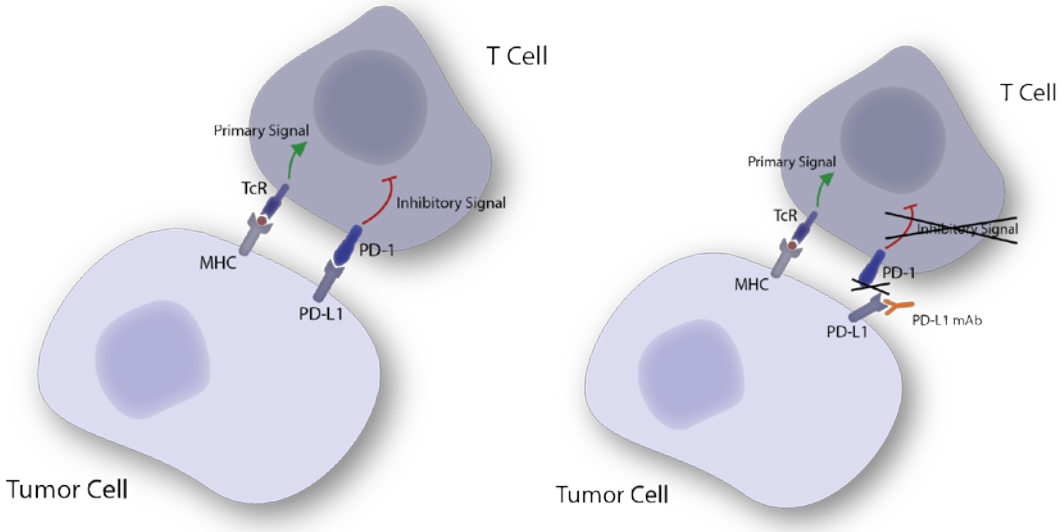

Figure 12. *Overview of the PD-1/PD-L1 pathway and its effect on T cell inhibition in the tumor microenvironment (to the left). A tumor cell escapes the immune system by expressing PD-L1 and thus inhibiting T cells. MHC = Major histocompatibility complex, TcR = T cell receptor.* ***Figure 13.*** *Overview of the MoA of a PD-L1 antibody (to the right). The PD-L1 antibody blocks the interaction between PD-1 and PD-L1 and thus the inhibitory signal is lost.*

4.4.1.3 NewLink Genetics: Background and IDO-inhibitor Program

NewLink Genetics was found in 1999 by Charles Link, MD, and Nicholas Vahanian, MD, a biotech company focusing on cancer (NewLink Genetics, 2016). In 2014 NewLink Genetics had two main oncology approaches in their clinical pipeline, a cancer vaccine based on their HyperAcute platform and two IDO-inhibitors (biomedtracker, 2016).

IDO or indoleamine-2,3-dioxygenase is an enzyme that catalyze the degradation of L-tryptophan, an essential amino acid, to N-formylkynurenine (Pruitt, et al., 2013). N-formylkynurenine is then converted into kynurenine. The IDO enzyme is the rate-limiting step in degradation of tryptophan (Munn, et al., 1999). As a result, IDO causes depletion of tryptophan which inhibits T cell proliferation (Munn, et al., 1999). IDO is naturally expressed by dendritic cells and when this is done by antigen-presenting cells it leads to tryptophan depletion resulting in T cell anergy and recruitment of Tregs [10](Mellor, et al., 2004). One explanation of the recruitment of Tregs is that the increase in kynurenine drives the conversion or recruitment of T helper cells into Tregs (Nguyen, et al., 2014).

Various cancer types use the IDO pathway as a way to escape the immune system by overexpressing IDO and thus depleting L-tryptophan in the tumor microenvironment (Uyttenhove, et al. 2003; Jiang, et al., 2015). The MoA for an IDO-inhibitor can be seen in figure 12 and 13.

[10] Tregs - Regulatory T cell, also known as Suppressor T cells, is a subpopulation of T cells that modulate the immune system to maintain tolerance to self-antigens.

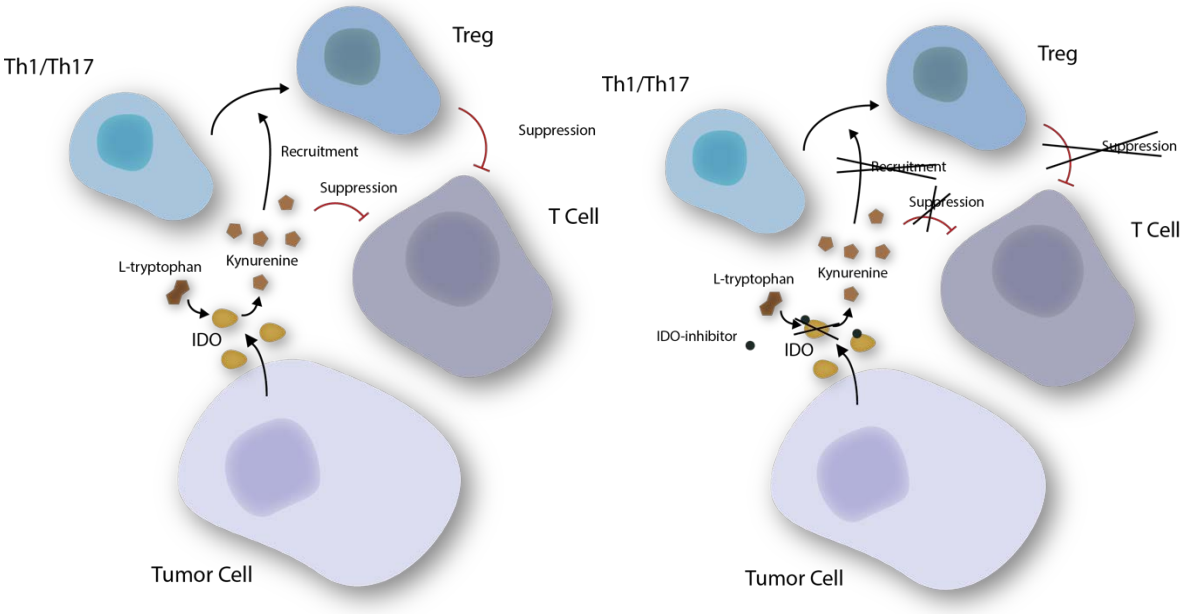

Figure 14. Overview of the IDO-pathway and its effect on T cell suppression in the tumor microenvironment. **Figure 15.** Overview of the MoA of an IDO-inhibitor. *Th1 = T helper 1 cell, Th17 = T helper 17 cell.*

In April, 2014, NewLink Genetics presented preclinical results of combining their IDO-inhibitors with PD-1/PD-L1/PD-L2 blockade and the results demonstrated a synergistic effect (NewLink Genetics, 2014).

4.4.1.4 Strategic Fit, IDO-inhibitor as a complement to Genentech's Oncology Pipeline

At the time of the deal between Genentech and NewLink Genetics there was a strong scientific rationale to combine a PD-1/PD-l1 inhibitor with an IDO-inhibitor. Beside the preclinical data generated and presented by NewLink Genetics, several publications had been made showing a synergistic effect from combining PD-1/PD-L1 blockade with IDO-inhibitors, Spranger (et al., 2014) and Holmgaard (et al., 2013) among others. The MoA of combining PD-L1 blockade and an IDO-inhibitor can be seen in figure 14.

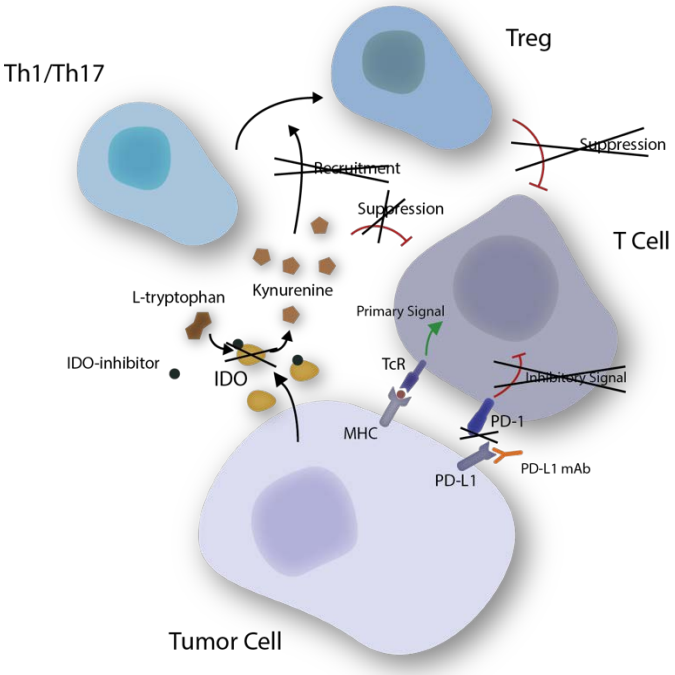

***Figure 16**. Overview of the MoA for combined PD-L1 blockade and IDO inhibition.*

In addition to the preclinical data supporting PD-1/PD-L1 blockade with IDO inhibition, Genentech had previously expressed an interest in the combination. Genentech announced a clinical trial collaboration on combining Atezolizumab with an IDO-inhibitor from Incyte in the summer of 2013 (FierceBiotech, 2014).

In 2014 there were three IDO-inhibitors in the clinical pipeline (Biomedtracker, 2016). The most advanced was Epacadostat in phase II from Incyte who had signed clinical trial collaboration with several partners before the time of the Genentech and NewLink Genetics deal (Biomedtracker, 2016). The two other belonged to NewLink Genetics, Indoximod and NLG-919 (Biomedtracker, 2016). With Incyte holding on to the rights for Epacadostat the competition for clinical IDO-inhibitors can be assumed to be high.

4.4.1.5 Results of High Strategic Fit and Competition on the Asset

NewLink Genetics NLG-919 was an asset that arguably was highly complementary to Genentech's clinical oncology pipeline and especially to their PD-L1 inhibitor, Atezolizumab, since there was a strong scientific rationale to combine them. The scientific rationale can be explained by evaluating the combined MoA from NLG-919 and Atezolizumab, see figure 14. In addition, the generated scientific data, by both NewLink Genetics and academia, regarding combination of IDO-inhibitors with PD-1/PD-L1 blockade was likely also a highly influential factor that drove the strategic fit. Genentech had already expressed interest in the biology of the IDO-pathway and in short NLG-919 was the only available clinical IDO-inhibitor on the market. Of course NewLink Genetics was aware of this fact and it is likely that it influenced NewLink Genetics strategy when it came down to setting up the deal structure and financial terms.

It is also not unreasonable to think that other companies having a PD-1/PD-L1 in their pipeline, e.g. Merck & Co, would have been interested in NewLink Genetics NLG-919 and competed for the asset. Merck & Co did get their hands on an IDO-inhibitor in 2016 when they acquired IOmet Pharma, a small private UK biotech company developing IDO/TDO inhibitors (Fiercebiotech, 2016). The strong scientific fit and high competition from being the only available clinical IDO-inhibitors is likely what drove both the likelihood of the deal and in addition the ridiculous high valuation.

5. Discussion

In this chapter the results will be discussed in relation to theory, theoretical framework and to each other.

5.1 Interviews, Questionnaire and Case Study in Relation to Theory

5.1.1 Success Factors

The interviews were conducted with biotech professionals whereas the questionnaire included small biotech, mid-size and big pharma industry professionals with a slight skewness towards mid-size and big pharma. The reason for focusing more on mid-size and big pharma in the questionnaire was, as mentioned in the methodology, to be able to test how the results from the interviews relate to the whole industry, which has not been explored in previous research.

When comparing the answers from the interviews and the questionnaire, a few success factors stand out from the rest. In general, the results are well aligned between the two groups. *Strategic fit* is regarded as one of the most important or even the most important factor by both groups. Moreover, in the case study of the licensing deal of an IDO-inhibitor between NewLink Genetics and Genentech the importance of *strategic fit* is validated as it as has a major impact on the deal. We would argue that these results point to *strategic fit* being a crucial success factor in a product out-licensing deal between biotech and big pharma.

Other factors that are regarded as important by both groups are *relationship, commercial attractiveness* and *scientific attractiveness* (data-set). When it comes to *scientific attractiveness* and data the biotech professionals regarded it as more important than what mid-size and big pharma experts did. This can however to some extent be explained by how a large pharmaceutical company generally operates. A large pharmaceutical company has rigorous internal processes on several hierarchy levels that needs to be cleared for an in-licensing opportunity. This explains why big pharma sees *internal alignment* as a more important success factor than *scientific attractiveness*.

The licensee's *internal alignment* is, however, out of the licensor's direct control. What a biotech company needs to do is to convince enough people at a potential partner company to create and facilitate *internal alignment* in regard to the asset. The data shows that *strategic fit* is a key success factor to create *internal alignment* but that *relationship, commercial and scientific attractiveness* are important aspects as well. Investing to create and facilitate *internal alignment* at the partner can be a way for a biotech company to increase its chances for successful licensing activities.

Two success factors that not were mentioned by the biotech professionals to the same extent were *financials terms (aligning financial terms with the value of the asset)* and *negotiation aspects* such as *negotiation skills, preparation and attitude (going for a win-win situation)*. These factors shed important light on what is important to a big pharma company after they declared an interest in an asset, which is of great importance to a biotech company to be aware of to have successful licensing activities.

5.1.2 Strategic Fit

We argue that in the pharmaceutical industry the concept of strategic fit often is applied in a slightly different way compared to the term as defined by J. Law (2016). According to us a good strategic fit in the pharmaceutical industry would rather be defined as: "The extent to which diversification into *the same* field fits with the future scope of a firm" and not "The extent to which diversification into *another* field fits with the future scope of a firm". This definition of strategic fit can be explained by the history of the pharmaceutical industry. A pharmaceutical company builds up expertise in specific indications and needs to constantly fuel its pipeline to be able to keep a successful franchise alive. This has an effect on the investments made by a large pharmaceutical company. The pharmaceutical company invests to diversify and broaden its indication franchise. This definition of strategic fit is in line with the results obtained in this thesis.

From the results, we would argue that *strategic fit* as a concept used in the pharmaceutical industry includes the following key components: 1) *complementary to existing product portfolio,* 2) *aligned with overall strategy* and 3) *existing salesforce or late-stage clinical asset within the same indication.* These components have a large impact on the likelihood of the deal and are aspects that need to be considered by a biotech company when it reaches out to potential partners. An example of a good strategic fit within the pharmaceutical industry is thus: "we have a product and salesforce within indication X and this in-licensing opportunity would allow us to extend our indication X franchise into new patient populations".

The component of *strategic fit* from the interviews and questionnaire that was regarded as key, *complementary to existing product portfolio,* is well aligned with the case study. In the case study the scientific rationale behind combining an IDO-inhibitor and PD-l/PD-L1 blockade is what drives the deal. It is quite clear that NewLink Genetics IDO-inhibitor, NGL-919, complemented Genentech's immune-oncology pipeline at the time of the deal and especially Atezolizumab, see figure 14.

We would further argue that Hass (et al., 2011) definition of complementary assets, or a strategic fit, is not specific enough to define a strategic fit. The usual role for a biotech company is the innovator and the pharmaceutical company the development and commercialization arm of said innovations. By using Hass (et al., 2011) framework, more or less all biotech companies would be a good strategic fit for a larger pharmaceutical company, however this is not case. The next step would be to further research how is a complementary asset defined. What are the key aspect of a good complementary asset to an existing portfolio. This would be a key question for a biotech company.

An interesting aspect is internal cannibalization. One of the participants in the questionnaire stated that if an asset is better than an internal competing program, risk of cannibalization is a positive thing. However, as our data indicates, this is a point of view that is not shared among all industry experts. This could in a larger perspective mean that pharmaceutical companies would rather pass on in-licensing an asset that can cannibalize their portfolio and thus opening up for a competitor to do it than do it themselves.

5.1.3 Deal-breakers

There is a consensus between the results from the interviews and the questionnaire that *intellectual property* is a deal-breaker. This is backed up by the result that *IP* does not seem to add any additional financial value nor to increase the likelihood of a successful deal. However, it needs to be there which solidifies *IP* as a deal-breaker.

The *FTO* results are mixed. From the questionnaire the results point to *FTO* as a deal-breaker. However, an interesting aspect was raised during the interviews that *FTO* is becoming less and less important and there are certainly a lot of examples supporting this argument.

Arguments can be made that the industry is ready to launch at risk, at least the large pharmaceutical companies. When you have reached regulatory approval of an asset with blockbuster potential, launching and risking to have to pay a royalty rate to the party with dominant IP could be regarded as a "luxury problem" since this means that your asset has successfully cleared clinical development. In addition, the risk of a judge approving an injunction for an approved drug is likely very low, at least for a life threatening disease. The opportunity outweighs the risk.

5.1.4 Value Drivers

From the interviews the factor *competition for an asset* was mentioned as the main value driver of additional financial value or premium value. The factor *competition* was not included in the questionnaire which makes it impossible to assess. It is possible to suspect that *competition* is what drives the high valuation of NewLink Genetics IDO-inhibitor in the case study. Genentech was certainly not the only company interesting in combining IDO-inhibiton with PD-1/PD-L1 blockade so it is reasonable to think that more than one actor was involved in the deal process.

In the questionnaire factors related to the *commercial attractiveness* such as *market potential, differentiation* and *reimbursement* were mentioned as adding additional financial value. We do however suspect that the participants misinterpreted this question and did not noticed the emphasis on additional value which would be the premium value of an asset.

From an economical theory perspective, it comes natural that *competition* for an asset increase the financial value, as this is just a case of demand and supply. Therefore, we would argue that *competition* or the perception of *competition* is the main value driver of premium or additional value.

5.1.5 Likelihood of Completion

Relationship appears as a highly influential factor in regards to increasing the likelihood of deal completion. It is reasonable to expect that this helps to overcome the different obstacles of a deal process. Arguably, it is easier to manage obstacles in the process if the negotiators and executive management approve of each other. Unsurprisingly, a*lignment with overall strategy* has a large impact on the likelihood of a deal as well.

5.2 Comparison Theoretical framework, Interviews, Questionnaire and Case Study

Arnold (et al., 2002) have argued that quantitative factors only can account for 32-54 % of the deal value and that the rest of the value comes from qualitative factors. Moreover, Arnold (et al., 2002) argued that qualitative factors are for example *negotiation skills*.
What our data shows in contradiction to Arnold's theory is that *negotiation skills* do not have an impact on the premium value of a deal. However, our data shows that the premium value comes from a qualitative factor, *competition* or perceived competition for an asset. Arnold (et al., 2002) did not analyze the factors impact on the likelihood of a deal. Our data also shows that qualitative factors accounts for an even larger impact on the likelihood of a deal being executed than on the valuation of the deal.

A problem with the analysis done by Arnold (et al., 2002) is that they have only interviewed what they define as “biotech leaders” and not “leaders” from big pharma. This creates a skewness in the results and makes you question if the perceived value drivers that Arnold presents are valid for the whole industry.

One example is how reimbursement is not considered important according to Arnold’s analysis whereas, according to our research, it is (in particular to executives from large pharmaceutical companies). We would therefore argue that our data represent the industry as a whole better and that reimbursement possibilities are highly important.

5.3 Results in Relation to R&D Productivity

Scientific attractiveness and strategic fit are key success factors in product licensing in the pharmaceutical industry. Additionally, relationship and other qualitative factors are major forces in the deal making process. To increase the R&D productivity, pharmaceutical companies need to choose the best assets from the biotech companies with the highest scientific attractiveness. However, these decisions may be overshadowed by qualitative factors such as relationship which might have a negative impact on the industry's overall R&D productivity. For a biotech company it is key to build up good relationships in the industry and most important generate scientific data that reflect the stage of the asset in order have successful licensing activities.

6. Conclusion

Licensing in the biotech and pharmaceutical industry is a complex activity. Our results show that there is a range of success factors that influence the outcome. In general, there are a few success factors that stand out as more important than others. From the results it is apparent that *strategic fit* is a crucial success factor from both the biotech and large pharmaceutical perspective. For a biotech company, to succeed, it is key to facilitate *internal alignment* within the potential large pharmaceutical partner. *Relationship* and *scientific attractiveness* are the main success factors involved in creating *internal alignment*.

In the pharmaceutical industry the concept of *strategic fit* is, based on our findings, defined and used differently compared to business research in general. According to our findings *strategic fit* is defined as "the extent to which diversification into *the same* field fits with the future scope of a firm". *Strategic fit* involves a few key components based on our research: 1) *complementary to existing product portfolio*, 2) *aligned with overall strategy* and 3) *existing salesforce or late-stage clinical asset within the same indication*. These results give an idea of which characteristics a biotech company should look for in a potential partner.

The results indicate that different types of success factors influence different aspect of a licensing deal. Qualitative factors such as *strategic fit* and *relationship* have a large impact on the likelihood of a deal. In comparison, quantitative factors that make up the *commercial attractiveness* have the largest influence on increasing the financial value, e.g. *market potential, reimbursement* and *differentiation.* In contradiction to these findings, Arnold (et al., 2002) and her team have shown that reimbursement is not one of the top financial value drivers. We would argue that our result is a more accurate representation of the pharmaceutical industry as a whole due to a more diverse data gathering. Collecting data from both the biotech and the large pharmaceutical actors. One key question of financial value drivers is what drives a premium value, a higher value than the result fo a valuation, e.g. DCF or rNPV. Based on our results, the factor *competition* for the asset to be licensed stands out as the main success factors that has an impact on the premium value.

Intellectual property in the form of intellectual property rights or rather the lack of, stands out in our result as the most significant deal-breaker. Intellectual property does not increase the likelihood of the deal not does it influence the financial value but it needs to be present for a deal to be possible. Interestingly, *FTO* as a deal-breaker is more contested.

To summarize, the results from our study can offer valuable insights to a biotech company and assist them in the development of successful licensing activities. These results need to be further validated given the lack of research in the field. What would be interesting to research further in the future is how to assess what factor determine whether an asset is complementary to an existing product portfolio or not since this is a key component of *strategic fit.*

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8. Appendix

8.1. Questionnaire

Success factors in licensing within the pharmaceutical industry

1. Welcome!

Thank you for participating in our survey!

This survey is a part of our master thesis at Chalmers University of Technology researching *Critical Success Factors for Product Licensing in the Pharmaceutical Industry.* All answers will be made anonymously.

If you have any questions or comments do not hesitate to contact us!

Regards,
Jimmie Hofman and Adam Niklasson

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Success factors in licensing within the pharmaceutical industry

2. Company Profile

1. What is your title?

2. Years of business development/licensing experience in the pharmaceutical indusrty?

3. What is the market cap of your company?

3. Success factors for a product licensing deal

1. In a recent licensing deal of a pharmaceutical program, that you were a part of, what would you argue were the 5 most important factors that influenced the completion of the deal? (Feel free to include a comment to each answer if applicable)

1	
Comment	
2	
Comment	
3	
Comment	
4	
Comment	
5	
Comment	

2. What in your experience would you consider a *deal breaker* and why?

With *deal breaker* we mean a factor that is a requirement but not necessarily a value driver

(Name up to 3 and feel free to leave a comment to each answer)

1	
Comment	
2	
Comment	
3	
Comment	

3. Through out our research we have identified *Strategic Fit* as an important *Success Factor* for product out-licensing.

The concept of *Strategic Fit* is broad and complex and has therefore been divided into sub-factors. What type of impact if any would you say that these sub-factors have on a licensing deal? Please feel free to add up to two additional sub-factors.

	1 - Absolute Obstacle	2 - Negative Impact	3 - No Impact	4 - Positive Impact	5 - Significant Success Factor
Existing sales force within the indication/therapeutic area	☐	☐	☐	☐	☐
Clinical stage program within the same indication/therapeutic area	☐	☐	☐	☐	☐
Complementary to existing product portfolio within the same indication	☐	☐	☐	☐	☐
Competing with internal programs and product portfolio	☐	☐	☐	☐	☐
Aligned with overall company strategy (e.g. "We are only looking at clinical assets in indication x")	☐	☐	☐	☐	☐
Having done deals/worked on similar modality (e.g. formats: small molecule vs biologics)	☐	☐	☐	☐	☐
Additional sub-factor 1 (please specify below):	☐	☐	☐	☐	☐
Additional sub-factor 2 (please specify below):	☐	☐	☐	☐	☐

Sub-factor 1/Sub-factor 2 (please specify)

4. When presented with a *positive outlook* on the following factors - how do they impact the deal?

***Positive outlook* is defined as what you would consider a favorable level. E.g. The Market Potential is very high, is this a requirement for the deal (deal breaker), does it add financial value to the deal and does it impact the likelihood of a deal?**

(You can select multiple answers for each factor)

	Absolute requirement	**No** additional financial value	**Moderate** additional financial value	**Significant** additional financial value	**Does not** increase deal likelihood	**Moderately** increase deal likelihood	**Significantly** increase deal likelihood
Market Potential (including market size and patient population)	☐	☐	☐	☐	☐	☐	☐

Strategy (the strategic fit with the company's pipeline and potential synergies)	☐	☐	☐	☐	☐	☐	☐
Differentiation from Competition (competition from other companies on the same target or other substitute products)	☐	☐	☐	☐	☐	☐	☐
Quality of Dataset (of the licensed asset)	☐	☐	☐	☐	☐	☐	☐
Scientific Reputation (of the licensor)	☐	☐	☐	☐	☐	☐	☐
Registration Pathway (including end-points and trial duration)	☐	☐	☐	☐	☐	☐	☐
Development Cost (including preclinical and clinical investment needs)	☐	☐	☐	☐	☐	☐	☐
Intellectual Property (Patent protection/other exclusivity and IP strength)	☐	☐	☐	☐	☐	☐	☐
Intellectual Property (Freedom to operate/FTO)	☐	☐	☐	☐	☐	☐	☐
Control of Development and Commercialization (licensee's control)	☐	☐	☐	☐	☐	☐	☐
Reimbursement (willingness of payer to pay for the treatment)	☐	☐	☐	☐	☐	☐	☐
Relationship (social relationship between the parties, e.g. executive management)	☐	☐	☐	☐	☐	☐	☐
Negotiation skils (of the licensor)	☐	☐	☐	☐	☐	☐	☐
Company Reputation (of the licensor, e.g. track record of successful deals/collaborations)	☐	☐	☐	☐	☐	☐	☐
Additional factor 1 (please specify below)	☐	☐	☐	☐	☐	☐	☐
Additional factor 2 (please specify below)	☐	☐	☐	☐	☐	☐	☐

Please specify factor 1/factor 2

5. Please rank the top 3 factors in the previous question (question 4), including your additional factors

1 - Most important	
2 - Second most important	
3 - Third most important	