Deal Structures in the Life Sciences Industry and their Financial Statement Implications

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St. Gallen, May 19, 2014

The President:

Prof. Dr. Thomas Bieger
For Sara and Anna
Thank you for all your support!
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<tr>
<td>AICPA</td>
<td>American Institute of Certified Public Accountants</td>
</tr>
<tr>
<td>Big 4</td>
<td>The group of the following four public accounting firms: Ernst &amp; Young (EY), Deloitte, KPMG and PricewaterhouseCoopers (PwC)</td>
</tr>
<tr>
<td>Big pharma</td>
<td>Pharmaceutical companies that evolved from chemical-producing companies and have ethical drug revenues of multibillion dollars based on mainly small-molecule drugs.¹</td>
</tr>
<tr>
<td>Biologics</td>
<td>Drugs, which – unlike traditional chemical-based drugs such as tablets and capsules – are developed with live processes</td>
</tr>
<tr>
<td>Biotech companies</td>
<td>Companies that use biotechnology to develop therapeutic products for human health care applications, including both small-molecule and biologics platforms.²</td>
</tr>
<tr>
<td>Blockbuster</td>
<td>A drug with at least USD 1 billion in annual revenues</td>
</tr>
<tr>
<td>Capex</td>
<td>Capital Expenditure</td>
</tr>
<tr>
<td>CFO</td>
<td>Chief Financial Officer</td>
</tr>
<tr>
<td>CRO</td>
<td>Contract Research Organization</td>
</tr>
<tr>
<td>CU</td>
<td>Currency Units</td>
</tr>
<tr>
<td>DCF</td>
<td>Discounted Cash Flow</td>
</tr>
<tr>
<td>EAT</td>
<td>Earnings After Tax</td>
</tr>
<tr>
<td>EBIT</td>
<td>Earnings before Interest and Taxes</td>
</tr>
<tr>
<td>EBITDA</td>
<td>Earnings before Interest, Taxes, Depreciation and Amortization</td>
</tr>
<tr>
<td>EITF</td>
<td>Emerging Issues Task Force</td>
</tr>
<tr>
<td>EMEA</td>
<td>European Medicines Evaluation Agency</td>
</tr>
<tr>
<td>FASB</td>
<td>Financial Accounting Standards Board, an independent organization funded entirely by the private sector</td>
</tr>
<tr>
<td>FCF</td>
<td>Free Cash Flows</td>
</tr>
<tr>
<td>FDA</td>
<td>U.S. Food and Drug Administration</td>
</tr>
<tr>
<td>FIPCO</td>
<td>Fully Integrated Pharmaceutical Company</td>
</tr>
<tr>
<td>GAAP</td>
<td>Generally Accepted Accounting Principles</td>
</tr>
<tr>
<td>GmbH</td>
<td>Gesellschaft mit begrenzter Haftung (limited liability company)</td>
</tr>
<tr>
<td>IAS</td>
<td>International Accounting Standard</td>
</tr>
<tr>
<td>IASB</td>
<td>International Accounting Standards Board</td>
</tr>
<tr>
<td>IFRIC</td>
<td>International Financial Reporting Interpretation Committee</td>
</tr>
<tr>
<td>IFRS</td>
<td>International Financial Reporting Standards</td>
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¹ Deloitte Research (2005), p. 3.
² Deloitte Research (2005), p. 3.
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>IND</td>
<td>Investigational New Drug (U.S.); the equivalent in Europe is a clinical trial application for an Investigational Medicinal Product (see “IMP”)</td>
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<tr>
<td>IMP</td>
<td>Investigational Medicinal Product (Europe); the equivalent in the U.S. is a clinical trial application for an Investigational New Drug (see “IND”)</td>
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<tr>
<td>IP</td>
<td>Intellectual Property</td>
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<tr>
<td>IPO</td>
<td>Initial Public Offer</td>
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<tr>
<td>IPR&amp;D</td>
<td>In-process Research and Development</td>
</tr>
<tr>
<td>M&amp;A</td>
<td>Mergers and Acquisitions</td>
</tr>
<tr>
<td>NA</td>
<td>Not available</td>
</tr>
<tr>
<td>NDA</td>
<td>New Drug Application</td>
</tr>
<tr>
<td>NPV</td>
<td>Net Present Value</td>
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<tr>
<td>P/E-Ratio</td>
<td>Price-Earnings-Ratio</td>
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<tr>
<td>OTC</td>
<td>Over-the-counter drugs</td>
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<tr>
<td>POC</td>
<td>Proof of concept</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>Research and Development</td>
</tr>
<tr>
<td>ROIC</td>
<td>Return on Invested Capital</td>
</tr>
<tr>
<td>SEC</td>
<td>Securities and Exchange Commission</td>
</tr>
<tr>
<td>SG&amp;A</td>
<td>Sales General and Administrative expenses</td>
</tr>
<tr>
<td>SIC</td>
<td>Standard Interpretations Committee</td>
</tr>
<tr>
<td>Small Biotech</td>
<td>Refer to “Biotech companies”</td>
</tr>
<tr>
<td>US GAAP</td>
<td>Generally Accepted Accounting Principles in the United States</td>
</tr>
<tr>
<td>VC</td>
<td>Venture Capital</td>
</tr>
<tr>
<td>VIE</td>
<td>Variable Interest Entity</td>
</tr>
<tr>
<td>WACC</td>
<td>Weighted Average Cost of Capital</td>
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Executive Summary

The life sciences industry is characterized by a high volume and great diversity of deal structures entered into between large pharmaceutical companies and small biotechnology companies. Although these deal structure activities generally are and should be driven by the business development department within life sciences companies, there are also important accounting considerations for companies to be mindful of. This is because for several deal structures, business development executives are indifferent in terms of what structure to choose. However, since the accounting for different structures can vary significantly, an early involvement of and a continuous flow of information to the accounting/finance function can be a critical success factor of the deal structure. Life sciences executives who understand these flexibilities and are able to find the right balance between the business development and accounting perspectives by negotiating deal structures with a sound knowledge of the accounting implications are more likely to structure deals in a way that will be in the best interest of the company as a whole.

The thesis is structured in three sections. In the first section, the author will provide the necessary background information about the life sciences industry, which is aimed at providing the reader with a general understanding of the characteristics of the life sciences industry that form the basis of why deal structuring is such an important topic for the industry. In the second section, the main deal structure types in the life sciences industry are presented, covering both business development and financial aspects. Based on this background information about the industry and the most common deal structure types in the industry, the author then addresses in the third section specific questions that have a high relevance from an accounting perspective; one analysis focusing on questions regarding what constitutes a business in the life sciences industry, and the other analysis focusing on when control may be exercised in life sciences arrangements through means other than a majority of the voting rights. These two analyses are brought together in one comprehensive case study analyzing the accounting and income statement volatility of four major deal structure types. In a final synopsis, the author emphasizes the relationship between the business development aspects of deal structuring discussed in the earlier part of the thesis and the accounting aspects of deal structuring discussed in the later part of thesis, allowing the reader to have one holistic view on deal structuring.

To enhance readability, instead of providing the relevant accounting literature and standards in a single chapter, the author has integrated the accounting guidance into the respective sections or footnotes. Where a lack of accounting guidance or diversity in practice has been noted as part of the research conducted, they are pointed out in the respective sections. In addition, all recommendations from an accounting standard setting point of view are being summarized in one tabular format in the last chapter of this thesis.
Zusammenfassung


1 Introduction

1.1 Relevance of the research subject

The life sciences industry is an industry that is characterized by a quantitatively large number and qualitative wide diversity of deal structures. Why deals are entered into more frequently in the life sciences industry compared to other industries has drawn significant scholarly interest in the past decades. What most of this research has concluded is that the reason for life sciences companies being more active in terms of entering into transactions is in part due to small life sciences companies lacking the knowledge and resources to effectively go through the entire life sciences value chain from discovery to product commercialization, and in part due to the management of large life sciences companies fearing that their in-house research and development capacities and resources alone will not provide sufficient output for further growth. The reason why on top of the quantitatively high number of deals the diversity of deals is also much higher in the life sciences industry, however, is more related to the nature of the life sciences industry: as a result of large life sciences companies competing for the most promising R&D assets, deals tend to be entered into very early in the research and development process. However, because at such an early stage the uncertainty related to the research and development is also still very high, the deals have to adequately balance the risks between the parties involved, which makes the deals more complex. These aspects of life sciences deal structuring (e.g., the fact that many deals are entered into and that the there is a wide diversity of deal structures) can be categorized as the “business development” aspects of life sciences deal structuring.

On the other hand, when asking the question as to what is driving life sciences managers’ goal of always continuing to grow their businesses, there is the increasing pressure of capital markets on companies to show growing revenues and profitability. There is an increasing interconnectivity of the global capital markets and investors’ flexibility to

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5 Friedman (2008), p. 91.
invest in different industries and companies, in order to not lose out on the competition for capital. Therefore, life sciences companies must adapt to what capital markets and investors want to see, a continuous increase in revenues and profits, although based on the unique characteristics in the life sciences industry revenues and profits may not always be the best performance measures. For example, a significant drop in revenues from one year to the next as a result of a life sciences company losing patent protection on a single drug with no immediate replenishment of these revenues because the next new drug candidate is still being developed, is often penalized by the capital markets with a significant drop in the share price. However, the root cause of this revenue drop is in fact based on an insufficient R&D productivity over the past decades rather than anything going wrong in the period during which the drug is losing patent protection, an event that could be foreseen since product launch and, thus, should not come as a surprise to anyone.\(^7\)

Connecting the business development perspective with the capital markets perspective, what life sciences managers want to achieve by entering into new deals – knowing when their drugs will lose patent protection – is to “smooth” their revenue and profitability as much as possible in order to meet the capital markets’ expectations and, as such, limit share price volatility.

However, despite the difficulty in deal structuring from a business development perspective, (e.g., which companies to partner with and what deal structure to select) there is an increasingly complex accounting perspective, which life sciences M&A managers should be mindful of to be able to anticipate what impact the different deal structures have on the financial statements and on shareholder value.\(^8\) Otherwise, the goal of not having a high volatility in revenues and profitability may be distorted if deals have

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\(^7\) By definition, the R&D productivity describes the ratio of input in R&D versus its output. Over the past decade, larger pharmaceutical companies have experienced difficulties in expanding their drug portfolios because there is a general decline in productivity as measured by the average research and development cost per newly approved drug, which includes the amount spent on failed drugs. Lütolf-Carroll (2009), p. 185.

to be accounted for very differently compared to how management had envisioned them to be accounted for when entering into the deal.\(^9\)

Accounting for deal structures, which at first may seem a straightforward exercise, has become increasingly complex over the past two decades with an increasing number of accounting standards and interpretation guidance being issued. With this increasing complexity in the accounting guidance, life sciences managers often find themselves in a dilemma where deals that are very attractive from a business development perspective are entered into, but then, when they are accounted for, result in an accounting that comes as a surprise to them. Linking the business development perspective of deal structuring to the accounting perspective of deal structuring is the subject of this thesis. Interestingly, and this will be shown as part of the research, often deal aspects that are relevant from a business development perspective are not necessarily relevant from an accounting perspective, and vice versa.

1.2 Objective of the thesis

The goal of this thesis is to develop a framework to allow the management of large life sciences companies to adequately consider, next to the important business development aspects, the accounting implications of different deal structures. However, given the diversity of deal structures, it is not the goal of this thesis to only present a limited number of deal structures and just apply the current accounting guidance to those deal structures. Instead the discussion will focus on identifying individual “drivers” that result in a deal structure being more likely to be accounted for in one way versus another way.

To provide a better understanding of the industry and the motivations of all the involved parties who enter into deals, this thesis will in the initial chapters 2 and 3 cover both the perspective of the “large” life sciences company (e.g., also commonly referred to as “big pharma”, which is generally the acquirer or the licensee) and the “small” life sciences

\(^9\) Per Hunt (2011), M&A practitioners with a solid grasp of accounting tend to have a competitive advantage in deal negotiations, as they can anticipate the impact of changes on shareholder value. Hunt (2011), p. 180.
company (e.g., also commonly referred to as “small biotech”, which is generally the
seller or the licensor). However, for the subsequent chapters, when the detailed
accounting aspects and considerations are discussed and applied to deal structures,
reference will only be made to the perspective of the “large” life sciences company (e.g.,
the company that is the buyer or the licensee). Including both perspectives for all parts of
the thesis would have resulted in the scope of the research being too broad and the thesis
losing relevance for its readers.

From an accounting perspective, this thesis will primarily focus on International
Financial Reporting Standards (IFRS) issued by the International Accounting Standards
Board (IASB). It should be noted that in many areas that are relevant for life sciences
deal structuring accounting, IFRS and US GAAP have now converged to a large extent.
Since there are still many large pharmaceutical companies based in the U.S. that prepare
their financial statements in accordance with US GAAP, the thesis will still highlight in
separate text boxes / excursuses the US GAAP accounting if that accounting is materially
different from the accounting under IFRS.

From a standard setter perspective, when presenting the current accounting guidance for
deal structures, the thesis will also bring in the considerations and intentions that standard
setters had when drafting the guidance. The author collected this information from the so-
called “basis for conclusions” issued as part of the respective standards, interpretative
guidance published by large public accounting firms as well as meeting materials of the
standard setter boards. Where it becomes apparent that some of those considerations or
intentions have not been accomplished in practice or where there is a lack of guidance,
suggestions will be made regarding how accounting definitions or guidance may need to
be clarified or expanded to address these shortfalls.
1.3 Structure of the thesis

The thesis is structured in three sections. In the first section, the author will provide the necessary background information about the life sciences industry, which is aimed at providing the reader with a general understanding of the characteristics of the life sciences industry that form the basis of why deal structuring is such an important topic for the industry. In the second section, the main deal structure types in the life sciences industry are presented, covering both business development and financial aspects. Based on this background information about the industry and the most common deal structure types in the industry, the author then addresses in the third section specific questions that have a high relevance from an accounting perspective; one analysis focusing on questions regarding what constitutes a business in the life sciences industry, and the other analysis focusing on when control may be exercised in life sciences arrangements through means other than a majority of the voting rights. These two analyses are brought together in one comprehensive case study analyzing the accounting and income statement volatility of four major deal structure types. In a final synopsis, the author emphasizes the relationship between the business development aspects of deal structuring discussed in the earlier part of the thesis and the accounting aspects of deal structuring discussed in the later part of thesis, allowing the reader to have one holistic view on deal structuring.

To enhance readability, instead of providing the relevant accounting literature and standards in a single chapter, the author has integrated the accounting guidance into the respective sections or footnotes. Where a lack of accounting guidance or diversity in practice has been noted as part of the research conducted, they are pointed out in the respective sections. In addition, all recommendations from an accounting standard setting point of view are being summarized in one tabular format in the last chapter of this thesis.
1.4 Methodology

The methodical approach of this thesis is based on an understanding of accounting as an application-oriented science, which means the research process is initiated by identifying problems in praxis and serves the purpose of generating solutions for those problems.\textsuperscript{10} To ensure the thesis is of relevance for practitioners in the life sciences industry, it goes beyond the theoretical analysis of accounting guidance and literature and is based to a large extent on the empirical analysis of data collected from life sciences deal structuring databases, companies’ press releases made at the time that new deals were entered into, disclosures in annual or quarterly financial information, as well as practical examples and case studies. The interpretations derived are then later confirmed in follow-up interviews with subject matter specialists.

2 Understanding the Life Sciences Industry

The life sciences industry is characterized by an unprecedented frequency and variety of deals that both large and small life sciences companies, investors and universities enter into with each other.\textsuperscript{11} Value creation in this industry is determined by many factors, including the innovative capacity of a firm – measured as the number, type, and phase of development of proprietary products in the pipeline –, the management of internally and externally derived IP rights and know-how, as well as the development of firm capabilities, such as negotiation and business development.\textsuperscript{12} This chapter aims at providing necessary background information about the industry that will help the reader understand the characteristics of the industry and understand why – based on those characteristics – deal structures play such an important role in the life sciences industry.

2.1 The Evolution of the Life Sciences Industry

What first started with the chemical industry later turned into the pharmaceutical industry and, with the later addition of biotechnology, today is broadly summarized as the life sciences industry.

While the innovation activities of established chemical and pharmaceutical companies were traditionally based on organic chemistry, biochemistry and chemical engineering, today’s biotechnology industry is based on the discovery in the early 1970s of the method by which genes could be cut and spliced.\textsuperscript{13} Using this method, biotechnology has built a reputation in many novel areas, such as cell biology, molecular genetics, protein chemistry and enzymology and includes the use of recombinant DNA and cell fusion techniques as well as bioprocessing technology to make or modify products.\textsuperscript{14}

\textsuperscript{11} Friedman (2008), p. 91.
\textsuperscript{12} Lütfolf-Carroll (2009), p. 182.
\textsuperscript{13} Gassmann/Reepmeyer/von Zedtwitz (2008), p. 33.
However, it was not until 1980 that the US Supreme Court ruled that genetically engineered organisms can be patented, thereby guaranteeing biotechnology companies patent protection for their inventions.\textsuperscript{15} In the same year, Genentech, a firm that at that time had no revenues, went public in the US and raised a significant amount of capital. In 1982, the first genetically engineered drug, Humulin, was approved.\textsuperscript{16}

### 2.2 Research and Development in the Life Sciences Industry

Research and development is considered the most success-critical area in the life sciences industry.\textsuperscript{17} Compared to other industries, the innovation process in the life sciences industry has some very special characteristics, most notably the regulatory environment, which directly impacts the development time and marketing opportunities, as well as the very high risk during the product development.\textsuperscript{18} In this section, both the regulatory environment, consisting of the legal patent protection and the regulatory approval process for new drug candidates, as well as the high risks in the development process will be further illustrated.

#### 2.2.1 Patent Protection in the Life Sciences Industry

Patents are essential to the industry because it is not difficult for a competitor to ascertain the respective substances of a drug and, consequently, copy or imitate products. This means that without patent protection the life sciences industry would likely be confronted with companies just waiting for other companies to incur the significant R&D costs to develop new drugs to then copy the drug. This importance of patent protection has been confirmed by an analysis performed by Steven Seget (Seget (2002)) where it was

\textsuperscript{15} Keegan (2008), p. 143.
\textsuperscript{16} Keegan (2008), p. 143.
\textsuperscript{17} Zentes/Swoboda/Morschett (2005), p. 1235.
\textsuperscript{18} In the past, the success ratios were that only 1 of 5,000 product ideas on average was eventually launched on the market, and only 1 out of 10,000 substances eventually became a marketable product, whereas today with an increasing use of screening technologies and modern information technology, this ratio has improved significantly. Gassmann, Reepmeyer, and von Zedtwitz (2008), p. 56.
concluded that 65 percent of pharmaceutical inventions would not have been introduced without patent protection, compared to a cross-industry average of eight percent.\textsuperscript{19}

With the very long development times in the life sciences industry, timing of patent application can become a challenge for a life sciences company because a company has to balance the risks of filing the patent application too early in the development process (and as a result having a shorter period to exclusively market the drug) and filing the patent application too late (and, thus, risking that a competitor files for the intellectual property protection).\textsuperscript{20} Therefore, finding the right time to file for a patent involves a careful analysis of what R&D projects other life sciences companies may be working on in parallel. However, when in doubt about what other life sciences companies are researching and developing, most life sciences managers would probably agree that it is better to file a patent a little too early and possibly lose a few years of exclusivity rather than risking losing the exclusivity to a competitor for the product’s entire life cycle.

\subsection*{2.2.2 Preclinical tests, clinical tests and regulatory approval}

Prior to any drug being sold in a market, it needs to have fulfilled strict efficacy, safety, and toxicity criteria evidenced by various tests, the results of which are reviewed and approved by the regulatory authorities. The tests can be broadly categorized into “preclinical” and “clinical” tests. Preclinical evaluations are carried out first \textit{in vitro} in a laboratory environment – for example, using specific assays in cell lines and then in animals, where combinations of genetic, biochemical, pathological, and environmental factors are present together \textit{in vivo}.\textsuperscript{21} Introducing the drug candidate into the body of

\begin{flushleft}
\textsuperscript{20} In practice, this means that the effective period of patent protection is rarely more than eight years in the life sciences industry. Gassmann/Reempmeyer/von Zedtwitz (2008), p. 135.  \\
\textsuperscript{21} “\textit{In vitro}” is Latin for "in glass" but as used in the life sciences context, it refers to studies in experimental biology are those that are conducted using components of an organism that have been isolated from their usual biological surroundings in order to permit a more detailed or more convenient analysis than can be done with whole organisms. In contrast, “\textit{in vivo}” work is that which is conducted with living organisms in their normal, intact state, while “ex vivo” refers to studies that are conducted on functional organs that have been removed from the intact organism. Lütolf-Carroll (2009), p. 177.
\end{flushleft}
animals as part of the preclinical tests should reveal any unexpected secondary effects and improve the assessment of the safety, toxicity, and efficacy.

After preclinical testing has been completed, life sciences companies have to file for an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA), with the European Medicines Agency (EMEA), or with the equivalent regulatory authorities in other jurisdictions. This filing is generally the first touch point the life sciences company has with the regulatory authorities, although at that point it is still many years away from potentially obtaining regulatory approval for the product candidate. This filing of an IND or equivalent generally serves the purpose that the regulatory authorities agree with the results of the preclinical tests and are informed that it is now planned to administer the drug candidate to humans. If the FDA or regulatory equivalent in another country does not object to the IND filing within the specified time period, clinical testing may begin.22

After a drug compound has filed for an IND application and the regulatory authorities have no objections, the drug candidate is administered to the human body to determine if the drug is also safe and effective in humans, and to ascertain what the side effects may be.

Clinical tests are divided into four phases. Phase I is used to determine whether the drug candidate’s positive animal properties can be extended to humans (compatibility). This first Phase generally involves between 20 to 80 healthy volunteers to determine safety and the proper dosage of the drug candidate and this phase can last up to two years.23 Then in Phase II patients who have the targeted disease are treated to find out if the substance helps the patients fight the disease (efficacy).24 Depending on how severe the expected side effects of the drug candidates are, the clinical testing in Phase I may be conducted with only a very few healthy individuals, or Phase I may even be skipped and the clinical testing would start directly with Phase II, meaning patients who have the targeted disease. As an example, some oncology drug candidates, which are likely to help

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22 Lütolf-Carroll (2009), p.177.
fight cancer, sometimes also have such severe side effects that it would be irresponsible to expose healthy volunteers to such drugs in a Phase I study.\(^\text{25}\)

If results are positive for Phase II, a Phase III study is conducted based on a much larger number of patients in order to establish the proper dosage and to determine any adverse reactions to long-term use.\(^\text{26}\) It is generally also not until Phase III that side effects as a result of the combined use of the drug candidate with another drug are noted.\(^\text{27}\)

If Phase III results are also positive, a New Drug Application (NDA) for approval to market the drug is filed with the FDA (in the United States), or with the EMEA (in Europe) or with another regulatory agency in the respective jurisdiction. Once regulatory approval has been obtained, the life sciences company may launch the commercial sale.

The last and final phase of clinical testing is the Phase IV study after regulatory approval has been obtained to determine the long-term effects and optimal use of the drug. Life sciences companies in the past couple of years have significantly increased their focus on this last clinical trial study to be able to spot any long-term negative side effects of their drugs as early as possible and to limit any potential harm the drug can cause to patients. Also, by conducting Phase IV studies, a company shows an element of corporate social responsibility, which may also be viewed as a mitigating factor in cases where long-term side effects are noted later and a company is sued by the harmed patient population.

Because competitors have often already developed or are in the process of developing drugs for the same or similar indications, a Phase IV study may also help to differentiate the own drug from the drugs of the competitors (e.g., by performing a comparative study).\(^\text{28}\) In fact, life sciences companies today are often required to also conduct trials that compare a drug to competing drugs rather than just a placebo, which may implicitly

\(^{25}\) Interview with Dr. Jan Lichtenberg, CEO and Co-Founder of InSphero AG, Zurich
\(^{26}\) Gassmann/Reepmeyer/von Zedtwitz (2008), p. 64.
\(^{27}\) If the other drug that the drug candidates conflicts with is only available on prescription, the negative side effects may not cause the drug candidate to fail because doctors may be able to ensure that patients do not take both drugs at the same time. However, if the other drug is an over-the-counter drug, this would mean that the drug candidate being tested will fail because it will not be possible to ascertain that no patients take both drugs at the same time.
\(^{28}\) Schöffski/Fricke/Guminski (2008), p. 114.
result in some companies funding studies that show a competitor’s drug to be superior.\textsuperscript{29} Also, from an economic / return on investment perspective, it is usually not until Phase IV when a company will find out whether health insurance companies will reimburse the patients for the drug (in full, partially or not at all), which can have a significant impact on future sales. Thus, different from other industries where companies usually can determine the market potential and future sales volume of their products fairly easily and accurately and may decide to discontinue an R&D project whenever the expected costs are to exceed the expected revenues, a life sciences company often does not get any type of assurance about future prices and sales volumes until after the drug has been approved, which means at a time when almost all of the R&D costs have already been incurred.

The time periods for each phase in the preclinical and clinical studies can vary significantly. The time period for drug discovery through to preclinical testing may be four to six years for target identification and validation, including lead compound identification and optimization, together with subsequent preclinical testing.\textsuperscript{30} Typical times for clinical trials are one to two years for Phase I, approximately two years for Phase II, three to four years for Phase III, and one to two years for regulatory approval.\textsuperscript{31} In total, it generally takes anywhere from nine to 15 years to take a drug candidate from the discovery phase to the market.\textsuperscript{32}

Figure 1 further illustrates the different preclinical and clinical testing phases in the life sciences industry.

\textsuperscript{29} Ernst & Young (2013b), p. 13.  
\textsuperscript{30} Lütolf-Carroll (2009), p. 178.  
\textsuperscript{31} Lütolf-Carroll (2009), p. 178.  
Figure 1: Schematic Representation of a Typical Drug Development Pipeline

Figure 2 shows the relationship between the number of substances that are approximately needed during each phase of the drug development process and one substance that will obtain regulatory approval ten to twelve years later.

Figure 2: The phases, time lines, and attrition that characterize the invention of new drugs.

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2.2.3 Risks in the drug development process

Depending on the stage of the drug development process, there are different risks that life sciences companies are facing:\(^35\)

- **Attrition rates**: Risks in connection with attrition rates relate to all the risks that may result in a failure of the clinical studies if drug efficacy, safety, toxicity, or other regulatory requirements are not met.\(^36\) For example, the probability of investigational compounds (at Phase I) entering Phase II and Phase III is only 71.0% and 31.4%, respectively, which is depicted schematically in Figure 1 and Figure 2.\(^37\)

- **Technical risks**: Technical risks associated with drug research and development may include, for example, those related to poor expression or production of proteins by cell lines, problems during scale-up from laboratory, or problems with pilot scale quantities of the drug transitioning to large-scale manufacturing.\(^38\)

- **Compliance risks**: Compliance risks are those associated with meeting all the requirements to obtain regulatory approval – for example, from the FDA or EMEA. However, a company may continue to be exposed to compliance risks even after regulatory approval has been obtained – for example, because some long-term effects of a drug use may not be noted until several years later or as part of a Phase IV study. In terms of manufacturing, selling and marketing pharmaceutical drugs, there are further compliance risks due to strict regulations life sciences companies have to comply with.

- **Operational risks**: Operational risks relate to the execution of the different research and development processes including the risks of finding qualified people with the necessary experience and skill set.\(^39\)

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\(^35\) The following list of risks is based on the risks identified by Lütolf-Carroll (2009), p. 178-179.

\(^36\) Lütolf-Carroll (2009), p. 178.

\(^37\) DiMasi/Hansen/Grabowski (2003), p. 162.

\(^38\) Lütolf-Carroll (2009), p. 179.

\(^39\) Lütolf-Carroll (2009), p. 179.
• **Intellectual property risks**: Intellectual property (IP) risks are those of not filing or not filing timely for patent application, thus, potentially losing the IP to a competitor.

• **Financial risks**: The risk associated with not obtaining sufficient funding to conduct research and development activities and, at a later stage, commercialization activities.

• **Market risks**: Market risks are those of market acceptance of the drug but also include pricing considerations, both of which depend to a large extent on what alternatives the affected patients have. For example, it may become apparent during the clinical development that a competing drug serves the patient’s unmet need in a more effective way or reaches regulatory approval significantly earlier, in which case a withdrawal from further clinical trials should be considered.\(^{40}\) Also, reimbursements by health insurance companies (whether the costs will get reimbursed in full, partially or not at all) as well as the patient population are elements of market risk. As the following example (Example 1) will show, estimating future sales is not only about estimating the patient population for the indication for which the drug is developed but also about considering what other indications the drug may be used for, because with already one additional indication, the patient population and, as a result the sales, may significantly increase. Or, looking at it from the development perspective, a company may erroneously discontinue the development of a drug because it failed to do an in-depth analysis in terms of what other indications the drug could potentially be used for. In such a case, the company would be underestimating revenues and concluding that the future revenues would not be sufficient to recover the development costs of the drug.

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\(^{40}\) Lütolf-Carroll (2009), p. 179.
clinical studies and, by dropping the dose of finasteride, found a way to help patients suffering from male pattern baldness (MPB), a hereditary condition that affects close to 50 percent of the male population who are 50 years or older.

In 1997, Merck was successful in obtaining FDA approval for this second indication of finasteride for treatment of MPB, which is marketed under the brand name Propecia. Although the compound finasteride lost patent protection a few years ago, Merck in 2012 still recorded sales of USD 424 million with Propecia, which is more than twice the amount of sales recorded with Proscar (USD 217 million).

Fortunately, when developing the compound, Merck estimated the sales even for just the BPH indication to be sufficient to cover its development cost. However, if those sales estimates would have not been sufficient, the development may have been discontinued without ever finding out about finasteride also helping patients suffering from MPB.

Example 1: Additional sales for indications not yet anticipated when developing the drug

The life sciences industry also differs from other industries in terms of the R&D go/no-go decision process. For most industries, the decision to terminate an R&D project is made solely on the basis of economic considerations (e.g., will the future benefits exceed the total costs). Although economic aspects definitely also play into the life sciences go/no-go decision process, the majority of life sciences R&D projects are stopped due to scientific reasons, such as a lack of efficacy or safety that might only become visible at late-stage clinical trials. Another reason for stopping projects is that most life sciences companies are forced to filter for what they think are the most promising projects and only focus their development efforts on those because there is generally not sufficient funding available to continue with all R&D projects.

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41 Based on: Hofmann (2013), p. 5.
43 This is true especially because, as projects move from one development phase to the next, development costs increase exponentially.
This continuous selection process bears additional risks because for each project that is being discontinued, there is the possibility that a drug candidate’s value has been underestimated and that something potentially “big” has been given up.

2.3 Drug designations

2.3.1 Prescription drugs, over-the-counter drugs and generic drugs

Prescription drugs can be distinguished from over-the-counter (OTC) drugs by the fact that prescription drugs are generally only sold by pharmacies and hospitals because they require a knowledgeable doctor or pharmacist to be familiar with the drug, e.g. because of potential severe side effects or other risks that may result from taking the drug. OTC drugs, on the other hand, do not require a doctor or pharmacist to closely monitor the administration of a drug to the patient because OTC drugs are usually used for minor ailments such as a headache or the flu.44

The term “generic drug” is defined as a drug for which the patent protection period has ended and, as a result, competitors may enter the market with a copy of the drug substance. Because the competitors entering the market do not have to recoup any significant R&D expenses, prices of generic drugs are also significantly lower. Upon patent expiration, some prescription drugs lose up to 90 percent in revenues to generic competition within just a few weeks.45 A generic drug can be either a prescription drug or an OTC drug.

2.3.2 Orphan drugs

Life sciences companies, just like any other companies that operate to generate a profit, are willing to make investments only if the future return is expected to be positive. The same applies to investments in life sciences R&D. Prior to any significant R&D

investment being made, a life sciences company would assess (a) what are the chances of this drug obtaining regulatory approval and (b) if the drug reaches regulatory approval, what will be the expected sales generated with this drug. Since the expected revenue in the pharmaceutical industry is a derivative of the number of patients with a certain indication, it may be that for some indications the patient population is too small to justify significant investments in R&D. In those instances, life sciences companies may apply for the so-called “orphan drug status”, which is granted by regulatory authorities if on average less than 5 in 10,000 people in the EU (EMEA definition) or fewer than 200,000 people in the United States (FDA definition) are affected by the particular disease. The “orphan drug” designation enables life sciences companies to obtain regulatory and financial incentives, such as protocol assistance and marketing exclusivity, for a period of up to ten years, to exclude other companies from receiving a license to work on a similar drug during that period of exclusivity, thereby giving the researching company a better chance to recuperate its R&D expenses. Based on a study performed by Putnam Associates (Putnam Associates (2011)), developing orphan drugs has become increasingly attractive due to a 37% higher probability of obtaining regulatory approval, the smaller trial sizes with lower overall development costs, an on average 26% shorter clinical development time, and other financial incentives, such as a 50% tax credit on clinical development costs.

2.4 Business Models in the Life Sciences Industry

2.4.1 The Blockbuster Model

For the past few decades the business model that all large pharmaceutical companies strove for in order to grow their revenues and profits was the so-called “blockbuster model.” Blockbuster drugs are defined as those with at least USD 1 billion in annual revenues. However, blockbusters have one significant drawback, which is the significant

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drop in revenues that they are exposed to at the end of the patent protection period, one of the most prominent examples being the drop in sales of Pfizer’s cholesterol drug, Lipitor, which lost U.S. market exclusivity in November 2011. Capital markets and investor funds are acting more and more on a global scale and are flexible regarding the industries in which they invest. Explaining to an investor that significant volatility in revenues and income are in the nature of the life sciences industry may not be good enough in the competition for global investors’ funds. As such, many life sciences companies have started to try to manage their drug portfolio more rigorously, e.g. by entering into a variety of deal structures with the ultimate goal to fill the R&D pipeline so that for every expiring patent the drop in revenues as a result of the patent cliff are offset by new revenues from introducing new drugs into the market. However, with the success and timing of R&D outcomes in the life sciences industry being very difficult to anticipate, most life sciences companies that rely on the blockbuster model are still exposed to significant income statement volatility.

2.4.2 The Personalized Medicine Model

Both the high dependency on individual blockbuster drugs with their significant impact on revenues and income, as well as the high development cost with relative small chances of success have resulted in the development of a new commercial model for life sciences companies, the so-called “personalized medicine model.” The characteristic of this model is less about targeting niche indications but about personalizing the drug type, dosage, and duration of the treatment to the genetic profile of a patient. With people sharing about 99 percent identical DNA, the remaining one percent of differing DNA provides the opportunity for tailor-made drugs. Insights from that genetic data have redirected how we think about diseases because, for example, for cancer — the area where personalized medicine approaches have made the greatest headway — it has become increasingly

49 Some drugs can lose up to 90 percent in market share within just a few weeks after patent expiration. Garnier (2008), p. 71.
50 In 2012, for the quarter ended September 30, 2012, Pfizer reported a 87% drop in US Lipitor sales, as compared to the same quarter in the prior year. Loftus (2012), p. 2.
apparent that what is relevant is not where the disease is manifested ("breast cancer" or “blood cancer”) but the mechanism that causes it (e.g., a specific genetic mutation).\textsuperscript{52} Moreover, recent studies have shown that drugs following the traditional “one size fits all” approach generally only help 20 to 28 percent of the patients, with the remaining 72 percent actually being harmed by the drug, which also explains the push for the personalized medicine model.\textsuperscript{53}

Thus, although total sales of individual drugs may be less under the personalized medicine model compared to the blockbuster model, the research and development activities in the personalized medicine model are more effective because the target population is more segmented, allowing better treatment for the individual basis of disease.\textsuperscript{54} As such, not only is every dollar spent on R&D more cost-effective under the personalized medicine model, but compared to the blockbuster model a life sciences company is also less exposed to the market risk when a drug loses patent protection.

\section{2.5 Managing Capital Market and Investor Expectations}

Over the past decades the life sciences industry has shown worldwide sales growth at an annual rate of over 10 percent and today these double-digit growth rates are incorporated into the industry’s overall growth expectations.\textsuperscript{55} However, due to a significant number of patent expirations of blockbuster drugs from 2012 through 2014, this growth is now slowing down dramatically.\textsuperscript{56} As success raises expectation of further success, capital markets and investors do not always consider or want to understand the characteristics of the life sciences industry in terms of income statement volatility, which puts significant pressure on management of life sciences companies because if these capital markets and investors’ expectations are not satisfied, funds could quickly be moved to other

\begin{thebibliography}{9}
\bibitem{EY} Ernst & Young (2012), p. 18.
\bibitem{Kutter} Kutter (2013), p. 70.
\bibitem{Zentes} Zentes/Swoboda/Morschett (2005), p. 1235.
\bibitem{Duff} Duff & Phelps (2012), p. 4.
\end{thebibliography}
companies or other industries. Going a step further, if a company has less financing, it is even more likely to have gaps in the financing of its R&D pipeline - a vicious circle that is difficult to escape. Thus, even with a very promising drug development pipeline, the unpredictability of drug development and the resulting uncertainty in connection with revenue projections is one of the greatest challenges that life sciences executives face.

But managing investors’ and capital markets’ expectations does not only mean meeting top line revenue expectations. It also means being able to manage the scientific risks and results. There are many uncertainties inherent in the development process and any adverse news about a compound in development can cause immediate reactions on the capital markets and destroy significant amounts of shareholder value within minutes.

Also, since capital markets are aware that during the life sciences development process the development costs increase exponentially, an announcement about a discontinuation of a Phase III clinical trial generally will have a more significant impact on shareholder value, as compared to an announcement of a preclinical trial discontinuation. As such, there has been a focus on trying to identify methods to allow individual R&D projects to “fail fast”, which means that for any R&D project, the earlier a failure can be discovered, the higher can the potential savings be on R&D expenses.

As such, with these known uncertainties in the industry (the patent cliff and significant exposure to individual R&D projects), many life sciences companies have been working intensively on managing their drug portfolio more rigorously by exploring options outside of their own R&D capacities to mitigate the risks to the largest extent possible.

For all those companies, these options seem to focus on one single goal: How do I

58 Depending on the size of their current business, pharmaceutical companies are required to deliver between two and four new drugs every year in order to maintain or exceed the double-digit growth expectations. Gassmann/Reepmeyer/von Zedtwitz (2008), p. 51.
59 As the R&D pipeline is one of the key indicators for future revenues, stock prices fluctuate with good or bad news emanating from the R&D pipeline. Gassmann/Reepmeyer/von Zedtwitz (2008), p. 11 and 108.
60 This is because capital markets understand that, with a Phase III discontinuation, it becomes evident that the significant R&D costs that have been spent over the past couple of years are sunk costs. Also, with Phase III clinical trials, capital markets may already have had some revenue expectations for the upcoming years, which with the discontinuation will need to be taken out of the forecast.
61 Ernst & Young (2010), p. 6.
participate in the maximum amount of R&D projects (maximizing the “shots on goal”) with having the least amount of R&D risks and costs?

With this increasing complexity in the industry – due to rising drug discovery expenses, costly clinical trials, rigorous government regulatory procedures, and huge investments in manufacturing, marketing, and distributing drug products to patients – the structuring of both informal and formal alliances has become an essential part of the business model of many life sciences companies.\textsuperscript{63} In fact, research on the biotechnology industry found that there is a positive relationship between the number of a company’s strategic alliances and its product development.\textsuperscript{64}

### 2.6 Motivations to Enter into Deals in the Life Sciences Industry

Based on the goal of life sciences companies to minimize the uncertainty and risks associated with the drug development while maximizing the drug development output, the motivations of life sciences companies to enter into deals will now be explored, both from a large pharmaceutical company (“big pharma”) perspective as well as from a small biotechnology company (“small biotech”) perspective. Such motivations can be categorized as being scientific, financial, or commercial in nature.

#### 2.6.1 Scientific Motivation

Although the desire to obtain valuable resources, including know-how, technologies, and capabilities possessed by target firms has always been a driver of deal activities, this motive is especially relevant in the life sciences industry where, because of the rapid innovation, technological complexity, and highly specialized skills and know-how, the pace and magnitude of technological change may not allow firms to internally develop all

\textsuperscript{63} Lütolf-Carroll (2009), p.181 and 182.
the necessary technologies and capabilities to remain competitive.\textsuperscript{65} Research has been
carried out to understand why the innovation level in large pharmaceutical companies is
lower than in small biotech / development stage entities, and it is commonly believed that
the main reason for the lower R&D output at big pharma is the administrative burden that
increases with the size of the company, which then hinders innovation.\textsuperscript{66} Another reason
is that the larger a company gets, the more scientists build up an internal barrier because
they feel that the majority of the benefits from their innovations are absorbed by the
administration costs of running a large company (which is demotivating for the scientists
and ultimately results in a lower R&D output). Usually, small biotech companies are
organized flexibly in overlapping interdisciplinary project teams with minimal hierarchy
in order to create a lean and effective organization for drug discovery and commercial
development driven by an entrepreneurial spirit.\textsuperscript{67} In contrast, large pharmaceutical
companies are characterized by a formal structure, high levels of hierarchy, and long and
slow decision-making processes.\textsuperscript{68} Thus, for big pharma to access innovation by
partnering with small biotech, from an organizational point of view, big pharma has to
find the balance between securing its interest in any future R&D output while at the same
time preserving autonomy for the acquired firms in order to avoid harming their
innovative capabilities.\textsuperscript{69}

Schweizer (2005, 2009) found that most top managers leave biotech firms after the
acquisition or merger, which Schweizer attributes to the fact that the pharmaceutical
companies do not leave the biotechnology companies sufficient autonomy to maintain the
entrepreneurial and risk-taking spirit.\textsuperscript{70} However, on the other hand there are benefits
from consolidating the R&D functions of two companies, such as a better utilization of
specialized equipment or infrastructure, greater risk diversification, as well as enabling
one of the core competencies of R&D management, the ability to stop probable failures

\textsuperscript{65} Faulkner/Teerikangas/Joseph (2012), p. 638; Zentes/Swoboda/Morschett (2005), p. 1241, 1245;
\textsuperscript{68} Schweizer (2009), p. 135.
\textsuperscript{69} Faulkner/Teerikangas/Joseph (2012), p. 644.
early and redeploy resources to higher-probability products. For a small laboratory of a single company, R&D resources may sometimes continue to be deployed to a project with very limited chances of success just because of a lack of worthwhile alternatives. Thus, a larger laboratory, if managed well, is more efficient.

Roche acquired a majority shareholding in Genentech in 1990. With Genentech being one of the most R&D efficient life sciences companies in the 1990’s and early twentieth century, the Chairman of Roche’s Board of Directors always argued that the success of Genentech was also attributable to the fact that Roche left Genentech independent to the largest extent possible. As such, it came unexpected when in 2008 Roche decided to acquire all of the remaining shareholding of Genentech. Although it would be difficult to draw a direct link between terminations of top management and the full takeover of Genentech by Roche in 2008, as a matter of fact, in 2009 and 2010 Genentech’s head of development, Susan Desmond-Hellmann, and Genentech’s Chief Scientific Officer, Marc Tessier-Lavigne, both left Genentech to go back into academia at the University of California and the Rockefeller University in New York, respectively. With the loss of two such high potential researchers, many people argued that Roche, with the acquisition of the remaining shareholding of Genentech, crossed the line of no longer giving Genentech sufficient autonomy.

Example 2: Roche’s acquisition of Genentech

However, entering into deals with big pharma can also be interesting and rewarding from the perspective of the small biotech company. Small biotech companies often do not have a diversified portfolio, and therefore, the risk of R&D development is very high because a set-back with one R&D project can destroy significant amounts of shareholder value. By entering into a transaction with big pharma, a small biotech company can not only diversify some of the risk associated with individual R&D projects, but more importantly present a strong credential, which increases the small biotech firm’s overall credibility.

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and may again attract the attention of other investors or other big pharma companies to enable future deals.\textsuperscript{74} Further, bringing a compound through the last stages of a clinical trial or applying for regulatory approval are areas that often big pharma is more familiar with and where the small biotechs can benefit and learn from big pharma.\textsuperscript{75} Studies have shown that alliance formation patterns for small biotech companies are age-dependent and nonlinear, peaking at around four years after founding, then declining until the ten-year mark, after which they rise again, which roughly corresponds to the needs associated with the biotechnology product development process, which requires access to research and development expertise early on, followed by commercialization capabilities later in a firm’s life.\textsuperscript{76}

\section*{2.6.2 Financial Motivation}

As mentioned in section 2.5, since investors and capital markets sometimes have difficulties with fully understanding the R&D specifics of the industry, especially as it relates to the volatility in sales and R&D expenses, management of large public life sciences companies is increasingly looking for ways to smooth revenues and externalize R&D expenses by entering into different collaborations. With externalizing R&D, these life sciences companies are in a position to increase the number of drug programs to which they have access without increasing, to the same degree, the capital or resource investment required to access them.\textsuperscript{77} By and large, these structures aim at having preferential rights and preferential access to the R&D pipeline of the target company.

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{74} For the investor community understanding the underlying R&D is often too complex because their background is usually not R&D or medicine. That is why their investments are often influenced by which big pharma companies a small biotech company may have already entered into collaborations with. Refer also to Gassmann/Reepmeyer/von Zedtwitz (2008), p. 79; Zentes/Swoboda/Morschett (2005), p. 1246; Patzelt/Brenner (2008), p. 110.
\item \textsuperscript{75} Zentes/Swoboda/Morschett (2005), p. 1246.
\item \textsuperscript{76} Patzelt/Brenner (2008), p. 109.
\item \textsuperscript{77} Based on a study performed by McKinsey, half of the late-stage pipeline compounds of large pharmaceutical companies are now externally sourced. McKinsey (2010), p. 2.
\end{itemize}
\end{footnotesize}
rather than assuming day-to-day operational responsibilities and commitments of resources and management time.\textsuperscript{78}

For a small biotech company, the main financial motivation to enter into alliances with big pharma companies is to secure the access to capital for its cost-intensive clinical development activities.\textsuperscript{79} Despite the maturing of the biotechnology sector, the majority of companies is still years away from launching their first product and, thus, is in a constant need for capital with the main financial risk being to run out of liquidity.\textsuperscript{80} \textsuperscript{81}

Management of biotech companies is aware that one of the key financial ratios that an investor looks at when evaluating investments in the biotechnology industry is the “cash burn” ratio, which provides information about how soon the company will need a new round of financing. Regardless of how innovative a research project of a company is, if there is not sufficient capital to realize the innovation, the research will also never result in any marketable products.

Also, for small biotech companies, the funding through alliances has become more important because accessing capital through the other traditional types of funding (e.g., venture capitalists, public investors (IPOs)) has become increasingly difficult.\textsuperscript{82} Thus, in the current market environment, entering into deals with big pharma companies has become one of the most essential sources of financing for small biotech companies.

\subsection*{2.6.3 Commercial Motivation}

In addition to the scientific and financial motivations, there is often also a commercial motivation to spur deal activity, and that is because time-to-market is extremely important in the life sciences industry. The first in the market captures between 40 to 60

\textsuperscript{78} McKinsey (2010), p. 3.
\textsuperscript{79} Zentes/Swoboda/Morschett (2005), p. 1241.
\textsuperscript{80} Bogdan/Villiger (2010), p. 3; Lütolf-Carroll (2009), p.179.
\textsuperscript{81} There is virtually no other high-growth sector that has attracted more funding by governments, pharmaceutical companies, the equity capital markets, and venture capitalists than the biotechnology sector. Schweizer/Knyphausen-Aufsess (2008), p. 137.
\textsuperscript{82} Schweizer/Knyphausen-Aufsess (2008), p. 138. Also, as a result of the risk awareness of today’s investors, most of the public financing goes to established public companies rather than small biotech / start-up companies. Ernst & Young (2010), p. 15; Schweizer/Knyphausen-Aufsess (2008), p. 139.
percent of the market share, the second only around 15 percent, and coming in third usually means a negative business.83

Successfully marketing a new drug largely depends on how specialized the target patient population is and on how quickly a sales and distribution network can be set up for that patient population. For example, if a company that already has marketed drugs in a niche-market, which requires a specialized sales and distribution network, develops an additional drug for that same niche-market, this company would be able to sell the new drug from day one through its existing sales and distribution network. However, a company that tries to enter that same niche-market without any existing sales and distribution network would first have to incur significant time and resources (e.g., determine which doctors treat such patients, train its sales representative, etc.) to set-up such a network. This is why companies, if they do not already have an existing sales and distribution network for a particular patient population, have to evaluate how large of an investment (both in terms of costs and lost market share due to a later market entry) would be necessary to set-up such network. While the clinical development time for a product is in the range of seven to nine years before it reaches the market, the time to reach peak sales can again take that long if there is no existing sales and distribution network.84 If it is expected to take too long or to be too expensive to set-up such a network, partnering with a company that already has such a network for the respective niche-market could be advantageous.85 Especially given the limited time of patent protection, waiting to set-up a new sales and distribution network may cause significant revenue losses.86

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83 Delaying market introduction of a blockbuster drug by two months not only involves the risk that a competitor seizes significant market share, it also means a net loss of USD 100 million, or almost USD 2 million a day. Gassmann/Reepmeyer/von Zedtwitz (2008), p. 16.
84 Austin (2008), p. 115.
86 Also, often life sciences companies have an established sales and distribution network only in some geographic regions but not in others. In those instances, partnerships may just be for certain geographic regions. For example, many U.S. and European companies typically introduce their new drugs on the Japanese market only in collaboration with a local pharmaceutical company because the accelerated market penetration generates higher sales than the compensation for the alliance partner. Gassmann, Reepmeyer, von Zedtwitz (2008), p. 77.
In March 2009, Actelion Ltd, based in Basel, Switzerland, acquired from privately-held GeneraMedix Inc. the worldwide development and commercialization rights to an improved formulation of epoprostenol sodium for the intravenous treatment of pulmonary arterial hypertension (PAH). At the time of the transaction, GeneraMedix did not have any sales and distribution network for the niche market PAH, whereas Actelion could leverage on its existing infrastructure and expertise in this specialized field and start to sell the drug as soon as regulatory approval was obtained for the different jurisdictions.

This transaction is a good example of where the benefits of using an existing sales and distribution network of another company and, thus, significantly shortening the time-to-market, outweigh the benefits of first investing to set-up a sales and distribution network and selling the drug oneself.

Example 3: Actelion’s acquisition of a new formulation of intravenous epoprostenol from GeneraMedix Inc.\(^{87}\)

On the other hand, partnering for drug commercialization may also be of interest for big pharma companies. For example, a big pharmaceutical company may find itself in a situation where there is a revenue gap between one large blockbuster drug going off-patent in one year and the next drug for the same niche market still being developed and not expected to be sold until a couple of years later. In such a scenario, utilizing the existing sales and distribution network to sell the drugs of other life sciences companies and charging a service fee to those companies economically may make more sense than winding down the existing sales and distribution network and having to invest to rebuild a new network again in just a few years’ time.

\(^{87}\) Actelion (2010), p. 75.
2.7 Excursus: Valuation in the Life Sciences Industry

Valuation in the life sciences industry is important because when structuring deals, life sciences executives will find themselves confronted with questions such as the following:

a) What is the value of the target assets or the target company?
b) What premium is the acquirer willing to pay over the fair value of the target assets or the target company and what justifies paying a premium (e.g., control premium)?
c) Make or buy considerations: How much would it cost to develop an asset similar to the target asset? Are these costs more than the price of the asset, also considering that making the asset would take significantly longer than buying the asset (with time-to-market being critical in the life sciences industry)?
d) Compared to buying the asset in its entirety, how much would the price decrease if only a license for specific jurisdictions was acquired? If such license does not need to be exclusive, how much would the price decrease if the license was non-exclusive?
e) If there is the possibility to defer some amount of the purchase price, how would such deferred consideration impact the purchase price?
f) If there is the possibility to make some amount of the purchase price contingent on a future event (e.g., a milestone such as clinical trial results or a regulatory approval), how would such contingent consideration impact the purchase price?
g) If there is the possibility to first purchase an option with having the right to either exercise the option at some later point in time or walk away, how much more would the acquirer be willing to pay to have such an option?
h) If there is the possibility to pay with anything but cash (e.g., own shares), how would this impact the purchase price?

While the above list of questions does not attempt to indicate all possible considerations when valuing subject assets or companies in the life sciences industry, it does show that for any company entering into deals, specific valuation considerations are an important factor in determining both the right deal structure and the right form and amount of the consideration.

Compared to other industries, valuation in the life sciences industry is more challenging because of the fact that the most valuable assets in most life sciences companies are the
R&D projects, which due to their inherent complexity and length of development time, have a significant amount of uncertainty associated with them (e.g., IPR&D assets). The main concerns are the choice of the right valuation method, the methodology itself, the input parameters and the interpretation of the results.

Figure 3 provides a summary of the different factors to be considered when valuing an IPR&D asset, distinguishing between early lifecycle and late lifecycle projects.

Both IFRS and US GAAP are based on the same fair value guidance (IFRS 13 *Fair Value Measurement* and ASC 820 *Fair Value Measurements and Disclosures*, which for the most part are identical standards). These standards establish a single definition of fair value and a consistent framework for measuring fair value to increase consistency and comparability in fair value estimates. The definition of fair value under these standards is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction (i.e., not a forced liquidation or distress sale) between market participants at the measurement date. This definition introduced the notion that fair value is an “exit” price a market participant would pay the seller for the subject asset.

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88 Among the largest transactions in the industry, IPR&D has accounted for approximately 20% of the deal value in recent years (based on a sampling of the 15 largest transactions in 2008-2009 and 2010-2011). Duff & Phelps (2012), p. 6.
92 IFRS 13.IN8; ASC 820-10-20.
An asset’s “entry” price is the price paid, but the asset’s exit price can fluctuate dramatically, reflecting changing market, industry, or regulatory conditions. Although the standards allow acquirers to choose between using a market approach (e.g., valuation based on prices paid for comparable assets or in recent transactions), an income approach (e.g., discounted cash flow), or a replacement cost approach (which involves estimating what it would cost to physically replace an asset), the standards do require sufficient disclosure about the chosen valuation approach to enable users of the financial statements to understand how a subject asset has been valued.

2.7.1 Valuation approaches

As mentioned in the previous section, from an accounting perspective, the allowable methods to determine fair value are the market approach, the income approach, or the replacement cost approach. As further detailed in this section, each of the methods has its strengths and weaknesses, and each can be more or less useful in a particular valuation context.

In practice it is rare that a company would use only one of these methods for the subject valuation. Although each valuation method is likely to result in a different fair value, it is actually often not until the different results are compared that the different valuations are fully understood (e.g., to understand what are the key factors that are driving the value).

2.7.1.1 Market approach

The market approach requires the identification of an appropriate comparable transaction or industry norm. Although this approach is relatively easy to understand and seems easy to apply in practice, the difficulty, especially in the life sciences industry, lies in

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97 Schmachtenberg/Pfister/Schäfer (2009), p. 106.
finding a similar or comparable transaction that closely matches the subject valuation (because patents and other IP rights are, by nature, unique). Even if a transaction that seems to be similar or comparable is found, there may be difficulties in accessing the relevant information and agreements (because such information would generally not be publicly available). As such, if the market approach is used, practitioners often create a comparable family of transactions for which the information is available, and from this family of transactions, the results are then interpolated and extrapolated to predict how the market would have valued the subject opportunity incorporating all the *mutatis mutandis* (changes as need be changed) for a meaningful comparable valuation.\(^98\) The more judgment that will have to be applied to interpolate and extrapolate the results, the less accurate the valuation using the market approach is expected to be. Thus, if significant judgments have to be made, consideration should be given as to whether the other valuation methods may provide better results to fair value the subject asset or business.

### 2.7.1.2 Income Methods

The two major quantitative valuation approaches applied in life sciences practice are the Discounted Cash Flow (DCF) method and the real options method. While DCF has been the gold standard for years, real options valuation is gaining grounds and is regarded as a possible alternative in life sciences practice, although both methods have their advantages and disadvantages.\(^99\)

#### 2.7.1.2.1 Discounted Cash Flow (DCF) method

In life sciences valuation practice, especially for the valuation of IPR&D assets, the discounted cash flow (DCF) method is still being predominantly used for valuation. The DCF method is based on creating pro forma models of estimated net cash flows a market

\(^{98}\) Razgaitis (2009), p. 573.

participant is expected to generate from the highest and best use of the asset, so-called Free Cash Flows (FCFs).\textsuperscript{100} Coming up with this cash flow forecast seems to be one of the most challenging things because, first, one has to determine from a market participant’s perspective what the highest and best use is, which may be different from how the acquirer is planning to use the asset.\textsuperscript{101} Also, forecasting revenues that are many years in the future and relate to drugs that may never obtain regulatory approval and, thus, may never be sold, poses a challenge for life sciences executives. Finally, once the annual FCFs have been determined, they need to be discounted. The discount rate should address both time value of money considerations and also include a risk premium to reflect the risk associated with the subject asset or company.

Although in practice the DCF method is still considered the “gold standard” of business valuation, there are certain limitations because many key value drivers such as buyer investment, operating costs, and revenues and growth in such revenues, are difficult to estimate, and have limited comparables.\textsuperscript{102} Another disadvantage of the DCF method is that it can only reflect “one path” of the future upon which the entire model is then based. That this path may change due to unforeseen events or that there may be other options that only materialize in the future, the DCF method can only implicitly reflect with an adjustment of the discount rate (increasing it for higher risks and decreasing it for lower risks). The Real Options Method, which will be presented in the following section, addresses exactly these drawbacks of the DCF method and allows different paths and options to be reflected in the valuation.

2.7.1.2.2 Real Options method

The Real Options method has been developed to overcome the shortfalls of the DCF method because when properly understood and applied, the method represents the reality much better than the DCF method as it acknowledges that estimated input parameters for

\textsuperscript{100} Smith/Lajoux (2012), p. 48; Razgaitis (2009), p. 574.
\textsuperscript{102} Razgaitis (2009), p. 575.
the valuation can change over time and that the management can react to this. For example, in the life sciences context, while a product candidate is tested in clinical development, there is always both a potential downside that the product candidate fails and a potential upside if the clinical results show that the drug candidate can be used for additional indications. For example, for the active ingredient Sildenafil, Pfizer initially conducted clinical trials solely to test for patients suffering from Pulmonary Arterial Hypertension (PAH, high blood pressure in the lungs), and it was not until conducting clinical trials that it was noted that Sildenafil also helps men suffering from erectile dysfunction. The result of this unexpected discovery is the drug Viagra with annual revenues peaking at USD 1,934 million in 2008, significantly more than the revenues that were initially estimated for Sildenafil, based on the assumption that it would only be used for patients with PAH. Thus, such positive developments along the development path of a drug, which life sciences executives need to act on quickly, is something that the Real Options method can reflect.

A common misconception in practice is that Real Options should be valued like financial options using recognized financial methodologies such as Black Scholes but, in fact, the Real Options method is nothing but an expansion of the DCF method, simply also taking into account real flexibility of the management by showing multiple possible paths (i.e., a decision tree) and assigning probabilities of occurrence to each of the different paths. Bruner (2004) and Smith and Lajoux (2012) distinguish between three different categories of options:

- **Growth options**: the right to make future investments and the potential to pursue alternate markets in the future.
- **Flexibility options**: the right to switch investments, which allows for different ways to exploit acquired assets in alternative future scenarios.
- **Divestiture options**: the right to sell or liquidate in the future, which mitigates the risk by enabling a company to “unacquire” all or part of an acquisition in the future.

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Growth options are particularly valuable in industries like the life sciences industry where there may be a very significant increase in future demand, but where there is also considerable technological risk and uncertainty.¹⁰⁶ Ignoring such options for purposes of the valuation may result in a significant undervaluation of the subject asset or company. According to Bruner (2004), where companies are growing, where they have the ability to do things other firms cannot, and/or where they have unique assets, the ratio of real option value to the total value of the firm can easily exceed 50 percent.¹⁰⁷

That even the real option valuation can fall short of the actual value of a biotech company is further illustrated by the following practical Example 4.

In January 1999, Warner Lambert Company (“Warner Lambert”) acquired Agouron Pharmaceuticals (“Agouron”) for USD 2.1 billion. Up to 1997, Agouron had no revenues and by 1999 was still reporting a significant loss. Agouron had focused on discovering new molecular entities (NMEs) for treating cancer and HIV. In 1994, Agouron had two drugs in Phase I clinical trials and one in preclinical development. Kellog and Charnes (2000) estimated the value of Agouron shares using decision tree and binomial lattice methods of real option valuation over the period 1994-1996 when the Agouron’s activities were entirely focused on R&D and the company was almost solely a growth option.

Investing in R&D is like buying a call option on uncertain future discoveries with the exercise price equaling the investment necessary to commercialize the discovery in the future. In Agouron’s case, Agouron had three ongoing R&D projects, each with its own stream of options, i.e. the options of whether to terminate the project or invest in further development.

(Continuation)

Kellog and Charnes (Kellog/Charnes (2000), p. 83) found that at four of five points in time, Agouron’s share price was materially higher than values estimated by the real options approaches (refer to Figure 4). They concluded that real options valued the company reasonably well when all of Agouron’s projects were in Phase I or earlier, but that as they approached the successful release, the actual price materially exceeded the estimated value. To explain the difference between the share price and the estimated real options values, they backsolved for valuation assumptions that would produce estimated values equal to the actual price: shorter duration of clinical trial phases, higher probabilities of success in clinical phases, and higher revenues for the successful product (Kellog/Charnes (2000), p. 83-84).

Figure 4: Real Options Values for Agouron Pharmaceuticals (Values in Dollars per Share)
This Agouron Pharmaceuticals case is a good example to show the usefulness of the real options valuation approach in the instance of firms with no revenue, a high proportion of intangible assets, and/or a future that is highly contingent on outcomes of definable processes or events, because in such cases, discounted cash flow or multiples-based approaches will poorly capture the economic content of the company.

**Example 4: Agouron Pharmaceuticals: Valuing the Pure Research Firms**

### 2.7.1.3 Cost Methods

Cost methods are based on the underlying premise that a prudent investor would not pay more for an asset than its replacement or reproduction cost. Cost methods are, with some exceptions, the least indicative of the fair value of an asset or a company because no rational buyer will pay more than an opportunity is worth, irrespective of what the replacement costs are, and no rational seller will sell for less than it is presently worth, even if the costs were much lower. However, the seller’s project costs might be a useful starting point for estimating what it might cost a buyer to recreate the technology because if it will cost the buyer an amount $X$ to reconstruct the seller’s technology, then the buyer will not pay much more than the amount $X$ unless there is a significant time-to-market advantage in doing so or some other barrier to the buyer’s use of the technology.

### 2.7.2 Valuation-related assumptions

The credibility of valuations ultimately depends on the validity of the underlying assumptions. Apart from the difficulty of selecting the right valuation approach and

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108 The entire practical example is based on “Four mini-cases in the analysis of real options” in Bruner (2004), p. 442-444.
method, diversity in practice exists on how to define the input parameters in life sciences valuation.\textsuperscript{113} According to Bodgan and Villiger (2010),\textsuperscript{114} the following parameters are problematic in life sciences valuation practice:

- Discount rate
- Costs
- Success rate
- Peak sales

In order to consistently project cash flows, a target-product profile (based on the therapeutic area, impact-profile, scientific data for the registration authorities, competitive landscape, as well as the medical requirements and market expectations) has to be established first in collaboration with R&D and marketing departments, based on which the R&D, production and marketing costs as well as the revenue expectations can be derived.\textsuperscript{115} Key drivers that need to be captured in the valuation is the likelihood of success of the R&D project, the scope of IP rights and patent protection, as well as the competitive landscape (e.g., what other companies are currently conducting research in this area and what is the likelihood of the emergence of alternative technologies / drugs).\textsuperscript{116} Last but not least, the payers’ needs should also be considered in the valuation as they have the final word on price and reimbursement levels, which can have a significant impact on forecasted sales and peak sales.\textsuperscript{117}

### 2.7.3 Control Premiums

In the valuation context, it is often argued that the price of an investment is not always based on the amount of shares multiplied by the current value of a share, but that for investments that result in the investor being able to exercise control, a control premium is paid.

\textsuperscript{113} Bodgan/Villiger (2010), p. 7.
\textsuperscript{114} Bodgan/Villiger (2010), p. 7.
\textsuperscript{115} Gassmann/Reepmeyer/von Zedtwitz (2008), p. 66.
\textsuperscript{116} Razgaitis (2009), p. 579.
\textsuperscript{117} Gassmann/Reepmeyer/von Zedtwitz (2008), p. 17.
The concept of a control premium refers to the fact that an acquirer when acquiring a stake in a company is generally willing to pay a premium if the stake is large enough for the acquirer to gain control of the acquiree. That is, owning an investment that also provides control over the investee is considered to be less risky than a minority stake because by exercising control the controlling shareholder is in a position to manage and potentially restructure the company in ways that a minority shareholder cannot (e.g., appoint management, define compensation and benefit policies, buy or sell assets, deploy resources, and recapitalize or dissolve the business). \(^{118}\) Bruner (2004) determined that the value of control is not fixed but variable and drew the following two conclusions:\(^{119}\)

1. The value of control is contingent and not fixed because if the current strategy is working well, the option to change the strategy is out-of-the-money. However, if the current strategy is not working well, the option to change the strategy will be in-the-money. As such, the value of control will vary, depending on the economic success of the current strategy.

2. Because the drivers of the value of control are based on the uncertainty and volatility of the business, the value of control increases with the level of uncertainty and volatility.

Based on the theory of Bruner (2004), the relationship between the overall value of the target company and the value of the control premium is inverse: if the company is doing well, this would result in a high share price, whereas the control premium would have minimal value, and vice versa. In summary, how much an acquirer is willing to pay for a control premium is a direct reflection on his expectations that he will recover the value of the premium by making better management decisions for the target firm.\(^{120}\)

\(^{118}\) Lütolf-Carroll (2009), p.533.


\(^{120}\) DePamphilis (2012), p. 23.
3 Presenting the main deal structure types

As shown in the previous chapters, entering into and managing alliances has become critical to the innovation process and business model in the life sciences industry, both for large pharmaceutical companies and small biotechnology companies. Although in the life sciences industry there is no “typical deal structure” (each deal is unique and may contain clauses that make it difficult to come up with a “one size fits all solution”), the majority of deal structures have certain common elements to still allow a categorization into the following six major deal structure types:

- Co-development arrangements and in-licensing arrangements
- Out-licensing arrangements
- Joint arrangements and equity investments with less than a majority of voting rights
- Options-based M&A
- M&A and equity investments with more than a majority of voting rights
- Asset acquisitions

In this chapter, each of the above listed deal structure types will be further illustrated. The illustration will be mainly covering the business development aspects rather than the accounting aspects, which will be addressed in detail in chapters 4, 5 and 6.

3.1 Co-development arrangements and in-licensing arrangements

3.1.1 Business development objectives

Co-development and in-licensing arrangements are considered the “loosest tie” in terms of life sciences collaboration arrangements because they generally only involve two companies sharing information in a specific research area or establishing a joint team that performs mutual research and development activities. These arrangements may involve
the assignment of rights between the parties (e.g., one party granting a license to another party or both parties co-owning the intellectual property resulting from the R&D efforts), but may also be arranged as a pure fee-for-service research arrangement with no assignment of rights.\textsuperscript{121}

The most common example of this deal structure type is a co-development arrangement in combination with a licensing arrangement, where, for example, a small biotech company has a substance in clinical development but does not have the funds to conduct the remainder of the clinical development studies and, thus, sells to a big pharma company a license to co-develop and then later sell the drug in certain jurisdictions (e.g., because the big pharma company already has an established sales and distribution network in these jurisdiction for the targeted patient population).

Co-development and licensing arrangements generally do not involve the creation of a separate legal entity or vehicle. Instead, both partners continue to own their operating assets and continue to employ their employees, and what is stipulated in the agreement more relates to how much resources each party will contribute to the mutual research and development activities, what rights are assigned, and what information will be shared. Further, if mutual research is being conducted, the agreement generally also calls for both parties to establish a Joint Steering Committee (JSC) to deal with matters of governance requiring decisions involving both parties (e.g., reviewing clinical development results or making decisions about the further development of a compound or technology).\textsuperscript{122}

If structured as a license deal, the licensee (e.g., big pharma) acquires intellectual property rights of the licensor (e.g., small biotech), whereas intellectual property subject to the deal are usually rights for either a drug compound or a specific biotechnological procedure (i.e., a platform technology). License deals may be narrowed down for the licensee to use the rights solely for a specified purpose, limited period and/or in a defined jurisdiction. Also, license arrangements may be structured to be exclusive (only one licensee) or non-exclusive (multiple licensees).\textsuperscript{123} An exclusive license is generally

\textsuperscript{121} Austin (2008), p. 111.
\textsuperscript{122} Austin (2008), p. 170.
\textsuperscript{123} Friedman (2008), p. 77.
priced higher because in addition to providing the licensee with the freedom to operate, it also provides a competitive advantage as it confers a barrier to market entry over competitors.\footnote{\textcite{Megantz2002}, p. 84. The license type (exclusive versus non-exclusive), therefore, also becomes an integral part in connection with determining the value of a license. \textcite{Austin2008}, p. 114.}

However, the key characteristic of a license is that even for the exclusive licenses the ownership of the asset (e.g., the IP) still remains with the licensor and the licensee only obtains the permission to use the asset over a defined period or for a defined territory.\footnote{\textcite{Austin2008}, p. 114.}

From a business development perspective, the advantage for big pharma in this deal structure is the expansion of the portfolio of potential drug candidates while leaving most of the R&D risk and cost to the other party.\footnote{\textcite{Gassmann/Reepmeyer/vonZedtwitz2008}, p. 81; \textcite{Zentes/Swoboda/Morschett2005}, p. 560.} In addition, the in-licensed compound or technology often is selected by big pharma because it complements the existing R&D pipeline.\footnote{\textcite{Gassmann/Reepmeyer/vonZedtwitz2008}, p. 81; \textcite{Zentes/Swoboda/Morschett2005}, p. 1245.} That is, if big pharma already has a drug for the same or similar indication, there may also be motivations to enter into such deals to continue to use or better leverage the existing sales and distribution network for the targeted market. On the other hand, to establish such network, small biotech would have to incur significant time and effort. Thus, in such cases, the collaboration often also involves a commercialization agreement where big pharma is responsible for the commercialization of the drug using its existing sales and distribution network. However, instead of big pharma being solely responsible for the commercialization and paying small biotech royalties on commercial sales, the deal can also be structured by assigning individual sales jurisdictions to either party, in which case both parties record the revenues from selling the drug in their respective jurisdictions.\footnote{For example, such arrangement is common for larger U.S. biotech companies that may have a well-established sales and distribution network in the U.S. but not outside the U.S. In those instances, the agreement may foresee for the biotech to retain the commercialization rights in the U.S. and for big pharma to have the commercialization rights outside the U.S. However, even large multinational pharmaceutical companies have greater or lesser sales and distribution strengths in different jurisdictions across the world and may choose to partner with another company to maximize their return through the best utilization of resources. \textcite{Austin2008}, p. 111.} A reduced time-to-market is often one of the more significant motivations for both big pharma and small biotech to enter into a licensing deal because
no matter how innovative the IP is, if it is not introduced into the market in time, a drug may not be generating sufficient revenues to recoup its R&D expenses due to the limited time of patent exclusivity.\(^{129}\)

In summary, even if small biotech may be giving up a significant portion of revenues as part of such co-development and licensing arrangements, the reason this deal structure can still be very attractive for small biotech companies is because the benefits from receiving the different forms of payments (and, thus, securing financing) and the benefits from the drug entering the market sooner, generally more than outweigh the portion of revenues ceded to the partnering firm (e.g., big pharma).

A disadvantage of in-licensing individual compounds or technologies from the perspective of big pharma is that the participation is limited to the individual compound or technology that is subject to the deal. However, this very same reason (limiting the license to only one compound or technology) is also a disadvantage for the small biotech because to secure the next round of financing, it may be pressured to focus all of its resources on the development of the one compound / technology, although other assets in the pipeline may in the meantime have become more promising. Since this limitation of focusing on only one compound / technology can be a disadvantage for both big pharma and small biotech, a variation of the licensing structure has been established in practice that works as follows: The two companies agree on a period over which big pharma provides a steady flow of funding to small biotech, and, in exchange, the small biotech grants big pharma options to co-develop any of its compounds / technologies that it develops during this period. Such a deal structure addresses both disadvantages mentioned above by providing big pharma with the option to co-develop any promising targets in small biotech’s pipeline and at the same time relieving small biotech from continuously having to worry about the next round of financing and focusing the R&D resources on R&D projects that may no longer be the most promising projects.\(^{130}\)

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\(^{130}\) Such deal structure has been adapted in a collaboration between Sanofi and Regeneron Pharmaceuticals, where Sanofi provides Regeneron with a steady flow of funding over a ten year alliance and in exchange Regeneron provides Sanofi with a steady stream of targets which Sanofi can opt to co-develop. Refer to: Ernst & Young (2010), p. 16.
In summary, the success of co-development and in-licensing arrangements to a large extent is based on sharing information between the parties as well as a significant degree of trust because for the confidential information that is shared, each party must be confident that this information will not be used inappropriately by the other party.\textsuperscript{131}

### 3.1.2 Financial objectives

To address the uncertainties in terms of R&D development and market risks that only resolve over the time of the collaboration, co-development and licensing arrangements encompass up-front payments, staged milestone payments as well as royalty payments based on sales once the drug has obtained regulatory approval and is being marketed.\textsuperscript{132} Up-front payments act as an advance and are not tied to actual performance, whereas milestone payments and royalty payments are tied to future success.\textsuperscript{133} Also, the payments over the time of the collaboration are usually inversely linked to the level of risk, meaning the earlier a license agreement is entered into and, as such, the higher the development risks still are, the smaller are the up-front payments and the greater are the milestone payments that become payable as uncertainties resolve.\textsuperscript{134} Large initial license payments coupled with low or no running royalties shift more of the risk to the licensee, while a low initial payment together with higher running royalties is riskier for the licensor.\textsuperscript{135}

Royalties on sales in the biotechnology industry generally fall within the range of 8\% to 12\%, depending on stage of development, strength of the underlying IP, and distribution methods.\textsuperscript{136} However, instead of royalty payments as a percentage of revenues, royalties can also be structured in the form of sales-related milestone payments where – in addition

\textsuperscript{131} Gaughan (2007), p. 527.  
\textsuperscript{132} Zentes/Swoboda/Morschett (2005), p. 1245.  
\textsuperscript{133} Friedman (2008), p. 78.  
\textsuperscript{134} PricewaterhouseCoopers (2012b), p. 4.  
\textsuperscript{135} Megantz (2002), p. 3.  
\textsuperscript{136} Megantz (2002), p. 64.
to or instead of the royalties based on a percentage of sales – payments become due when a certain level of cumulative sales has been reached.\textsuperscript{137}

Therefore, in summary, co-development arrangements and in-licensing agreements offer access to immediate cash for small biotech companies and access to innovative products for big pharma companies and are likely to grow as a source of revenues for both.\textsuperscript{138}

3.1.3 Illustrative example – Collaboration between Pfizer and BMS\textsuperscript{139}

In April 2007, Bristol-Myers Squibb (BMS) and Pfizer announced that they had entered into a worldwide collaboration to develop and commercialize apixaban, an anticoagulant discovered by BMS being studied for the prevention and treatment of a broad range of venous and arterial thrombotic conditions.

As per the agreement, Pfizer is required to make an up-front payment of USD 250 million to BMS and is required to fund 60\% of all planned development costs effective 1 January 2007 going forward with BMS funding the remaining 40\%. Further, BMS is entitled to receive additional payments of up to USD 750 million tied to different development and regulatory milestones. Once the product has been approved, commercialization expenses and profits/losses will be shared equally on a global basis.

In a separate agreement, Pfizer granted BMS rights to co-develop and commercialize a Pfizer metabolic discovery program, including preclinical compounds with applications in obesity and diabetes in exchange for a USD 50 million up-front payment from BMS to Pfizer. For this metabolic disorders program, development expenses, commercialization expenses, and profits/losses will be shared in a ratio of 60/40 between Pfizer and BMS.

\textsuperscript{137} Such sales-related milestone payments may be based on either overall cumulative sales or annual cumulative sales (e.g., the first time that annual sales exceed USD 100 million). Austin (2008), p. 117.
\textsuperscript{138} Bogdan/Villiger (2010), p. 3.
\textsuperscript{139} Example based on information provided in the companies’ press releases when the deal was entered into and information provided in the life sciences deal databases of Thomson Reuters Recap and IMS PharmaDeals.
This arrangement between Pfizer and BMS shows that the co-development and licensing arrangement deal structures are definitely not limited to arrangements between big pharma and small biotech but may also be attractive to be entered into by two large and global pharmaceutical companies such as Pfizer and BMS. In this specific arrangement, both parties noted that instead of competing in the fields of cardiovascular and metabolic disorders programs, benefits can be maximized by combining both companies’ expertise in these fields, both in the development and commercialization. That the diversification of risks was one of the motivations to enter into this arrangement is supported by the following statement by Jim Cornelius, at that time CEO of BMS: "This collaboration supports our strategy to focus on serious diseases, maintain commercial emphasis on specialists and high-prescribing primary care physicians, and work with partners to offset the risks inherent with developing certain medicines."  

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140 Source: Thomson Reuters Recap Deal Database.
3.2 Out-licensing arrangements

3.2.1 Business development objectives

Out-licensing as a deal structure has experienced remarkable growth over the past two decades. The reason why many life sciences companies have been reluctant in the past to out-license any of their R&D assets is mainly because of political reasons within large organizations, namely that the individuals who may decide to out-license a technology or compound are afraid that they out-license a compound that is then later successfully developed to become a blockbuster drug for the other company (the licensee). Another reason why many life sciences companies in the past have been reluctant to use out-licensing deals is because of the general belief that if big pharma, which is generally viewed to have the necessary resources to bring any compound to market, wants to out-license a compound or technology, then there is likely something wrong or unfavorable about this compound or technology.

However, the reality is that today also big pharma has only a limited amount of resources and, thus, is required to discontinue a significant amount of R&D projects each year. Most of the time, these projects are discontinued not because of problems with the compound or technology, but because it is decided that the R&D project does not fit into the company’s overall drug portfolio. However, not only terminated compounds but any compound that can potentially be developed more efficiently by an external partner should be considered for out-licensing.

But out-licensing also lowers the risk because less investment and fewer resources are needed and much of the risk remains largely offloaded onto the partner responsible for the further development. In other words, the big pharma company generally only has an upside potential with out-licensing deals because in case of a product failure, there are usually no negative consequences for the big pharma company. Because the R&D on the

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144 Reepmeyer (2005), p. 75.
145 Austin (2008), p. 117.
147 Reepmeyer (2005), p. 78.
technology or compound would have usually been discontinued otherwise, any positive results that come out of an out-licensing deal are often just viewed as a positive surprise. However, out-licensing may also be attractive for developed technologies – for example, if a company only has the resources to sell the product with the related IP in one market and it would take significant time and effort to build a strong sales and distribution network in another market. Thus, potentially any compound or technology that can be developed or introduced into the market more efficiently or faster by another party should be considered for out-licensing.

Thus, in summary, the benefits of a successfully executed out-licensing program provides a life sciences company with several benefits, such as additional revenue generation, cost and resource effectiveness, or mitigation of R&D related risks.°

### 3.2.2 Financial objectives

The financial objectives of an out-licensing deal are similar to that of a co-development and in-licensing deal, as discussed in section 3.1.2, except that from the perspective of a pharmaceutical company, the flow of payment is the other way around. Thus, instead of having to make up-front, milestone and royalty payments, those payments are received from the party to which the compound or technology has been out-licensed.

However, out-licensing generally also entails some costs that are incurred at the outset of the arrangement (e.g., marketing and legal expenses). As revenues increase, the net cash flow will become positive and will grow over a period of time until new technologies or drugs may take away market share or patents may expire resulting in flat or decreasing revenues.° Figure 6 further illustrates this relationship between time and the licensor’s net cash flow in an out-licensing arrangement.

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Also, as big pharma companies are afraid to lose out on the upside potential of a certain compound or technology, they often do not enter into out-licensing deals unless the out-licensing arrangement also provides for some sort of option to license back the R&D asset at pre-negotiated prices if certain milestones are met (so-called “call-back options”).

3.2.3 Illustrative example – Out-licensing of preclinical compounds from Eli Lilly to Transition Therapeutics

In March 2010, Eli Lilly and Company (“Lilly”) entered into an arrangement with Transition Therapeutics Inc. (“Transition”) to outlicense several preclinical compounds in

153 Example based on information provided in the companies’ press releases when the deal was entered into and information provided in the life sciences deal databases of Thomson Reuters Recap and IMS PharmaDeals.
the area of diabetes. Under the terms of the arrangement, Transition made an up-front payment of USD 1 million to Lilly in exchange for exclusive worldwide rights to develop and commercialize these compounds. Further, as per the agreement, Lilly retained the option to re-acquire the rights to the compounds at a later point in time, which is exercisable up until the end of Phase II development. If Lilly exercises those rights, Transition would be eligible to receive milestone payments of approximately USD 250 million as well as up to low double digit royalties on any sales of products containing the compounds. If Lilly does not exercise its option, it would be eligible to receive low single digit royalties from Transition on sales of products containing the compounds. Figure 7 further illustrates the arrangement entered into between Lilly and Transition.

**Figure 7: Out-licensing arrangement entered into between Eli Lilly and Transition Therapeutics**

In June 2013, Lilly announced that it would exercise its option to re-acquire all rights of the type 2 diabetes drug candidate TT-401 in exchange for a milestone payment of USD

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154 Source: Thomson Reuters Recap Deal Database.
7 million to Transition. Except for a USD 14 million contribution by Transition during the Phase II clinical study, Lilly will be responsible for and assume all costs related to all future development and commercialization activities of TT-401. If TT-401 is successfully commercialized, Transition will be eligible to receive USD 24 million in additional milestone payments as well as a double-digit royalty on sales of TT-401 and a low single-digit royalty on related compounds.

This example reflects the benefits of out-licensing from the perspective of big pharma, which is confirmed with the following quotation by David E. Moller, M.D., at the time the deal was entered into Lilly Vice President of Endocrine and Cardiovascular Research: “The Lilly strategy in R&D embraces the notion of shared-risk discovery and early development efforts that can lead to clinical testing of a broader array of molecules.” With out-licensing these compounds, Lilly was able to have its internal R&D resources focus on other (maybe at that time more promising) R&D projects, while at the same time not discontinuing the development of the preclinical diabetes compounds and not giving up on any potential upside of these compounds by structuring the deal to include a call-back option, which Lilly ended up exercising in June 2013.

3.3 Joint arrangements and equity investments with less than a majority of voting rights

3.3.1 Business development objectives

Joint arrangements and equity investments with less than a majority of voting rights encompass more involvement between the partners than co-development and in-licensing arrangements discussed in the previous section, but less involvement than mergers and acquisitions, which will be further discussed in section 3.5.
A joint arrangement is defined as a partnership between two or more parties with the purpose of undertaking a specific activity.\textsuperscript{155} Further characteristics are the time period of the arrangement usually being limited in duration and the partners maintaining their own separate business operations as they did before entering into the arrangement.\textsuperscript{156} Generally, the parties in the joint arrangement will each take on an active role in the specific activity, contributing either intellectual property, financial resources, assets or a combination of the three.\textsuperscript{157} The reason why joint arrangements are chosen as a deal structure is generally because two companies have specialized resources that when combined can be used to create or market a specific product.\textsuperscript{158} Further, risks can be shared with the partner and are generally limited to those of the joint activity as well as limited over time, whereas the potential upside can be significant if the skills and resources are complementary.\textsuperscript{159} Example 5 will further illustrate the benefits of a joint arrangement structure in the life sciences context.

A large pharmaceutical company (“big pharma”) is conducting R&D on a drug candidate and is seeking to use specific R&D resources that a small biotech company has. Big pharma has a widespread sales and distribution network that would be able to rapidly capture market share when the product is eventually approved. In addition to the R&D resources that the big pharma is interested in, the small biotech also has R&D resources for several other areas of R&D focus.

In this example, both parties bring resources to the table and each can gain from the other’s skills. However, for big pharma to acquire the small biotech company as a whole may be an expensive way to get to the intended result because the big pharma does not plan to use most of the other R&D resources that the small biotech employs. Thus, for such a set-up, the joint arrangement structure is likely to be the preferred deal structure because the involvement of both parties will be limited to this one

\textsuperscript{155} Hunt (2011), p. 265.
\textsuperscript{156} Gaughan (2007), p. 520.
\textsuperscript{159} Megantz (2002), p. 3.
activity, and once that activity has been completed, neither party has any further obligations.

Example 5: Common joint arrangement structure between a pharmaceutical and a biotech company

However, different from Example 5, the specialized resources do not necessarily need to be different by nature (e.g., R&D resources and marketing resources). Also common in the life sciences industry are joint arrangements for products that are already approved but where partners split the marketing of the drug into different geographic jurisdictions because the two companies complement each other well in terms of who has the most advanced sales and distribution network in which local jurisdictions.

Zentes, Swoboda and Morschett (2005) summarize the advantages and disadvantages of forming a joint arrangement as follows:

<table>
<thead>
<tr>
<th>Advantages of forming a joint arrangement</th>
<th>Disadvantages of forming a joint arrangement</th>
</tr>
</thead>
<tbody>
<tr>
<td>➢ Cost savings due to economies of scale, division of labor or the utilization of otherwise unused capacity</td>
<td>➢ Transaction costs: costs to initiate, find an agreement, control and administration of the joint arrangement</td>
</tr>
<tr>
<td>➢ Access to otherwise not accessible resources</td>
<td>➢ Some of the own specific resources have to be shared with the partner, which could potentially weaken a company’s competitive position</td>
</tr>
<tr>
<td>➢ Savings of capital commitment costs</td>
<td>➢ Conflicts as a result of allocating resources</td>
</tr>
<tr>
<td>➢ Cost savings of personnel costs in management functions</td>
<td>➢ Complexity of managing the joint arrangement due to shared disposition over resources</td>
</tr>
<tr>
<td>➢ Access to (local) market knowledge of the partner</td>
<td>➢ Own goals and strategies cannot be pursued independently of the joint arrangement partner</td>
</tr>
<tr>
<td>➢ Access to government authorities or important customers</td>
<td>➢ Reduction of competition</td>
</tr>
<tr>
<td>➢ Reduction of competition</td>
<td>➢ Diversification of the investment risk</td>
</tr>
<tr>
<td>➢ Diversification of the investment risk</td>
<td>➢ Reduced time-to-market and faster amortization of investment costs</td>
</tr>
<tr>
<td>➢ Reduced time-to-market and faster amortization of investment costs</td>
<td>➢ Diversification of the product portfolio</td>
</tr>
</tbody>
</table>

Figure 8: Advantages and disadvantages of forming a joint arrangement

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Similar to co-development arrangements or in-licensing arrangements, joint arrangements often involve the establishment of a Joint Steering Committee (JSC), a committee with representatives from both parties which has the ultimate decision-making power for any matters of governance as part of the arrangement. For example, in the research and development phase, it may be up to the JSC to review any study results and make the ultimate “go” or “no-go” decision for the respective drug candidate. Thus, in these instances, it would generally also be the JSC that – based on the contractual arrangement of the deal – has the decision-making rights related to the R&D activities. The structure of such a committee and the voting rights will be stated in the contract.¹⁶³

An equity investment with less than a majority of voting rights is a deal structure where big pharma purchases shares of small biotech as a strategic investment. Depending on the percentage of ownership that big pharma obtains, big pharma either holds an investment with no significant influence (generally assumed if the equity share is less than 20%) or a significant influence investment (generally assumed if the equity share is in the range from 20% to 50%). However, significant influence may also be exercised in situations with less than 20% or more than 50% ownership by other means of exercising significant influence (e.g., this may be the case in a situation where the investor has a 10% ownership but 30% of the seats in the board of directors, allowing it to influence the decisions of the board). As it will be shown in section 5 of this thesis, such deal structures (equity investments with less than a majority of voting rights but where the investor may exercise control through means other than voting rights) can become very difficult to assess from a control perspective, which may then also have a significant impact on the accounting.

Equity investments with less than a majority of voting rights are viewed as mainly serving a strategic purpose because they often are the big pharma company’s initial step to a subsequent acquisition of the small biotech.¹⁶⁴ This may become especially relevant in a situation where the small biotech becomes an acquisition target because any big pharma with an existing equity share would be deemed to have a “head start” compared

to any other big pharma company interested to acquire the biotech target. However, the flipside to this is that for the small biotech to have an investor with significant influence may limit its options to partner with or obtain funding from other big pharma companies or investors because these other companies or investors may “shy away” if a competitor is already exercising significant influence at that biotech target.

Thus, in summary, joint ventures and equity investments with less than a majority of voting rights are often used as an alternative to mergers and acquisitions, when the parties may not wish to cede autonomy that may result from an outright merger or sale, yet the parties are eager to capitalize on opportunities presented by the counterparty. Also, these deal structures can be an effective way to create shareholder value because they may allow initiating higher risk projects that each party’s existing shareholders would not be willing to support if entered into independently. Last but not least, if successful, joint arrangements and equity investments with less than a majority of voting rights can also be considered a “dry run” for a potential acquisition at a later point in time. Because if the partners find out as part of the arrangement that they do not work well together or there are substantial differences (e.g., cultural differences), an advantage to this deal structure is that it can be curtailed at comparatively lower costs than if there had been a full merger or acquisition arrangement.

### 3.3.2 Financial objectives

For joint arrangements, a formal agreement among the partners generally sets forth what each partner is contributing at the formation of the arrangement, the extent to which each partner will exercise control over the joint activities and the extent to which each partner will participate in the entity’s profits or losses. Economically and from a deal negotiation perspective, if the contribution of each partner differs significantly in value,
there is a presumption that the partner that is contributing the higher value assets also receives more control rights. However, this does not necessarily need to be the case.

In practice, life sciences executives may often refer to the terms “joint arrangement” and “joint venture.” However, whether “joint control” from a legal perspective indeed exists often depends on the specific facts as stipulated in the agreement. Just because the agreement may be titled “joint arrangement” or “joint venture”, in itself, does not stipulate that rights and obligations are indeed equally shared between the parties. Section 5.1.4.1 of this thesis further expands on when joint control exists, a question that is very relevant when considering how to account for the arrangement.

For equity investments with less than a majority of voting rights, the financial terms are generally limited to the share of equity ownership being acquired and the price for that share of equity. The distribution of profits or losses does not need to be formally documented in an agreement but is generally based on the equity ownership (e.g., if an investor owns 30% of a company, that investor is also entitled to receive 30% of the profits generated by the investee unless the parties agree to a different profit distribution).

3.3.3 Illustrative example – Equity investment by GSK in Aspen Pharmacare

GSK in its 2012 Form 20-F disclosed the following information relating to its equity investment in Aspen Pharmacare.

“At 31 December 2012, the Group owned 84.7 million shares or 19% of Aspen Pharmacare Holdings Limited. Aspen, listed on the Johannesburg Stock Exchange, is Africa’s largest pharmaceutical manufacturer and a major supplier of branded and generic pharmaceutical, healthcare and nutritional products to the southern African and selected international markets. The investment had a book value at 31 December 2012 of £430 million (2011 – £393 million) and a market value of £1,037 million (2011 – £627 million). Although the Group holds less than 20% of the ownership interest and voting control of Aspen, the Group has the ability to exercise significant influence through both
its shareholding and its nominated director’s active participation on the Aspen Board of Directors.”

This example of GSK’s equity investment in Aspen Pharmacare illustrates that – although significant influence is presumed to exist if the equity share is in the range from 20% to 50% - significant influence may also be exercised in situations with less than 20% ownership through other means of exercising significant influence (e.g., based on the distribution of board seats that allows the investor to exercise significant influence).

### 3.4 Options-based M&A

#### 3.4.1 Business development and financial objectives

Options-based M&A, which has become more and more popular in the last few years, mirrors the fundamentals of the life sciences industry: To further limit the exposure to R&D risks, the industry has come up with deal structures that are referred to as options-based M&A transactions. In this type of transaction, big pharma does not acquire or in-license an asset but rather pays for the exclusive right, with no obligation, to acquire or in-license the asset (or a group of assets, businesses, or entities as a whole) at a later point in time on predetermined terms. From a legal perspective, an option is defined as the right, not the obligation, to make a future decision, contractually agreed upon between two parties, where the option fee can be considered to be the down payment on the opportunity.

An option may be exercisable at any time during the option period or be exercisable only when certain events occur (e.g., a drug candidate reaching the next clinical development phase or obtaining regulatory approval). Once any predetermined terms are met, the option seller (e.g., the small biotech) is obligated to fulfill the transaction if requested by the option holder (e.g., big pharma). The concept behind such a structure is the provision

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of a fixed level of cash which helps the small biotech secure financing in the short term and which secures the opportunity for the investor (e.g., big pharma) without obligating the investor to either purchase the underlying of the option or to fund additional cash.\textsuperscript{173}

For the company that gives out such an option (e.g., small biotech), the advantage of this deal structure is that a serious buyer exists, and that there is some payment to be received for the option.\textsuperscript{174} However, the downside to option deals from the perspective of small biotech is that during the option period the small biotech is generally prohibited from further marketing the opportunity to other interested investors, some of which may be willing to offer more than the investor holding the option (a restriction that is commonly referred to as the “no shop” provision).\textsuperscript{175}

The key advantages of an option deal for big pharma is the access to an increased number of drug candidates with only a limited investment until a key technical outcome is known and the ability to lock out competitors over the option period.\textsuperscript{176} The additional time gained can then be used to conduct further due diligence, incl. possible test marketing.\textsuperscript{177} Big pharma companies that have been actively using options-based transactions include GSK (in deals with Vernalis, Presena, Chroma Therapeutics, Supergen, Concert Pharmaceuticals and others) and Novartis (in deals with Proteon and Elixir Pharmaceuticals).\textsuperscript{178}

\begin{itemize}
\item[\textsuperscript{173}] Austin (2008), p. 132.
\item[\textsuperscript{174}] Razgaitis (2009), p. 521.
\item[\textsuperscript{175}] Razgaitis (2009), p. 521.
\item[\textsuperscript{177}] Razgaitis (2009), p. 521.
\item[\textsuperscript{178}] Ernst & Young (2010), p. 10.
\end{itemize}
3.4.2 Illustrative example – Novartis’ option to license a drug candidate

In August 2010 Novartis acquired from Quark Pharmaceuticals ("Quark") an option to obtain an exclusive worldwide license to develop and commercialize its p53 temporary inhibitor siRNA drug QPI-1002, at that time in clinical trial Phase II.

As part of this arrangement, Novartis paid USD 10 million for the option and, in the event that Novartis decides to exercise the option, Quark would receive an option exercise fees and milestone payments that could potentially total USD 670 million and, in addition, potential royalties on sales of licensed products.

Figure 9: Option arrangement entered into between Novartis and Quark Pharmaceuticals

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179 Example based on information provided in the companies’ press releases when the deal was entered into and information provided in the life sciences deal databases of Thomson Reuters Recap and IMS PharmaDeals.

180 Source: Thomson Reuters Recap Deal Database.
3.5 M&A and equity investments with more than a majority of voting rights

3.5.1 Business development objectives

The mergers and acquisition deal structure is the most traditional deal structure and also the deal structure that is most widely used in other industries. Broadly speaking, as part of a merger or acquisition, one company obtains control over another company and from that day on has to consolidate the two businesses in one set of financial statements.\(^{181}\)

One of the most frequently named reasons for acquisitions in the life sciences industry is the access to new markets and industry subsectors as well as the exploitation of synergy effects, resulting in the reduction of costs in administration, sales and development.\(^{182}\) However, acquiring another entity in full not only provides advantages for the acquirer but it also brings risks because with acquiring another legal entity an acquirer is also assuming any potential contingencies that the acquiree has, some of which the acquiree may not even be aware of at the time of the acquisition. Thus, for this deal structure, more than for any other deal structure, a thorough due diligence is required to evaluate any business, legal, compliance, and financial risks.

Also, contingent liabilities may only develop as a result of the acquisition because the target company may have some co-development and licensing arrangements with other companies, some of which may be competitors for the acquirer at a global level. In these instances, careful study of the existing arrangements is required to understand whether or not such arrangements may be terminated post-acquisition and under what terms.\(^{183}\)

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\(^{181}\) Even if the term merger is often used, from an accounting perspective there always has to be one acquirer and one acquiree. Thus, from this point on reference will only be made to the term „acquisition.“


\(^{183}\) Austin (2008), p. 122.
3.5.2 Financial objectives

3.5.2.1 Earnouts and contingent considerations

Earnouts and contingent considerations represent supplemental payments after a sale, contingent on the achievement of arbitrary future performance targets.\textsuperscript{184} Although in practice the terms “earnouts” and “contingent consideration” are often used interchangeably, from a legal definition point of view a distinction can be drawn between the two: while an earnout is typically closely linked to the achievement of financial goals, in particular, projected financial performance, a contingent consideration is more often associated with non-financial objectives (e.g., the regulatory approval of a product).\textsuperscript{185}

If two independent parties are asked about what they think is going to be the future of a particular drug candidate in 10 to 15 years or what is going to be the future of a particular biotech company as a whole in 10 to 15 years, one is likely to get very different responses. As mentioned in section 2.2.3 of this thesis, this is due to the many risks and uncertainties that are inherent in this industry, especially for biotech companies. The same is true for two parties, a seller and a buyer, that are trying to agree on a certain price for a particular drug candidate or for a biotech company as a whole. If those two parties were to agree on one single amount at the outset of the arrangement, all the uncertainties and risks, as well as the upside potential would need to be priced into that one single amount. Then, as the future unfolds, one of the two, the buyer or the seller, will likely feel they should have agreed to a different amount because it is unlikely that for both of them the commercial outcome will be identical to the value ascribed at the outset of the arrangement.\textsuperscript{186}

As such, since in the life sciences industry acquisitions are almost always driven by a company’s desire to access another company’s R&D pipeline, the uncertainties that are


\textsuperscript{185} Hunt (2011), p. 677. In this thesis the terms “earnout” and “contingent consideration” will be used interchangeably as this thesis deals with the financial statement implications of earnouts and contingent considerations and from that perspective the two are treated the same way. Further, in this thesis reference will be made to the term “structured deals”, which is defined as acquisitions where not the entire purchase price is paid up-front but where a portion of the purchase price is tied to future milestones (i.e., earnouts).

\textsuperscript{186} Razgaitis (2009), p. 504.
inherent in each R&D pipeline resulted in an increasing popularity of structured deals. Figure 10 provides an overview of the development of structured deals over the period 2005 to 2011 compared to acquisitions where the entire purchase price was paid up-front.

The principal advantage of an earnout is that it allows the buyer to increase the purchase price without necessarily increasing its risk, which can be extremely useful for breaking deadlocks in deal negotiations. Further, if the key personnel of the target are also shareholders of the target, earnouts can help to retain and motivate this personnel and thereby align the incentives of management with the objectives of the acquirer.

The targets subject to earnouts should be structured to be achievable but still represent a challenge. This is because the motivation may be lost if the targets are almost impossible to achieve or if the performance targets are already reached after a relatively short period of time after the acquisition, effectively guaranteeing the maximum payout.

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187 Population is all biotech "Big Exits" (defined as acquisitions where the up-front payment (not including any milestones to be earned) totaled $75 million or more). Source: Silicon Valley Bank (2012), p. 5.
Another important consideration in connection with earnouts is that the target measures should be long-term and also not be linked to only one performance measure. Otherwise, the management of the acquired firm may have an incentive to take actions that are not in the best interest of the acquirer as, for example, cutting back on advertising and training expenses only to improve the operation’s short term earnings performance.¹⁹¹

Last but not least, when making use of earnouts, the acquirer and seller should agree on how the future performance against the targets should be measured. On the one hand, disputes often arise for financial measurement targets such as “core earnings”, in terms of which items should be included and excluded to measure the performance. On the other hand, difficulties in measurement exist because after the acquisition, the target is generally integrated into the acquiring entity, which makes it difficult to then later carve out and evaluate the performance of just the acquired business. Also, if there are synergies that result in higher revenues or cost savings, it is virtually impossible to later determine to what extent each part of the business (the acquired business and the acquiring business) contributed to these higher revenues or cost savings.¹⁹²

Figure 11 provides an overview of the relative distribution of earn-out terms in the life sciences industry based on a total population of 47 acquisitions in the period from Q3 2008 through Q2 2012, for which Shareholder Representative Services LLC served as the shareholder representative.

3.5.2.2 Contingent Value Rights (CVRs)

In M&A transactions, contingent value rights are commitments by the issuing company (i.e., the acquirer) to pay additional cash or securities to the holder of the CVR (i.e., the seller) if the share price of the issuing company falls below a specified level at some future date. Chatterjee and Yan (2008) found that CVRs are more likely to be used when the acquiring firm issues stock to the target firm’s shareholders that it believes is undervalued due to asymmetric information. In other words, the issuance of CVRs expresses buyer confidence in the future success of the transaction. The key difference between earnouts and CVRs is that earnouts represent call options for the target representing claims on future upside performance and are employed when there is substantial disagreement between the buyer and seller on price, whereas CVRs are put

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193 As a percentage of all milestone events. Source: Shareholder Representative Services (2012), p. 17.
options limiting the downside loss on the form of payment received by sellers.\textsuperscript{197} Also, CVRs are typically traded on the public exchange market.\textsuperscript{198}

In January 2011, Ligand Pharmaceuticals Inc. (“Ligand”) entered into an agreement to acquire CyDex Pharmaceuticals Inc. (“CyDex”). As part of this arrangement, CyDex shareholders received USD 31.2 million in up-front cash, a USD 4.3 million cash payment on the one-year anniversary of closing and Contingent Value Rights (CVRs) related to certain transactions and pursuant to a revenue share plan. More specifically, Ligand will deliver to the CVR holders 50\% of all up-front and milestone payments received by Ligand under this licensing agreement from The Medicines Company (when and as received by Ligand) after subtraction of any corresponding milestone payments (potentially up to $5 million) made back to Prism Pharmaceuticals.\textsuperscript{199}

Example 6: Acquisition of CyDex Pharmaceuticals by Ligand Pharmaceuticals using CVRs\textsuperscript{200}

3.5.2.3 Deferred considerations

A combination of a fixed consideration paid up-front and a contingent consideration is the so-called deferred consideration. Different from the contingent consideration, a deferred consideration is unconditional (i.e., a fixed amount), but the payment is not made all up-front when the agreement is entered into but instead spread over time (e.g., 20\% of the total consideration is payable every anniversary date for a total of five consecutive years). If the payments are being deferred for more than a year, from an accounting perspective, they should be discounted to reflect the time value of money. Since such payments are unconditional, and assuming the buyer risk of credit default is

\textsuperscript{197} DePamphilis (2011), p. 65.
\textsuperscript{198} Deloitte (2012a), p. 29.
\textsuperscript{199} The program had been previously licensed to Prism Pharmaceuticals Inc., but full rights were returned in 2010 when both parties agreed to terminate the agreement in return for a cash payment and future potential milestone and royalty payments.
\textsuperscript{200} Example based on information provided in the companies’ press releases when the deal was entered into and information provided in the life sciences deal databases of Thomson Reuters Recap and IMS PharmaDeals.
low, then the discount rate would generally be the seller’s Weighted Average Cost of Capital (WACC), or a small risk premium above the WACC since there is always some risk.\textsuperscript{201}

### 3.5.2.4 Equity and debt

Receiving equity as a form of the consideration transferred may be interesting for sellers who want to participate in any appreciation in the acquirer’s stock.\textsuperscript{202} Using equity as a form of consideration transferred is generally not used if the acquirer is a public company because in that case the equity can be considered a cash equivalent because it can be converted into cash at any time. However, if the acquirer is a private company, equity is not available to the general public, and, in such cases, the use of equity can be attractive for a seller because of the potential of a significant appreciation in the value of the shares, especially in the case of an IPO.\textsuperscript{203}

Using equity as consideration transferred can also be useful to overcome deadlocks in deal negotiations – especially in the life sciences context where there are a lot of uncertainties about the future development. Instead of agreeing on a fixed purchase price in cash, the parties would find an agreement to settle part of the consideration in equity, so that the seller participates in any appreciation of the acquirer’s stock as uncertainties resolve.\textsuperscript{204} One of the disadvantages of using equity as consideration transferred is the earnings per share dilution for existing shareholders.

Instead of equity, or in addition to equity, acquirers may also issue long-term debt as a form of consideration transferred. The attractiveness of long-term debt is its relatively low after-tax cost due to the fact that the interest is tax deductible, although too much debt can also increase the risk of default on loan repayments and bankruptcy.\textsuperscript{205}

\begin{footnotesize}
\textsuperscript{201} Razgaitis (2009), p. 504.
\textsuperscript{202} DePamphilis (2011), p. 58.
\textsuperscript{203} Razgaitis (2009), p. 525.
\textsuperscript{204} DePamphilis (2011), p. 57.
\textsuperscript{205} DePamphilis (2011), p. 156.
\end{footnotesize}
3.6 Asset acquisitions

3.6.1 Business development and financial objectives

Instead of in-licensing a product or acquiring an entire company, a company may also just acquire individual assets and liabilities from another company. An asset acquisition is a deal structure that is a mixture between an in-licensing deal (as discussed in chapter 3.1) and the acquisition of an entity as a whole (as discussed in chapter 3.5). While generally only one or a few R&D assets are subject to the deal (similar to an in-licensing deal), all rights and obligations in relation to these assets are transferring ownership (similar to an acquisition of an entity as a whole). An asset acquisition may be the most practical deal structure when the acquirer is only interested in a product line or division within a group, and those product lines or divisions are not organized as separate legal entities.

An advantage of an asset acquisition is that the buyer is generally not responsible for the seller’s overall liabilities and contingencies as a company, but is only responsible for any liabilities and contingencies associated with the acquired assets, which means there are fewer risks, as compared to the acquisition of another entity as a whole, but still more risks than a licensing arrangement where a company only acquires the right to use an asset. Examples of liabilities or contingencies in connection with the acquisition of individual assets or products include potential past or future development issues (e.g., claims for adverse clinical events).

Also from a payment structure perspective, asset acquisitions are similar to license deals and the acquisition of an entity as a whole as asset acquisitions may involve up-front payments, milestone payments or royalty payments (or a combination of the three).

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3.6.2 Illustrative example – Acquisition of assets by Cell Therapeutics Inc.

In April 2012, Cell Therapeutics Inc. (“CTI”) entered into an asset purchase agreement with S*BIO Pte Ltd. (“S*BIO”) pursuant to which CTI acquired the worldwide rights to the compound “pacritinib.” Pacritinib is an oral JAK2 (Janus Kinase 2) selective inhibitor for patients with primary myelofibrosis (MF) or MF secondary to other myeloproliferative neoplasms. Pacritinib has an orphan drug designation in the United States and Europe for MF.

In consideration of the assets and rights acquired under the agreement, CTI had to make an up-front payment of USD 15.0 million in cash and issued 15,000 shares of Series 16 convertible preferred stock to S*BIO at the closing in May 2012, which have been fair valued at the acquisition date at USD 11.3 million.

Under the terms of the agreement, S*BIO also has a contingent right to certain milestone payments from CTI up to an aggregate amount of USD 132.5 million for regulatory success and sales-based milestone payments, as well as single-digit royalties on net sales.

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208 Based on information provided in the companies’ press releases when the deal was entered into, information provided in the life sciences deal databases of Thomson Reuters Recap and IMS PharmaDeals as well as financial statement disclosure made by Cell Therapeutics Inc. in SEC Form 10-Q for the quarterly period ended June 30, 2012. Cell Therapeutics (2012), p. 15.

209 Refer to section 2.3.2 for a detailed explanation of what an orphan drug designation is.
4 Life Sciences Deal Structuring Analysis 1: Business Combinations versus Asset Acquisitions

In December 2007, as part of their long-term convergence initiative, the FASB and IASB issued their first converged accounting standard, the revised standard on business combinations (FASB Statement 141 (R)\textsuperscript{210} and revised IFRS 3). One of the most significant changes with the new standards – which became effective for annual periods beginning on or after December 15, 2008 (US GAAP) and July 1, 2009 (IFRS) – was that the definition of what constitutes a business and, as such, is subject to the new guidance, was significantly expanded. As a result of this broader definition of what constitutes a business, the expectation was that significantly more transactions involving development stage entities would need to be accounted for as a business combination. This is especially true for the life sciences industry where many transactions involve development stage entities, which under the previous business combination guidance were often not considered businesses from an accounting perspective, but with the broadened definition of a business are more likely to meet the definition of a business.\textsuperscript{211}

If what is being acquired does not meet the definition of a business, the transaction will be accounted for as an acquisition of assets, which is significantly different from the accounting for a business combination.\textsuperscript{212} Although in theory the distinction of what constitutes a business combination and what constitutes an asset acquisition may seem unambiguous, in practice categorizing transactions as either business combinations or asset acquisitions can become very complex and often requires significant judgment that – when applied – can have a significant impact on a company’s earnings, financial ratios, and business metrics, both as of the acquisition date (initial accounting) and as part of the subsequent accounting (e.g., future amortization, depreciation and possible

\textsuperscript{210} FASB Statement 141 (R) was subsequently codified as ASC 805 Business Combinations. As such, for the remainder of this thesis reference will solely be made to ‘ASC 805’.

\textsuperscript{211} PricewaterhouseCoopers (2010), p. 3.

\textsuperscript{212} Refer to section 4.2 of this thesis for the key differences in the accounting for business combinations versus asset acquisitions.
impairment). Therefore, understanding what the key drivers are that make a transaction more likely to qualify as a business combination or an asset acquisition is critical for life sciences executives to anticipate the financial statement implications prior to entering into new deals.

4.1 Definition of a business

The definition of a business as per the revised standards is as follows: “An integrated set of activities and assets that is capable of being conducted and managed for the purpose of providing a return in the form of dividends, lower costs or other economic benefits directly to investors or other owners, members or participants.” With the broadening of the definition of a business, the acquired set of activities and assets would only need to have inputs and processes applied to those inputs, which together are or will be used to create outputs, whereas under the previous guidance all three elements (inputs, processes and outputs) were needed for an acquired set of activities and assets to be considered a business. The revised standards further clarify that, to be considered a business, an acquired set of activities and assets does not need to include all of the inputs or processes that the seller used in operating the business if a market participant is capable of continuing to produce outputs, for example, by integrating the business with its own inputs and processes. Further, the revised standard clarifies that a development stage entity may be considered a business as long as it has both inputs and processes and is pursuing a plan to eventually produce outputs.

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214 IFRS 3, Appendix A: Defined terms; ASC 805-10-20.
217 IFRS 3.B10. While development stage entities under the previous guidance generally did not meet the definition of a business, in the basis for conclusion of the revised standards the boards explicitly mention that the change in the definition of a business was merely to avoid an “unduly restrictive interpretation” particularly relating to development stage entities. IFRS 3.BC18.
4.1.1 Inputs, processes and outputs

IFRS 3.B7 and ASC 805-10-55-4 define the three elements of a business (inputs, processes, and outputs) as follows:

- **Input**: Any economic resource that creates, or has the ability to create, outputs when one or more processes are applied to it. Examples include non-current assets (including intangible assets or rights to use non-current assets), intellectual property, the ability to obtain access to necessary materials or rights and employees.

- **Process**: Any system, standard, protocol, convention or rule that when applied to an input or inputs, creates or has the ability to create outputs. Examples include strategic management processes, operational processes and resource management processes. These processes typically are documented, but an organized workforce having the necessary skills and experience following rules and conventions may provide the necessary processes that are capable of being applied to inputs to create outputs. \(^{218}\)

- **Output**: The result of inputs and processes applied to those inputs that provide or have the ability to provide a return in the form of dividends, lower costs or other economic benefits directly to investors or other owners, members or participants.

As mentioned above, for an acquired set of activities and assets to be considered a business, it does not need to include all of the inputs or processes necessary to operate as a business (i.e., it does not need to be self-sustaining). \(^{219}\) Instead, what needs to be assessed is whether, from the perspective of a market participant, a market participant would have the missing inputs or processes necessary to operate the set of activities and assets as a business, irrespective of whether a seller in the past operated the set as a business or whether the acquirer in the future intends to operate the set as a business. \(^{220}\) Moreover, even if the elements that are missing from the acquired set are not present with

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\(^{218}\) Accounting, billing, payroll and other administrative systems typically are not processes used to create outputs. IFRS 3.B7 and ASC 805-10-55-4.

\(^{219}\) Ernst & Young (2009a), p. 3.

a market participant, but can be easily obtained (i.e., the missing elements are “minor”), it is commonly believed that the acquired set should be considered a business.\textsuperscript{221}

Applying the definitions of inputs, processes and outputs as per the standards to the life sciences industry, inputs, processes and outputs could mean the following:\textsuperscript{222}

**Inputs** – intellectual property, scientific equipment, unpatented technology and ideas.

**Processes** – research methods, an organized workforce, written procedures for research, manufacturing or selling, outsourcing arrangements.

**Outputs** – completed intellectual property, pharmaceutical products.

One of the most relevant questions in the life sciences context is what constitutes a process. If a small biotech has an organized workforce to conduct R&D activities and this workforce is being acquired by a big pharma, there is a presumption that in addition to inputs the R&D process has been transferred.\textsuperscript{223} On the other hand, if only the IP is being acquired (with no employees) and the R&D activities continue to be conducted by the seller (the small biotech), it is likely that big pharma only acquired the rights to the IP (inputs) and no processes. As the empirical analysis in section 4.3 of this thesis will show, the most judgmental cases are those where the acquirer does not directly acquire any workforce, but indirectly acquirers the workforce’s know-how and experience in the form of documentation or written policies and procedures, allowing the acquirer to seamlessly continue with the R&D activities where the seller has left off. In these scenarios, the essential question is whether this R&D documentation or written policies and procedures that have been transferred as part of the acquisition meet the definition of a process, which life sciences companies in practice seem to interpret differently.

\textsuperscript{221} Ernst & Young (2009a), p. 3; PricewaterhouseCoopers (2011a), p. 1 - 5.
\textsuperscript{222} Based on PricewaterhouseCoopers (2010), p. 3.
\textsuperscript{223} IASB (2013a), p. 15; Ernst & Young (2009a), p. 4.
4.1.2 Definition of a “market participant”

Although IFRS 3 and ASC 805 both make reference to the term “market participant”, the definition of this term is included in the respective “fair value measurement” standards, ASC 820 Fair Value Measurement and IFRS 13 Fair Value Measurement. According to those standards, market participants are defined as buyers and sellers in the principal (or most advantageous) market for the asset or liability that are:

a. Independent of the reporting entity; that is, they are not related parties.

b. Knowledgeable, having a reasonable understanding about the asset or liability and the transaction based on all available information, including information that might be obtained through due diligence efforts that are usual and customary.

c. Able to transact for the asset or liability.

d. Willing to transact for the asset or liability; that is, they are motivated but not forced or otherwise compelled to do so.

Applying the definition of a market participant in the context of deals in the life sciences industry may be challenging. Although independence, the ability to transact, and the willingness to transact are all criteria that one should be able to assess relatively objectively, determining what is the principal (or most advantageous) market for what is being acquired, who are the buyers and sellers in that market, and assessing whether these buyers and sellers have a reasonable understanding about what is being acquired and the transaction, all represent areas that require significant judgment.

4.1.3 Development stage entities

Under the previous business combination guidance, it was noted that in order to be considered a business, what is being acquired must have substantially all the inputs, processes, and outputs necessary to be self-sustaining. Although the previous guidance did not specifically define the term “self-sustaining”, it did explicitly state that a development stage entity is presumed to not be a business because it does not have “the

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224 IFRS 13, Appendix A: Defined terms; ASC 820-10-20.
ability to obtain access to the customers that purchase the outputs of the acquired set” and because its current activities are focused on the development of a business rather than the operation of a business. With this statement it was made clear that to be considered self-sustaining and to qualify as a business, what is required is the activity of actively selling goods or services on the market, which resulted in most small biotech companies that primarily focus on R&D activities but not on actively selling goods or services to not qualify as businesses.

The problems that this former definition of a business caused in the life sciences industry were twofold: On the one hand, the question often arose as to what would be considered the dividing line between what is considered a development stage entity and what is considered an entity past the development stage. For example, would the threshold to no longer be considered a development stage entity be passed with the first sales, although the company may still overall be incurring losses? Or is the definition of “self-sustaining” only considered to be met when from its sales of goods and services an entity is expected to generate sufficient revenues to operate at a profit? On the other hand, what made the former definition of a business difficult to apply in life sciences practice is the fact that there has been a shift in the business models of small biotech companies in the past approximately twenty years where based on the long development cycles as well as the significant investment requirements, the goal of management of small biotech companies today is often no longer to at one point be selling a drug on the market but to at some point successfully outlicense or sell the IP being developed. Thus, the question came up as to whether it was still meaningful to continue to focus the definition of a business on the mere commercialization of products or services if most biotech companies today no longer pursue a plan to at some point be selling a pharmaceutical product or services on the market but instead consider their developed IP to be the output.

As such, with the revision of the business combination guidance, the standard setters also updated the definition of a development stage entity. Under the revised guidance there is no longer reference being made to a requirement of being “self-sustaining” but instead it

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225 EITF 98-3.
226 Interview with Dr. Guido Ströhlein, CEO ChromaCon AG, Zurich, Switzerland.
is acknowledged that “the nature of the elements of a business varies by industry and by the structure of an entity’s operations (activities).” Further, the new guidance states in assessing whether a development stage entity is a business it should be considered whether “planned principal activities” have begun and whether a “plan to pursue outputs” exists, but it no longer ties the definition of a business to the activity of selling goods or services to customers. Therefore, the assessment of what are the “planned principal activities” and what is the “plan to produce outputs” under the revised guidance require financial statement preparers to apply more judgment. For a small biotech company that may not intend to at some point be actively selling drugs on the market but to just engage in R&D activities with the goal to eventually be selling or outlicensing the IP, this means that its R&D activities could be considered the “planned principal activities” and that the developed IP could be interpreted ‘output’.

Also, what is important to note is that the updated guidance on development stage entities is not so much tied to the development stage entity as a legal entity but more to the “planned principal activities” and the “plan to pursue outputs.” That means already an individual R&D activity within a development stage entity (e.g., small biotech) may meet the definition of a business, or put differently, one development stage entity may consist of multiple businesses if it conducts multiple R&D activities.

### 4.2 Key differences in the accounting for business combinations vs. asset acquisitions

Having outlined the theory of what constitutes a business in the life sciences context, in this chapter the main differences in the accounting for the acquisition of a business (also referred to as a business combination) and the acquisition of assets will be presented to illustrate what are the significant financial statement implications if a deal is structured as either a business combination or an asset acquisition.

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229 Interview with Scott Bruns, Global Life Sciences Assurance Leader, EY, Indianapolis.
When the revised business combination guidance was issued, the IASB and FASB acknowledged the fact that there are significant differences in the accounting for a business combination and an asset acquisition. However, both boards noted that having to broaden the scope of the revised business combination guidance beyond acquisitions of businesses would first require further research and deliberation of additional issues and would delay the implementation of the revised standards' improvements to practice.230

4.2.1 Assets acquired and liabilities assumed

Once it has been determined whether a transaction qualifies as a business combination or an asset acquisition, the respective assets acquired and liabilities assumed need to be recorded in the acquirer’s books. In terms of what should be recorded as separate assets and liabilities (the recognition criteria), the guidance for business combinations and asset acquisitions does not significantly differ except for the accounting for acquired contingencies.

Contingencies are defined as uncertainties – such as potential legal, environmental, and warranty claims about which the future may not be fully known at the time a transaction is consummated – that may result in the recognition of future assets or liabilities.231 If a transaction qualifies as a business combination, an acquirer recognizes in its balance sheet all acquired contingencies as contingent liabilities measured at fair value as of the acquisition date if the contingencies represent a present obligation arising from a past event and can be reliably measured, even if it is not probable that an outflow of resources will be required to settle the obligation.232 Also, as part of the subsequent accounting, as new information becomes available, the acquirer must revalue the liability to its current fair value reflecting the new information and record the impact of changes in the fair values in earnings.233 On the other hand, contingencies acquired in connection with an asset acquisition are recognized in the balance sheet of the acquirer as a liability only if

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232 IFRS 3.23.
they meet the recognition criteria in IAS 37.\textsuperscript{234} As per IAS 37, a provision is recorded when (i) an entity has a present obligation (legal or constructive) as a result of a past event, (ii) it is probable (more likely than not) that an outflow of resources embodying economic benefits will be required to settle the obligation, and (iii) a reliable estimate can be made of the amount of the obligation.\textsuperscript{235}

Although the recognition criteria of assets acquired and liabilities assumed, except for acquired contingencies, is not significantly different between business combinations and asset acquisitions, a significant difference does exist in terms of the measurement of the assets acquired and liabilities assumed. For business combinations, the guidance in IFRS 3 and ASC 805 requires acquisition date fair value measurement of all identifiable assets acquired and liabilities assumed irrespective of the amount of the consideration transferred to acquire those assets and liabilities and irrespective of whether these assets and liabilities have been recorded in the books of the acquiree, with any excess of the fair value of the total consideration transferred over the fair value of the acquired net assets being recorded as an asset (goodwill), and any excess of the fair value of the acquired net assets over the fair value of the total consideration transferred being recorded as a gain (so-called bargain purchase).\textsuperscript{236} In contrast, under asset acquisition accounting, the total measurement amount is capped at the fair value of the total consideration transferred. That is, the transaction is accounted for by allocating the cost of the transaction to the assets and liabilities acquired based on their relative fair values with no goodwill or bargain purchase being recognized.\textsuperscript{237} The following Example 7 will further illustrate this difference in the accounting for asset acquisitions and business combinations.

\begin{footnotesize}
\begin{enumerate}
\item\textsuperscript{234} PricewaterhouseCoopers (2011a), p. C – 7.
\item\textsuperscript{235} IAS 37.14.
\item\textsuperscript{236} Based on the guidance in IFRS 3.36, a bargain purchase gain may only be recognized once the acquirer has reassessed all components of the computation to ensure that the measurements are based on all available information as of the acquisition date.
\item\textsuperscript{237} IFRS 3.2; PricewaterhouseCoopers (2010), p. 3.
\end{enumerate}
\end{footnotesize}
On January 1, 2013, Entity A purchases an approved drug candidate, some equipment and some inventory for a total consideration of EUR 500,000. Entity A concludes that what is being acquired does not meet the definition of a business. The fair value of the acquired assets as of the acquisition date is as follows:

<table>
<thead>
<tr>
<th>Asset descriptions</th>
<th>Fair value</th>
<th>Percent of total fair value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved drug candidate</td>
<td>EUR 350,000</td>
<td>64%</td>
</tr>
<tr>
<td>Equipment</td>
<td>EUR 100,000</td>
<td>18%</td>
</tr>
<tr>
<td>Inventory</td>
<td>EUR 100,000</td>
<td>18%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>EUR 550,000</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

Since for asset acquisitions the consideration transferred is the maximum amount that can be recorded as assets in the balance sheet, the individual assets would be recorded in the acquirer’s balance sheet based on their relative fair values as follows:

<table>
<thead>
<tr>
<th>Asset descriptions</th>
<th>Relative Fair Value Calculation</th>
<th>Allocated Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved drug candidate</td>
<td>64% x EUR 500,000</td>
<td>EUR 320,000</td>
</tr>
<tr>
<td>Equipment</td>
<td>18% x EUR 500,000</td>
<td>EUR 90,000</td>
</tr>
<tr>
<td>Inventory</td>
<td>18% x EUR 500,000</td>
<td>EUR 90,000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>EUR 500,000</strong></td>
</tr>
</tbody>
</table>

If the same transaction qualified as a business combination, Entity A would record the assets at their respective acquisition date fair values and the EUR 50,000 difference to the fair value of the consideration transferred as a bargain purchase (gain).

*Example 7: Application of the Relative Fair Value Method for Asset Acquisitions*  

Different from Example 7, if an acquirer is paying more than the aggregate fair value of the acquired net assets, an acquirer should first assess whether the transaction is indeed an asset acquisition and not a business combination because the business combination standards explicitly state that, “in the absence of evidence to the contrary, a particular set of assets and activities in which goodwill is present shall be presumed to be a

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238 Author’s own compilation.
business. If the conclusion remains that what is being acquired does not meet the definition of a business and the acquirer also determined that there are no other assets acquired that need to be identified and separately fair valued, the relative fair value method will need to be applied resulting in the recognition of the acquired net assets at amounts greater than their fair values. However, because assets should not be recorded in the books at an amount greater than their fair value, an impairment would need to be recorded immediately after the application of the relative fair value method, although such scenarios can be considered rare in practice because when acquiring assets an acquirer would usually not be expected to pay a price significantly above the fair value of those assets.

4.2.2 Excursus: Differences between IFRS and US GAAP in the accounting for asset acquisitions and in-licensing deals

Under IFRS, payments to acquire IPR&D assets (no matter whether acquired as part of a business combination, as part of an asset acquisition or as part of an in-licensing deal) always meet the recognition criteria of an asset because under IFRS the price an entity pays to acquire separately an intangible asset is a direct reflection of its expectations about the probability that the expected future economic benefits from the asset will flow to the entity, which is why the probability recognition criterion is always considered to be met for separately acquired intangibles. Under US GAAP, however, R&D assets acquired in an asset acquisition, including a license to an asset, are capitalized only if the assets have an alternative future use; otherwise, they need to be immediately expensed at their respective acquisition date fair values.

Because US GAAP does not provide a definition of the term “alternative future use”, there has been discussion in academia and practice about what “alternative future use” means, especially for companies in the life sciences industry. The AICPA in its

240 IAS 38.25.
241 ASC 730-10-25-2.
December 2013 Accounting and Valuation Guide “Assets Acquired to Be Used in Research and Development Activities” noted that determining whether an alternative future use exists for an asset has to be based on specific facts and circumstances. More specifically, in its Accounting and Valuation Guide the AICPA included an example of when the criteria of “alternative future use” would not be met in the life sciences context (refer to Example 8):

**Fact pattern:** Company A acquired a license that gives it the exclusive right to develop and market a certain compound for the treatment of various diseases. At the time of the acquisition, the compound was in early stage clinical trials as a drug for treating certain cancers. The project met the definition of an asset and the additional recognition criteria applicable to specific IPR&D projects because it is incomplete and presumed to have substance because it was the only asset acquired. It is believed the same compound also might be effective in treating a type of cardiovascular disease. At the time of the transaction, the cancer treatment projects were in early stage testing and human studies for toxicity (safety) of the compound were not yet completed. If the results of those studies are negative, the project will be abandoned and the compound would also not be considered for use in a development project to address the cardiovascular disease.

**Question:** Should the potential use of the license rights to the compound for a project addressing cardiovascular disease represent an alternative future use?

**Answer:** No. The IPR&D Task Force believes that studies for toxicity represent a contingency that must be resolved before an alternative future use is reasonably expected to occur. Unless the compound successfully completes the toxicity studies for the indication for cancers, it will not be considered for use in treating any other disease.

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*Example 8: The AICPA interpretation of “alternative future use” in the life sciences context*

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242 AICPA (2013), section 3.17.
243 Source: AICPA (2013), section 3.22.
Further, the AICPA in its Accounting and Valuation Guide states that, in the life sciences industry, R&D projects acquired should only be considered “complete” for accounting purposes once they have obtained regulatory approval.\textsuperscript{244}

Thus, what is important to consider for US GAAP reporters who plan to enter into an asset acquisition or licensing deal is whether the R&D assets acquired are still considered “incomplete” as of the acquisition date and, as such, need to be immediately expensed, or whether they are “complete” and need to be capitalized, which are two very different expense recognition patterns. Therefore, under US GAAP for the acquisition of assets that are close to obtaining regulatory approval, choosing the right acquisition date is key if a particular accounting treatment (immediate expensing or capitalization) is preferred.

Based on research performed by Ernst & Young (2010), the largest IPR&D in-licensing deals entered into in recent years were completed by European life sciences companies (IFRS reporters), which could be an indication that companies prefer the “smoothing” of expenses recognition through capitalization and subsequent amortization, as compared to having the significant income statement volatility when an IPR&D in-licensing deal is entered into (US GAAP reporters).\textsuperscript{245} However, there are also disadvantages with the capitalization of IPR&D assets because it provides greater transparency to the capital markets in the event of future set-backs in the development (distortion of future earnings from IPR&D impairment charges, whereas if the asset has already been fully expensed as of the acquisition date, there is also no basis for potential future impairment charges).

4.2.3 Transaction-related costs

Transaction-related costs include costs like (a) finder’s fees, (b) advisory, legal, accounting, valuation and other professional or consulting fees, (c) general administrative costs, including the costs of maintaining an internal acquisitions department, and (d) costs of registering and issuing debt and equity securities.\textsuperscript{246} Except for the costs to issue debt

\textsuperscript{244} AICPA (2013), section 2.17.
\textsuperscript{245} Ernst & Young (2010), p. 77.
\textsuperscript{246} IFRS 3.53 and ASC 805-10-25-23.
and equity securities, which shall be accounted for in accordance with IAS 32 and IAS 39, all transaction-related costs incurred in connection with business combinations need to be expensed and are not included as part of the consideration transferred, whereas the same costs incurred in connection with an asset acquisition are included in the consideration transferred and, thus, are implicitly capitalized as part of the cost of the net assets acquired.\textsuperscript{247}

4.2.4 Deferred tax assets and liabilities

While deferred taxes are recorded on most temporary book to tax differences of assets acquired and liabilities assumed in connection with a business combination, IAS 12.15 prohibits the recognition of deferred taxes for temporary differences that arise upon recording an asset or liability in a transaction which (i) is not a business combination, and (ii) at the time of the transaction, affects neither accounting nor taxable income. Accordingly, deferred taxes are generally not recognized for book to tax differences on asset acquisitions.\textsuperscript{248}

4.2.5 Contingent considerations

For transactions that qualify as a business combination, the acquirer shall classify an obligation to pay contingent consideration as a liability or as equity on the basis of the definitions of an equity instrument and a financial liability in paragraph 11 of IAS 32 \textit{Financial Instruments: Presentation}, or other applicable IFRSs.\textsuperscript{249} After initial accounting, contingent consideration liabilities in connection with a business combination that have been classified as a liability are re-measured at fair value with any changes in

\textsuperscript{249} IFRS 3.40.
fair value recognized in income, whereas contingent considerations classified as equity shall not be remeasured with the subsequent settlement accounted for within equity.\textsuperscript{250}

With respect to contingent considerations in connection with asset acquisitions, diversity in practice seems to exist, which has also been acknowledged by the IFRS Interpretations Committee (IFRIC), who added the issue to its agenda.\textsuperscript{251} In its Agenda Paper dated July 2013 (IASB (2013c)), the IFRIC noted it tentatively agreed that the fair value of those contingent or variable payments that are not dependent on the purchaser’s future activity should be included in the initial measurement of the liability on the date of purchase of the asset in accordance with IAS 32 / IAS 39 / IFRS 9.\textsuperscript{252} Whereas for contingent or variable payments that are dependent on the purchaser’s future activity, the IFRIC could not reach a consensus, but acknowledged that there are generally two views of how to account for such contingent or variable payments in connection with asset acquisitions. One view (“Alternative 1”) is that all such contingent or variable payments agreed upon in the purchase contract meet the initial recognition criteria of a financial liability and should, as such, be initially included in the measurement of the liability to make payments for the separate purchase of an asset (provided that the asset has been received by the purchaser).\textsuperscript{253} The other view (“Alternative 2”) is that variable payments for the separate acquisition of an asset that are dependent on the purchaser’s future activity are executory contracts until the activity requiring the payment is performed, which means they do not meet the initial recognition criteria of a financial liability until the activity requiring the payment is performed.\textsuperscript{254} Proponents of Alternative 2 also point to IAS 37, stating that according to IAS 37.19 only obligations arising from past events that exist independently of the entity’s future actions (i.e., the future conduct of its business) should be recognized as liabilities.\textsuperscript{255} In addition to the lack of guidance for the initial accounting

\textsuperscript{250} IFRS 3.58.
\textsuperscript{251} IASB (2013c).
\textsuperscript{252} This is because if the occurrence or non-occurrence of the future event that triggers the payment was under the control of the purchaser, the purchaser could avoid the variable payments, in which case, based on the guidance in IAS 32.13, there would be no contractual obligation and with no contractual obligation there would also be no financial liability as defined by IAS 32.20 and IAS 32.25. Lüdenbach (2013), 298.
\textsuperscript{253} IASB (2013c), p. 6.
\textsuperscript{254} IASB (2013c), p. 8.
\textsuperscript{255} IASB (2013c), p. 8; Lüdenbach (2013), 298.
of such variable payments, the IFRIC also noted that, once a liability has been recognized, the guidance is not clear regarding how subsequent adjustments of the liability resulting from the revision of the estimates of payments should be accounted for, whether they should be systematically recognized in profit or loss (as IAS 39 would seem to suggest) or whether this adjustment should (at least partially) be capitalized as part of the cost of the corresponding tangible/intangible asset acquired.\textsuperscript{256}

The IASB at its July 2013 meeting acknowledged the lack of guidance and diversity in practice for both the initial and subsequent accounting for variable payments for the acquisition of tangible or intangible assets and decided that it would reconsider the accounting guidance for such payments, but only after the proposals in the Exposure Draft Leases (published in May 2013, which also addresses the accounting for variable payments) have been redeliberated.\textsuperscript{257} As such, financial statement preparers currently have a choice in terms of how to account for such payments, although interpretations by the Big 4 public accounting firms and accounting policy disclosures made by large life sciences companies seem to suggest that in practice, most life sciences companies seem to choose an accounting policy that is closer to Alternative 2.\textsuperscript{258} An explanation for this could be that financial statement preparers have a preference for an accounting policy that results in liabilities not being recorded prior to being probable and reliably estimable, and an accounting policy that results in less income statement volatility.\textsuperscript{259}

Irrespective of whether the deal is accounted for as an asset acquisition or a business combination, care should be taken whether the contingent consideration payments are consideration for the net assets or business acquired, or whether they are compensation for the employees or former shareholders, in which case the acquirer should account for

\textsuperscript{256} IASB (2013c), p. 2.
\textsuperscript{257} IASB (2103d), p. 8.
\textsuperscript{259} This is consistent with contingent consideration payments as part of business combinations becoming less attractive with the revisions of the business combination standards because such payments now have to be fair valued as of the acquisition date with any changes in fair value being recorded in earnings, resulting in a much higher earnings volatility. DePamphilis (2011), p. 24.
these payments as compensation expense over the period that the respective services are rendered. In IFRS 3.B55, it is noted that arrangements where the payments to employees or selling shareholders are automatically forfeited if employment terminates should always be considered compensatory in nature, whereas for all other arrangements, the individual facts and circumstances need to be considered. IFRS 3.B55 provides some considerations that should facilitate this assessment.

4.3 Empirical analysis of Life Sciences practical examples accounted for as either a business combination or an asset acquisition

The goal of this empirical analysis is to show that for the acquisitions of IPR&D assets or the acquisition of IPR&D licensing rights where the acquirer intends to continue with the R&D activities without taking on any of the workforce, there is a very fine line in practice in terms of whether such transactions are accounted for as asset acquisitions or as business combinations. Similar transactions seem to be accounted for differently because of different interpretations in practice in terms of what should be considered a ‘process’ and what should be considered an ‘output’.

It is important to note at this point that the purpose of this empirical analysis is by no means to make any type of qualitative statements or assessment of what transactions have been accounted for correctly and what transactions may not have been accounted for correctly. Instead, the empirical analysis will try to highlight that – because the definition of a ‘process’ and an ‘output’ is not very precise in the guidance – financial statement preparers seem to interpret what constitutes a ‘process’ and what constitutes an ‘output’ differently, which can then, in a second step, impact the overall conclusion of whether the transaction is accounted for as an asset acquisition or a business combination. The room for interpretation of what constitutes a ‘process’ and what constitute an ‘output’ is further evidenced by the regulators issuing comment letters around these

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<sup>260</sup> There is by far not enough publicly available information that would allow anyone outside of a company to make any type of qualitative statements in terms of whether a life sciences deal has been accounted for correctly.
topics trying to understand a company’s rationale for deciding one way versus the other.\textsuperscript{261} However, as the analysis will show, even those companies that have been challenged by regulators about the proper classification of a transaction as either an asset acquisition or a business combination could sufficiently argue for either position without such inquiries by regulators resulting in a correction or a restatement.

It should be noted that since the guidance on the classification of transactions as either a business combination or an asset acquisition is virtually identical under IFRS and US GAAP, in the following empirical analysis the focus was not on only finding examples of transactions accounted for under IFRS, but on trying to find examples that illustrate well the fine line between classifying a transaction as either a business combination or an asset acquisition, no matter whether the acquirer is an IFRS or a US GAAP reporter.

\textbf{4.3.1 Acquisition of IPR&D assets by OncoSec Medical Incorporated accounted for as an asset acquisition\textsuperscript{262}}

In March 2011, OncoSec Medical Incorporated ("OncoSec") entered into an asset purchase agreement with Inovio Pharmaceuticals, Inc. ("Inovio"), whereby OncoSec agreed to purchase certain assets of Inovio related to certain non-DNA vaccine and selective electrochemical tumor ablation ("SECTA") technology, including, among other things: (a) certain patents, including patent applications, and trademarks related to the SECTA technology; (b) certain equipment, machinery, inventory and other tangible assets related to the technology; (c) certain engineering and quality documentation related to the technology; and (d) the assignment of certain contracts related to the technology. In return, the OncoSec is obligated to pay Inovio USD 3 million in scheduled payments over the period of two years from the closing date of the asset purchase agreement and a royalty on commercial product sales related to the SECTA technology.

\textsuperscript{261} Deloitte (2012b), p. 24.
\textsuperscript{262} Based on information provided in the companies’ press releases when the deal was entered into, information provided in the life sciences deal databases of Thomson Reuters Recap and IMS PharmaDeals as well as financial statement disclosure made by OncoSec Medical Incorporated in SEC Form 10-K for the annual period ending July 31, 2011. OncoSec Medical Incorporated (2011a), p. 51.
OncoSec evaluated the asset purchase agreement based on the business combination guidance and determined that the assets acquired did not meet the definition of a business as the assets consisted solely of the SECTA technology and certain other tangible assets and also no rights to any employees previously involved with the technology, or research processes previously in place at Inovio, were transferred. As such, OncoSec accounted for the transaction as an asset acquisition allocating the purchase price of USD 3 million to the acquired tangible and intangible assets based on their relative fair values.

This accounting position was challenged by the SEC in a comment letter dated July 28, 2011, where the SEC asked OncoSec to provide details about its analysis supporting the conclusion that the transaction does not meet the definition of a business combination.\textsuperscript{263}

In its response letter to the SEC, OncoSec noted that as part of its assessment of whether the acquired assets meet the definition of a business it determined that it acquired inputs but no processes or outputs. In its response letter OncoSec explicitly noted the inputs it had identified, one of the inputs being “clinical trials documentation (files and previous Clinical Research Organization (“CRO”) contracts which provide documentation on the clinical trials previously conducted by Inovio.”\textsuperscript{264} In fact, OncoSec even explicitly states that it evaluated the clinical trials documentation and determined that it is useful to OncoSec and will allow OncoSec to resume with advancement of its technology at substantially the same stage that it was previously abandoned by Inovio.

This response shows that OncoSec, when assessing whether a business has been acquired, did not interpreted the definition of a process in IFRS 3 (“any system, standard, protocol, convention or rule that when applied to an input or inputs, creates or has the ability to create outputs”\textsuperscript{265}) in such a way that “outputs” in the life sciences industry could also be interpreted to be “developed IP.” Because if it had viewed outputs to include “developed IP” it would likely viewed the clinical trial documentation received as a process because it allowed OncoSec to almost seamlessly continue with the R&D activities.

\textsuperscript{263} OncoSec Medical Incorporated (2011b), p. 1.
\textsuperscript{264} OncoSec Medical Incorporated (2011b), p. 2.
\textsuperscript{265} IFRS 3.B7, ASC 805-10-55-4.
Based on the fact that there do not seem to have been any additional comments by the SEC in connection with the classification of this transaction as an asset acquisition, it appears that the SEC did not object to the accounting treatment.\textsuperscript{266}

As noted above, under the terms of the agreement, OncoSec also agreed to a royalty on commercial product sales related to the SECTA technology. If the conclusion had been that the transaction qualifies as a business combination, such royalties would have had to be accounted for as a contingent consideration liability as of the acquisition date. However, since the transaction was determined to be an asset acquisition, such royalties are not being accounted for until such royalties become probable.

### 4.3.2 Acquisition of IPR&D assets by Alexion Pharmaceuticals, Inc. accounted for as a business combination\textsuperscript{267}

In February 2011, Alexion Pharmaceuticals, Inc. ("Alexion") acquired certain IPR&D assets from Orphatec Pharmaceuticals GmbH ("Orphatec"), a privately held development-stage biotechnology company with headquarters in Cologne, Germany, related to a preclinical product candidate for an investigational therapy for patients with molybdenum cofactor deficiency (MoCD) Type A, an ultra-rare genetic disorder characterized by severe brain damage and rapid death in newborns.

At the time of the acquisition, the product candidate was in preclinical development, and reading the companies’ press releases at the time of the acquisition, the financial statement disclosures and Alexion’s pipeline information as presented on its website, all indicate that Alexion is the party that has been continuing with the R&D activities of the

\textsuperscript{266} For the sake of clarity, it should be noted that for none of the practical examples included in this section 4.3 of the thesis the author claims that either the company’s accounting for the transaction or the SEC’s views are incorrect. Instead, the intention of providing these practical examples and the discussions that these companies had with the regulators as documented in comment letters is to show how judgmental the determination of what constitutes a business is in the life sciences industry.

\textsuperscript{267} Based on information provided in the companies’ press releases when the deal was entered into, information provided in the life sciences deal databases of Thomson Reuters Recap and IMS PharmaDeals as well as financial statement disclosure made by Alexion Pharmaceuticals, Inc. in SEC Form 10-K for the annual period ending December 31, 2011. Alexion Pharmaceuticals (2012), p. F-17 and F-18.
product candidate, which means there has likely also been some clinical development materials or documentation that have been transferred from Orphatec to Alexion in connection with the acquisition.

The following table shows the acquisition date fair values of the identifiable assets acquired as part of the transaction.

| In-process research and development (IPR&D) | USD 8,050,000 |
| Other noncurrent assets                   | USD 73,000   |
| **Fair value of assets acquired**         | **USD 8,123,000** |

As the above table shows, the only significant assets acquired by Alexion are the IPR&D assets. Still, as disclosed in the Form 10-K for the annual period ending December 31, 2011, the transaction was accounted for as a business combination. As such, Alexion must have concluded that with the acquisition of the IPR&D assets and with Alexion continuing the development efforts also processes have been acquired.

In addition to USD 3 million in up-front payments, Alexion may be required to make an additional USD 42 million in cash milestone payments upon various development, regulatory and commercial milestones. As further detailed in section 4.2.5, contingent considerations in connection with business combinations need to be fair valued as of the acquisition date and included in the total consideration transferred. Alexion determined the fair value of the contingent consideration to be approximately USD 5.1 million. Any changes in the fair value of these contingent consideration (the variability of which could go down to zero if no payments need to be made or all the way up to USD 42 million if all milestone payments need to be made) will have to be recorded through profit and loss.

If the same transaction of acquiring IPR&D assets had been accounted for as an asset acquisition, similar to the previous practical example in section 4.3.1, the milestone payments would not be included in the initial consideration transferred at their respective
fair values, but such payments would be recorded as liability when deemed probable with a corresponding increase in the IPR&D asset (meaning no income statement volatility).  

4.3.3 Acquisition of a separate legal entity by Acorda Therapeutics, Inc. accounted for as an asset acquisition

In February 2012, Acorda Therapeutics, Inc. ("Acorda") signed an agreement to acquire the entire legal entity, Neuronex, Inc. ("Neuronex"), a privately-held development stage pharmaceutical company developing a proprietary nasal spray formulation of diazepam as an acute treatment for selected, refractory patients with epilepsy, on stable regimens of antiepileptic drugs, or AEDs, who require intermittent use of diazepam to control bouts of increased seizure activity also known as cluster or acute repetitive seizures, or ARS.

As disclosed in its Form 10-K for the period ending December 31, 2012, Acorda will continue with the R&D efforts commenced by Neuronex prior to the acquisition and plans to submit a 505(b)(2)-type New Drug Application (NDA) for Diazepam Nasal Spray to the FDA in 2013, with potential FDA approval and commercial launch in 2014.

Acorda evaluated the transaction based upon the business combination guidance, and, despite the fact that it is continuing with the R&D efforts commenced by Neuronex, concluded that it will only acquire inputs and no processes from Neuronex and, as such, accounted for the transaction as an asset acquisition.

This accounting position was challenged by the SEC in a comment letter dated August 31, 2012, where the SEC asked Acorda to provide details about its analysis supporting

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268 This is the IFRS treatment. As mentioned in section 4.2.1, under US GAAP IPR&D assets acquired outside of a business combination need to be fair valued and immediately expensed.

269 Based on information provided in the companies’ press releases when the deal was entered into, information provided in the life sciences deal databases of Thomson Reuters Recap and IMS PharmaDeals as well as financial statement disclosure made by Acorda Therapeutics, Inc. in SEC Form 10-K for the annual period ending December 31, 2012. Acorda Therapeutics (2013), p. 4, 12, 13 and F-27.
the conclusion that the acquisition of Neuronex should be accounted for as an asset acquisition. Specifically, the SEC asked to address the following items:²⁷⁰

- To confirm that the entire legal entity, Neuronex, Inc., is being acquired as part of this transaction.
- When Neuronex or any predecessor entity was legally founded and when it began operations.
- When Neuronex began developing Diazepam nasal spray, or DZNS.
- To elaborate on the claim that Neuronex does not have any processes, specifically addressing how Neuronex has managed the development of DZNS and/or any other product candidates without strategic management, operational and/or resource management processes that at a minimum include the:
  - Design and implementation of a development plan for the candidate(s);
  - Execution of the development plan(s) including, but not limited to, product formulation, performing pre-clinical toxicology studies, filing an IND with the FDA, performing clinical trials and having a pre-NDA meeting with the FDA;
  - Evaluation of the execution of the steps identified in the preceding bullet point;
  - Managing of the performance of employees and external service providers under the development plan(s); and
  - Tracking of and payment to employees and external service providers for services rendered under the development plan(s).
- Whether Neuronex historically had any employees and why it will not have any employees at the acquisition date as disclosed on page 14 of the 2011 Form 10-K. More specifically, whether Acorda has hired or expects to hire or engages or expects to engage as consultants any former employees/consultants of Neuronex.

As a response to this SEC comment letter, Acorda responded that the reason why it concluded that no processes have been acquired is because “Neuronex has no capabilities or infrastructure for commercialization, supply chain management, manufacturing, business development, etc. Nor do they have anything in place to support the production

²⁷⁰ Acorda Therapeutics (2012), p. 3.
of outputs, (i.e., credit and collections, QA, inventory warehousing, etc.).” This response shows that Acorda, when performing the assessment of whether processes have been acquired, interpreted the definition of processes (“any system, standard, protocol, convention or rule that when applied to an input or inputs, creates or has the ability to create outputs”) in such a way that only a marketable product should be considered an output. However, as outlined in section 4.1.3, for development stage entities in the life sciences industry, the definition of output does not necessarily need to be a “marketed drug” but could also be interpreted to mean IP that is being developed with the purpose to later sell or outlicense. Based on the fact that there do not seem to have been any additional comments by the SEC in connection with the classification of this acquisition of a separate legal entity as an asset acquisition, it appears that the SEC did not object to this accounting treatment.

4.3.4 Acquisition of worldwide rights to a Phase III compound by Forest Laboratories accounted for as an asset acquisition

In April 2011, Forest Laboratories, Inc. ("Forest") entered into an agreement with Blue Ash Therapeutics LLC ("Blue Ash") to acquire the worldwide rights to the compound azimilide, a novel Class III antiarrhythmic agent. Pursuant to the agreement, Forest made an up-front payment of USD 40 million to Blue Ash and will be responsible for all future development and commercialization activities and associated costs. In addition, Forest will be obligated to make future milestone payments upon successful commercialization of azimilide as well as royalties based on net sales of the product.

At the time of the acquisition, the compound Pegsiticase was in clinical development Phase III, and, as disclosed in Forest’s financial statements, press release at the time the

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273 Based on information provided in the companies’ press releases when the deal was entered into, information provided in the life sciences deal databases of Thomson Reuters Recap and IMS PharmaDeals as well as financial statement disclosure made by Forest Laboratories, Inc. in SEC Form 10-K for the annual period ending March 31, 2012. Forest Laboratories (2012), p. 13, 67 and 82.
transaction was entered into and pipeline information as presented on its website, Forest is the party that has been continuing with the R&D activities of azimilide, which means there has likely also been some clinical development materials or documentation that have been transferred from Blue Ash to Forest in connection with this acquisition.\footnote{In its press release dated April 19, 2011, Forest Laboratories, Inc. is quoting its CEO at that time, Howard Solomon, as saying: “We will conduct the final registration trial required for approval in the United States under a previously established FDA Special Protocol Assessment (SPA).” Forest Laboratories (2011), p. 1. This statement makes it very clear that Forest is continuing with the development efforts of Blue Ash and, as such, would have also obtained development documentation and materials from Blue Ash to be able to continue with the efforts.}

As disclosed in its Form 10-K for the annual period ending March 31, 2012, Forest accounted for the acquisition as an asset acquisition. As a result, all contingent payments (e.g., future milestone payments upon successful commercialization and royalties based on net sales) Forest would not have to account for until they are deemed probable and the total purchase price is limited to the USD 40 million. In contrast, if Forest had concluded that the transaction qualifies as a business combination (similar to how other companies concluded that the acquisition of rights where the acquirer continues with the R&D activities qualifies as a business combination, refer to section 4.3.5), then the purchase price would have had to include the probability weighted net present value of these contingent payments (milestones and royalties), and the contingent payments would have had to be recorded as a contingent consideration liability on Forest’s balance sheet as of the acquisition date.

### 4.3.5 Acquisition of licensing rights to a Phase II compound by Salix Pharmaceuticals, Ltd. accounted for as a business combination\footnote{Based on information provided in the companies’ press releases when the deal was entered into, information provided in the life sciences deal databases of Thomson Reuters Recap and IMS PharmaDeals as well as financial statement disclosure made by Salix Pharmaceuticals, Ltd. in SEC Form 10-Q for the quarterly period ending September 30, 2012. Salix Pharmaceuticals (2012a), p. 12.}

In August 2012, Salix Pharmaceuticals, Ltd. ("Salix") and Alfa Wassermann Inc. ("AW") entered into an agreement by which Salix received an exclusive license to develop and commercialize rifaximin products for travelers’ diarrhea (TD), hepatic encephalopathy
(HE) or irritable bowel syndrome (IBS) in the United States and Canada. In addition, the agreement provides Salix with an exclusive license to develop and commercialize rifaximin products for Crohn’s disease in the United States and Canada and a non-exclusive license to develop such products worldwide.

Salix paid Alfa a non-refundable up-front fee of USD 10.0 million and is obligated to make a USD 25.0 million milestone payment upon receipt of marketing authorization in the United States for an extended intestinal release, or EIR, formulation product for CD, and additional milestones based on net sales of EIR formulation products for CD of up to $200.0 million. In addition, the Company is required to pay Alfa royalties on sales of rifaximin products for Crohn’s at percentage rates ranging in the low double digits.

Salix accounted for the transaction as a business combination recording USD 23.4 million of acquired IPR&D assets at their respective fair values as of the acquisition date as indefinite lived intangible assets and recording USD 13.4 million of the acquisition date fair value of the contingent consideration as a long-term liability on the consolidated balance sheet.

This conclusion to account for the acquisition of license rights as a business combination was challenged by the SEC in a comment letter dated December 11, 2012, where the SEC asked Salix to provide its analysis of how it concluded that the AW transaction qualified as a business combination.276

In its response letter to the SEC, Salix argued that because know-how in the form of materials have been acquired that would allow Salix to continue with the R&D activities started by AW, it was concluded that in addition to inputs also processes have been acquired and, as such, the transaction would qualify as a business combination.277 Based on the fact that there do not seem to have been any additional comments by the SEC in connection with the classification of this transaction as a business combination, it appears that the SEC did not object to the accounting treatment.

4.4 Conclusion and proposal of a revised definition of “a business” to address the shortfalls

As the empirical analysis has shown, for acquisitions of IPR&D assets (R&D projects or licenses), where the acquirer intends to continue with the R&D activities started by the acquire, but does not take on any of the workforce, there is a very fine line in practice in terms of whether such transactions are accounted for as asset acquisitions or as business combinations. For all of the above-mentioned practical examples, the driving force of whether the transaction was concluded to be an asset acquisition or a business combination was what the respective financial statement preparers considered to be a ‘process’ and what they considered to be an ‘output’. In this section the author will highlight the shortfalls of the existing definitions of ‘process’ and ‘output’ and propose revised definitions of the terms.

4.4.1 Definition of “process” in IFRS 3 and ASC 805

As mentioned in section 4.1.1, in the life sciences industry for IPR&D assets or licenses acquired, where the acquirer is continuing with the R&D activities that were commenced by the seller, but without taking on any of the workforce, there would generally also be some sort of materials, know-how, or documentation transferred from the seller to the acquirer. The dividing line between companies concluding that these acquisitions of IPR&D assets or licenses qualify as a business combination versus an asset acquisition rests with whether the documentation and materials obtained to continue with the R&D activities are viewed as a process or as merely an additional input.

Because with the transfer of materials and documentation from one party to another, one could probably always argue that only a stack of paper, but no know-how (i.e., a process) is being transferred, the question of whether a process has been acquired should, in the view of the author, be more tied to the question of how much of the materials and documentation the acquirer will be using to continue with the R&D activities. In other words, if the materials and documentation are necessary for the acquirer to continue with
the R&D activities where the seller left off, then it can be assumed that with the materials and documentation, the acquirer also acquired some sort of process.

Thus, to ensure a consistent application in practice, the definition of a process in IFRS 3 and ASC 805 should be expanded to state that whenever as part of an acquisition no workforce is transferred, but only know-how is transferred in the form of materials and documentation that allows the acquirer to seamlessly continue with the activities (e.g., R&D activities) where the seller has left off, that in such cases there is a rebuttable presumption that a process has been acquired, which together with the assets (inputs) would give rise to a business. Or, worded differently, the author is of the view that for transactions where no workforce, but only written documentation is transferred, but where the written documentation enables the acquirer to be at a level of know-how and information similar to a scenario where the workforce had been acquired, the conclusion in terms of whether a business has been acquired should not be any different, as compared to the scenario where the workforce is acquired. Whereas for transactions where the acquirer only acquires the IP/rights, but where the seller continues with the R&D, or where the acquirer continues with the R&D, but the acquirer (or a market participant) would not need any of the acquired documentation to continue with the R&D efforts, such documentation would likely also not meet the definition of a process. Such a clarification is deemed necessary because the current definition of a ‘process’ in IFRS 3 (“any system, standard, protocol, convention or rule that when applied to an input or inputs, creates or has the ability to create outputs”) is not specific enough. In fact, the IFRIC at its July 2011 meeting acknowledged that IFRS 3 does not provide any explicit specifications in terms of what needs to be present for a process to qualify as one that could give rise to a business.²⁷⁸

Thus, as long as the business combination guidance, as it relates to the definition of a business, is not refined, financial statement preparers must be careful in determining what constitutes a business. Even if an agreement is labeled “asset acquisition” or “license agreement,” it is possible that in addition to assets or a license, processes have also been

acquired, especially in the life sciences industry, where what is being acquired is often IPR&D and where the acquirer often plans to continue with the R&D activities.

As part of the IFRS 3 post-implementation review, which formally began on July 25, 2013, the IFRIC has started to reach out to financial statement preparers from different industries, including the life sciences industry, noting that the acquisition of IPR&D assets in the life sciences industry without also acquiring the related workforce or formal materials and documentation would be rare. Based on this view and the fact that many acquisitions of IPR&D assets in the life sciences sector today are not accounted for as business combinations, the IASB as part of the IFRS 3 post-implementation review will likely see a need for providing a more precise definition of what constitutes a ‘process’.

Even with such clarification in the business combination standard, where the IASB would, in substance, follow the author’s above proposal of a revised definition of what constitutes a ‘process’, executives in life sciences companies should remain conscious of when they acquire IPR&D assets. That is because for a product candidate that is close to obtaining regulatory approval, less documentation may need to be transferred for the acquirer to complete the development efforts, and the less documentation is transferred or is needed for the acquirer to continue with the R&D efforts, the more likely it will be that the conclusion is that no process has been transferred. Thus, acquirers in the life sciences industry should be mindful that delaying an acquisition of late stage IPR&D assets by a few months or a year could be the deciding factor of whether an acquisition is accounted for as a business combination or an asset acquisition. At the same time, waiting too long after the regulatory approval may again make it more likely that with the set-up of a sales and distribution network, a process is being acquired, which then again would make the transaction more likely to be a business combination.

IASB (2013a), p. 69.
280 This is based on the thought that the closer an R&D project is to regulatory approval, the less R&D work the acquirer would have to continue with and, as a result, the less documentation the acquirer would have to obtain. And, the less documentation that needs to be transferred, the more likely it is that just an asset, with no processes, has been transferred (because the acquirer will not have to take over the R&D process).
4.4.2 Definition of "output" in IFRS 3 and ASC 805

The other shortfall in the guidance is the definition of ‘output’. The standards explicitly mention that for an integrated set of activities and assets to qualify as a business, only inputs and processes need to be present, which together are or will be used to create outputs.\(^{281}\) However, what the standards fail to acknowledge is that what is considered an output is different depending from what perspective the assessment is made.

For a big pharma company, ‘output’ would generally mean an approved drug that can be marketed. However, as mentioned in section 4.1.3, inquiring with the management of small biotech companies, the majority of these companies today no longer pursue a plan to at some point sell a drug on the market, but due to the significant development time and the difficulties to obtain financing, they nowadays generally only pursue a plan to develop a drug candidate to a certain stage (e.g., entering Phase III) to then sell or outlicense the drug candidate to another company (e.g., a big pharma company). In other words, the business model for such small biotech companies today is generally not to actively sell a drug on the market, but to develop a drug candidate to a certain level, at which it can then be sold or outlicensed. As such, from the small biotech’s perspective, ‘output’ would mean the IP and know-how that is being developed up to a certain level.\(^{282}\)

As part of the IFRS 3 post-implementation review, where the IFRIC has been asking both financial statement preparers from different industries (including the life sciences industry) and the large public accounting firms to provide comments and suggestions, the author provided the comment that what is considered to be ‘output’ in the life sciences industry to a large extent depends on from which perspective the assessment is made. The

\(^{281}\) IFRS 3.B8; ASC 805-10-55-5.

\(^{282}\) This distinction is best illustrated by the acquisition of Neuronex by Acorda (section 4.3.3) where Acorda concluded that the acquisition would not qualify as a business combination because Neuronex did not have any capabilities or infrastructure to support the commercialization of the drug. However, if Acorda had viewed the proprietary nasal spray formulation developed by Neuronex as an ‘output’, the conclusion would have likely been that a business was acquired.
IFRIC acknowledged this viewpoint, which may result in the IASB as part of the IFRS 3 post-implementation review also redefining the term ‘output’.\textsuperscript{283}

\textsuperscript{283} It should be noted that the author provided this comment to the IFRIC through the channel of one of the large public accounting firms, which have been specifically asked by the IFRIC to provide comments as part of the IFRS 3 post-implementation review. Further, it may be that other respondents have provided the same or similar comments. Thus, the fact that the IFRIC acknowledged this point in its Agenda Paper dated May 2013 (IASB (2013a), p. 14) may not be solely based on the comments provided by the author.
5 Life Sciences Deal Structuring Analysis 2: Assessment of Control

5.1 The control concept under IFRS 10

The control concept in IFRS is based on the guidance in IFRS 10 Consolidated Financial Statements, which the IASB issued in May 2011. Based on this guidance in IFRS 10, an investor controls an investee if and only if the investor has all of the following:\(^\text{284}\)\(^\text{285}\)

- Power over the investee
- Exposure, or rights, to variable returns from its involvement with the investee; and
- The ability to use its power over the investee to affect the amount of the investor’s returns.

Figure 12 further illustrates the new control assessment in IFRS 10.

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\(^{284}\) IFRS 10.7.

\(^{285}\) IFRS 10 uses the term “investor” to refer to a reporting entity that potentially controls one or more other entities, and “investee” to refer to an entity that is, or may potentially be, the subsidiary of a reporting entity. Because in the life sciences context it is usually a big pharma company obtaining control over a small biotech company, in this thesis the terms “investor” and “big pharma”, as well as the terms “investee” and “small biotech” will be used interchangeably.

\(^{286}\) Source: Ernst & Young (2011a), p. 5.
Often, decision-making is controlled by voting rights. In these scenarios, if the voting rights also give the holder exposure to variable returns, control is determined by whatever investor holds a majority of the voting rights. However, especially in the life sciences industry, deal structures may not always involve voting rights, or voting rights may exist, but these rights only relate to the more administrative tasks, in which case control may be exercised through other rights. In those instances, to determine what are the rights that impact the relevant activities of an investee and to identify who has control, it is critical to understand the purpose and design of an investee. As explicitly mentioned in IFRS 10, when trying to understand the purpose and design of an investee, consideration should also be given to the risks (both downside and upside risks) to which the investee was designed to be exposed, the risks it was designed to pass on to the parties involved with the investee and whether the investor is exposed to some or all of those risks.\(^{287}\)

The focus in this chapter 5 will be on assessing control for life sciences arrangements where control is not determined by the majority of the voting rights but through other means (e.g., contractual arrangements). As such, of the six main life sciences deal structure types presented in section 3, the discussion in this chapter will mainly focus on co-development arrangements and licensing arrangements, joint arrangements and equity investments with less than a majority of voting rights as well as options-based M&A. That is because for asset acquisitions where the title of individual assets and liabilities transfers to the acquirer and for mergers and acquisitions arrangements where the title of an entire business transfers to the acquirer, there are only a few ambiguities or difficulties in applying the control guidance in IFRS 10 in life sciences practice.\(^{288}\)

### 5.1.1 Power over an investee

The first criterion to be analyzed is whether the investor has power over the investee. Based on IFRS 10.10, an investor has power over an investee when it has existing rights

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\(^{287}\) IFRS 10.B8.

\(^{288}\) The complexity in accounting for asset acquisitions and business combinations in the life sciences industry is more the question of what constitutes a business. Refer to section 4 for details on this topic.
that give it the current ability to direct the relevant activities, i.e. the activities that significantly affect the investee's returns. Thus, to assess whether an investor has power, one needs to evaluate both the “relevant activities” of the investee and the “existing rights” of the investor.

5.1.1.1 Relevant activities

As defined in IFRS 10.10, relevant activities are the activities that significantly affect the investee's returns. In the life sciences context, the relevant activities often relate to the investee performing research and development, manufacturing, or marketing and distribution activities, but other activities such as selling and purchasing goods or services, acquiring and disposing of assets or establishing budgets could be relevant activities as well. In life sciences practice, an investee or an arrangement often will involve more than just one activity. In these instances, careful consideration is needed to evaluate all activities, which potentially could be relevant activities, to then decide which set of activities most significantly affects the returns of the investee. Section 5.2.1 will further illustrate the difficulties in applying this concept to arrangements in the life sciences industry.

5.1.1.2 Existing rights

Once it has been determined what the relevant activities of the investee are, it has to be determined which investor, if any, has the current ability to direct those activities. When power over an investee is solely driven by the majority of voting rights, assessing who has power is generally not complex. However, often, and this is especially relevant in the life sciences industry, the relevant activities of an investee are not directed through current voting rights, but rather, are directed through other means, such as potential voting rights or contractual arrangements. Thus, an investor may have power over an investee even when it has less than a majority of the current voting rights of that investee after considering all the facts and circumstances.

IFRS 10.B42 further illustrates this point.
Both IFRS 10.BC51 and IFRS 10.B42(d) emphasize that what is relevant for the power assessment is whether an investor has rights that enables it to make decisions at the time that the decisions about the relevant activities need to be made, which sometimes may only be at some point in the future. Thus, although ‘current’ in practice is understood as ‘as of today’ or ‘this instant’, the IASB’s use of the term in IFRS 10 refers to the ability to make decisions about an investee’s relevant activities when they need to be made.289

As mentioned in the introduction to this chapter, as part of this thesis the focus will be on arrangements where power over an investee is not driven by the majority of voting rights but where, instead, power is based on less than a 50% share of voting rights, potential voting rights, or rights arising from other contractual arrangements.

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289 Ernst & Young (2011a), p. 20.
5.1.1.2.1 Power based on less than 50% of the voting rights (de facto control)

IFRS 10 introduced a concept referred to as “de facto control” that previously did not exist under IFRS and that still does not exist under US GAAP.\(^{290}\) This concept refers to scenarios where voting rights drive the relevant activities, but where the shareholder structure is so dispersed that no single party owns more than 50% of the voting rights. In such scenarios, one investor may still be considered to have power over the investee because of the size of the investor’s holding of voting rights relative to the size and dispersion of holdings of the other vote holders.\(^{291}\) Thus, effective control can be achieved at less than 50% ownership if other shareholders own relatively smaller stakes and do not band together to offset the votes cast by the largest shareholder.\(^{292}\)

These scenarios are illustrated as examples in IFRS 10 and deal with situations where an investor is holding 30% to 49% of the voting rights, and where due to the fact that the remaining shareholders are widely dispersed (and in practice would not be able to easily cooperate to outvote the investor), the investor may in fact have the current ability to direct the relevant activities. Another example in IFRS 10 refers to a scenario where an investor holds 35% of the voting rights of the investee and where only 75% of the voting rights have been present at recent shareholders’ meetings. In such a scenario, because the investor would also likely not have the ability to direct the relevant activities at the next shareholders’ meeting (because 35% is less than half of the 75% votes that are generally present), IFRS 10 states that the investor would likely also not have power over the investee.\(^{293}\) Although the examples as presented in IFRS 10 make sense in theory, applying the guidance in practice can be very challenging, especially when one has to assess the past attendance of shareholders at recent shareholders’ meetings. These practical difficulties will be further illustrated in section 5.2.2.

\(^{290}\) Ernst & Young (2013a), p. 33.
\(^{291}\) IFRS 10.B42.
\(^{293}\) IFRS 10.B45, Example 8.
5.1.1.2.2 Potential voting rights

As per IFRS 10.B42, when assessing whether an investor's voting rights are sufficient to give it power, an investor also should consider potential voting rights held by the investor or potential voting rights held by others. The most common example of potential voting rights in the life sciences industry is an option. Thus, for the remainder of this section, reference is made to the term ‘options’, but the concepts explained and the examples provided apply to potential voting rights in general.

IFRS 10.B47 states that options may only be considered in the control assessment if the options are substantive, which means the option holder would need to have the practical ability to exercise that option. Further, IFRS 10.B23 states that in determining whether rights are substantive, it should be determined whether there are any barriers to exercise and whether the party that holds the right would benefit from the exercise of those rights. Based on this guidance and the examples provided in IFRS 10.B50, Ernst & Young (2011a) adapted the following factors to assess whether an option is substantive:\textsuperscript{294}

- Exercise price or conversion price, relative to market terms
- Ability to obtain financing
- Timing and length of exercise period

Figure 13 further illustrates when those factors may indicate an option to be substantive and when they may indicate an option to be non-substantive.

\textsuperscript{294} Ernst & Young (2011a), p. 19.
As mentioned above, an investor only has power over an investee if the investor has existing rights that give it the current ability to direct an investee’s relevant activities. For an option, this means the option has to be currently exercisable: however, not only from a legal perspective but also from an economic perspective, meaning the option has to be “attractive” to be exercised. However, as noted in section 5.1.1.2, ‘current’ in the context of IFRS 10 does not mean ‘as of today’ or ‘in this instant’ but is more broadly defined as the point in time when decisions about an investee’s relevant activities need to be made.

Determining the exercisability based on the timing and length of the exercise period for most life sciences option arrangements should not be difficult to assess as the exercise period is generally stipulated as part of the terms of the agreement. Also, determining the “financial ability to exercise” should in most cases not be difficult when assessing the financial and liquidity position of an investor. However, in addition to an investor’s current financial and liquidity position, an investor’s ability to access additional funds through banks or investors should be assessed because even if an investor may not have


\[296\] Although different financial statement readers when reviewing financial statements and key ratios may come to different conclusions in terms of the financial and liquidity situation of a company. However, this topic of differing subjective assessments of financial statement readers is not intended to be covered as part of this thesis.
sufficient cash available to exercise an option, this should not be considered an ‘economic barrier’ if this investor can easily obtain such funds from banks or investors.²⁹⁷ Also, the financial ability to exercise should be assessed in the context of the exercise price of the option because an investors that holds an in-the-money options can be expected to more easily obtain financing than an investor that holds an out-of-the-money option.²⁹⁸ However, the third factor, the exercise price relative to market terms and the “attractiveness” of the option, is the factor that requires the most significant judgment when determining whether an option is substantive. These practical difficulties will be further illustrated in section 5.2.2 of this thesis.

5.1.1.2.3 Contractual arrangements

When assessing which investor has power over an investee, it is important to also review any contractual arrangements entered into between the investor and the investee. That is because an investor may also have power over an investee with no voting rights but by the relevant activities being driven by the rights as provided in a contract and the investor having ownership of those rights. This is especially relevant in the life sciences industry where arrangements often do not involve the transfer of voting rights but instead are solely based on contracts, which determine who is directing what activities. For example, in connection with a co-development agreement entered into between a big pharma and a small biotech, it may be that as per the agreement big pharma has the final vote on all development decisions. If the R&D activities subject to the co-development arrangement are determined to be the relevant activities for the small biotech (i.e., the investee), then the investor may have power over the investee by means of a contractual arrangement. To assess which investor, if any, has power over an investee, it is important to assess all contractual arrangements that the investor and the investee have entered into because some agreements may override, supersede or contradict with previous agreements, so the assessment needs to be done combined for all contractual arrangements in aggregate.

²⁹⁷ Ernst & Young (2011a), p. 20.
5.1.2 Exposure to variable returns

For an investor to have control of an investee, in addition to having power over an investee, the investor also needs to have an exposure to variable returns, both positive and negative, from its involvement with the investee. The following are common examples of variable returns in the life sciences industry:299

a) Dividends on equity securities that expose the investor to credit risks of the investee
b) Fixed interest on debt securities that expose the investor to credit risks of the investee
c) Variable interest on debt securities
d) Other distributions of economic benefits (e.g., R&D services performed by the investee that are free or not priced at current market rates)
e) Changes in the value of an investment in an investee
f) Remuneration for providing services to an investee (e.g., management services)
g) Tax benefits and access to liquidity that an investor has from its involvement with the investee
h) Economics of sale and cost savings that an investor has from its involvement with the investee (e.g., from merging the R&D operations)
i) Scarce products, proprietary knowledge and synergies
j) Milestone and royalty payments that are contingent on the success of the investee
k) Changes in the value of a license acquired from the investee
l) Profit share arrangements.

It is important to note that the variable returns do not necessarily have to come directly from the investee, but they have to stem from the investor’s involvement with the investee.300 Of the above examples of variable returns that are common in the life sciences industry, the examples e), g), h) and i) are scenarios where the variable return to the investor is not directly from the investee but results from the investor’s involvement with the investee.

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299 Based on examples of exposures to variable returns in Ernst & Young (2011a), p. 24, but adapted by the author to more life sciences specific examples.
300 IFRS 10.B55.
5.1.3 Link between power and returns

The third and last criterion that IFRS 10 stipulates in terms of an investor having control of an investee is that the investor must have the ability to use its power (first criterion) to affect the amount of the investor’s variable returns (second criterion). In other words, there has to be a link between power and the variable returns, which means the investor must have the ability to use its power to affect the amount of the investor’s variable returns. If an investor has power over an investee but cannot use that power to influence the returns, the investor would not be deemed to have control of an investee. Or the other way around, an investor may have an exposure to variable returns from an investee (e.g., because it holds a small investment in the investee), but if it cannot direct the activities that most significantly affect the investee’s returns (i.e., the relevant activities), it would also not be deemed to have control of the investee. Thus, the variability of the investor’s returns has to be “in response to” how the investor directs the relevant activities of the investee.

Applying this criterion to life sciences arrangements where an investor may have power through means other than a majority of the voting rights, this criterion would generally be met because any positive developments in directing the relevant activities – for example, obtaining regulatory approval for a drug candidate – would also be beneficial to the investor (e.g., in the form of an increase in the value of the equity investment, license, option, etc.), and any negative developments in directing the relevant activities (e.g., the failure of a product candidate) would also be unfavorable for the investor (e.g., impairment of capitalized up-front or milestone payments, impairment of the value of an option or equity investment, etc.).

5.1.4 Joint arrangements (as defined in IFRS 11)

With the issuance of IFRS 10, the IASB also issued a new standard to address the accounting for joint arrangements, which is IFRS 11 Joint Arrangements. IFRS 11 is based on the definition of control in IFRS 10 but expands that definition to define “joint control.”
5.1.4.1 Joint control

IFRS 11.7 defines “joint control” as the contractually agreed sharing of control of an arrangement, which exists only when decisions about the relevant activities require the unanimous consent of the parties sharing control. Thus, the key elements of joint control are:

- A contractually agreed arrangement
- The determination of the relevant activities and who has the rights to direct the relevant activities
- The determination of whether unanimous consent is needed for the decisions about the relevant activities

With respect to the determination of the relevant activities and who makes the decisions about the relevant activities, the guidance in IFRS 11 is consistent with that in IFRS 10, i.e. the activities that significantly affect the returns of the arrangement. With respect to the definition of “unanimous consent”, IFRS 11.B9 notes that unanimous consent means that any party with joint control of the arrangement by not agreeing or participating in the decision making can prevent the other parties from making decisions about the relevant activities. With this definition, it is clear that “control” and “joint control” are mutually exclusive, meaning if it is determined that one party has control, there cannot be joint control, and vice versa.

Similar to the IFRS 10 control assessment, the determination of joint control requires an assessment of all existing rights, meaning both voting rights and contractual rights, which may stem from the agreement entered into between the investor and the investee or other agreements that the investor and investee have entered into. Thus, just because the parties may have equal ownership interests does not mean joint control exists because, based on a contractual arrangement, one party may have rights to direct the relevant activities and then that party would have control (i.e., joint control would not exist).\(^\text{301}\)

As mentioned in section 3.1, co-development and licensing arrangements in the life sciences industry often involve the establishment of a Joint Steering Committee (JSC), a committee with representatives from each of the involved parties which is provided with the decision-making authority for specific activities (e.g., the R&D activities that are subject to the arrangement). For example, in connection with R&D activities, it may be up to the JSC to review any study results and make the ultimate “go” or “no-go” decision for the respective drug candidate.

Although the JSC may consist of an equal number of representatives from both parties and in practice may find a consensus most of the times, to determine who has control or whether joint control exists one needs to assess what dispute resolution provision the charter agreement of the JSC provides in the event that the JSC cannot reach a consensus. In the life sciences industry, the charter agreement of a JSC often stipulates that if the JSC cannot reach a consensus the issue should be elevated to the respective CEOs and only if the CEOs also cannot find a consensus, the charter agreement of the JSC may determine one party to have the ultimate decision-making right. Assuming that the activities directed by the JSC are also the relevant activities of the investee, whatever party has this ultimate decision-making right in the JSC would also be the party that has power over the investee. However, if no such ultimate decision-making right is provided in the charter agreement, this may provide evidence that joint control as defined in IFRS 11 exists.

What is important to keep in mind is that in life sciences business development practice deals are often referred to as “joint ventures” or the agreement of such deals may even be labeled “joint ventures.” However, whether joint control indeed exists and whether the deal indeed qualifies as a joint venture versus a joint operation needs to be assessed based on the above described criteria in IFRS 11. Just because a deal is referred to as a joint venture does not make it a joint venture from an accounting perspective and, vice versa, something that may not be referred to as a joint venture may very well meet the definition of a joint venture as noted in IFRS 11.
5.1.4.2 Joint operation versus joint venture

IFRS 11 distinguishes two different types of joint arrangements, a joint operation and a joint venture, which are defined as follows:302

Joint operation: A joint arrangement whereby the parties that have joint control of the arrangement have rights to the assets, and obligations for the liabilities, relating to the arrangement.

Joint venture: A joint arrangement whereby the parties that have joint control of the arrangement have rights to the net assets of the arrangement.

Therefore, a joint arrangement is either classified as a joint operation or a joint venture, depending on whether the joint control provides the investor with rights to the assets and obligations for the liabilities of the arrangement or whether the joint control provides the investor with rights to the net assets of the arrangement.

When determining whether a joint arrangement is a joint operation or a joint venture, one first should assess whether there is a separate vehicle because, based on IFRS 11.B16, a joint arrangement that is not structured through a separate vehicle is automatically a joint operation. This is because without the existence of such a vehicle, the parties have rights to the individual assets and obligations for the individual liabilities of the arrangement.303

The term ‘separate vehicle’ is broader than just “legal entity”, and is defined in IFRS 11 as “a separately identifiable financial structure, including separate legal entities or entities recognized by statute, regardless of whether those entities have a legal personality.”304

However, if a separate vehicle exists, IFRS 11.B15 notes that the following additional factors need to be considered:

- the legal form of the separate vehicle;
- the terms of the contractual arrangement; and
- when relevant, other facts and circumstances.

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302 IFRS 11, Appendix A.
304 IFRS 11, Appendix A.
If one or more of the above factors indicates that the parties have the right to the assets and obligations for the liabilities, the joint arrangement would be a joint operation.\(^{305}\) It is important to note that the above factors need to be considered in aggregate because although one factor may provide an indicator for a joint venture or a joint operation, this factor may be overridden or “unwound” by the other factors. For example, the contractual arrangement between the parties to the joint arrangement may reverse or modify the rights and obligations conferred by the legal form of the vehicle.\(^{306}\)

An example of “other facts and circumstances” that may be relevant for the assessment of whether a joint arrangement is a joint operation or a joint venture is the question as to how independent the separate vehicle operates. When the activities of an arrangement are primarily designed for the provisions of output to the involved parties and the vehicle does not sell a significant portion of its outputs to third parties but just to the involved parties and their affiliates, this may provide an indicator that the parties have rights to substantially all the economic benefits of the assets of the arrangement and, thus, the arrangement should be classified as a joint operation.\(^{307}\) Significant judgment will be required to assess these “other facts and circumstances”, combined with the factors of the legal form of the vehicle and the terms of the contractual arrangement.

Figure 1 provides some examples on what other facts and circumstances may need to be assessed in assessing whether a joint arrangement is a joint operation or joint venture.

\begin{table}[!h]
\centering
\begin{tabular}{|c|p{10cm}<|p{10cm}<|}
\hline
 & Joint operation & Joint venture \\
\hline
Restrictions on selling output & Restricted from selling output to third parties & None; may be able to sell output to other parties \\
\hline
Requirements to purchase output & Parties (individually or collectively) must purchase substantially all of output produced & None; other parties might purchase output \\
\hline
Source of cash flows to pay liabilities & The parties to the joint arrangement & Third parties, through their purchases of output \\
\hline
Expected financial performance & Designed to operate at breakeven, or to generate losses that will be funded by the parties & Designed to generate a profit \\
\hline
\end{tabular}
\caption{Other factors and circumstances to consider when classifying a joint arrangement as either a joint operation or a joint venture \(^{308}\)}
\end{table}

\(^{305}\) Ernst & Young (2011b), p. 19.
\(^{306}\) Deloitte (2013), p. 3.
\(^{308}\) Source: Ernst & Young (2011b), p. 23.
5.1.4.3 Accounting for joint arrangements

The distinction between a joint operation and a joint venture as discussed in the previous section is important because the accounting for the two types of joint arrangements is different. For a joint operation, the parties recognize their assets, liabilities, revenues, and expenses, and/or their relative shares of those items, if any, in accordance with the IFRSs applicable to the particular assets, liabilities, revenues and expenses, whereas for a joint venture the parties recognize their interest in the joint venture as an investment and account for the investment using the equity method (as defined in IAS 28, which means the same accounting as for significant influence investments or associates).\(^{309}\)

One of the key differences when accounting for joint operations versus joint ventures is that there is no liability limitation for the parties engaged in a joint operation (all parties are jointly and severally liable for the obligations of the arrangement), whereas for parties engaged in joint ventures the liability under the arrangement is limited to their respective investments in the arrangement.\(^{310}\) In other words, for a joint operation the assets and obligations are recognized without limitation, even if that results in the liabilities exceeding the assets, whereas in contrast, in a joint venture, a party has an interest in the net assets and that party’s loss is limited to its investment, meaning even if the losses of the joint venture exceed the investment, such losses are not recognized unless the party has a legal or constructive obligation to make payments on behalf of the joint venture.\(^{311}\)

5.1.4.4 Continuous assessment

IFRS 11 states that if facts and circumstances change an entity shall reassess whether it still has joint control of the arrangement and, if joint control still exists, whether the type of joint arrangement in which it is involved has changed.\(^{312}\) IFRS 11 does not contain any additional guidance in terms of a continuous reassessment similar to the guidance that is

\(^{309}\text{IFRS 11.21 and IFRS 11.24. Refer to section 6.3.1.1 for details of the accounting for joint ventures and investments in associates using the equity method.}\)

\(^{310}\text{Deloitte (2013), p. 3.}\)

\(^{311}\text{Ernst & Young (2011b), p. 18.}\)

\(^{312}\text{IFRS 11.13 and IFRS 11.19.}\)
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included in IFRS 10. However, based on the fact that the two standards are based on the same control concept, the continuous reassessment guidance in IFRS 10 is generally viewed to be applicable to joint arrangements in analogy.

5.1.4.5 Applying the guidance in IFRS 11 to the Life Sciences industry

In the life sciences industry, the arrangements that are most likely to qualify as a joint arrangement are the co-development / co-marketing type of arrangements between two life sciences companies. When assessing these arrangements under IFRS 11, one first needs to assess what are the relevant activities of the arrangement because it may be that the arrangement provides for unanimous consent between the two parties but that this unanimous consent is for activities that are not the relevant activities. In such a case, the arrangement does not fall in the scope of IFRS 11 because the decisions about the relevant activities do not require unanimous consent. However, if it was determined that the decisions about the relevant activities require the unanimous consent, the arrangement would be considered a joint arrangement, and it would need to be determined whether the arrangement qualifies as a joint operation or a joint venture.

In life sciences practice, co-development or co-marketing type of arrangements often do not involve the establishment of a separate vehicle. Instead, the parties share their knowledge and resources and may agree on a specific revenue, cost or net income split. That is, at each period end the parties will share their revenue and expense information and split the costs in accordance with the percentage agreed upon in the agreement. Thus, based on the guidance in IFRS 11.B16, a joint arrangement that is not structured through a separate vehicle is automatically a joint operation. However, if the arrangement was structured through a separate vehicle, the parties need to assess whether based on the legal form of the vehicle, the terms in the agreement, or other facts and circumstances

313 IFRS 10.B80 through B85.
there are indicators that they have the right to the assets and obligations for the liabilities, in which case the joint arrangement would be considered a joint operation.

5.2 Practicability assessment of the IFRS 10 and IFRS 11 control guidance to deal structures in the life sciences industry

5.2.1 Determining the relevant activities

For investors in the life sciences industry, when performing the IFRS 10 / IFRS 11 relevant activities assessment in practice, there are a number of practical difficulties and complexities that require a significant amount of judgment for life sciences companies. These practical difficulties and complexities are further discussed in this section.

5.2.1.1 Assessing the relevant activities with one set of activities being contingent on the positive outcome of another set of activities

Often, arrangements in the life sciences industry involve more than one activity – for example when two companies agree to collaborate for both the R&D activities as well as the commercialization activities of a product candidate. As mentioned in section 5.1.1.1, whenever there are multiple activities, an assessment has to be made which activity significantly affects the investee’s returns, and if there are more than one activity that significantly affects the investee’s returns the assessment needs to go on to determine what activity most significantly affects the investee’s returns. Example 9, which is included in IFRS 10 (IFRS 10.B13) and is a life sciences example, further illustrates the concept of multiple relevant activities.

Two investors form an investee to develop and market a medical product. One investor is responsible for developing and obtaining regulatory approval of the medical product – that responsibility includes having the unilateral ability to make all decisions relating to the development of the product and to obtaining regulatory approval. Once the regulator has approved the product, the other investor will manufacture and market it – this investor has the unilateral ability to make all decisions about the manufacture and marketing of the product. If all the activities – developing and obtaining regulatory approval as well as manufacturing and marketing of the medical product – are relevant activities, each investor needs to determine whether it is able to direct the activities that most significantly affect the investee's returns. Accordingly, each investor needs to consider whether developing and obtaining regulatory approval or the manufacturing and marketing of the medical product is the activity that most significantly affects the investee's returns and whether it is able to direct that activity. In determining which investor has power, the investors would consider:

(a) the purpose and design of the investee;
(b) the factors that determine the profit margin, revenue and value of the investee as well as the value of the medical product;
(c) the effect on the investee's returns resulting from each investor's decision-making authority with respect to the factors in (b); and
(d) the investors' exposure to variability of returns.

In this particular example, the investors would also consider:

(e) the uncertainty of, and effort required in, obtaining regulatory approval (considering the investor's record of successfully developing and obtaining regulatory approval of medical products); and
(f) which investor controls the medical product once the development phase is successful.

Example 9: Identifying relevant activities in life sciences arrangements\(^{317}\)

Not uncommon in the life sciences industry, one activity may be contingent on another activity. For example and as illustrated in Example 9, the manufacturing and marketing activity is contingent on the successful completion of the research and development activity, because only if the research and development activity is successful will there be marketable drug. Thus, thinking about the two activities in terms of one being dependent on the successful completion of the other, one may argue that generally the activity that other activities are dependent on should also be considered to be most relevant. Example 10, which is a continuation of Example 9, will further illustrate this point.

Assume the same facts as in Example 9 as well as the following costs and benefits associated with the different activities:

- R&D expenses up to the regulatory approval: CU 50 million
- Expenses incurred in connection with obtaining regulatory approval: CU 10 million
- Expected revenues if drug is successful: CU 150 million
- Expected manufacturing and marketing expenses if drug is successful: CU 40 million

Based on these figures, the positive return would be maximized if the drug development was successful, the drug was approved and the product can be launched in the market, resulting in a positive return of CU 50 million (CU 150 – CU 50 – CU 10 – CU 40 = CU 50). The maximum negative return would be capped at CU 60 million, the sum of the R&D expenses and the expenses incurred in connection with obtaining regulatory approval, because if the drug fails there would also be no manufacturing and marketing expenses to be incurred. Thus, based on the definition of relevant activities in IFRS 10 (i.e., the activities of the investee that most significantly affect the investee's returns), in the above example it could be argued that the R&D activities are the activities of the investee that most significantly affect the investee's returns, because both the highest positive return and the lowest negative return are based on the result of the R&D activities.

Example 10: Determining the relevant activities based on the highest positive and lowest negative returns (continuation of Example 9)

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318 Example 9 is from IFRS 10.B13. The continuation in Example 10 is the author’s own compilation.
Unfortunately, IFRS 10 does not provide a more precise definition or description in terms of what are the relevant activities other than saying that the relevant activities are those activities that most significantly affect the returns of the investee. IFRS 10 does not provide a definition of ‘return’, and the IASB in its basis for conclusion noted that a broad definition of ‘return’ was intended to include both direct financial returns and more indirect synergistic returns. However, such broad definition of ‘return’ can pose different questions and can result in different interpretations and diversity in practice, as Example 10 shows.

5.2.1.2 Bias in the determination of the relevant activities

Although IFRS 10.B5 states that an investor shall consider the purpose and design of the investee in order to identify the relevant activities, different from other IFRS guidance (e.g., the guidance on fair value measurement as part of business combinations where IFRS 3 states that the measurement should be from a market participant’s perspective), IFRS 10 does not explicitly state that the assessment of relevant activities should be from the perspective of an unrelated third-party or a “market participant” to avoid bias. This implicitly may result in an investor who is responsible for only one activity intuitively determining that set of activities to be the most relevant activity, only because this activity also is the activity that the investor is most familiar with, experienced with and knowledgeable about. In other words, if one investor does not know much about the activities that other investors are responsible for, it will also be difficult for that investor to come to a conclusion as to whether the activities that these other investors are responsible for significantly affect the investee’s returns. Thus, in understanding the purpose and design of an investee the question is how much does an investor need to understand about all the other activities conducted by other investors to make a knowledgeable and objective assessment of which activity most significantly affects the investee’s returns.

A statement in IFRS 10 that the assessment of relevant activities should be made from the perspective of an unrelated third-party or market participant would likely result in more
investors forcing themselves to try to understand better the activities that other investors are responsible for and, thus, would result in investors making a more objective assessment. Without such explicit statement in IFRS 10 that the assessment should be from the perspective of an unrelated third-party or a ‘market participant’ (as defined in IFRS 13, Appendix A), there will always be the risk that investors judge the set of activities that they are involved with or responsible for as more significant than other activities.

5.2.1.3 Assessing past track records in successfully developing drug candidates

The above Example 9, which is an example included in IFRS 10 (IFRS 10.B13), notes that the investors should also consider as part of the relevant activities assessment the “record of successfully developing and obtaining regulatory approval of medical products” of the investor that is responsible for developing and obtaining regulatory approval. Although examples provided in a standard are generally aimed at providing clarification, the author sees the following implementation issues in life sciences practice with the IASB including such a statement that the “record of successfully developing and obtaining regulatory approval of medical products” should also be considered:

- While the investor responsible for developing and obtaining regulatory approval of the medical product may be well informed about its own track record in developing pharmaceutical products, the question is how much of that information would be accessible for the other investors (e.g., the investor responsible for the manufacturing and marketing activities). Information about a pharmaceutical company’s past track records, unless it relates to late-stage trials, is generally very sensitive information that is not publicly available. Thus, two investors that are independently assessing the relevant activities of the investee and, in theory, should come to the same conclusion, may have to base their assessment on two different levels of available information. It would be helpful if IFRS 10 explicitly stated that the assessment of a company’s past clinical development track record should be limited to the information that is publicly available to avoid contradicting conclusions by two investors that assess the same
arrangement (since IFRS 10 implies that the same investee cannot be controlled and consolidated by two different investors).

- Further, with IFRS 10 in this example explicitly stating that the past track record in successfully developing drug candidates should be assessed, even if all investors would have the same level of information to make such assessment, the question remains how such information should be interpreted when determining what the relevant activities are. For example, a negative past track record (e.g., not many drug candidates having obtained regulatory approval) could be interpreted as either the manufacturing and sales activities being the relevant activities (because the manufacturing and sales activities have a better past track record), or it could be interpreted as the development activities being the relevant activities (because the manufacturing and sales activities are unlikely to take place if the development activities are not successful). It would be helpful for the financial statement preparers if IFRS 10 in the Example 9 was more specific in terms of stating how a positive or negative past track should be considered in the assessment of relevant activities.

- Another question would be what level of past success in developing drug candidates is needed to make an overall conclusion that a past track record is a successful record. In the life sciences industry, with on average only 1 of 5,000 product ideas eventually being launched on the market and only 1 out of 10,000 substances becoming a marketable product (refer to footnote 18), this assessment may be a very difficult one. Also, the assessment of the past track record may be a difficult one where the past success in R&D is tied to a few individuals or a Head of Clinical Development, and it is known that those individuals are no longer employed by the investor responsible for developing and obtaining regulatory approval. Would such factors also need to be considered in assessing the relevant activities?
5.2.1.4 Facts and circumstances that would trigger a reassessment of control

As noted in IFRS 10.8, an investor shall reassess whether it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control. IFRS 10.B80-B85 provides details about what changes in facts in circumstances may trigger a reassessment of control (for example, because of changes to decision-making rights or changes to the exposure of variable returns), but it does not explicitly say whether a change in what are the investee’s relevant activities would also be considered a triggering event. Changes to the relevant activities are especially relevant for life sciences companies, as the following example (Example 11), which is a continuation of Example 9, will show:

Assume the same facts as in Example 9, except that the conclusion with respect to the relevant activities is that the manufacturing and marketing activity is the relevant activity of the investee, which means the investor that is responsible for that activity has power. After several years of conducting R&D, it turns out that the drug candidate has significant side effects resulting in the drug development being stopped.

In such a scenario, where the manufacturing and marketing activity was deemed to be the relevant activity, but then due to the failure of the drug candidate, it turns out that this activity will never take place, can this activity then still be considered to be the relevant activity or would the discontinuation of the R&D trigger a reassessment of control, incl. a reassessment of is the relevant activity as defined in IFRS 10?

Example 11: Determining the relevant activities with sequential activities and the latter not taking place (continuation of Example 9)\textsuperscript{319}

This lack of guidance was confirmed in an interview that the author conducted with a Life Sciences IFRS Partner of a large public accounting firm.\textsuperscript{320} Discussing this lack of guidance and inquiring what that accounting firm’s view or interpretation is in terms of whether a change in what the investee’s relevant activities are would trigger a

\textsuperscript{319} Example 9 is from IFRS 10.B13. The continuation in Example 11 is the author’s own compilation.

\textsuperscript{320} Interview with Eric Ohlund, Life Sciences IFRS Partner, Ernst & Young Zurich, Switzerland.
reassessment of control, the interviewee indicated that his company’s view for life sciences arrangement as indicated in Example 11 would be to distinguish between changes in relevant activities that are pre-determined and changes that are not pre-determined.\textsuperscript{321} However, even with this view of a large public accounting firm, the question remains what changes would be considered “pre-determined” and what changes would not be considered “pre-determined.” For example, it would be questionable if in a scenario as presented in Example 11 a path of successful R&D development followed by manufacturing and marketing activities can be considered the “pre-determined” path if one considers the very low development success rates in life sciences R&D development.

It would be helpful if IFRS 10 was more explicit regarding this question, and if the reassessment guidance in IFRS 10.B80-B85 also included a statement whether a change in what are the investee’s relevant activities should be considered a triggering event to reassess control.

5.2.1.5 Assessing R&D activities as relevant activities with the investee conducting R&D activities for more than one drug candidate

The above presented Example 9 from IFRS 10 deals with an investee engaging in the development of only one drug candidate. However, in life sciences practice the situations are often more complex because the investee is generally involved in conducting R&D on more than just one drug candidate. In these situations, where the investee engages in R&D activities for multiple drug candidates and the arrangement with the investor relates to only to one drug candidate, the question is whether the one drug candidate subject to the arrangement with the investor should be determinative for the overall R&D activities of the investee. The following Example 12 will further illustrate this question.

\textsuperscript{321} Ernst & Young (2013a), p. 8.
Assume the same facts as in Example 9 except that the conclusion with respect to the relevant activities is that the R&D activities are the relevant activities of the investee, which means the investor that is responsible for those activities has power. Also, assume that in addition to the one drug candidate that is subject to the arrangement with the investor, the investee engages in R&D activities of other drug candidates that are not subject to the arrangement.

Assessment: If the overall R&D activities are deemed to be the relevant activities of the investee but, in addition to the one R&D project that is subject to the arrangement with the investor, the investee also engages in several other R&D projects that are not subject to the arrangement with the investor, a second qualitative assessment will have to be made how relevant the R&D project that is subject to the arrangement is in relation to the overall R&D activities. In a situation where the R&D project subject to the arrangement is a late stage clinical development candidate and the investee only has one other candidate, which is in an early stage clinical development phase, the answer should probably be that the R&D project subject to the arrangement should be decisive for the R&D activities in general. However, in another scenario where the R&D project subject to the arrangement is only one of a total of four late stage clinical development candidates, the answer would probably be different because with four late stage clinical development candidates the research of only one candidate is likely not going to be decisive for the overall R&D activities, which include three other late stage clinical development candidates.

Example 12: Assessing R&D activities as relevant activities with the investee conducting R&D activities for more than just one drug candidate (continuation of Example 9)\textsuperscript{322}

As Example 12 illustrates, in a situation where the R&D activities are deemed to be the relevant activities but the investee has several other late stage drug candidates, of which only one is subject to the arrangement with the investor, a significant amount of judgment will be required to qualitative rank the different R&D projects and to conclude whether

\textsuperscript{322} Example 9 is from IFRS 10.B13. The continuation in Example 12 is the author’s own compilation.
the R&D activities subject to the arrangement with the investor should be decisive for the overall R&D activities of the investee.

US GAAP, in the Variable Interest Entities (VIE) guidance,\textsuperscript{323} provides specific guidance for a scenario as the one discussed in Example 12. The guidance notes that an investor that has a variable interest in specified assets (e.g., an interest in (unrecognized) R&D projects or IP as a result of a collaboration as described in Example 12) should be considered to have a variable interest in the investee as a whole if the fair value of these specified assets is more than half of the total fair value of the investee’s assets.\textsuperscript{324} If an investor only has a variable interest in specified assets of an investee but not a variable interest in the investee as a whole, the VIE guidance notes that an investor cannot be deemed to control an investee pursuant to the Variable Interest Model.\textsuperscript{325}

Although the determination of the fair value of the specified assets and the determination of the total fair value of the investee’s assets – especially in the life sciences industry when trying to fair value R&D projects – is complex and requires management to make a significant amount of assumptions, it should be noted that from an accounting perspective US GAAP provides clear guidance in terms of when an individual R&D activity should be considered determinative for the overall R&D of an investee, namely when its fair value is more than half of the total fair value of the investee’s assets.

\subsection{5.2.1.6 Determining the unit of account for the relevant activities assessment}

In life sciences scenarios where an investee engages in multiple R&D activities another question is: what is the unit of account when assessing what activities are the relevant activities? Example 9 through Example 12 assumed the unit of account for the relevant activities assessment to be either the overall R&D activities or the overall manufacturing and marketing activities. However, the question is whether the relevant activities assessment could not also be performed at a lower level, namely the individual R&D

\textsuperscript{323} ASC 810-10-25.
\textsuperscript{324} ASC 810-10-25-55.
\textsuperscript{325} Ernst & Young (2009b), p. 9.
project / drug candidate level, especially in situations where the investee engages in R&D activities for more than one drug candidates. Example 13 further illustrates this question.

Assume the same facts as in Example 9 except that in addition to the one drug candidate that is subject to the arrangement the investee also engages in R&D activities for other drug candidates that are not subject to the arrangement. Also, assume that if the investor was to perform the relevant activities assessment at the overall level for all R&D activities combined, this would result in a conclusion that the R&D activities are deemed to be the relevant activities of the investee.

If that same investor was to perform the relevant activities assessment at the individual R&D project / drug candidate level and compare the relevance of the R&D activities of each individual R&D project / drug candidate to the overall manufacturing and marketing activities, the conclusion may be different because individually the R&D activities for each R&D project / drug candidate may be deemed less relevant, as compared to the overall manufacturing and marketing activities. Thus, as this example shows, the determination of what the investor deems to be the unit of account for the relevant activities assessment may impact the overall IFRS 10 control assessment.

Example 13: Unit of account for the relevant activities assessment (continuation of Example 9)\(^{326}\)

It would be helpful if IFRS 10 provided some guidance at which unit of account level the relevant activities assessment should be performed. For example, a definition of a relevant activity as an activity that is overseen by a “Chief Operating Decision Maker” (as defined in IFRS 8) may provide financial statement preparers with clear guidance at what unit of account level the relevant activities assessment should be made. At a minimum, IFRS 10 should be explicit on the topic that as part of the relevant activities assessment the unit of account level of different activities should be comparable, so that a situation as the one illustrated in Example 13, where individual R&D projects are compared to the overall manufacturing and marketing activities, are avoided because

\(^{326}\) Example 9 is from IFRS 10.B13. The continuation in Example 13 is the author’s own compilation.
such scenarios will almost always result in a biased assessment due to different unit of account sizes.

5.2.2 Assessing existing rights

Once it has been determined what the relevant activities are, the question of what investor, if any, has existing rights to direct the relevant activities, has to be answered. For the assessment of the existing rights, the author also sees several practical difficulties and complexities for companies in the life sciences industry, which will be discussed in the remainder of this section.

5.2.2.1 Assessing the past attendance at recent shareholders’ meetings

Similar to how the IASB in Example 1 in IFRS 10 (Example 9 in this thesis) is asking investors to also consider in the relevant activities assessment the past track record in successfully developing drug candidates, in Example 8 in IFRS 10 (IFRS 10.B45), it is noted that an investor in assessing voting rights in the context of de facto control should also assess the past attendance of shareholders at recent shareholders’ meetings. This is because in situations where an investor does not hold the majority of voting rights but the majority of voting rights that are generally present at the shareholders’ meetings when decisions about the relevant activities are made, this may indicate that the investor has the practical ability to direct the relevant activities, meaning he may have de facto control.

The IASB asking investors to analyze past history to derive a conclusion of what is likely going to happen in the future makes sense in theory but, again, brings up the question of how much weight should be given to this historical fact pattern, especially if – because of new facts and circumstances – there is reason to believe that the historical fact pattern is likely going to change in the future.

For example, in the context of past attendance records at shareholders’ meetings, it may be that based on both the current shareholding of the investor and past attendances at shareholders’ meetings, the investor barely holds the majority of rights present at recent
shareholders’ meeting. However, if it is known that in the current year a new shareholder acquired a 5% shareholding and those 5% – if present at the next shareholders’ meeting – would change the majority proportions for votes at the next shareholders’ meeting, how should such information be considered in the control assessment? Should an investor in such a scenario try to find out information about whether the new investor is likely to attend the next shareholders’ meeting (e.g., based on his past record of showing up at shareholders’ meetings of other investees that this new investor may hold shares of)?

Further, with the IASB explicitly stating that historical information about the attendance at recent shareholders’ meetings be analyzed and considered in the assessment, similar to how the past track record of successfully developing drug candidates should be analyzed in the relevant activities assessment, the question remains as to how much information is available and accessible to the investors when performing this assessment. While for public companies there may be publicly available records that evidence the attendance at recent shareholders’ meeting, such information is generally not publicly available or easily accessible for private companies. Also, with private company investees, some investors may have a longer investor-investee relationship than other investors, which again may result in two investors that in theory should come to the same conclusion, having two different levels of available information to base their assessment on. As such, similar to the assessment of an investee’s past clinical development track record, the author suggests the information about the attendance at recent shareholders’ meetings that should be assessed to be limited to only that information that is publicly available.

5.2.2.2 Assessing whether an option is in-the-money or out-of-the-money for highly volatile shares

As per IFRS 10.B23(c), options are more likely to be substantive when they are in-the-money. Although the exercise price is generally noted in the agreement and the share price is something that is either directly observable (e.g., for public companies) or can be determined based on a valuation (e.g., for private companies), the question is as of what date or over what period should the share price be assessed to determine if an option is in-the-money, because especially for small start-up companies in the life sciences
industry, the share price can be extremely volatile resulting in the option to continuously shift from being in- to being out-of-the-money. In such a scenario, assuming the other two factors to indicate that the option is substantive are met, the question is as of what date would the “exercise price” criterion also deemed to be met and the option be substantive. Is this the first time that the option is in the money resulting in the option to switching in between being substantive and non-substantive for volatile shares, or should an option not be considered to be in-the-money from an IFRS 10 perspective until it has been in-the-money for a longer period of time (e.g., average share price over the past 30 or 90 days)?

Although it makes sense for the IASB to not provide any stringent rules in IFRS 10 with respect to when an option should be considered in-the-money (since that would only attract investors to structure arrangements around those rules), it would help if IFRS 10 at least provided some general guidance to clarify whether the assessment of an option being in- or out-of-the-money should only be as of a particular date or whether it should be assessed over a period of time. Interpreting the guidance in IFRS 10.B23(c) very literally, for very volatile shares where the “exercise price” criterion is what is driving an investor to have power over an investee, this may result in an investee changing from being consolidated to being deconsolidated on a daily basis, which likely was not the intention of the IASB when drafting IFRS 10.

5.2.2.3 Assessing control premiums in the discussion of whether an option is in-the-money or out-of-the-money

In the previous section it was assumed that for the determination of whether an option is in-the-money or out-of-the-money the exercise price of the option should be compared to the fair value of the underlying (e.g., the shares). However, in practice this assessment would be more complex and judgmental because of the concept of a control premium.

As discussed in section 2.7.3, companies that acquire a stake in a target company large enough to gain control over the target company are generally willing to pay a premium for this right to exercise control. IFRS 10 is silent as to whether a control premium that an
investor is willing to pay should be considered in the assessment of whether an option is in-the-money. The scenarios for which this is relevant are those where an investor has an option to acquire a majority stake in an investee and where based on the exercise price and the current share price, the option is out-of-the-money, meaning the exercise price is more than the current share price. However, if one included in the consideration a potential control premium and if this control premium was added to the current share price, the option would be considered to be in-the-money.\textsuperscript{327} The fact that IFRS 10 does not at least acknowledge the concept of a control premium may result in significant diversity in practice with some investors considering in the evaluation of whether an option is in the money a control premium and others not considering a control premium, which – as the previous example showed – may result in one investor concluding that an option is substantive and consolidating an investee with the other concluding that it is not substantive and not consolidating. Why the consideration of control premiums is so relevant is because of the fact that they can be expected to be present in almost all option arrangement to acquire a majority or close to a majority of the voting rights. In other words, control premiums are present in all option structures where the assessment of whether the option is substantive is likely to also drive the overall control assessment.

It is important to note that the control premium concept not only exists for options to acquire a majority stake but may also be present for options to acquire a less than majority stake if the acquirer believes that effective control over key decisions can be achieved (through \textit{de facto control}).\textsuperscript{328} As such, instead of staying silent on the concept of a control premium, the IASB could actually use that concept to identify scenarios of \textit{de

\textsuperscript{327} Based on a study by FactSet Mergerstat for the fourth quarter 2012 (FactSet Mergerstat (2013), p. 9), the twelve-month median control premium for the industry “Chemicals and Allied Products”, which FactSet Mergerstat considers the Life Sciences industry to be part of, was 36.9%, meaning the scenarios referred to here would be for all options to acquire a controlling financial interest where the exercise price is up to 36.9% higher than the current share price because all such options may still be considered to be “in-the-money” when giving consideration to a control premium.

\textsuperscript{328} DePamphilis (2012), p. 388.
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*facto control* by explicitly stating if a control premium is present for options to acquire less than a majority stake there is a rebuttable presumption that *de facto control* exists.\textsuperscript{329}

5.2.2.4 Assessing whether an option is substantive whenever decisions need to be made

IFRS 10.BC51 states that for an investor to have control, the investor needs to be able to make decisions about the relevant activities at the time when those decisions need to be made. In the context of options, this means that options need to be substantive whenever the decisions about the relevant activities need to be made. In other word, if, for example, an option was deeply out-of-the-money today or at the reporting date, but it is expected to be in-the-money when the decisions about the relevant activities of the investee need to be made, then the conclusion may be that this option is still considered substantive.\textsuperscript{330} As such, for investees where the relevant activities can only be directed at the annual shareholders’ meeting, an investor has to assess whether it expects the option to be substantive at the time of the next annual shareholders’ meeting.

Determining whether an option is substantive, an investor should be able to assess the “financial ability to exercise” and the “exercise period” as of a future date still relatively objectively. However, assessing the “attractiveness” of an option as of a future date (its exercise price in relation to the future share price and assessing whether the investor may benefit from exercising the option at that future date for other reasons) will pose practical difficulties for most investors. Especially with respect to the following three points, the author sees significant difficulties to overcome in practice:

- Since financial statements are generally issued prior to the next shareholders’ meeting, this will inevitably result in situations where an investor will need to assess what the impact of the investee’s release of the financial results will be on the investee’s share price. This is because any significant share price volatility as a result of the release

\textsuperscript{329} Similar to the guidance in IFRS 3.B12, which states that, in the absence of evidence to the contrary, a particular set of assets and activities in which goodwill is present shall be presumed to be a business.

\textsuperscript{330} Ernst & Young (2011a), p. 20.
may result in the investor’s option changing from being in-the-money to being out-of-
the-money, or vice versa, and as such, may result in the option becoming substantive
or no longer being substantive. With IFRS 10 asking an investor to assess past history
for different aspects of the control assessment presuming that what happened in the
past will likely also happen in the future, the question is whether an investor for the
expected volatility after an earnings release should also assess past share price data.

- IFRS 10.B23(c) states that in addition to assessing whether an option is in the money,
an investor should assess whether it would benefit from the exercise of the option for
other reasons (e.g., by realizing synergies between the investor and the investee).
Thus, an investor, in addition to drawing assumptions about how the share price will
develop (the previous point), the investor also needs to draw assumptions in terms of
whether it thinks it will benefit from exercising the options at that future date for other
reasons. Especially in the life sciences environment, much can happen within only a
few months resulting in an option to be very “attractive” or to be very “unattractive” to
be exercised as of a future date. Irrespective of that, an investor as of the balance sheet
date will have to make a call whether it thinks it may benefit from the exercise of the
option for other reasons at the time when the about the relevant activities need to be
made.

- The exercise prices of options in life sciences practice today is often not fixed but
based on a formula with different variables serving as inputs. Thus, in those instances,
to make an assessment of whether an option is substantive in the future when
decisions need to be made, an investor would not only have to make an assessment in
terms of how the share price is expected to develop in the future but also assess how
the variables that are the inputs to the exercise price formula are expected to develop
in the future.
5.2.2.5 The investor’s intention to exercise the option

Whereas the previous consolidation guidance in IAS 27 explicitly stated that an investor’s intentions to exercise the option or not should not be considered, IFRS 10 is silent on whether the investor’s intention should be considered in the assessment. However, with IFRS 10.B23(c) stating that in determining whether rights are substantive it should also be considered whether the investor would benefit from exercising the option for other reasons, the IASB implicitly states that an investor’s intentions are considered. That is because an investor that will benefit from the exercise of the option economically can also always be expected to have an intention to exercise the option.

With this statement, the IASB implicitly provided investors with something that is close to an option of whether they assess an option as substantive or not. In an extreme scenario where the power assessment comes down to whether an option is substantive, an investor is implicitly given a choice to consolidate. That is because – no matter how deeply out of the money an option may be – an investor will likely always see some sort of benefits (e.g., in the form of energies) some time in the future that it ties to the exercise of the option. Or, worded differently, it will be very hard for financial statement readers and auditors to argue against an investor’s position that it thinks it will benefit from the exercise of an option because nowhere in IFRS 10 does it say that the benefits from exercising the option have to be immediate. In fact, it even mentions synergies as one of the examples of benefits that – as everyone would agree – are benefits that are generally not immediate. This is even more true the other way around, for financial statement readers or auditors to argue against an investor’s position that it does not think it will benefit from the exercise of an option.

This guidance in IFRS 10.B23(c), that an investor should also assess whether it may benefit from exercising the option for other reasons, is very relevant for deals in the life sciences industry because deals may be structured with the options being significantly out-of-the-money but with the investor being able to benefit from the exercise of the option for other reasons – for example, because the investor has an existing sales and

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distribution network for a specific indication and with exercising the option would have
synergies by better utilizing this existing sales and distribution network. However, that
same option held by another investor who may not have such an existing sales and
distribution network may result in the conclusion that the option is not substantive.

It will be interesting to see how this guidance in IFRS 10.B23 (c) will be applied in
practice, especially in the life sciences industry. It is not unlikely that the IASB at some
point in the future is going to again shift away from this very investor-specific assessment
of whether an option is substantive and will issue guidance to make the assessment more
objective, similar to how it was in IAS 27.\footnote{With this guidance in IFRS 10 to include subjectivity in the assessment, the IASB seems to have chosen
a different path compared to other standards issued in the recent past (e.g., IFRS 13 \textit{Fair value measurement}, paragraph IFRS 13.89) where it is explicitly noted that entity-specific considerations should
be ignored and instead a market participant view should be taken.}

\section*{5.2.2.6 Assessing whether options held by another investor are substantive}

As noted in IFRS 10.B42(b), when assessing power, an investor also has to consider
potential voting rights held by others. Thus, similar to how an investor needs to assess
whether its own potential voting right are substantive, it will also need to assess whether
the potential voting rights held by another investor are substantive. The practical
difficulty in such a scenario is again accessing information that is not publicly available
and that the other investor that holds the potential voting rights may also not be willing to
share. Particularly, assessing whether the other investor would benefit from exercising his
option for other reasons (e.g., realizing synergies) may to a large extent depend on the
other investor’s internal plans, strategy and vision, information that is generally not
publicly available. Similarly, assessing the financial ability of another investor to exercise
its option may be difficult to do solely based on publicly available information, because,
as mentioned in section 5.1.1.2.2, this assessment also encompasses assessing the ability
to obtain financing from banks, which, especially if the other investor is a private
company, may be challenging to assess because of not having sufficient information as to
whether the other investor can easily access funds.
Further, the requirement of considering options held by others in the IFRS 10 control assessment also assumes that an investor is fully informed about what are all the options that other investors are holding. While this may still be manageable for a shareholder structure of just a few investors, the more shareholders there are, the more difficult it will be for individual investors to know how many and what kind of options other investors may have.

5.2.2.7 Options to acquire voting rights versus options to acquire assets, incl. group of assets that constitute a business

One of the most significant shortfalls of IFRS 10 in the view of the author is the fact that IFRS 10 only applies to potential voting rights, meaning options to acquire shares and voting rights of an investee, but it does not apply to options to acquire individual assets or a group of assets, even if that group of assets constitutes a business.

As explained in section 3.4, options-based M&A has become increasingly popular in the life sciences industry over the past decade, and the type of option deals entered spread over a wide range of different options, from options to commercial rights, options to licenses, option to acquire assets, options to invest and options to acquire voting rights. In other words, even for those option deals where an investor has an option to acquire substantially all of the assets and liabilities of an investee (i.e., those assets and liabilities constitute a business) IFRS 10 would still not be applicable because the option is not to acquire voting rights.

As part of this thesis, the author analyzed a total of 494 option deals entered into in the period from June 2009 to July 2013 (period of 49 months).333 Following the download, the author analyzed each of the 494 option deals further to assess what type of option the deal encompassed, distinguishing between the following seven option deal categories.

333 The population is based on a download of all deals indicated as “option” deals in the life sciences deal databases of Thomson Reuters Recap. Data was downloaded on August 8, 2013.
1. Option to commercial rights
2. Option to IPR&D/technology
3. Option to license
4. Option to acquire voting rights
5. Option to invest
6. Option to purchase assets
7. Other options

Based on this research, the author found the relative distribution of the different option types to be as shown in Figure 15.

Figure 15: Relative distribution of different option deals of a total of 494 option deals in the period from June 2009 through July 2013

Thus, of the total population of 494 life sciences option deals entered into in the period from June 2009 through July 2013, only 32 or 6% were option deals to acquire voting rights, which means it is also only those 6% that the potential voting rights guidance in IFRS 10 applies.

334 The total population of 494 option deals has been downloaded from the life sciences deal databases of Thomson Reuters Recap on August 8, 2013. Categorization into the different option types is based on research performed by the author reading press releases of the involved parties when announcing the deal as well as financial statement disclosures of the party acquiring the option.
What is interesting is that from a business development perspective, big pharma investor companies are generally indifferent in terms of whether they choose a deal structure with an option to acquire the majority of voting rights or a deal structure where they acquire substantially all of the assets and liabilities of an investee. In both cases, the big pharma company obtains control over the investee as a business. However, from an IFRS 10 consolidation perspective, the two deal structures are treated differently because one is subject to the requirements in IFRS 10 and the other one is not.\(^{335}\) The following Example 14 will further illustrate this point.

A big pharma company is interested in the acquisition of a small biotech, but not until the small biotech’s lead compound has reached the clinical development Phase III. As such, big pharma structures the deal to pay CU 20 million for an option to acquire all voting rights of the small biotech that becomes exercisable only if small biotech’s lead compound reaches Phase III. If the big pharma company decides to exercise the option, the option exercise fee that becomes payable is an additional CU 80 million. Because this option represents a potential voting right (i.e., an option to acquire shares), it falls in the scope of IFRS 10 and big pharma would have to continuously assess whether the option is substantive and, if the option is substantive, may have to consolidate small biotech already prior to exercising the option.

If big pharma instead structured the deal to – instead of having an option to acquire all shares of small biotech – had an option to acquire substantially all of the assets and liabilities of small biotech, then from a business development perspective not much would change because the big pharma company still holds an option to acquire the small biotech business as a whole. However, from an accounting perspective, this deal structure would be significantly different because such an option would not fall in the scope of IFRS 10. Thus, for an option to acquire substantially all of the assets and liabilities, big pharma would not have to assess whether such option is substantive,

\(^{335}\) This is especially interesting considering that if either one of the two options is exercised, the big pharma company would have to account for what is being acquired identically, namely as an acquisition of a business under IFRS 3.
and there is no possibility that a conclusion can be reached that big pharma controls and needs to consolidate the small biotech prior to exercising the option.

Example 14: Options to acquire the majority of voting rights versus options to acquire substantially all of the assets and liabilities

Example 14 illustrates that – while it may not be relevant from a business development perspective whether an option deal is structured with an option to acquire all of the voting rights of another entity versus an option to acquire substantially all of the assets and liabilities of the other entity, such deals may be accounted for entirely differently since the first option deal is in scope of IFRS 10 and may result in the investee having to be consolidated, whereas the second one is not in the scope of IFRS 10 and, thus, would also not result in any consolidation of the investee prior to the exercise of the option. For life sciences entities that are indifferent between those two types of option deals from a business development perspective, this is an important consideration to keep in mind.

5.3 Practical example: Applying the IFRS 10 guidance to the Novartis option deal to acquire Alcon

In April 2008, Novartis announced that it had entered into an arrangement with Nestlé, providing Novartis with the right to acquire in two steps Nestlé’s 77% majority ownership in Alcon, at that time the world’s largest eye care company. The transaction’s first step was to acquire a 25% stake in Alcon and that step was completed in July 2008. As part of the second step, Novartis and Nestlé agreed on a call option (for Novartis) and a put option (for Nestlé) to transfer the remaining 52% Alcon shareholding owned by Nestlé. The option period for both the call and the put option commenced on 1 January 2010 and expired on 31 July 2011. The call option provided Novartis with the right to buy Nestlé’s remaining Alcon shares at a fixed price of USD 181 per share and the put option provided Nestlé with the right to sell its remaining Alcon shares to Novartis at the

Author’s own compilation.
lower of Novartis’s call price of USD 181 per share or at a 20.5% premium above the market price of Alcon shares calculated as the average price of Alcon shares during the week preceding the exercise date of the put option.

Novartis announced at the beginning of January 2010, which means right at the beginning of the exercise period, that it would exercise its call option to acquire at a fixed price of USD 181 per share the remaining 52% of Alcon. In the following practical example, it will be assumed that Novartis had not exercised the call option at the beginning of the exercise period, and it will be assessed whether, based on the IFRS 10 guidance on potential voting rights, Novartis would have been deemed to have power over Alcon in January 2010 even without exercising its call option.

Because the option was not exercisable until January 2010, based on the potential voting right guidance in IFRS 10, January 2010 would have also been the earliest that the option to acquire the remaining 52% in Alcon could have been substantive. As such, in assessing whether the Novartis option is substantive, the “timing and length of exercise period” criterion would be met starting from 1 January 2010 and, in the following, the other two criteria, “ability to obtain financing” and “exercise price or conversion price, relative to market terms” will be assessed.

With respect to Novartis’ financial ability to exercise the option, although the exercise price to acquire the remaining 52% of shares was approx. USD 28.3 billion and Novartis as of 31 December 2009 only had USD 2.9 billion in cash and cash equivalents, for a company of the size and financial stability of Novartis, it can be assumed that sufficient funds can be accessed from banks and investors to finance the payment of such exercise price, which would mean the criterion of the “financial ability to exercise” would also be met.

With respect to the exercise price or conversion price, where an investor needs to assess the “attractiveness” of an option both based on the exercise price in relation to current market terms and based on other benefits that the investor may have from exercising the option (e.g., by realizing synergies), as part of this case study, the exercise price in

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relation to the market terms (i.e., the share price at that time) will be analyzed first. Figure 16 shows the Alcon closing share price in USD in the period from 1 December 2009 to 31 January 2010.

Based on the above shown share price development in December 2009 and January 2010, the Novartis call option, which has an exercise price of USD 181, cannot be considered to be in-the-money considering just the share price during those two months. However, since Novartis with exercising the option also obtains control of Alcon, the option may still be considered “in-the-money” relative to market terms if a control premium is factored in the assessment. As further discussed in section 5.2.2.3, based on a study by FactSet Mergerstat, the median control premium for companies in the “Chemicals and Allied Products” industry, which FactSet Mergerstat considers the Life Sciences industry

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338 Based on publicly available share price information.
to be part of, was 36.9%. Applying a 36.9% control premium to the Novartis – Alcon deal would mean that the Alcon share price would only need to be above USD 132\textsuperscript{340} for it to be considered “in-the-money” because any difference between a share price of USD 132 and the exercise price of USD 181 could be justified with the existence of a control premium. This example illustrates very well that whether or not a control premium is considered can have a significant impact on the overall control assessment because one investor may acknowledge the fact that there is a control premium and conclude that a share price between USD 132 and USD 181 should still be considered “in-the-money”, whereas another investor does not include a control premium in his or her assessment and conclude that the option would only be in-the-money if the Alcon share price was above USD 181.

However, even if the option cannot be considered “in-the-money” if considering relative market terms, based on IFRS 10.B23(c), the option may still be substantive if Novartis would benefit from the exercise of the option for other reasons. Assessing how attractive an option is for an investor for other reasons is very judgmental. One way to assess the option’s attractiveness in January 2010 for Novartis would be to review the statements that Novartis made in January 2010 in connection with the Alcon option deal. The following summarizes the key points publicly announced by Novartis in its Form 20-F for the period ending December 31, 2009, which Novartis filed with the SEC on January 26, 2010, only a few days after it had announced the exercise of its option:

“On January 4, 2010, Novartis announced its intention to gain full ownership of Alcon Inc. (NYSE: ACL) by first completing the April 2008 agreement with Nestlé S.A. to acquire a 77% majority stake and subsequently entering into an all-share direct merger with Alcon for the remaining 23% minority stake. Novartis believes this merger, which will be implemented under the Swiss Merger Act, is in the interest of all stakeholders and will provide the needed clarity on Alcon's future. Alcon will strengthen the Group's healthcare portfolio with greater access to the fast-growing global eye care sector, which is driven by an aging population, innovation and emerging markets. Alcon and Novartis

\textsuperscript{340} USD 132 = USD 181 divided by 1.369 (based on a median control premium of 36.9%).
have attractive global activities in eye care, each offering their own competitive positions in highly complementary segments that together cover more than 70% of activities in the global vision care sector. Aligning these strengths can result in offering even more compelling products that make a difference for patients around the world. Following successful completion of the merger, Alcon would be established as a new Novartis division that incorporates these highly complementary assets. This new eye care division will have enhanced opportunities to accelerate expansion in high-growth regions, generate greater value from combined product portfolios and capitalize on strengthened R&D capabilities.\textsuperscript{341}

Based on the above statements, it seems clear that Novartis as the investor anticipated significant benefits from exercising the option (e.g., by realizing synergies between Novartis and Alcon). Thus, applying the IFRS 10 guidance to the Novartis – Alcon deal Novartis would have likely concluded that, irrespective of the Alcon share price, that it “would benefit for other reasons from the exercise” of the option.\textsuperscript{342}

The author in section 5.2.2.5 stated that IFRS 10 for some scenarios implicitly provides investors with an option to conclude on whether an option is substantive or not. Applying this statement to the Novartis – Alcon IFRS 10 practical example, what was meant is that if Novartis in January 2010 had concluded that it would not have any significant benefits from exercising the option, it would have been difficult for financial statement preparers and auditors to argue against such a statement, which is intimately tied to management’s intentions, vision and strategy of how to run the business in the future.

The Alcon deal is especially interesting to assess in the context of the IFRS 10 control guidance because in addition to the call option that Novartis had, Nestlé also had a put option for the remaining 52% ownership in Alcon exercisable from 1 January 2010 to 31 July 2011. With this put option, Nestlé was able to require Novartis (even if Novartis was not interested) to acquire the remaining stake at a 20.5% premium to Alcon’s share price at the time of exercise, but not exceeding USD 181 per share.

\textsuperscript{341} Novartis (2010), p. 92.  
\textsuperscript{342} IFRS 10.B23(c).
IFRS 10.B42(b) states that an investor when assessing power also needs to assess options held by others. In the interpretative guidance, this requirement of assessing options held by others is viewed to only be applicable in scenarios where an investor holds a majority of the voting rights and where another investor holds a substantive call option to acquire a majority of the voting rights, in which case the majority shareholder is likely deemed to not have power.\footnote{Ernst & Young (2011a), p. 19.} It is unclear though whether the guidance in IFRS 10.B42(b) would also be applicable to a scenario similar to the Novartis – Nestlé scenario, where another investor (Nestlé) holds the majority stake but has a put option to sell the majority stake to the investor (Novartis). It is unclear whether for such scenarios the guidance in IFRS 10.B42(b) would need to be applied in analogy, and an investor would need to assess whether a put option to sell shares held by a majority shareholder also needs to be assessed as part of the control assessment. Applying the guidance in IFRS 10.B42(b) in analogy, it would seem that such put options would also need to be assessed: however, an argument can also be made that as long as the option is in the control of the majority shareholder/investor, that investor is also “pulling the strings” including the decision as to when the put option should be exercised.\footnote{Interview with Eric Ohlund, Life Sciences IFRS Partner, Ernst & Young Zurich, Switzerland.} Thus, based on the guidance in IFRS 10, it is not clear whether in the Novartis – Alcon example Novartis would have also had to assess if the put option held by Nestlé (at that time majority shareholder) is substantive.

In summary, applying the IFRS 10 control guidance to the Novartis – Alcon option deal has illustrated the significant judgment when assessing whether such an option is substantive. Based on the analysis above, it seems that it can be argued in either direction when assessing the exercise price relative to market terms or when assessing whether Novartis would be benefiting from the exercise of the option for other reasons.
5.4 Proposal to revise the control guidance to address the shortfalls

5.4.1 The assessment of relevant activities

As the analysis has shown, assessing the relevant activities for most life sciences arrangements is critical in assessing who has control. Although IFRS 10 was intended to provide a broader consolidation framework that would allow less companies to structure arrangements in order to achieve a particular outcome, the guidance lacks important cornerstones for financial statement preparers to be able to apply the new control model. In the following, based on the above analysis, the author will articulate the most critical points that would warrant an expansion or revision of the standard.

First, IFRS 10 should provide a more precise definition or description in terms of what should be considered the relevant activities. Especially in life sciences arrangements, where often one set of activities is dependent on another set of activities, it would be helpful to know whether the order of activities or one being dependent on the other should be taken into consideration in the relevant activities assessment.

Second, financial statement preparers are puzzled to what extent the assessment of the relevant activities can be a subjective one or to what extent they should force themselves to try to get a good understanding of the activities that other investors are involved in. An explicit statement in IFRS 10 that the assessment of relevant activities should be made from the perspective of an unrelated third party or market participant (as defined in IFRS 13, Appendix A) would likely prompt investors to try to better understand the activities that other investors are involved in. With such an explicit statement, the assessment of what the relevant activities are will be a more objective one and, as a result, also ensure a more consistent application of the IFRS 10 control guidance in practice.

Third, the statement in IFRS 10.B13 that an investor, as part of the relevant activities assessment, should also consider the past track records in successfully developing drug candidates should be removed from the standard, as this statement, instead of clarifying, only poses additional questions for financial statement preparers, as illustrated in section 5.2.1.3.
Fourth, IFRS 10 should be explicit as to whether a later change of what are the relevant activities of the investee would also trigger a reassessment of control or whether the relevant activities assessment should only be performed once at inception and then not be subsequently changed for purposes of the control assessment. This is especially relevant for scenarios where a small biotech’s relevant activities are to conduct R&D activities and it may initially only conduct R&D activities for one drug candidate, but where the R&D activities are later expanded to include other drug candidates. In such a scenario, where only the first drug candidate is subject to the collaboration with a big pharma company and where the big pharma company through the contractual arrangement is able to direct the activities of this drug candidate, the big pharma is likely to have power over the small biotech. However, if with the addition of other drug candidates to the R&D activities, the drug candidate subject to the collaboration is later only one of many drug candidates, the question is whether the big pharma company can then still be considered to be able to direct the overall R&D activities of the small biotech (which are the relevant activities). For these types of scenarios, it would be helpful if IFRS 10 provided some explicit guidance similar to the US GAAP VIE guidance, as presented in section 5.2.1.5.

Last but not least, it would be helpful if IFRS 10 provided guidance at which unit of account level the relevant activities assessment should be performed, at a minimum stating that, as part of the relevant activities assessment, the unit of account level of different activities should be comparable to avoid unwarranted bias in the assessment solely due to different unit of account sizes.

5.4.2 The assessment of existing rights

As the analysis has shown, not only assessing the relevant activities, but also assessing the existing rights as part of the IFRS 10 control assessment results in practical difficulties when applied to life sciences deal structures.

First, the statement in IFRS 10.B45 that an investor, when assessing the existing rights, should also assess historical information about the attendance at recent shareholders’ meetings should be removed from the standard, as this statement, instead of clarifying the
guidance, only poses new questions for financial statement preparers, as illustrated in section 5.2.2.1. It can be expected that, similar to many other accounting questions, financial statement preparers and auditors will also consider historical fact patterns without this being explicitly mentioned in the standard. However, explicitly mentioning in the standard that the historical fact pattern should be considered in the assessment leads to the historical fact pattern being given more attention and relevance than warranted because there can always be good reasons as to why what happened in the past is likely not going to continue in the future and it is important to weigh such reasons more than the historical fact pattern.

Second, when assessing potential voting rights, it would be helpful if IFRS 10 provided some practical guidance as to when an option should be considered in-the-money or out-of-the-money, at least stating whether the assessment should be made only as of a particular date or whether it should be made over a period of time. This is especially relevant for highly-volatile shares that may shift from being in-the-money to being out-of-the-money on a daily basis.

Third, IFRS 10 is silent as to whether the concept of a control premium should be considered in the assessment of whether an option is in-the-money. As the practical example of Novartis’ option to acquire Alcon (refer to section 5.3) has shown, whether or not a control premium is considered in the assessment of whether an option is in-the-money can have a significant impact on the control assessment because for options with an exercise price above the market price, such options may still be considered in-the-money when a control premium is considered, but considered out-of-the-money when a control premium is not considered. Without IFRS 10 at least acknowledging the concept of a control premium, there will be significant diversity in practice.

Fourth, as the practical example of Novartis’ option to acquire Alcon (refer to section 5.3) has shown, assessing whether an investor will benefit from exercising the option for

345 For example, when accounting for accruals (e.g., bonus accruals), financial statement preparers would generally also include in their assessment their knowledge of how accurate accrual estimates have been in the past. In other words, if a company has historically always been underaccrued, it would try to understand the reason to be able to come up with a more precise accrual estimate for the current period.
other reasons is a very subjective assessment. The IASB, with this guidance, implicitly provided companies with an option when assessing whether options are substantive because for both financial statement readers and auditors, it will be difficult to prove management wrong in its assessment that the company will profit from the exercise of an option for other reasons. Or the other way around, if management states that it does not think that it will benefit from the exercise of an option, it will also be difficult to challenge this position. Since with IFRS 12 Disclosure of Interests in Other Entities an entity is required to disclose the significant judgments and assumptions it has made in determining whether it has control (or does not have control), it will be interesting to see to what extent management will disclose its rationale for these type of assessments, which are based on future strategic plans and expected synergies, information that historically has not been shared outside of a circle of board members and executive management.

Last, but certainly not least, IFRS 10 only addresses options to acquire voting rights (potential voting rights) and not options to acquire assets, even if such assets represent a business. Although from a business development perspective, life sciences companies are usually indifferent to whether they hold an option to acquire the majority of the voting rights of an investee or whether they hold an option to acquire substantially all of the assets of an investee, from an accounting perspective, these two deals are treated completely different, since the first one is in the scope of IFRS 10, whereas the second one is not (although economically, the two are the same deal structure). This is the most significant postulation resulting from this IFRS 10 control analysis as part of this thesis, that IFRS 10 should not only address options to acquire voting rights, but also address options to acquire assets and a group of assets that constitutes a business.
6 Case study: Comparing the financial statement implications of the different deal structure types

The objective of this case study is to map out the different income statement volatility considerations for each of the different types of deal structures. For life sciences executives, there is an increasing complexity to understanding the financial statement implications of deal structures. As such, the author has developed a model in which, from a business development net present value perspective – assuming all parties have the same level of information – each deal structure is identical. As the analysis will show, although identical from a net present value perspective, there are significant differences in how these deal structures have to be accounted for under IFRS. Some structures have the expense recognition more front-loaded, others have the expense recognition more back-loaded, and still others have the expense recognition distributed fairly equally over time.

After defining some overall assumptions that are needed to ensure comparability between the different deal structures, the net income / loss development will be graphically illustrated over a period of 15 years. In the final section of this chapter 6, the net income / loss graphs of the different deal structures are presented in one comparative illustration.

6.1 Summary of the base case scenario and assumptions / valuation of the subject assets

The valuation of the subject assets that are subject to this hypothetical deal structure has been built on the following assumptions:

- Decision by the regulatory authorities about product approval at the end of 2019.
- Commercialization period of 10 years (starting in 2020), with peak sales in 2024 and with cost of sales at 10% of sales and SG&A expenses at 25% of sales.
- Discount rate of 20% to reflect the high risk in the five years of development and the risks in connection with the potential commercialization (market risks, uncertainties about potential products developed by competitors for the same indication, etc.).
- Discount factor is based on the mid-year convention (which is commonly used in valuation practice and generally known to provide more accurate valuation results because it is based on the assumption that not all cash is flowing to the entity at the end of a period, but equally throughout the period).

Based on these assumptions, the result is a discounted cash flow fair value of CU 351. Refer to Appendix A for the actual valuation of the subject assets.

In the following sections 6.2 through 6.5, the author will model different deal structures to match from a net present value perspective the value of CU 351 (for a 100% acquisition) or the value of CU 105 (for a 30% acquisition). This is based on the fact that assuming perfect symmetry of information, these are the maximum amounts that an acquirer can be expected to be willing to pay for a 100% or a 30% ownership.

Modeling the different deal structures so that they are identical from a net present value perspective is important to allow for comparability and a statement that, from a business development perspective, an acquirer can be expected to be indifferent in terms of which deal structure to choose.

6.2 Acquisition of individual assets / rights to individual assets that do not constitute a business

6.2.1 Key accounting considerations for the life sciences industry

As discussed in chapter 4, the key consideration when acquiring individual compounds, technologies, or rights (licenses) to such compounds / technologies is whether what is being acquired meets the definition of a business. As sections 4 and 5 have shown, for many deal structures the determination of what transaction qualifies as a business combination is very subjective, and diversity in practice exists. In this section, the author
will focus on the key income statement considerations for transactions that do not qualify as a business combination; in section 6.5, the author will cover the income statement considerations of transactions that do qualify as a business combination; and in section 6.6 the author will provide an illustrative comparison of the two deal structures to compare and understand the differences.

### 6.2.1.1 Up-front payments and development milestones

Under IFRS, the price an entity pays to separately acquire an intangible asset is a direct reflection of its expectations about the probability that the expected future economic benefits from the asset will flow to the entity. As such, the probability recognition criterion is always considered to be satisfied for separately-acquired intangibles. Applying this guidance to life sciences arrangements that involve up-front payments, an investor should capitalize as an intangible asset such up-front payment and amortize the intangible asset from the date it is available for use. Once the asset is available for use, the respective amortization expense should be recorded as cost of sales.

**Novartis’ accounting policy disclosures for up-front and milestone payments made:**

In its 2012 annual report, IFRS-filer Novartis makes transparent disclosures that IPR&D assets capitalized also include up-front and milestone payments on licensed and acquired compounds, that once a project included in IPR&D has been successfully developed it is transferred to the “Currently marketed product” category, and that the amortization expense of currently marketed products is recorded as cost of sales.

*Example 15: Accounting policy disclosure for up-front and milestone payments capitalized as IPR&D*

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346 IAS 38.25.
347 Achleitner/Behr/Schäfer (2009), p. 98.
348 Based on the guidance in IAS 38.8. In the life sciences context intangible assets related to IPR&D are generally deemed to be “available for use” when regulatory approval is obtained. Prior to being available for use, the intangible asset should be tested for impairment at least once annually (IAS 36.10 (a)).
With respect to any subsequent development milestone payments, an investor needs to assess whether such payments are to fund research or to acquire an asset. Since under most life sciences collaboration arrangements, the investor (e.g., big pharma) would not obtain full rights to the license until it has made all milestone payments, one view in practice is that such milestone payments should be considered to be part of the cost to acquire the IPR&D assets (and should, thus, be capitalized). However, if in the collaboration agreement the wording around milestone payments is more focused on the funding of small biotech’s ongoing research activities, the conclusion from an accounting perspective may be that the payments do not relate to the acquisition of an asset, but are to fund the ongoing research activities of the biotech.\textsuperscript{351} Thus, because an investor (e.g., big pharma) at the stage of entering into a license agreement that involves the payment of development milestone payments may still be in a position to influence the wording in the agreement related to such milestone payments, such investor implicitly may also still have a choice in terms of how to account for such milestone payments. If the language in the agreement related to such milestone payments explicitly states that such payments are for the funding of research, they would likely need to be expensed as R&D expenses, whereas if the language in the agreement states that these payments are to acquire an asset, the payment would likely have to be capitalized. However, the wording in an agreement may not only impact whether a payment is being expensed or capitalized, but it also impacts where in the income statement the respective charges are being classified, since the immediate expense of a payment that reflects R&D funding would be expensed as R&D, whereas – as mentioned in the previous paragraph – the amortization of a capitalized intangible would be recorded as cost of sales.

The following accounting policy disclosure example (Example 16) from the annual report of the German Merck (Merck KGaA) for the 12-month period ending December 31, 2012 further illustrates this fine line when distinguishing between milestone payments being capitalized and milestone payments being expensed.

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Merck KGaA accounting policy for collaboration upfront or milestone payments:

“In addition to our own research and development, Merck is also a partner in collaborations aimed at developing marketable products. These collaborations typically involve payments for the achievement of certain milestones. Here, assessments are made as to whether these upfront or milestone payments represent compensation for services performed (research and development expense) or whether the payments represent the acquisition of an asset that has to be capitalized. Reimbursements for R & D are offset against research and development costs.”

Example 16: Accounting policy disclosure example for collaboration upfront and milestone payments

With respect to timing of when subsequent development milestone payments should be accounted for, the IFRIC is currently discussing whether such contingent payments should be accounted for at the inception of the asset acquisition (similar to the accounting of a business combination) or when such payments become probable (general liability accounting guidance in IAS 37). In practice, life sciences companies seem to account for such payments based on the general liability accounting guidance in IAS 37 as the following exemplary disclosure of Bayer in its 212 annual report (Example 17) shows.

Bayer’s disclosure of commitments in connection with collaboration arrangements:

“The Bayer Group has entered into cooperation agreements with third parties under which it has agreed to fund various research and development projects or has assumed other payment obligations based on the achievement of certain milestones or other specific conditions. If all of these payments have to be made, their maturity distribution as of December 31, 2012 was expected to be as set forth in the following table. The amounts shown represent the maximum payments to be made, and it is unlikely that they will all fall due. Since the achievement of the conditions for

353 Refer to section 4.2.5 for details on this discussion.
payment is highly uncertain, both the amounts and the dates of the actual payments may vary considerably from those stated in the table.”

<table>
<thead>
<tr>
<th></th>
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<tr>
<td></td>
<td>€ million</td>
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<tr>
<td>2012</td>
<td>314</td>
<td>238</td>
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<td>2013</td>
<td>101</td>
<td>93</td>
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<td>2014</td>
<td>135</td>
<td>186</td>
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<td>2015</td>
<td>135</td>
<td>101</td>
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<tr>
<td>2016</td>
<td>83</td>
<td>74</td>
</tr>
<tr>
<td>2017 or later</td>
<td>574</td>
<td>1,106</td>
</tr>
<tr>
<td>Total</td>
<td>1,542</td>
<td>1,798</td>
</tr>
</tbody>
</table>

Figure 17: Bayer’s disclosures of commitments in connection with collaboration arrangements

“Should the achievement of the milestones or specific conditions become sufficiently probable, a provision or other liability is recognized in the statement of financial position, and this may also lead to the recognition of an intangible asset in the same amount. The above table includes neither current revenue based royalty payments nor future payments that are probable and therefore already reflected in the statement of financial position.”

Example 17: Disclosure example of commitments in connection with collaboration arrangements

6.2.1.2 Sales target milestones and royalty payments

When determining the proper accounting for sales target milestones and royalty payments in connection with asset acquisitions, there is no explicit guidance in IFRS.

Addressing this question specifically for asset acquisitions in the life sciences industry, PricewaterhouseCoopers (2012a) is of the view that in such scenarios, companies should distinguish between the following two types of deals:

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a) Deals that only have sales target milestones with no separate royalty payments or royalty payments that are not at fair value.

b) Deals that have sales target milestones and separate royalty payments that are at fair value.

If the arrangement only provides for sales target milestones with no separate royalty payments or royalty payments that are at a rate below fair value, the sales target milestones are implicitly viewed as in substance royalty payments and, thus, should also be accounted for as such (expensed). 357 Whereas if the arrangement encompasses both sales target milestones and royalty payments at fair value, the sales target milestones are viewed as consideration for the development services provided by the partnering company, in which case the sales target milestones are accounted for as an increase in the product rights intangible asset. 358 In addition to the question of what such payments represent (whether in substance royalty payments or whether in substance consideration for the acquisition of an asset), the question remains as to when such payments need to be accounted for (at the time of the acquisition, over time from the date of acquisition to the date such payments have to be made or only when such payments become probable). 359

6.2.1.3 Amortization and impairments

For all up-front, development milestone, and sales target milestone payments capitalized as an intangible asset, a company has to determine whether these assets are definite-lived intangibles or indefinite-lived intangibles. In the life sciences industry, any up-front or milestone payments capitalized that relate to the acquisition of product rights or IP of a

358 It should be noted, though, that PricewaterhouseCoopers when articulating this view also noted that this view is predicated on current life sciences industry practice at the date of the publication (July 2012) and that this topic is currently being considered and discussed by the IFRS Interpretations Committee and could be effected by any additional guidance or amendments issued from the IFRS Interpretations Committee project. PricewaterhouseCoopers (2012a), p. 64-65. The IFRS Interpretations Committee project referred to by PricewaterhouseCoopers is the project “Variable payments for the separate acquisition of PPE and intangible assets.” Refer to section 4.2.5 of this thesis for details on this IFRIC project.
359 This is in reference to the current IFRIC discussions on when to account for contingent considerations in connection with asset acquisitions. Refer to section 4.2.5 of this thesis for details on this IFRIC project.
product candidate that has not yet obtained regulatory approval are generally accounted for as IPR&D intangible assets (indefinite-lived intangible assets). Thus, an asset that is accounted for as an IPR&D asset and for which later regulatory approval is obtained shall then be considered “available for use,” which means the asset changes from being an indefinite-lived intangible asset to being a definite-lived intangible, and a company shall begin amortizing such asset.

IFRS does not provide explicit guidance as to where in the income statement the amortization expense of intangible assets should be classified. For those IFRS filers that are registered with the SEC, a view communicated by the SEC in SAB Topic 11.B and various SEC comment letters may be relevant, which is that the amortization of intangible assets should be included in cost of goods sold. Also, PricewaterhouseCoopers (2012a) notes that in life sciences practice, the amortization of capitalized intangibles relating to a marketed product is generally recorded as cost of goods sold if the income statement is presented by function or as amortization expense if presenting the income statement by nature of expense.

With respect to the amortization period start date and the amortization method used, IAS 38.97 states that amortization shall begin when the asset is available for use (which for the life sciences industry generally is when the drug has obtained regulatory approval) and that “the amortization method used shall reflect the pattern in which the asset’s future economic benefits are expected to be consumed.” In the life sciences industry, based on the fact that a drug generates approximately 90% of its total cash inflows during the period of patent protection, the period of patent protection is generally used as the amortization period. Although for most pharmaceutical products the pattern in which

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361 However, care should be taken if the payments indeed relate to a product candidate to be marketed at a later point in time because in some deals life sciences companies are acquiring a technology from another company to use for its own development efforts and in those cases the technology or IP will generally be available for use already upon acquisition. Interview with Jennifer Lenahan, Associate Director Collaborations Finance, Astellas US LLC.
362 Refer to Jesswein (2011), p. 3.
364 IAS 38.97.
365 That is because amortizing an asset over its entire lifetime would result in amortization expense still being recorded in years after patent protection when the sales are immaterial to the overall sales volume.
the asset’s benefits are consumed is best reflected by the product’s sales curve over the period of patent protection, in practice, most life sciences companies use a straight-line amortization because the difference in annual amortization is generally not significantly different. The amortization period and the amortization method for a definite-lived intangible asset shall be reviewed at least once annually at each financial year end.

With respect to any potential impairments of the intangible assets capitalized, companies have to distinguish between indefinite-lived intangibles and definite-lived intangibles. Indefinite-lived intangibles shall be tested for impairment at least once annually or whenever there are indicators of impairment. For definite-lived intangibles, a company shall assess at the end of each reporting period whether there are any indicators of impairment and, if yes, shall test that asset for impairment. PricewaterhouseCoopers (2012a) provides some exemplary life sciences impairment indicators:

- development of a competing drug;
- changes in the legal framework covering patents, rights or licenses;
- failure of the drug’s efficacy after a mutation in the disease that it is supposed to treat;
- advances in medicine and/or technology that affect the medical treatments;
- lower than predicted sales;
- impact of publicity over brand names;
- change in the economic lives of similar assets;
- litigation;
- relationship with other intangible or tangible assets;
- changes or anticipated changes in participation rates or reimbursement policies of insurance companies; and
- Medicare and governments for drugs and other medical products.

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366 Interview with Jennifer Lenahan, Associate Director Collaborations Finance, Astellas US LLC, and based on the author’s professional experience auditing companies in the life sciences industry.
367 IAS 38.104.
368 IAS 36.10(a).
369 IAS 36.9.
370 PricewaterhouseCoopers (2012a), p. 13. IAS 36.12 also provides a list of general, non-industry specific impairment indicators.
When performing an impairment test, an asset is considered impaired if its carrying value or book value exceeds its recoverable amount, which is defined as the higher of the asset’s fair value less costs of disposal and its value in use. From an investor and capital market communication perspective, recording an impairment of an acquired asset constitutes a public admission by the firm’s management of having substantially overpaid for the acquired assets. As mentioned in section 4.2.2, one of the most significant differences between IFRS and US GAAP is in the accounting for up-front and milestone payments prior to regulatory approval being obtained because under US GAAP, such payments generally cannot be capitalized, but need to be immediately expensed. This difference between IFRS and US GAAP is interesting to analyze from a capital markets communication perspective because under US GAAP, such amounts are being expensed at the time of the acquisitions with a message to the capital markets that a very valuable asset has been acquired. Then if the acquired R&D project should be discontinued at a later point in time, under US GAAP, there is no impairment to be recorded (because the amounts have already been fully expensed as of the acquisition date), which means from a net income perspective, a company in the year of discontinuation is also not drawing the capital markets’ attention to the discontinuation, whereas under IFRS, a discontinuation will result in an impairment of the respective intangible assets, which is generally drawing significant capital market attention due to a significant expense recorded in the income statement. Thus, a company inclined to do so, from a capital markets communication perspective, could more easily disguise the discontinuation of an R&D project under US GAAP than under IFRS.

6.2.1.4 Transaction-related costs

Transaction-related costs incurred in connection with an asset acquisition are generally considered a component of the consideration transferred to acquire the assets or group of assets and, as such, are capitalized as a component of the cost of the assets in accordance

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371 IAS 36.8, IAS 36.6.
with the applicable standards (e.g., IAS 16 for property, plant and equipment, and IAS 38 for intangible assets).\footnote{PricewaterhouseCoopers (2011a), p. C-7.}

6.2.2 Modeling the deal payment structure to match the value of the subject assets

As mentioned in section 3.6.1, asset acquisitions (acquisition of the underlying assets or a license) generally involve up-front payments, milestone payments and royalty payments. Based on the valuation of the subject assets of CU 351, the payment structure of the asset acquisition has been modeled to reflect the CU 351 from a net present value perspective.

- Up-front payment of CU 80 and transaction-related costs of CU 20, which are both paid in 2014 when the deal is entered into.
- Regulatory approval milestone of CU 500 in 2019 if regulatory approval is obtained, which based on the specific deal terms should be considered a payment to acquire the assets rather than a payment to fund research.
- Sales target milestone of CU 150 in 2025 when annual sales reach CU 1,000 (if regulatory approval is obtained).
- Royalty payments at 4% of sales during the commercialization period (2020 through 2029). The 4% royalty rate is assumed to reflect the current fair value of royalties for similar products.
- Discount rate of 20% to reflect the high risk in the five years of development and the risks in connection with the potential commercialization (resulting in the regulatory approval milestone, the sales target milestone and the commercialization royalty payments potentially not becoming payable).
- Discount factor is not based on the mid-year convention since milestone payments and royalty payments can be expected to be payable at the end of the year rather than in the middle of the year.
Based on these assumptions, the net present value of all payments is CU 351, which matches the value of the subject assets. Refer to Appendix B for the full valuation.

6.2.3 Graphical illustration of the income statement volatility based on a positive scenario

In this section the author illustrates the net income / net loss development based on a positive scenario (successful development and commercialization) assuming that what is being acquired does not meet the definition of a business, resulting in the transaction being accounted for as an asset acquisition. This development is illustrated in Figure 18.

![Figure 18: Income statement volatility asset acquisition – positive scenario](image)

The net income / net loss development over the period of 15 years when accounting for the deal as an asset acquisition can be described as follows:

The CU 80 up-front payment, as well as the CU 20 transaction-related costs, which are both paid in 2014 when the deal is entered into, are being capitalized as one indefinite-

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374 Author’s own compilation. Refer to Appendix B for the underlying model.
lived intangible (IPR&D asset). This asset changes to a definite-lived intangible at the end of 2019, when regulatory approval is obtained. Subsequently, the asset is being amortized over the period of commercialization.

The CU 500 regulatory approval milestone and the CU 150 sales target milestone are accounted for as an increase in the product rights intangible asset at the time such milestones are payable because the asset acquisition also encompasses royalty payments that are at fair value. Because at the time that such payments are made regulatory approval has been obtained, these assets would be considered definite-lived intangibles and start to be amortized over the period of commercialization.

With respect to the royalty payments at a rate of 4% of sales, since the 4% royalty rate is considered to be at fair value, the royalty payments are accounted for as cost of sales in the same period as the corresponding sales.

Since the investor assumes full responsibility for the further development and subsequent commercialization, the investor also incurs the R&D expenses during the five years of development (from 2015 to 2019), as well as the product cost of sales of 10% and the SG&A expenses of 25% during the commercialization period.

6.2.4 Graphical illustration of the income statement volatility based on a negative scenario

In this section the author illustrates the net income / net loss development based on a negative scenario (unsuccessful development evidenced by the regulatory authorities not approving the product in 2019 and assuming no alternative future use of the IPR&D) assuming that what is being acquired does not meet the definition of a business, resulting in

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375 It should be noted that this accounting is based on the accounting for milestone payments in connection with asset acquisition that is believed to be the most common way of how companies account for such payments in life sciences practice. At the time of publication of this thesis there is no explicit guidance how to account for such payments in connection with asset acquisitions. Refer to section 4.2.5 for a discussion of different views on how such milestones could be accounted for under IFRS.

376 Refer to footnote 375.
in the transaction being accounted for as an asset acquisition. This development is illustrated in Figure 19.

![Figure 19: Income statement volatility asset acquisition – negative scenario](image)

The net income / net loss development over the period of 15 years when accounting for the deal as an asset acquisition can be described as follows:

Since the investor assumes full responsibility for the further development, the investor also incurs the R&D expenses during the five years of development (from 2015 to 2019).

With respect to the CU 80 up-front payment, as well as the CU 20 transaction-related costs, which are both capitalized in 2014 when the deal is entered into, these CU 100 have to be fully impaired in 2019 at the time the regulatory authorities have decided to not approve the product.

Once both the R&D expenses for the period from 2015 to 2019, as well as the CU 100 impairment have been recorded, there are no other expenses or income to be recorded.

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377 Author’s own compilation. Refer to Appendix B for the underlying model.
6.3 Joint ventures and significant influence equity investments

As discussed in section 3.3.2, for equity investments with less than a majority of voting rights but with significant influence, the financial terms of the deal define the share of equity ownership being acquired and the price for that share of equity. The distribution of profits or losses is then based on the equity ownership (i.e., if an investor owns 30% of a company, it entitles the investor to receive 30% of the profits generated by the investee).

This section will focus on the key income statement considerations for joint ventures and significant influence investments that are accounted for using the equity method.

6.3.1 Key accounting considerations for the life sciences industry

6.3.1.1 Equity-method accounting

Arrangements that meet the definition of a joint venture, as defined in IFRS 11,\(^{378}\) as well as equity investments where the investor exercises significant influence,\(^ {379}\) are accounted for based on the equity method in accordance with IAS 28.

Equity method is a method of accounting whereby the investment is initially recognized at cost and adjusted thereafter for the post-acquisition change in the investor’s share of net assets of the investee, meaning the profit or loss of the investor includes its share of the profit or loss of the investee, and the other comprehensive income of the investor includes its share of other comprehensive income of the investee.\(^ {380}\) To the extent that the investor receives cash dividends from the investee, these cash dividends are accounted for as a reduction of the investment in the investee, meaning the investor does not record such dividend receipts as income.\(^ {381}\)

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\(^{378}\) Refer to section 5.1.4 for details of when a deal structure is considered a joint venture as defined in IFRS 11.

\(^{379}\) Refer to section 3.3 for details on when an investor is generally considered to exercise “significant influence.”

\(^{380}\) IAS 28.IN7

If the purchase price paid for the investment is greater than the pro rata portion of the net fair value of the investee’s identifiable assets and liabilities, the investor has to calculate an implied goodwill that results from the investment. Calculating and keeping records of the investor’s share of the fair value of the investee's identifiable assets and liabilities is important to be able to record, for example, depreciation and amortization for assets.

6.3.1.2 Impairment of the investment

In addition to any changes in the value of the investment from applying the equity method, the investment value may also change as a result of an impairment of the investment.

To determine if there are indicators that the investment may be impaired, an investor shall look to IAS 39 Financial Instruments: Recognition and Measurement. If it is determined that there are indicators of impairment, the entire carrying amount of the investment is tested for impairment in accordance with IAS 36 as a single asset, by comparing its recoverable amount (higher of value in use and fair value less costs to sell) with its carrying amount. Impairment losses recorded for the investment shall be reversed to the extent that the recoverable amount of the investment subsequently recovers. Any increases in the fair value of an equity method investment above its carrying amount may not be recorded unless the investment is sold at that higher fair value, in which case the difference between the carrying amount of the investment and its fair value is recorded as a gain in the investor’s income statement at the time of sale.

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382 This goodwill is referred to as “implied goodwill” because it is not separately presented on the balance sheet of the investor as “goodwill” but included as part of the cost of the investment. Hunt (2011), p. 190; IAS 28.32.

383 This is because for some assets as part of the acquisition of the investment there may be a fair value step up and the depreciation or amortization recorded by the investor needs to reflect those higher fair values and cannot be based on the depreciation and amortization recorded by the investee in its books because that depreciation and amortization is based on the value of the assets prior to the fair value step-up.

384 In other words, any “implied goodwill” included in the carrying amount of the investment is not tested for impairment separately by applying the requirements for goodwill impairment testing in IAS 36. IAS 28.42.

385 IAS 28.42.
6.3.1.3 Transaction-related costs

Although no explicit guidance exists in IAS 28 regarding the accounting for transaction-related costs incurred in connection with the acquisition of an equity method investment, this question was specifically addressed to the IFRIC for clarification. At its July 2009 meeting, the IFRIC noted that IFRSs consistently require assets not measured at fair value through profit or loss to be measured at initial recognition at cost and that cost would generally include the purchase price, as well as other costs directly attributable to the acquisition of the asset, such as professional fees for legal services, transfer taxes, and other transaction costs. As such, transaction-related costs incurred in connection with the acquisition of an equity method investment are generally capitalized as part of the cost of the investment.

6.3.2 Modeling the deal payment structure to match the value of the subject assets

For purposes of this case study, the deal structure of a joint venture or equity investment with less than a majority of voting rights is assuming a 30% ownership of the investee that is accounted for using the equity method.

Based on the valuation of the subject assets of CU 351, the payment structure of the joint venture or significant influence equity investment has been modeled to reflect CU 105 from a net present value perspective, which adequately represents 30% of the total value of the subject assets of CU 351 (to ensure comparability with the other deal structures).

- Cost of the 30% equity investment of CU 100 and CU 5 of transaction-related costs, which are both paid in 2014 when the deal is entered into.
- Discount rate of 20% to reflect the high risk in the five years of development and the risks in connection with the potential commercialization.
- Discount factor is based on the mid-year convention (because cash / net income can be expected to flow to the entity equally throughout the period).
There is no distribution of cash dividends from the investee to the investor over the 15 year term. The investee does not engage in any activities that would result in any other comprehensive income. For simplification it should be assumed that the investee’s only asset is the IP related to the ongoing R&D.

Based on these assumptions, the net present value of all payments made by the investor to acquire a 30% ownership is CU 105, which from a net present value perspective is equivalent to 30% of the value of the subject assets (CU 351 x 30% = CU 105). Refer to Appendix C for the full valuation.

6.3.3 Graphical illustration of the income statement volatility based on a positive scenario

In this section the author illustrates the net income / net loss development of the 30% joint venture or significant influence equity investment accounted for using the equity method based on a positive scenario (successful development and commercialization). This development is illustrated in Figure 20.
The net income/net loss development over the period of 15 years when accounting for the deal as a 30% joint venture or equity method investment can be described as follows:

The CU 100 price to acquire the 30% investment, as well as the CU 5 transaction-related costs (which are both paid in 2014 when the deal is entered into) are being capitalized as part of the cost of the investment.

Subsequent to the capitalization of the investment, the investor records its share of the profit or loss of the investee, which means 30% of the net results from operations. In the first five years, while the investee still engages in the development, the investor records its 30% share of the R&D expenses incurred. Then, once commercialization has started and the investee operates at a profit, the investor records its 30% share of the net income generated by the investee.

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386 Author’s own compilation. Refer to Appendix C for the underlying model.
6.3.4 Graphical illustration of the income statement volatility based on a negative scenario

In this section the author illustrates the net income / net loss development of the 30% joint venture or significant influence equity investment accounted for using the equity method based on a negative scenario (unsuccessful development evidenced by the regulatory authorities not approving the product in 2019 and assuming no alternative future use of the IPR&D). This development is illustrated in Figure 21.

![Figure 21: Income statement volatility accounting for the transaction as a 30% joint venture or equity method investment – negative scenario](image)

The net income / net loss development over the period of 15 years when accounting for the deal as a 30% joint venture or equity method investment can be described as follows:

The CU 100 price to acquire the 30% investment, as well as the CU 5 transaction-related costs, which are both paid in 2014 when the deal is entered into, are being capitalized as part of the cost of the investment.

Subsequent to the capitalization of the investment, the investor records its share of the profit or loss of the investee in the period from 2015 to 2019, which means 30% of the

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387 Author’s own compilation. Refer to Appendix C for the underlying model.
R&D expenses incurred, with a corresponding reduction in the value of the investment. Then, at the end of 2019, when the regulatory authorities decide not to approve the product and when it is determined that there is no alternative future use for the developed IP, the investor records a full impairment on the value of the investment (since the only asset underlying the value of the investment was the value of the IPR&D). However, because the proportionate share of the R&D expenses in the period from 2015 to 2019 reduced the investment by CU 85 (30% of the total R&D expenses of CU 285), at the time of the impairment the net book value of the investment is only CU 20 and, therefore, the impairment is also only CU 20.

6.4 Acquisition of a call option

6.4.1 Key accounting considerations for the life sciences industry

6.4.1.1 Accounting for options prior to the exercise of the option

Although the accounting for M&A call options is, to a large extent, driven by what is being acquired, the common denominator of all call options is that a call option meets the definition of an asset, which means it should be recorded as such on the balance sheet. With respect to the recognition and measurement, three different types of options that are generally used in life sciences M&A transactions should be distinguished as:

1) options to acquire shares of another legal entity that is a public entity,
2) options to acquire shares of another legal entity that is a private entity, and
3) options to acquire assets of another entity (e.g., R&D projects or a license).

The first question that needs to be addressed is whether the option is a financial asset as defined in IAS 32.11. IAS 32.11 defines a financial asset as follows:
The first two option types (as listed above) – options to acquire shares of a public entity and options to acquire shares of a private company – would meet the definition of a financial asset because such options represent a contractual right to receive another financial asset (i.e., equity instruments of another entity). Conversely, the third type of options (options to acquire assets) would only qualify as financial assets if the assets that are being acquired are financial assets (e.g., cash, accounts receivable, etc.). While this guidance seems clear for options to acquire individual assets, the assessment is more difficult when the option is to acquire a group of assets (which may even constitute a business). This is because such a group of assets will likely include both financial and non-financial items and then the question is where investors would draw the line between concluding that such options do or do not meet the definition of a financial asset.

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388 Based on the definition of a financial asset in IAS 32.11.
389 Based on the definition of a financial asset in IAS 32.11.

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**IAS 32.11:** A financial asset is any asset that is:

(a) cash;

(b) an equity instrument of another entity;

(c) a contractual right:
   (i) to receive cash or another financial asset from another entity; or
   (ii) to exchange financial assets or financial liabilities with another entity under conditions that are potentially favourable to the entity; or

(d) a contract that will or may be settled in the entity's own equity instruments and is:
   (i) a non-derivative for which the entity is or may be obliged to receive a variable number of the entity's own equity instruments; or
   (ii) a derivative that will or may be settled other than by the exchange of a fixed amount of cash or another financial asset for a fixed number of the entity's own equity instruments. For this purpose the entity's own equity instruments do not include puttable financial instruments classified as equity instruments in accordance with paragraphs 16A and 16B, instruments that impose on the entity an obligation to deliver to another party a pro rata share of the net assets of the entity only on liquidation and are classified as equity instruments in accordance with paragraphs 16C and 16D, or instruments that are contracts for the future receipt or delivery of the entity's own equity instruments.
IFRS does not provide any guidance as to when such options to acquire a group of assets that has both financial and non-financial assets should be considered a financial asset.\textsuperscript{390} This means each investor has to define for himself what ratio of financial to non-financial items of a group of acquired assets would result in the option being considered a financial asset versus the option not being considered a financial asset.

In the following section, the accounting for options that are considered financial assets and the accounting for options that are not considered a financial asset will be presented.

6.4.1.1.1 Call options that meet the definition of a financial asset

For call options that meet the definition of a financial asset, the accounting under IFRS depends on whether such options meet the definition of a derivative. IAS 39.9 provides the following definition of a derivative.

\textbf{IAS 39.9:} A derivative is a financial instrument or other contract within the scope of this Standard with all three of the following characteristics:

\begin{itemize}
\item[(a)] its value changes in response to the change in a specified interest rate, financial instrument price, commodity price, foreign exchange rate, index of prices or rates, credit rating or credit index, or other variable, provided in the case of a non-financial variable that the variable is not specific to a party to the contract (sometimes called the 'underlying');
\item[(b)] it requires no initial net investment or an initial net investment that is smaller than would be required for other types of contracts that would be expected to have a similar response to changes in market factors; and
\item[(c)] it is settled at a future date.
\end{itemize}

As noted in IAS 39.9, the IFRS definition of a derivative does not require a financial instrument to be “net settleable,” but only “settleable.”\textsuperscript{391} IFRS is explicit that for an option, the criterion of “settled at a future date” is always considered to be met because such options are considered to be settled at the latest at their maturity, even if an option is

\textsuperscript{390} Böckem/Geier (2012), p. 495.
\textsuperscript{391} This is different from the derivative guidance under US GAAP, which requires net settlement (ASC 815-10-15-99); a difference between the two standards that becomes most relevant for options to acquire shares of a private company since those options would not be considered net settleable but only settleable.
unlikely to be exercised because it is out of the money.\textsuperscript{392} Also, with respect to the second characteristic, “an initial net investment that is smaller than would be required for other types of contracts that would be expected to have a similar response to changes in market factors,” an option contract would meet this criterion because the premium is less than the investment that would be required to obtain the underlying financial instrument to which the option is linked.\textsuperscript{393}

The first characteristic of a derivative, that its value changes in response to a change in a variable, provided that in the case of a non-financial variable, the variable is not specific to a party to the contract, in the life sciences industry is generally the most difficult to assess when determining whether options to acquire shares of another entity meet the definition of a derivative. That is because option deals in the life sciences industry are often structured with the exercisability of the options being dependent on whether a key clinical trial milestone is reached (e.g., the initiation of a Phase III clinical study), in which case the value of the option would change in response to the R&D results, with the R&D results being a non-financial variable that is specific to one party to the contract (generally the investee).

It should be noted though that the guidance in IFRS is not clear whether the reference to non-financial variables specific to one party of the contract means that all instruments with such an underlying would fail to meet the definition of a derivative or only those contracts that are insurance contracts.\textsuperscript{394} Although the IASB initially confirmed that it had intended the exclusion to apply only to contracts that are within the scope of IFRS 4, it became apparent that this would result in a significant change to current practice with many contracts, including contracts in the life sciences industry with payments being based on the success rate of a drug, being brought into the scope of IAS 39 and accounted for at fair value, which would not seem appropriate because, in effect, such entities would then be measuring these options at a fair value that is linked to the entity’s own business

\textsuperscript{393} IAS 39.AB11; IFRS 9.BA.3.
\textsuperscript{394} Ernst & Young (2013c), p. 2994.
risk or future profit streams. The IASB took notice of this concern raised by financial statement preparers and confirmed that for the interim, the exclusion would not only apply to contracts that are within the scope of IFRS 4, and stated it will consider addressing the issue in a future project.

Thus, in summary, unless the IASB would amend the definition of a derivative in IAS 39, for life sciences call options whose value changes in response to a non-financial variable specific to one of the parties of the contract (e.g., R&D results), the current practice continues to be that such call options do not meet the definition of a derivative and, as such, also do not need to be fair valued at each reporting date. Whereas, if the option deal was structured differently with the exercisability dependent on the share price reaching a certain threshold rather than on R&D results being achieved, such options, because the underlying variable is a financial variable (the share price), would generally meet the definition of a derivative and be measured at fair value at each reporting date.

In the view of the author, what is interesting about this distinction in the guidance is that option deals where the exercisability is dependent on R&D results, in substance and from a business development perspective, are often not that different from option deals where the exercisability is dependent on the share price reaching a certain threshold. That is, especially for small biotech companies, R&D results can significantly impact the company’s share price with positive R&D results, resulting in a significant increase in the share price, and negative R&D results, resulting in a significant decrease in the share price. In other words, a business development executive may be indifferent in terms of whether he/she structures an option deal with the exercisability being linked to the share price reaching a certain threshold or a major R&D milestone being achieved. However, the accounting for those two option types is significantly different with the first option type being measured at fair value and the second option type not being measured at fair value.

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395 Ernst & Young (2013c), p. 2994-2995.
As mentioned in section 3.4, the use of options-based M&A has become increasingly popular in the life sciences industry and, especially if there are two types of option deals that a business development executive may be indifferent about, it is important to involve the accounting/finance function within a company early on in the process to determine if structuring a deal in a certain way may be favorable from an accounting perspective.

Option contracts that are within the scope of IAS 39 (IFRS 9) are recognized as assets or liabilities when the holder or writer becomes a party to the contract. The initial measurement depends on whether the option meets the definition of a derivative. Although all options that qualify as financial assets are initially measured at fair value, for options that do not meet the definition of a derivative, transaction costs that are directly attributable to the acquisition of the option are also included as part of the initial measurement.

Also, the subsequent measurement of options in the scope of IAS 39 depends on whether the option meets the definition of a derivative. Options that meet the definition of a derivative are subsequently measured at fair value through profit or loss, except for those options to acquire shares of a private company whose fair value cannot be reliably measured, which shall be measured at cost. For options that are in the scope of IAS 39 (IFRS 9), but do not qualify as a derivative, there is no explicit guidance in IFRS in terms of how such options shall be subsequently measured. Although IAS 39.46 seems to suggest that such options shall be subsequently measured at fair value (by method of elimination because such options would not be considered “loans and receivables” or “held-to-maturity investments”), interpretative guidance and life sciences practice seem to be unanimous that such options shall not be subsequently measured at fair value. As such, the author is of the view that such call options could subsequently be recorded at

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398 IAS 39.AG35(d); IFRS 9.B3.1.2(d).
399 IAS 39.43.
400 IAS 39.46(c). This exception from fair value measurement in IAS 39 has been eliminated with IFRS 9.
401 PricewaterhouseCoopers (2012a), p. 50; Ernst & Young (2013c), p. 2994; Interview with Dr. Benedikt Brüggemann, KPMG AG, Berlin.
their original cost, less any recorded impairment losses, at amortized cost or at fair value, depending on the investor’s accounting policy election.\footnote{Although an accounting policy election, based on the requirements in IAS 8.15, the policy would need to be applied consistently for all such options that do not meet the definition of a financial asset.}

All options that are not measured at fair value through profit or loss are subject to review for impairment, in accordance with IAS 39.58-70 and IAS 39.AG84-AG93.\footnote{IAS 39.46.}

Thus, even for options that are not accounted for at fair value through profit or loss, there may still be significant income statement volatility as a result of an impairment of the financial asset, which in the life sciences option deal scenarios would generally stem from unfavorable news in the R&D process of the investee, which may result in the underlying (shares or R&D) to drop in value and, as a result, also lead to a full or partial impairment of the call option.

### 6.4.1.1.2 Call options that do not meet the definition of a financial asset

Options to acquire non-financial items or options to acquire a group of assets where the portion of non-financial assets versus financial assets is too significant for the investor to conclude that the option meets the definition of a financial asset\footnote{As mentioned in section 6.4.1, there is no specific guidance in IFRS in terms of whether options to acquire a group of assets that include both financial and non-financial assets would still meet the definition of a financial asset, and IFRS also does not provide any indications in terms of what ratio of financial to non-financial assets is needed to consider such options financial assets. Such determination has to be made by each investor individually and is therefore deemed to be judgmental.} would not be considered financial instruments and, thus, do not fall in the scope of IAS 39 with respect to the recognition and measurement of such options.\footnote{Böckem/Geier (2012), p. 495; Interview with Dr. Benedikt Brüggemann, KPMG AG, Berlin.}

Based on the fact that there is no explicit accounting guidance in IFRS addressing the subsequent accounting for such options that are not considered financial instruments, the author is of the view that the accounting would be based on an investor’s accounting
policy election of either accounting for such options at their original cost, less any recorded impairment losses, or at amortized cost, or at fair value.\footnote{Although an accounting policy election, such accounting policy would need to be applied consistently for all such options that do not meet the definition of a financial asset, based on the requirements in IAS 8.15.}

\subsection*{6.4.1.2 Exercise of the option}

In the previous section, the accounting for call options prior to the options being exercised has been discussed. This section will deal with the accounting at the time an option is exercised.

There may be different reasons why an investor decides to exercise its option during the option period. In the life sciences industry, the exercise is often directly or indirectly linked to promising results in the R&D pipeline of the investee that the investor would like to gain access to.

Generally, the price an entity pays to acquire separately an intangible asset is a direct reflection of its expectations about the probability that the expected future economic benefits from the asset will flow to the entity. Thus, the probability recognition criterion in IAS 38.21(a) is always considered to be met for separately acquired intangibles.\footnote{IAS 38.25.}

However, this conclusion may be different for option arrangements in the life sciences industry where the exercise price is economically correlated to the R&D costs incurred by the investee prior to the exercise of the option. If, economically, the exercise price is a predefined amount to compensate past R&D expenses (e.g., it is set at 140\% of the R&D expenses to give the investee a risk adjusted risk of return on its investment) and the R&D expenses were incurred prior to the capitalization criteria in IAS 38.57 being met, the exercise price would need to be expensed as incurred as IAS 38.71 states that expenditure on an intangible asset originally recognized as an expense shall not be recognized as part of the cost of an intangible asset.\footnote{PricewaterhouseCoopers (2012a), p. 50.}

Thus, investors, when structuring options deals to acquire R&D assets of an investee, should be conscious about how they
structure the exercise price clause of the agreement because an exercise price that is economically correlated to the R&D expenses incurred by the investee is likely to result in the investor having to expense such exercise price, whereas if the exercise price was set at a fixed price not correlated to the R&D expenses, then such amount would likely meet the capitalization criteria of a separately acquired intangible asset in IAS 38.25.

For option deals where the exercise price is not economically correlated with the R&D expenses of the investee and the exercise price meets the capitalization criteria in IAS 38.25, the exercise price and the carrying amount of the option, if any, are included as part of the acquisition consideration transferred. At the time of the exercise of the option it is important for investors to consider whether what is being acquired meets the definition of a business.\textsuperscript{409} If what is being acquired meets the definition of a business, the total consideration transferred needs to be allocated to the fair value of the acquired assets and liabilities with any difference being recorded as goodwill or bargain purchase, whereas if what is being acquired does not meet the definition of a business, the total consideration transferred is being allocated to the acquired assets and liabilities based on their relative fair value with no consideration allocated to a goodwill or bargain purchase.

Another important accounting consideration for investors to be aware of is the fact that for options that can be accounted for at either original cost, less any recorded impairment losses, or at amortized cost, or at fair value based on an investor’s accounting policy election, the investor’s accounting policy election does not only have a significant impact on the accounting prior to a potential option exercise, but also on the accounting after a potential option exercise. The following Example 18 will further illustrate this point.

\begin{example}
An investor holds an option to acquire R&D assets of an investee at a predefined price that does not economically correlate to the R&D expenses incurred by the investee. Because the option does not qualify as a financial asset (because the subject assets are non-financial assets) and there is no explicit guidance in IFRS in terms of how to account for such options, the accounting would need to be based on the investor’s
\end{example}

\textsuperscript{409} Refer to section 4 for a detailed discussion of what meets the definition of a business.
accounting policy election to account for such options at either their original cost, less any recorded impairment losses, or at amortized cost, or at fair value. Assume that the cost of the option was CU 10, the exercise price is fixed at CU 50, the total option exercise period is five years and that after three years the investee has very positive R&D results resulting in the option to be significantly ‘in the money’.

If the investor’s accounting policy election was to account for such options at their original cost less any recorded impairment losses, and assuming that there have been no impairments in the first three years of the option exercise period, the carrying amount of the option would always remain at its original cost of CU 10 even at the time the investee has the very positive R&D results. Then, at the time of the exercise of the option, the total consideration transferred would be CU 60, consisting of the CU 10 carrying amount of the option plus the CU 50 exercise price of the option.

If the investor’s accounting policy election was to account for such options at fair value, the carrying amount of the option would increase based on the positive R&D results of the investee because with the positive R&D results such option becomes more attractive to be exercised. Assume that the fair value of the option shortly prior to the exercise changed to be CU 30, then at the time of the exercise of the option the total consideration transferred would be CU 80, consisting of the CU 30 carrying amount of the option plus the CU 50 exercise price of the option.

In other words, for the same option deal what is being capitalized as part of the acquisition is CU 50 if the option had been accounted for at its original cost less any recorded impairment losses and CU 80 if the option had been accounted for at fair value. Since under both scenarios the same assets are being acquired, if the transaction is accounted for as a business combination, under both scenarios the acquired assets are recorded at their fair value with the incremental CU 20 being capitalized as part of goodwill. Whereas if the transaction did not qualify as a business combination, the total consideration of CU 60 or CU 80 would be allocated to the acquired assets based on their relative fair values. This means that in this Example 18, the accounting policy election of how to account for such options effectively resulted in CU 20 of additional
cost being capitalized in the balance sheet (as goodwill or assets), which implicitly increases the risk of a potential future impairment.

Example 18: Accounting for options at the time of exercise

As illustrated in Example 18, for options that do not meet the definition of a financial asset, the accounting for such options at fair value can be expected to result in a higher income statement volatility for the investor, as compared to the accounting at their original cost less any recorded impairment losses. Despite the fact that, if there is adverse news, under both scenarios the option’s carrying amount will need to be impaired, for any positive R&D results, the option that is accounted for at fair value will result in a gain in the income statement, whereas the option accounted for at cost will not change in value. But also when the option is exercised, if at the time of the exercise the fair value of the option is higher than its original cost, there is a higher asset base recorded on the balance sheet if the option is accounted for at fair value and such higher asset base increases the risk of a future goodwill or asset impairment.

6.4.1.3 Non-exercise / impairment of the option

As with any asset on the balance sheet, an investor needs to assess at the end of each reporting period whether there is any objective evidence that an option may be impaired. For options that meet the definition of a financial asset, an investor would follow the impairment guidance in IAS 39.58-59, and for options that do not meet the definition of a financial asset, an investor would follow the guidance in IAS 36 Impairment of Assets.

It should be noted that except for call options to acquire R&D where the R&D is being discontinued with no alternative future use of the underlying IP, option impairments would generally not be full but partial impairments as long as the option exercise period has not expired. That is because, even if the probability may be low, as long as the option

\footnote{410 Author’s own compilation.}
exercise period has not expired, there is always still a chance that things may change and the option may increase again in value.

6.4.2 Modeling the deal payment structure to match the value of the subject assets

For purposes of this case study, the deal structure of an acquisition call option assumes that the investor acquires a call option to acquire all of the shares of the investee who is developing the subject assets. Because the option is to acquire shares and since there are no exercisability restrictions based on the investee’s R&D results, the option is assumed to meet the definition of a derivative.

Based on the valuation of the subject assets of CU 351, the payment structure of the call option deal has been modeled to reflect CU 351 from a net present value perspective.

- Cost of the call option of CU 20, which is assumed to be the fair value of the option in 2014 when the deal is entered into.
- Based on the investee’s share price the option’s fair value changes as follows in the period from 2016 to 2019: CU -20 in 2016, CU +20 in 2017, CU -20 in 2018, CU +20 in 2019.
- CU 20 of transaction-related costs incurred in 2014 when the deal is entered into.
- Discount rate of 20% to reflect the high risk in the five years of development and the risks in connection with the potential commercialization.
- Option exercise price of CU 1,260 (fixed and not economically correlated to the R&D costs), which is being discounted at 35% to reflect the higher uncertainty due to the fact that this payment is optional. The option is exercisable at any time.
- Based on the nature of the subject assets acquired in 2019 it is assumed that when the option is exercised the transaction does not qualify as a business combination.
- Royalty payments of 4% of sales during the commercialization period (2020 through 2029). The 4% royalty rate is assumed to reflect the current fair value of royalties for similar products.
- Discount factor is not based on the mid-year convention since both the option exercise payment and the royalty payments can be expected to be payable at the end of the year rather than in the middle of the year.
- For simplification it should be assumed that the investee’s only asset is the IP related to the R&D and that at the time of the option exercise this IP has a fair value of CU 1,280.

Based on these assumptions, the net present value of all payments made by the investor in connection with this option deal is CU 351, which matches the value of the subject assets. Refer to Appendix D for the full valuation.

6.4.3 Graphical illustration of the income statement volatility based on a positive scenario

In this section the author illustrates the net income / net loss development of the option deal based on a positive scenario (assuming a successful development and successful commercialization). This development is illustrated in Figure 22.

![Figure 22: Income statement volatility acquisition call option deal – positive scenario](image)

411 Author’s own compilation. Refer to Appendix D for the underlying model.
The net income / net loss development over the period of 15 years when accounting for the deal as an option deal can be described as follows:

The CU 20 price to acquire the call option, since the CU 20 is assumed to be the fair value of the option in 2014 when the deal is entered into, is capitalized as part of the cost of the option.

Because the option is accounted for at fair value through profit or loss, based on the guidance in IAS 39.43, the CU 20 transaction-related costs are not capitalized as part of the option but expensed when incurred.

Subsequent to the capitalization of the option the investor records the changes in the fair value of the option in the period from 2015 through 2019.

Because during the period of development from 2015 through 2019 the investor only holds the option, but has not yet exercised the option, the investor also does not record any of the development costs incurred by the investee. However, since at the time of the option exercise the investor assumes full responsibility for the commercialization, the investor incurs the product cost of sales of 10% and the SG&A expenses of 25% during the commercialization period.

At the end of 2019, when the investor decides to exercise the option, based on the assumptions that what is being acquired does not meet the definition of a business, that the investee’s only asset is the IP related to the R&D and that at the time of the option exercise the acquired IP has a fair value of CU 1,280, the total consideration transferred of CU 1,280 (the sum of the carrying value of the option (at that time CU 20) and the option exercise price of CU 1,260) is allocated to the acquired IP related to the R&D. Subsequently this intangible asset is being amortized over the period of commercialization (10 years).
With respect to the royalty payments at a rate of 4% of sales, since the 4% royalty rate is considered to be at fair value, they are accounted for as cost of sales in the same period as the corresponding sales.\(^{412}\)

### 6.4.4 Graphical illustration of the income statement volatility based on a negative scenario

In this section the author illustrates the net income / net loss development of the option deal based on a negative scenario (unsuccessful development evidenced by the regulatory authorities not approving the product in 2019 and assuming no alternative future use of the IPR&D). This development is illustrated in Figure 23.

![Figure 23: Income statement volatility acquisition call option deal – negative scenario\(^ {413}\)](image)

The net income / net loss development over the period of 15 years when accounting for the deal as an option deal can be described as follows:

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\(^{412}\) It should be noted that this accounting is based on the accounting for royalty payments in connection with asset acquisition that is believed to be the most common way of how companies account for such royalties in life sciences practice. At the time of publication of this thesis there is no explicit guidance how to account for such milestones in connection with asset acquisitions. Refer to section 4.2.5 for a discussion of different views on how such milestones could be accounted for under IFRS.

\(^{413}\) Author’s own compilation. Refer to Appendix D for the underlying model.
The CU 20 price to acquire the call option, since the CU 20 is assumed to be the fair value of the option in 2014 when the deal is entered into, is capitalized as part of the cost of the option. Subsequent to the capitalization of the option, the investor records the changes in the fair value of the option in the period from 2015 through 2019 ending with a fair value of CU 20 at the end of 2019 when the regulatory authorities decide about the approval of the drug.

Because the option is accounted for at fair value through profit or loss, based on the guidance in IAS 39.43, the CU 20 transaction-related costs are not capitalized as part of the option but expensed when incurred.

Because during the period of development from 2015 through 2019 the investor only holds the option, but has not yet exercised the option, the investor also does not record any of the development costs incurred by the investee. However, since at the time of the option exercise the investor assumes full responsibility for the commercialization, the investor incurs the product cost of sales of 10% and the SG&A expenses of 25% during the commercialization period.

At the end of 2019, when the regulatory authorities decide to not approve the product and it is decided that there is no alternative future use of the R&D, the investor records a full impairment of the CU 20 value of the option.

### 6.5 Acquisition of a business

#### 6.5.1 Key accounting considerations for the life sciences industry

Section 6.2 covered the income statement considerations of transactions that qualify as a business combination. This section will focus on the key income statement considerations for transactions that qualify as a business combination. Section 6.6 will provide an illustrative comparison of the two deal structures (asset acquisition versus business combination) from an income statement volatility perspective.
6.5.1.1 Milestone and royalty payments

For transactions that qualify as a business combination, milestone and royalty payments that the acquirer and seller agree to are included in the acquisition date total consideration transferred at fair value. Changes in the contingent consideration liabilities subsequent to the acquisition date may be due to (a) changes in the estimate of the amount to be paid, (b) changes in the probabilities assigned to individual payments, or (c) simply due to time value of money as the contingent consideration liability is initially discounted, but is then subsequently accreted as time passes (often referred to as *accretion expense*).

The main challenge for life sciences companies when having to account for contingent consideration liabilities is to make estimates about the payout dates and amounts when determining the fair value of these liabilities. While such estimates may still be relatively easy to determine for development and sales-based milestones (because the amounts of such milestones are generally pre-determined and the timing of the payments can often be narrowed down to a period of a couple of years), determining the fair value of royalty payment contingent consideration liabilities is very complex. That is because royalty payments are a derivative of the sales made in future periods, which means to determine the fair value of these contingent consideration liabilities one needs to forecast future sales for as long as the two parties have agreed to pay royalties. Such period in practice would often be the period of the product lifecycle, which could be up to 20 years.

6.5.1.2 Amortization and impairments of acquired assets, incl. goodwill

As mentioned in section 4.2.1, for business combinations, all identifiable assets acquired and liabilities assumed are initially measured and recorded at their acquisition date fair values irrespective of the amount of the consideration transferred to acquire those assets and liabilities and irrespective of whether these assets and liabilities have previously been recorded in the books of the acquiree. Any excess of the fair value of the total consideration transferred over the fair value of the acquired net assets is recorded as

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414 IFRS 3.39.
goodwill, and any excess of the fair value of the acquired net assets over the fair value of
the total consideration transferred is recorded as a gain (so-called bargain purchase).^415

In the life sciences industry, the most common example of assets recorded in the
acquirer’s books that have previously not been recorded in the acquiree’s books are the
in-process research and development (IPR&D) assets. Such assets are recorded on the
books as indefinite-lived intangible assets until completion or abandonment, which
means they have to be tested for impairment at least once annually pursuant to IAS 38.108 (IFRS) and ASC 350-30-35-18 (US GAAP). Upon completion of development
(generally when regulatory approval to market is obtained), acquired IPR&D assets are
considered finite-lived intangible assets and the company will begin to amortize the asset
over the estimated useful life of the technology, whereas if the research is abandoned, the
R&D asset booked at the date of the acquisition will be considered impaired and
expensed.^416

The interesting thing about the impairment test of IPR&D assets is that all the additional
R&D expenses that the acquirer incurs subsequent to the business combination to further
advance the IPR&D asset cannot be capitalized, but need to be expensed as incurred,
which seems inconsistent because with the additional R&D activities after the business
combination the IPR&D assets are being advanced further and also more uncertainties
about the future success are being resolved. In other words, when testing IPR&D assets
for impairment in future years, the acquirer is comparing the fair value of the IPR&D
asset in its current stage at that time (taking into consideration how the asset has been
further advanced after the acquisition date), whereas the book value that the fair value is
compared to is still the fair value as of the acquisition date when the asset was not as far
advanced and when more uncertainties and risks about the future development existed. In
other words, as long as there are no negative R&D results or the project is being
 discontinued, an IPR&D asset is unlikely to be impaired because the fact that it is being

^415 Based on the guidance in IFRS 3.36, a bargain purchase gain may only be recognized once the acquirer
has reassessed all components of the computation to ensure that the measurements are based on all
available information as of the acquisition date.
advanced further and uncertainties are being resolved should generally support a higher fair value, as compared to the fair value as of the acquisition date.

In addition to the risk of IPR&D assets being impaired, an acquirer also has to monitor the risk of impairments of other assets acquired as part of the business combination, including goodwill. For goodwill and indefinite-lived intangible assets the impairment test has to be performed at least once annually; for definite-lived intangible and tangible assets that are being amortized or depreciated the acquirer only has to assess whether indicators of impairment are present and perform an impairment test only if such indicators are present. This risk of impairment of acquired assets or goodwill in future periods to some extent provides a control mechanism for acquirers to not significantly overpay as part of the acquisition.\textsuperscript{417}

With respect to the amortization period, amortization method and classification of amortization expense of acquired definite-lived intangible assets, the same accounting guidance and thought process applies as discussed in connection with asset acquisitions in section 6.2.1.3.

\textbf{6.5.1.3 Transaction-related costs}

Transaction-related costs incurred in connection with a business combination (e.g., finder’s fees, advisory, legal, accounting, valuation, and other professional or consulting fees, etc.) shall be expensed in the periods in which the costs are incurred and the services are received.\textsuperscript{418} This is a key difference, as compared to the accounting for asset acquisitions where such transaction-related costs are generally considered a component of the consideration transferred to acquire the assets or group of assets and, as such, are capitalized as a component of the cost of the assets.\textsuperscript{419}

\textsuperscript{418} Refer to IFRS 3.53. IFRS 3.53 states that the only exception to that is the cost to issue debt or equity securities, which shall be recognized in accordance with IAS 32 and IAS 39.
6.5.2 Modeling the deal payment structure to match the value of the subject assets

As mentioned in section 3.5, business combinations generally involve up-front payments, milestone payments and royalty payments. Based on the valuation of the subject assets of CU 351, the payment structure of the business combination has been modeled to reflect the CU 351 from a net present value perspective.

- Up-front payment of CU 220 and transaction-related costs of CU 20, which are both paid in 2014 when the deal is entered into.
- Regulatory approval milestone of CU 150 in 2019 if regulatory approval is obtained.
- Sales target milestone of CU 150 in 2025 when annual sales reach CU 1,000 (if regulatory approval is obtained).
- Royalty payments of 4% of sales during the commercialization period (2020 through 2029).
- Discount rate of 20% to reflect the high risk in the five years of development and the risks in connection with the potential commercialization (resulting in the regulatory approval milestone, the sales target milestone and the commercialization royalty payments potentially not becoming payable).
- Discount factor is not based on the mid-year convention since milestone payments and royalty payments can be expected to be payable at the end of the year rather than in the middle of the year.

Based on these assumptions, the net present value of all payments is CU 351, which matches the value of the subject assets. Refer to Appendix E for the full valuation.

6.5.3 Graphical illustration of the income statement volatility based on a positive scenario

In this section the author illustrates the net income / net loss development based on a positive scenario (successful development and commercialization) assuming that what is
being acquired meets the definition of a business, resulting in the transaction being accounted for as a business combination. This development is illustrated in Figure 24.

![Figure 24: Income statement volatility acquisition of a business – positive scenario](image)

The net income / net loss development over the period of 15 years when accounting for the deal as a business combination can be described as follows:

The CU 220 up-front payment paid in 2014, when the deal is entered into as well as the fair value of all contingent payments (regulatory approval milestone (CU 61), sales target milestone (CU 20), and royalty payments (CU 30)) are both considered part of the total consideration transferred. Therefore, the total consideration transferred to acquire the business is CU 331.

This total consideration transferred of CU 331 is then being allocated to the fair value of the acquired assets and liabilities assumed. Because in this case study the subject assets (IPR&D) are the only assets acquired, and the fair value of the subject assets is CU 351, CU 351 are being recorded as IPR&D assets and CU 20 are being recorded as a bargain purchase gain that is being recorded when the transaction is entered into in 2014.

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420 Author’s own compilation. Refer to Appendix E for the underlying model.
Also, in 2014 the acquirer has to record CU 20 transaction-related costs as an expense since such costs cannot be capitalized based on the guidance in IFRS 3.53.

The IPR&D asset (CU 351) is accounted for as an indefinite-lived intangible and changes to become a definite-lived intangible at the end of 2019, when regulatory approval is obtained. Subsequently the asset is being amortized over the period of commercialization.

The CU 150 regulatory approval milestone, the CU 150 sales target milestone, as well as the CU 210 estimated royalty payments, are all accounted for as contingent consideration liabilities, which means they are fair valued as of the acquisition date and subsequently adjusted for any changes in fair value with such changes in fair value being recorded in earnings. In this case study, it is assumed that there are no changes to the initial estimate of the timing and amount of these contingent consideration payments. Therefore, the fair value of the contingent consideration liabilities will only change due to the time value of money (accretion expense). The total accretion expense in this case study amounts to CU 400, which is the difference between the total payments to be made (CU 510 = CU 150 + CU 150 + CU 210) and the fair value of the contingent consideration liabilities as of the acquisition date (CU 110 = CU 60 + CU 20 + CU 30).

With respect to the income statement classification of any changes in the fair value of the contingent consideration IFRS does not provide any specific guidance. Most companies classify the changes in the fair value of the contingent consideration based on the nature of the contingent consideration (e.g., changes in the fair value of a regulatory approval milestone as R&D expense, etc.), which seems to make most sense.

Since the investor assumes full responsibility for the further development and subsequent commercialization, the investor also incurs the R&D expenses during the five years of development (from 2015 to 2019), as well as the product cost of sales of 10% and the SG&A expenses of 25% during the commercialization period.

As Figure 24 shows, the income statement volatility over the period of the collaboration spans from a loss of CU 106 in 2019 to a net income of CU 575 in 2025, and this is assuming no changes to the initial estimate of the timing and amount of the contingent
consideration payments. If there were changes to the initial estimate of the timing and amount of these contingent consideration payments the volatility would be even higher.

What seems to be a paradox from a business perspective is that when accounting for contingent consideration liabilities tied to development milestones, any set-backs or delays in the development will postpone the contingent consideration payment or make it less likely and, as such, result in a reduction of the contingent consideration liability with a corresponding gain in the income statement. Conversely, any favorable clinical trial data that results in the contingent milestone payment likely having to be made earlier or making it more likely will result in an increase in the contingent consideration liability with a corresponding expense in the income statement.

At the same time it would not be correct to assume that the positive income statement impact from a reduction in a contingent consideration liability provides an incentive for big pharma companies to overstate their contingent consideration liabilities (e.g., by assigning a probability that is too high) and then at a later point in time reducing these liabilities to create income because the reduction in the contingent consideration liabilities will always be associated by shareholders with negative R&D results which could then result in a significant drop in shareholder value.\(^{421}\)

### 6.5.4 Graphical illustration of the income statement volatility based on a negative scenario

In this section the author illustrates the net income / net loss development based on a negative scenario (unsuccessful development evidenced by the regulatory authorities not approving the product in 2019 and assuming no alternative future use of the IPR&D) assuming that what is being acquired meets the definition of a business, resulting in the

\(^{421}\) As mentioned in section 2.5, since for most life sciences companies the R&D pipeline is one of the key indicators for future success, stock prices fluctuate with good or bad news R&D results and any adverse news can cause immediate reactions on the capital markets and destroy significant amounts of shareholder value within minutes. Gassmann/Reepmeyer/von Zedtwitz (2008), p. 11 and 108.
transaction being accounted for as a business combination. This development is illustrated in Figure 25.

![Figure 25: Income statement volatility acquisition of business combination – negative scenario](image)

The net income / net loss development over the period of 15 years when accounting for the deal as a business combination can be described as follows:

In the period from 2014 through 2018, the accounting is identical to that under the positive scenario, which means the acquirer in 2014 when the transaction is entered into records the IPR&D asset at fair value (CU 351), based on a total consideration of CU 331 records a bargain purchase of CU 20 and records CU 20 of transaction-related costs as an expense. In addition to that, the acquirer records the accretion expense for the three different types of contingent consideration liabilities (regulatory approval milestone, sales target milestone, and royalty payments), as well as the annual R&D expenses of CU 55 in both 2015 and 2016, and of CU 60 in 2017, 2018, and 2019.

Then, in 2019, when the regulatory authorities decide to not approve the product and when the acquirer determines that there is no alternative future use for the IPR&D asset,

Author’s own compilation. Refer to Appendix E for the underlying model.
an impairment charge of CU 351 is recorded (the value of the IPR&D asset is unchanged from the initial recognition since it is an indefinite-lived intangible asset, which is not being amortized). This IPR&D impairment charge is offset by a CU 275 gain due to the release of the contingent consideration liabilities since with the regulatory authorities not approving the product the regulatory approval milestone, the sales target milestone and the royalties will all no longer have to be paid (the CU 275 are made up of CU 111 of the fair value of the contingent considerations as of the acquisition date and CU 164 of accretion expense recorded in the period from 2015).

### 6.6 Comparison of the income statement volatility of the different deal structure types

#### 6.6.1 Comparative analysis – positive scenario

Figure 26 shows a comparative analysis of the income statement volatility of the four different deal structure types walked through as part of the combined case study based on a positive scenario (successful development and commercialization).

While the asset acquisition and the acquisition of a business show a similar trend, the income statement volatility of the acquisition of a business is more volatile, which is attributable to the fact that as part of the acquisition of a business the regulatory approval milestone, sales target milestone and royalty payments are accounted for as contingent consideration liabilities as of the acquisition date, whereas as part of the asset acquisition the regulatory approval milestone, sales target milestone and royalty payments are all not accounted for until payable. This results in the acquisition of a business showing more expense in earlier years (mainly due to the accretion expense, which is already recorded in the period from 2014 through 2019) and the asset acquisition showing more expense in later years (e.g., all the royalty payments are being recorded during the commercialization period whereas for the acquisition of a business the royalty payments are accounted for as a contingent consideration liability).
For the acquisition of a call option, significant income statement volatility may occur in the period prior to the option exercise when the option is accounted for at fair value through profit or loss. Then, once the option is being exercised and the commercialization period begins, the income is lower compared to the acquisition of a business and the asset acquisition because of higher amortization expense.

As shown in Figure 26, the least volatile of all four researched deal structures is the 30% equity investment. That is because there is no contingent consideration liabilities to be recorded and the accounting is just based on the investor’s share of the profit or loss and other comprehensive income of the investee.

Figure 26: Comparative analysis of the income statement volatility of the four different deal structure types – positive scenario

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423 Author’s own compilation.

424 Since with an option deal almost all of the consideration to acquire the assets becomes payable only in 2019 when all of the uncertainties about the R&D have been resolved (in the form of the exercise price), the overall consideration transferred as part of an exercised option deal is also generally considerably higher than the total consideration transferred in an asset acquisition or an acquisition of a business where a significant portion of the consideration is paid already in 2014 when there are still several years of R&D activities and uncertainties left.
6.6.2 Comparative analysis – negative scenario

Figure 27 shows a comparative analysis of the income statement volatility of the four different deal structure types walked through as part of the combined case study based on a negative scenario (unsuccessful development evidenced by the regulatory authorities not approving the product in 2019 and assuming no alternative future use of the IPR&D).

While the asset acquisition and the acquisition of a business show a similar trend, the income statement volatility of the acquisition of a business is more volatile, which is attributable to the fact that as part of the acquisition of a business the regulatory approval milestone, sales target milestone and royalty payments are accounted for as contingent consideration liabilities as of the acquisition date with accretion expense recorded from Day 1, whereas as part of the asset acquisition the regulatory approval milestone, sales target milestone and royalty payments are all not accounted for until payable. Further, in 2019, at the time of the impairment, the net loss recorded for the acquisition of a business is CU 22 higher than the net loss recorded for the asset acquisition. This is due to the fact that for the acquisition of a business deal structure, in addition to recording a CU 351 impairment of the IPR&D asset, there is also a release of CU 229 of contingent consideration liabilities, whereas for the asset acquisition only the CU 100 IPR&D asset has to be impaired.

Comparing the option deal and the 30% equity investment deal also reveals an interesting insight. Although the option deal can be considered more volatile in the period from 2015 through 2019 when the option is accounted for at fair value through profit or loss, in 2019 the 30% equity method accounting deal structure results in a larger net loss because the 30% investment prior to the regulatory authorities rejecting the product had a higher value than the option. However, this is only because in this case study the fair value of the option was assumed to fluctuate between CU 20 and CU 0 in the period from 2016 to 2019, but in practice the fair value of an option may also fluctuate more significantly resulting in even larger impairments that could also be larger than the impairment of the 30% equity investment.
Figure 27: Comparative analysis of the income statement volatility of the four different deal structure types – negative scenario\textsuperscript{425}

\textsuperscript{425} Author’s own compilation.
7 Synopsis: Analysis of life sciences deal structures both from a business development and accounting perspective

As part of this thesis, the author assessed different life sciences deal structures both from a business development perspective (chapter 3) as well as from an accounting perspective (chapters 4, 5, and 6). While detailed analyses of the advantages and disadvantages for each deal structure type were provided, these analyses have been presented separately, once from a business development perspective and once from an accounting perspective.

The following Figure 28 now provides a table with a summary of the key deal structuring considerations along with a final synopsis comparing deal structures both from a business development as well as from an accounting perspective. This is relevant because – as mentioned several times in this thesis – decisions about choosing the right deal structure should not solely be based on accounting considerations or solely be based on business development considerations, but instead should be encompassing both perspectives. In practice this can be best accomplished by the business development department of a company taking the lead in identifying target assets or companies and then consulting with the accounting/finance function to understand the accounting implications and flexibilities. Executives in life sciences companies that understand these flexibilities and that are able to find the right balance between the business development and accounting perspectives are more likely to structure deals in a way that will be in the best interest of the company as a whole.
<table>
<thead>
<tr>
<th>Investment risk / sunk costs</th>
<th>Co-development arrangements and licensing arrangements</th>
<th>Joint venture / equity investment with less than a majority of voting rights</th>
<th>Options-based M&amp;A</th>
<th>M&amp;A and equity investment with more than a majority of voting rights</th>
<th>Asset acquisition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medium (but acquired rights could be re-sold if not impaired)</td>
<td>Medium (but equity investment could be re-sold if not impaired)</td>
<td>Low (limited to the price of the option)</td>
<td>High (but equity investment could be re-sold if not impaired)</td>
<td>High (but assets could be re-sold if not impaired)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Level of integration with the other party</th>
<th>Co-development arrangements and licensing arrangements</th>
<th>Joint venture / equity investment with less than a majority of voting rights</th>
<th>Options-based M&amp;A</th>
<th>M&amp;A and equity investment with more than a majority of voting rights</th>
<th>Asset acquisition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low (limited to a Joint Steering Committee)</td>
<td>Medium (usually only significant influence, no control)</td>
<td>Low up to exercise of option, after that high</td>
<td>High (control of the acquired option, after that high)</td>
<td>High (control of the acquired business assets)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Level of assumed R&amp;D risk</th>
<th>Co-development arrangements and licensing arrangements</th>
<th>Joint venture / equity investment with less than a majority of voting rights</th>
<th>Options-based M&amp;A</th>
<th>M&amp;A and equity investment with more than a majority of voting rights</th>
<th>Asset acquisition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most of the R&amp;D risks remain with the other party</td>
<td>Assumed R&amp;D risk based on the level of ownership</td>
<td>None (except for when the option is exercised)</td>
<td>Full assumption of R&amp;D risks (except for any payments tied to the achievement of milestones)</td>
<td>Full assumption of R&amp;D risks (except for any payments tied to the achievement of milestones)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of compounds / projects with potential (“shots on goal”)</th>
<th>Co-development arrangements and licensing arrangements</th>
<th>Joint venture / equity investment with less than a majority of voting rights</th>
<th>Options-based M&amp;A</th>
<th>M&amp;A and equity investment with more than a majority of voting rights</th>
<th>Asset acquisition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limited to those compounds / project subject to the arrangement</td>
<td>All compounds or projects of the joint venture or investee but benefits are limited to level of ownership</td>
<td>Limited to the compounds / projects subject to the option agreement</td>
<td>All compounds or projects of the investee (most “shots on goal”)</td>
<td>Limited to those compounds / projects acquired</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Payment structure</th>
<th>Co-development arrangements and licensing arrangements</th>
<th>Joint venture / equity investment with less than a majority of voting rights</th>
<th>Options-based M&amp;A</th>
<th>M&amp;A and equity investment with more than a majority of voting rights</th>
<th>Asset acquisition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up-front, milestone, and royalty payments</td>
<td>Price paid for equity investment (in cash or contributed assets)</td>
<td>Price paid to acquire the option and exercise price</td>
<td>Up-front, milestone, and royalty payments</td>
<td>Up-front, milestone, and royalty payments</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time horizon of partnership</th>
<th>Co-development arrangements and licensing arrangements</th>
<th>Joint venture / equity investment with less than a majority of voting rights</th>
<th>Options-based M&amp;A</th>
<th>M&amp;A and equity investment with more than a majority of voting rights</th>
<th>Asset acquisition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limited to time of co-development or co-commercialization</td>
<td>Indefinite unless the investment is sold</td>
<td>Limited to exercise period (unless the option is exercised)</td>
<td>Indefinite unless the business or the subsidiary is sold</td>
<td>Indefinite unless the assets are sold</td>
<td></td>
</tr>
</tbody>
</table>
Deal structures in the life sciences industry and their financial statement implications

(continuation of Figure 28 from previous page)

<table>
<thead>
<tr>
<th>Co-development arrangements and licensing arrangements</th>
<th>Joint venture / equity investment with less than a majority of voting rights</th>
<th>Options-based M&amp;A</th>
<th>M&amp;A and equity investment with more than a majority of voting rights</th>
<th>Asset acquisition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Usefulness to only access specified assets or skills of the other party</strong></td>
<td>Useful, contract can be drafted specific to certain assets or skills of the other party</td>
<td>Not useful (since equity investment is in the other party as a whole and not in specified assets or skills)</td>
<td>Useful, contract can be drafted specific to certain assets or skills of the other party</td>
<td>Not useful (because equity investment is in the other entity as a whole and not in specified assets or skills)</td>
</tr>
</tbody>
</table>

| **Income statement volatility if R&D is successful** | Low volatility. Gradual turn from losses to income when product is launched | Low volatility. Gradual turn from losses to income when product is launched | Volatile prior to option exercise if the option is measured at fair value | Expense recognition is more front-loaded due to the accretion of the contingent consideration liabilities prior to product launch | Expense recognition is more back-loaded because contingent payments are generally not accounted for until payable |

| **Income statement volatility if R&D is not successful** | Low volatility because there is generally nothing capitalized that could be impaired | Medium volatility due to impairment of the investment | Low volatility (limited to the impairment of the option) | High volatility due to the impairment of material intangible assets | Medium to high volatility due to the impairment of material intangible assets |

*Figure 28: Analysis of the deal structures both from a business development and accounting perspective*

Figure 28 illustrates well that in life sciences deal structuring business development and accounting have to be interlinked to form a basis for successful deals. For this to happen, the two functions within an organization need to have a process in place that ensures a continuous flow of information. Accounting is provided with the relevant information and feeds back to business development what the financial statement implications are.
8 Recommendations, outlook and future research

8.1 Key recommendations – IFRS 3 definition of a business

As noted in the introduction of this thesis, where it became apparent that there is a lack of accounting guidance in IFRS, suggestions will be made how the guidance may need to be clarified or expanded to address these shortfalls.

Based on the research conducted as part of this thesis, the following table provides a summary of the key recommendations as it relates to the IFRS 3 definition of a business.

<table>
<thead>
<tr>
<th>Key recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition of “process”</strong></td>
</tr>
</tbody>
</table>
| • The definition of a “process” in IFRS 3 should be expanded to explicitly state that if process materials and documentation is being acquired which would allow a market participant to continue with the R&D process where the seller left off, such process material and documentation would likely qualify as a “process” (even if the acquirer does not take over any employees or workforce from the seller).
| • The determination of whether the process materials and documentation would allow a market participant to continue with the R&D process where the seller has left off can be best made by assessing the following two questions:
| • Assuming that process materials and documentation have been acquired, at what stage would a market participant continue with the R&D and how long would it take to reach the next major milestone in the process?
| • Assuming that process materials and documentation have not been acquired, at what stage would a market participant continue with the R&D and how long would it take to reach the next major milestone in the process?
| • Based on the analysis of the previous questions, the wider the gap is in terms of at what stage the R&D can be continued and in terms of how long it will take to reach the next major milestone in the process, the more likely it is that the process materials and documentation acquired qualify as a “process.”
| **Definition of “output”** |
| • Many small biotech companies today no longer pursue a plan to at some point be selling a drug on the market, but instead pursue a plan to develop a drug candidate to a certain stage to then sell or outlicense the drug candidate. That means, for these companies the “output” would be the developed IP rather than an approved drug that can be marketed.
| • The guidance in IFRS 3 fails to acknowledge that what is considered an output to a large extent depends on the perspective of the assessment, resulting in some companies interpreting “output” only in the context of a marketed product and others acknowledging that “output” for a small biotech could also be developed IP.

*Figure 29: Summary of the recommendations related to the definition of a business in IFRS 3*
The IASB formally began the IFRS 3 post-implementation review on July 25, 2013. As part of this post-implementation review, the IFRIC asked financial statement preparers from different industries, including the life sciences industry, to provide feedback. Through the channel of one of the large public accounting firms, the author provided the recommendations in Figure 29 pointing out that the current definition of what constitutes a business in IFRS 3 results in diversity in life sciences practice due to companies interpreting the definition of ‘process’ and ‘output’ differently.

It remains to be seen whether the IASB as part of the IFRS 3 post-implementation review will amend the definition of what constitutes a ‘process’ to address the shortfalls and it will be subject to future research to see whether any amendments to the definition of a business will to some extent limit the room for interpretation that is the basis for today’s diversity in practice.

8.2 **Key recommendations – IFRS 10 control guidance**

In addition to the shortfalls discussed in the context of the definition of a business in IFRS 3, the research conducted as part of this thesis also identified various practical difficulties in applying the control guidance in IFRS 10 to different life sciences deal structures. The following table provides a summary of the key issues and recommendations identified based on the practicability assessments performed for both determining the relevant activities and assessing the existing rights.
## Key recommendations

<table>
<thead>
<tr>
<th><strong>Assessment of the relevant activities</strong></th>
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</thead>
<tbody>
<tr>
<td>• Where one set of activities is dependent on another set of activities it is unclear whether the order of activities or one being dependent on the other should be taken into consideration in the relevant activities assessment. IFRS 10 or interpretative guidance should be explicit to address this aspect.</td>
<td></td>
</tr>
<tr>
<td>• It is currently unclear to what extent the assessment of the relevant activities should be made from the perspective of a market participant or if it may also be a subjective assessment. Because the guidance is not explicit, there are differing views in practice, with some financial statement preparers basing the assessment on a market participant view and others basing it on their own (subjective) view. IFRS 10 or interpretative guidance should be explicit to address this aspect.</td>
<td></td>
</tr>
<tr>
<td>• The statement in IFRS 10.B13 that an investor as part of the relevant activities assessment should also consider the past track records in successfully developing drug candidates should be removed as this statement, instead of clarifying, only poses additional questions for financial statement preparers.</td>
<td></td>
</tr>
<tr>
<td>• IFRS 10 should be explicit as to whether a later change of what the relevant activities of the investee are would also trigger a reassessment of control or whether the relevant activities assessment should only be performed once at inception and then not be subsequently changed for purposes of the control assessment. IFRS 10 does not address this question. It would be helpful if some explicit guidance similar to the US GAAP VIE guidance in ASC 810-10-25 was provided.</td>
<td></td>
</tr>
<tr>
<td>• It is currently unclear at which unit of account level the relevant activities assessment should be performed. It would be helpful if IFRS 10 provided guidance at a minimum stating that as part of the relevant activities assessment, the unit of account level of different activities should be comparable to avoid unwarranted bias in the assessment solely due to different unit of account sizes.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Assessment of the existing rights</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• The statement in IFRS 10.B45 that an investor when assessing the existing rights should also assess historical information about the attendance at recent shareholders’ meetings should be removed as this statement, instead of clarifying the guidance, only poses new questions for financial statement preparers.</td>
<td></td>
</tr>
<tr>
<td>• When assessing potential voting rights, it would be helpful if IFRS 10 provided some practical guidance as to when an option should be considered in-the-money or out-of-the-money, at least stating whether the assessment should be made only as of a particular date or whether it should be made over a period of time.</td>
<td></td>
</tr>
<tr>
<td>• Because whether or not a control premium is considered in the assessment of whether an option is in-the-money can have a significant impact on the control assessment, IFRS 10 should be explicit as to whether control premiums should be considered in the assessment of whether an option is in-the-money.</td>
<td></td>
</tr>
<tr>
<td>• Assessing whether an investor will benefit from exercising the option for other reasons is a very subjective assessment implicitly providing companies with an option when assessing whether options are substantive. Future research will have to assess how much diversity in practice will result from this guidance.</td>
<td></td>
</tr>
<tr>
<td>• IFRS 10 only addresses options to acquire voting rights and not options to acquire assets, even if such assets represent a business. In addition to the potential voting rights guidance, IFRS 10 should also include guidance that addresses options to acquire assets or a group of assets that constitutes a business.</td>
<td></td>
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</tbody>
</table>

*Figure 30: Summary of the recommendations related to the control guidance in IFRS 10*
As the analysis within this thesis has shown, assessing the relevant activities and assessing the existing rights for most life sciences arrangements is key in determining who has control. Although IFRS 10 was intended to provide a broader consolidation framework that would allow fewer companies to structure arrangements in order to achieve a particular outcome, the guidance seems to leave many open questions that the standard setter should address as part of an IFRS 10 and IFRS 11 post-implementation review.

### 8.3 Key recommendations – IFRS guidance on call options

Further, a lack of guidance related to the accounting of various call options that are commonly used in life sciences deal structuring has been identified.

<table>
<thead>
<tr>
<th>Key recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Call options to acquire a group of assets containing both financial and non-financial items</strong></td>
</tr>
<tr>
<td>- For call options to acquire a group of assets that contains both financial and non-financial items, IFRS does not provide any guidance as to when such options should be considered financial assets. As such, with this lack of guidance it is left open to each investor to define what ratio of financial to non-financial items of a group of acquired assets would result in the option being considered a financial asset versus the option not being considered a financial asset. Revisions and updates to the IFRS accounting standards or interpretative guidance are needed to address the accounting for such options.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Options in the scope of IAS 39 (IFRS 9) but that do not qualify as a derivative</th>
</tr>
</thead>
<tbody>
<tr>
<td>- For options that are in the scope of IAS 39 (IFRS 9) but do not qualify as a derivative, there is no explicit guidance in terms of how such options shall be measured subsequently.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Call options that do not meet the definition of a financial asset</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Options to acquire non-financial items, or options to acquire a group of assets where the portion of non-financial assets versus financial assets is too significant for the investor to conclude that the option meets the definition of a financial asset, would not be considered financial instruments and, thus, do not fall in the scope of IAS 39 with respect to the recognition and measurement of such options. IFRS does not seem to provide any guidance for the accounting of such options. As such, the accounting is currently based on an investor’s accounting policy election of either accounting for such options at their original cost, less any recorded impairment losses, or at amortized cost, or at fair value.</td>
</tr>
</tbody>
</table>

*Figure 31: Summary of the recommendations related to the IFRS guidance on call options*
List of references


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AICPA (2013):

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Ernst & Young (2011b):

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Ernst & Young (2013b):

Ernst & Young (2013c):

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Dr. Benedikt Brüggemann
Wirtschaftsprüfer, Manager, Department of Professionel Practice (DPP)
*KPMG AG*, Berlin
*on August 12, 2013*

Scott Bruns
Global Life Sciences Assurance Leader
*Ernst & Young LLP*, Indianapolis
*on October 2, 2013*

Jennifer L. Lenahan
Associate Director, Collaborations Finance
*Astellas US LLC*, Chicago
*on June 5, 2013*

Dr. Jan Lichtenberg
CEO
*InSphero AG*, Zurich
*on May 28, 2013*

Eric Ohlund
Life Sciences IFRS Partner
*Ernst & Young AG*, Zurich
*on September 18, 2013*
Dr. Guido Ströhlein
CEO
ChromaCon AG, Zurich
on March 8, 2012
Appendices

Appendix A: Valuation of the subject assets

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<td>Value of the business (30%)</td>
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**Appendix B: Models asset acquisition**

**Payment structure asset acquisition:**

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Net result asset acquisition – positive scenario:

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### Net result asset acquisition – negative scenario:

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Appendix C: Models 30% equity investment

Payment structure 30% equity investment:

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Appendix D: Models acquisition call option

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**Appendix E: Models acquisition of a business**

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Net result acquisition of a business – negative scenario:

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Curriculum Vitae

WORK EXPERIENCE

Ernst & Young LLP, Chicago, U.S.A. 10/13 -
Global Life Sciences Assurance Sector Resident, Senior Manager Assurance Services

Ernst & Young AG, Zurich, Switzerland 10/08 - 09/13
Senior Manager in Assurance Services (focus on life sciences)

Institute of Accounting, Controlling and Auditing, University of St. Gallen 04/08 - 09/08
Assistant of Prof. Dr. Leibfried and Dr. Dirk Schäfer working on the 4th edition of the IFRS textbook “International Accounting Standards” by Achleitner/Behr

Ernst & Young AG, Zurich, Switzerland 10/07 - 03/08
Senior in Assurance Services (focus on life sciences)

Ernst & Young LLP, Boston, U.S.A. 11/04 - 09/07
Senior in Assurance Services working on various IFRS and US-GAAP audits of both private and public companies, incl. Foreign Private Issuers (FPI)

Ernst & Young AG, Düsseldorf, Germany 10/02 - 12/02
Intern in Assurance Services

KPMG AG, Düsseldorf, Germany 02/02 - 03/02
Intern in Audit Services

EDUCATION

University of St. Gallen, Switzerland 10/00 - 10/04
Master of Arts (areas of focus: Finance, Accounting, and Controlling)

University of Minnesota, Carlson School of Management, Minneapolis, U.S.A. 09/03 - 12/03
Exchange semester with focus on MBA courses in accounting and taxation

PUBLICATIONS

Schmachtenberg, Meixner, Schäfer, Die Folgebewertung von Mobilfunklizenzen nach HGB, IFRS und US-GAAP, Zeitschrift für kapitalmarktorientierte Rechnungslegung (KoR), 11/05, pages 512–523

Schmachtenberg, Pfister, Schäfer: Die Bilanzierung von aus defensiven Gründen erworbenen Marken nach IFRS und US-GAAP, Zeitschrift für kapitalmarktorientierte Rechnungslegung (KoR), 02/09, pages 100–112

PROFESSIONAL LICENSES

CPA: Licensed as a Certified Public Accountant (CPA) in the states of Massachusetts and Illinois