The recognition of R&D and IPR&D in the financial statement of medical biotech companies.

Regulation aspects with reference to IAS/IFRS and US GAAP – Theoretical and empirical analysis.

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Abstract

The sector of medical biotech companies is characterized by a significant development in terms of dimensional growth of the enterprises, market value of stocks, operations of merger & acquisition. Such entities are strongly characterized by a model of business focused on research and development activity that, through the definition of new genes or drugs, allows the possibility of producing future economic benefits in terms of cash flows to confer equilibrium to the company system.

The activity of research and development effected by this companies is countersigned by an extremely long trial, articulated in the different classical phases of definition and approval of a pharmaceutical drug. The trial is submitted further to the riskiness of the results that generally go along with the advanced development of every remarkable scientific discovery.

How to conjugate this business model with a representation of the performances in the Biotech Companies Financial Statement?

The answer to this question is different according to the normative contexts of reference. The International accounting standards allow the possibility of capitalizing exclusively the expenses of development of a new medicine, costs sustained after the achievement of certain conditions (that generally are verified only in the last part of the process of definition of a new drug). The US principles don't actually contemplate the possibility to consider the investments in research and development sustained by a biotech company as balance sheet asset intended to transfer economic utility in the future.

The issues to which this work wants to bring contribution, refer to the opportunity of standardisation of financial and economic communication relative to companies belonging to a sector where territorial and/or market differences have no importance and for which the possibility to be able to correctly represent huge investment is consistent with the logics of economic and financial communication of the company.

Furthermore it is also necessary to consider how in the operations of business combination, extremely frequent in the sector, the IPR&Ds are accounted.

The work, after having faced from a theoretical point of view the issue related to the recognition and measurement in biotech companies of research and development costs in different contexts introduces an approach on the field related to the economic and financial information presented by a sample of biotech companies using different rules.

The paper analyses the different R&D rules: IFRS and US GAAP, underlying the difference in the accounting, amortisation and impairment. A special focus is related to the accounting of IPR&D in business combination.
There is also an on field analysis concerning the evaluation of R&D in the most relevant European and US medical biotech Companies.

**Keyword:** Intangible asset, R&D, IPR&D, Goodwill, Biotech, Business Combination, IAS/IFRS

1. Introduction

The sector of medical biotech companies is in fast growth because of different reasons primarily regarding on one hand the evolution of the demand, and on the other hand the offer of biotechnological and pharmaceutical products.

Concerning the demand, the request of medicines comes from the rapid growth of the average age of the population in the industrialized countries, also including the Baby Boomers generation, currently looking for an increase in the level of cares at the beginning of the third age (Borem, Santos, Bowen 2003).

Concerning the offer, it is necessary to underline the development of a new model of research and development in the pharmaceutical sector, outsourced and developed in collaboration with University (spin off) and research organizations, and financed by very aggressive financial institutions and, in some cases, by public institutions (as it currently happens in China and India).

Moreover, within an extremely rapid evolution of the technology, different enterprises of the pharmaceutical sector (but also belonging to other intensive technology sectors) prefer to outsource the R&D processes, by the constitution of specific companies (often in partnership with University or other research centres) or by the acquisition of biotech companies working in the desired research fields.

From one hand, this last procedure has intensified in the pharmaceutical sector the M&A activities developed for "strategic" reasons, from the other, it has brought to the development of a real market of biotech enterprises, where enterprises working in different fields are present, but above all with developing products portfolio with different characteristics (Abate 2003).

2. Biotech companies and biotech sector

Within the enterprises which develop activities linked to biotechnologies, it is possible to identify three types of operators (Friedman 2006, Gaisford, Hobbs, 2001):

- Dedicated Biotechnology Farms (Dbfs), or undertaken to biotechnological vocation, usually spin-off of university laboratories, highly specialized in the molecular biology, in the genomica and, above all, in the investigation of the pathological mechanisms at molecular level;
- Great traditional pharmaceutical companies that develop and commercialize “run medicines” discovered, selected and on their way to the clinical development by biotech firms;
- Specialized companies (platform companies), that provide bases to the pharmaceutical and biotechnological industry, able to accelerate the process of drug discovery or to improve the release of active principles (drug delivery).
The perimeter delimiting these groups is very vanishing: the big pharma enterprises are strongly investing in molecular biology and genomics; the biopharma enterprises are becoming immersed in the field of the small organic molecules; the platform companies are directing to the development of medicines, pushed by the perspective of huge economic returns.

In any case, some structural characteristics can be identified which, independently from the geographical context of affiliation, characterize the specialized biotech enterprises that are remarkable to the goals of the present work:

- **Science-based.** As a lot of traditional pharmaceutical companies, the Dbfs have scientific vocation and they are characterized by an intense R&D activity, focused in the field of the biological macromolecules.
- **Future capital based financing.** The principal source of financing of the biotech companies is represented by the risk capital. The venture capitalists make their investments in stages, reserving themselves the right to abandon the not successful projects.
- **Low industrial concentration.** Contrarily to other high tech sectors (as the pharmaceutical), the biotech sector counts an elevated number of small and medium specialized entities, which are in the forefront of the research activity.
- **Scientist-entrepreneur character.** Many entrepreneurs working in the Dbfs are scientists coming from the academic world. An econometric analysis has shown that, in the United States, the location of the biotech start-ups is strongly influenced by the location of star scientists, who are inclined to operate in the most prestigious research centres, as those located in Stanford, Harvard, etc.
- **Geographical agglomeration.** The activities connected with biotechnological field tend to conglomerate in certain geographical areas, giving place to clusters. It is possible to verify that, in the clusters, the R&D activity not only stimulates the innovation, but it also fosters the circulation of new ideas, as well as the diffusion of the technologies over the geographical borders. The universities, the university hospitals and the public research entities have contributed to the progress in the biotechnologies and to the individualization of innovative approaches to the study of the pathologies.
- **Patents.** Within the industrial sectors with intense R&D activity, the biotech sector holds, beside the pharmaceutical one, a number of patents higher than the average.

**Tab. 1 The value chain in the pharmaceutical biotechnological business.**

As introduced before, the activity of the biotech firms is strongly focused on the research business (Arora, Gambardella 1990). That’s why it is important to underline, at least in the
main steps, which is the standard way to the completion of a biotechnology research (or biotech-pharmaceutical generally).

3. The main phases of the process of discovering a biotech drug

The R&D activity of a biotech enterprise can be articulated in the following steps (Friedman 2006, Duarte 2001):
- Discovery and pre-clinic phase;
- Phase I: first analyses on human beings;
- Phase II: evolved clinical studies;
- Phase III: measurability of the results.

Discovery and pre-clinic phase. The development process of a biotechnological origin drug begins, usually, with the scientific discovery of a gene involved in a pathology. The discovery can take up time for a very changeable period, generally among 2-10 years. After the discovery, an objective is defined for a therapeutic intervention. The pre-clinic tests are conducted in laboratory using single cells or, in some cases animal, in order to appraise the safety and the potential of effectiveness on the human beings. In case of encouraging results, the enterprise submits an application for "Detective New Drug" to the Food and Drug Administration (FDA) or to the European Medicines Evaluation Agency (EMEA) to be able to effect tests on the individuals. The discoveries or the results of the pre-clinic phase are the elements that often attract the greatest media attention. This phase occurs at an embryonic stage of the process, and often, after years of research and tests, a lot of proposed molecules or drugs don't overcome this stadium and therefore they will not be on sale on the market.

Phase I: tests. Analyses on human begin. The purpose of the first phase, through the use of a reduced number of patients, is to establish the safety and the parameters of maximum dosage. Phase II: the clinical studies are more evolved; such phase needs several months to be planned and set up, and to find out useful candidates. Phase II is conducted on a larger group of patients that present the pathology appointed as target, with the aim of studying the effectiveness of the drug to the various doses and confirming its safety. Accidental tests with the use of placebo are usually effected for scientifically examination of the results. Phase II often lasts two years, and in some cases a medicine can be undergone to a second multiple phase II to verify the reliability on different diseases (for example, treating different types of cancer). This can be the most critical phase in terms of difference between positive and negative results. Statistically a medicine that completes Phase II and passes to Phase III has a successfully probability to reach the market equal to 50% (although some studies suggest an higher percentage).

Tab. 2 Duration and probability of success in the various phases of the R&D process.

<table>
<thead>
<tr>
<th>Phases</th>
<th>Success probability</th>
<th>Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug discovery e Preclinic</td>
<td>1-10%</td>
<td>2-4</td>
</tr>
<tr>
<td>Clinic 1</td>
<td>11-20%</td>
<td>2</td>
</tr>
<tr>
<td>Clinic 2</td>
<td>21-60%</td>
<td>2</td>
</tr>
<tr>
<td>Clinic 3</td>
<td>61-90%</td>
<td>2-4</td>
</tr>
<tr>
<td>Registration</td>
<td>91-100%</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>-</td>
<td>9-13</td>
</tr>
</tbody>
</table>

Our processing on data from Pharmaceutical Research and Manufacturers Association 2006
Phase III: tests are structured with a specific goal, that is obtaining a measurable result that clearly shows the success in fighting the targeted disease. Curative purposes must have been approved by the appointed vigilance authority (Food and Drug Administration - FDA - or European Medicine Evaluation Agency - EMEA) as a consequence that will conduct to the approval of the product for commercialization.

The effected tests involve the use of an elevated number of patients appointed as target; some analyses are predisposed by using a procedure that doesn't allow either the patient either the doctor to know the individuals who had a placebo administered. Tests are frequently effected in different laboratories to show that the results are reproducible in different clinical contexts. This important phase lasts two or three years starting from the initial planning date and often multiple phases III can be conducted together for verifying different indications or supporting different combinations of therapy.

When a "run medicine" succeeds Phase III, the approval process can begin. The company collects all its clinical data and submits a request to the appointed entity to introduce the medicine on the market. The request often requires three or six months just to be prepared and a similar period of time can be required by the FDA/EMEA Committee to express a judgment with recommendation. The FDA/EMEA Council accounts experts about the characteristics of the pathology and who work in the specific therapeutic field. Subsequently the medicine is authorized or not authorized for commercialisation.

Tab. 3 Development phases of a biotech drug.

4. From the business model of a biotech company to the financial reporting representations

As a matter of fact, the function of the annual financial statement is to provide information about the equity-financial situation, the economic performance and the changes in the equity-financial situation of an enterprise, useful to a large number of stakeholders in the process of taking economic decision.
Among the stakeholders interested to the annual reports, it is possible to identify (IASB, Framework):

**Investors.** Those who bring risk capital and their consultants are interested to the risk connected to their investment and the relevant yield. They need information that help them to decide whether to buy, to maintain or to sell. The shareholders, moreover, are interested to have information that allow them to appraise the ability of the entity to pay dividends.

**Employees.** The employees and their representative groups have interest to have information regarding the stability and to the profitability of their employers. Besides, they are interested to the information on the wages levels, on the pensions benefits and on the opportunities of employment.

**Financiers.** The financiers are interested to the information that can allow them to understand if their financings and relevant interests will be paid at the established expirations.

**Suppliers and other commercial creditors.** The suppliers and the other commercial creditors are interested to the information that can enable them to determine if the amounts for which they are creditors will be paid at the established expirations. It is probable that the commercial creditors are interested to the fates of their debtor entity for a briefer period than the financiers, unless they are interested to the permanence in life of the entity itself, seeing that it represents one of their greatest clients.

**Clients.** The clients have interest to acquire information regarding the continuity of the entity, especially when they have a long term involvement or they depend on itself.

**Governments and public commissions/boards.** The governments and the public commissions/boards are interested to the division of the resources and, consequentially, to the activity of the entities. They also need information to control the activity of the entities, to set up the tax policies and to have a base of reference in the calculation of the national income and in similar statistics.

**The public.** Entities influence the different components of the public in different ways. For example, they can offer an essential contribution to the local economy by different ways, among which the number of employed persons and their support to the local suppliers. The financial statement can help the public by giving information regarding the trend and the recent developments in the health condition of the entity, and the fields of activity in which it works.

In Facing such information that all listed stakeholders need, it is opportune to wonder if the financial information furnished by the actual models of representation of the principal activities of the biotech companies, as for example the R&D activities, substantially satisfy the informative needs of the readers of the document.

The following proposed analysis gives evidence to the different accounting approach that the enterprises have to follow according to the International Financial Reporting Standard IAS/IFRS and the US GAAP.

### 5. Rules for R&D and IPR&D

The rules defined by the different international contexts (IFRS, US GAAP) are extremely variegated and they are hereby analyzed with regards to the following essential elements related to the biotech sector:
- treatment for R&D costs;
- business combinations & IPR&D.
5.1 IAS/IFRS

The international financial reporting standards characterize two typical ways, relevant to the accounting representation of an investments, that a biotech can make in research, development or, more in general, in intangible assets. Such typologies are represented in the following table.

Tab. 4 Investments in intangible assets.

<table>
<thead>
<tr>
<th>Investments in intangible assets</th>
<th>Internal generation/development activity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Purchase through acquisitions or business combinations</td>
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</table>

In any case the possibility for a biotech company to recognise such activities is subordinate to the satisfaction of the followings criteria:

a) compatibility with the definition of intangible asset;

b) probability of expected future economic benefits that are attributable to the asset;

c) reliability measurement of the cost of the assets.

This three requirements have to be respected at the moment of the initial recognition, and subsequently in order to capitalize further expenses related to the same asset (IAS 38 par. 18), as for instance costs for implementation of a part or maintenance.

For internally generation, the biotech entity is required to valuate the investments "in intangible assets" coming from the research and development activity, classifying the process of creation of the asset by considering its phase of progress (Alfredson, Leo, etc. 2005):

a) phase of research;

b) phase of development.

If the biotech enterprise is not able to distinguish between the phase of research from the phase of development of an internally generated intangible asset, it has to treat and account for the cost as if it has exclusively been sustained in the phase of research (par. 53).

Regarding the research phase, it is not possible to capitalize expenses sustained during such phase, since it is necessarily very difficult to identify the expected future economic attributable to them.

Expenditures on research (or connected to the research phase of an internal project) must be therefore recognized as a cost in the income statement of the exercise when they occur.

The basis presupposition is that, during the research phase of a project, the biotech doesn't have the possibility to demonstrate the existence of an intangible asset that will produce probable future economic benefits.

During the phase of development of an internal R&D project, the biotech entity must recognise an intangible asset arising from development (or from the phase of development of an internal project) if the entity can demonstrate all the following:

a) the technical feasibility of completing the intangible assets so that it will be available for use or sale;

b) the intention to complete the intangible assets and use or sell it;

c) the ability to use or sell the intangible asset;
d) the way according to which the intangible asset will produce probable future economic benefits;
e) the availability of technical, financial and other resources to complete the development and to use or sell the intangible assets;
f) the ability to measure reliably the expenditure attributable to intangible assets during its development.

Being the development phase subsequent to the research phase, the enterprise can therefore identify more easily an intangible asset and demonstrate that it will generate in the future, with higher probability, economic benefits. Nevertheless a defined border for the capitalization of the expenses of internal development doesn't exist. Therefore the management has to use all the available information on every project in order to make its evaluation.

In any case, an important indication that the biotech enterprise has potentially satisfied the criterions imposed by the principle, occurs when it submits to the competent authority the request for the final approval. This is surely the clearest indication of the technical feasibility related to the completion of the developing research, which is the most difficult requirement to demonstrate.

In many cases the presentation for the approval to the competent authorities represents the initial moment for the capitalization of the expenses. There are, nevertheless, some situations where the criterions could be also considered satisfied prior than the presentation of the request for the approval: for instance, the evaluation of the experience acquired by the enterprise in obtaining the approval of a drug on different markets. The different registration authorities (FDA etc.) can ask for documentation and therefore analogous or different test, more or less specific. When the procedure is similar, it is possible that the probability of approval, in presence of an authorization released for analogous tests, results very elevated; as a consequence, there’s the possibility to positively recognise the capitalization of development expenses, even in case of non-completion of the third phase of the development of the drug.

In case of developing "generic" medical preparations (actually not so frequent within the biotech industry), where the technical feasibility of the application has already been approved for other homologous products, the probability of launching in the market place is extremely elevated: that’s the reason why, in many cases, the criterions for the capitalization of the expenses can be considered satisfied even if they occur during phases which are far from the approval moment.

Therefore, regarding the definition of the requirements, exists a “shadow area”, which is up to the subjective evaluation of the management and which can often lead to business policy oriented either to the total recognition of the whole research and development activity as an expense charged in the income statement or to the capitalization of the expenses sustained from a certain moment (LEV 2001).
5.2 IPR&D in business combination under IAS/IFRS

When a research and development asset still in progress is acquired through a business combination (for instance purchase of firm or branch of firm, merger, etc.), the cost of the acquisition is represented by the fair value of the asset at the date of the transaction (IFRS 3 Business Combinations).

As in case of acquisition of single assets, when the intangible asset is acquired as part of a business combination, the element "probability of generating future benefits" is reflected in the fair value evaluation of the asset. When determining the fair value, the expectations of market have to be considered with reference to the probability that the future economic benefits attributable to the asset will flow to the entity. As a consequence, the recognition criterion connected to the probability of generating future economic benefits, results automatically satisfied in case of intangible assets acquired through a business combination. The biotech (or the pharmaceutical) company, that is the acquirer, has to report in its financial statement the research and development assets in progress even if they are not recognised in the financial statement of the acquired entity. This methodology involves a number of remarkable problems connected to the operations of business combination involving biotech companies, that is the evaluation of the fair value of the IPR&D assets acquired.

With reference to the evaluation to the fair value of an intangible asset (for instance an IPR&D) acquired through a business combination, the IASB characterizes the following elements:

a) the reliability in the measurement;
b) the united evaluation of the fair value;
c) the hierarchy in the determination of the fair value.
The aforesaid points are straight on explained.

a) The reliability in the measurement.
The fair value of an intangible asset acquired in a business combination can normally be
determined with such reliability to be recognised separately from goodwill. If the effected
evaluations in order to determinate the fair value put in evidence possible results with
different probabilities, it is necessary to use such factor of uncertainty for determining the fair
value of the asset.
In any case, there is a relative presumption that the fair value can be reliably measured in case
of intangible assets with finite useful life and, therefore, the typical ones developed by
biotech companies (IFRS 3).

b) The united evaluation of the fair value.
In certain business combinations, an intangible asset could be considered separable only
together with a limited group of tangible or intangible assets; in these situations the acquirer
entity recognises the group of assets as a single asset separately from goodwill.
The only circumstances in which it might not be possible to measure reliably the fair value
are when the intangible asset arises from legal or contractual rights and either:
- is not separable;
- is separable, but there is no evidence of other exchange transactions for the same or similar
assets. In such case the estimate of fair value would be dependent on immeasurable variables.
If the acquired intangible asset doesn't satisfy the recognition criterions, it is not recognised
as autonomous asset and it is included in the amount of goodwill, which represents the future
economic benefits arising from assets that cannot be identified and separately recognised.

c) The hierarchy in the determination of the fair value.
The best way to estimate the fair value is represented by the actual price quoted in an active
market, usually not available for most of the assets connected to the biotech.
If market prices are not available, the fair value can be estimated with reference to the most
recent similar transaction, unless remarkable changes in the economic circumstances have
occurred since the date of the transaction, to the date when the fair value is estimated.
In absence of active markets, the estimate of the fair value is effected appraising the amount
that, at the date of acquisition, the entity would have corresponded for the asset in a normal
bargaining among willing and aware parts, considering all the available information. In order
to determine such amount, the entity must refers to the results of recent transactions for
similar assets.
Entities regularly involved in the purchase and in the sale of such specific intangible assets,
have the possibility to use indirect techniques to estimate the fair value.
Such techniques also include, whereas appropriate, the application of multiples, able to
attribute the market transactions to certain guide indicators of profitability of the asset (as
revenues, market shares, earning, etc.) or the actualization of the attended future financial
cash flow arising from the asset (for example, royalties on marks and brevets).
The methodologies that the business practice provides for the evaluation of the intangibles in
the biotech sector can be attributed to the followings:
- use of available empirical indicators;
- cost based criterions;
- criterions based on the contribution offered to the business profitability;
- criterions connected to the loss to the entity arising from the absence of intangible assets.
- real options.
First methodology presupposes the individualization of multipliers deduced from the market,
which are connected to certain significant quantity used in order to estimate the assets
considered; they often are available only for some typologies of assets, as for instance patents and trademarks; as a consequence, the scarce information about the exchange transactions of intangible assets and the difficulty to identify items with similar characteristics to the evaluated assets, in some cases, limit the application of such approach to the biotech.

The cost based criterions recognise the intangible asset, object of the estimate, at its substitution (or reproduction) cost or at its historical cost updated, both sustained for the achievement of the item. In the first case, the goal is to actualize the costs that are necessary to a hypothetical reconstruction of the item object of estimate, ignoring the efforts and the resources used in past, with the aim to quantify the investment that would be necessary at the present moment to create an item with analogous characteristics. In the second case, the goal is to identify and actualize the costs sustained for creating the item, whose value derives therefore from the sum of the monetary expenditures, opportune inflation, sustained in the past by the enterprise.

The third methodology consists in the actualization of the differential incomes connected to the intangible asset: it is therefore necessary to underline the incomes arising from the asset, that is its specific contribution to the profit of the entity.

The fourth criterion (cost of loss) consists in the actualization of the losses that would flow to the enterprise as a consequence of the disposal of the asset; the deal is to determine the damage, in terms of lower contribution margin, during the time necessary for the substitution of the item.

The last criterion, the real options one, follows the methodology adopted in the financial field, through the application of the model of "option call".

After an operation of business combination involving a biotech entity, on accounting point of view, the elements represented in the following table will come up.
Tab. 6 Table about the impact of the purchase method in the exploitation of the IPR&Ds in a business combination involving Biotech companies (IAS/IFRS).

As showed in the figure, the operation of business combination, effected in the moment when the biotech company has positively succeeded the principal clinical phases of development of the medicine, involves the estimate of fair value of the amount related to the IPR&Ds belonging to the acquired entity’s portfolio and not previously recognised as intangible asset. During the following years, such intangible assets are increased by the development activity and the completion managed by the big pharma acquirer.

After the approval for commercialisation, the group will produce and commercialize the products, and it will account for the amortisation of the intangible assets that start transferring their economic utility.
5.3 R&D, IPR&D and US GAAP

The US GAAP don't generally provide the possibility to capitalize expenses related to intangible assets (FAS 142 proposes again the content of the APB Opinion 17 - Intangible Assets, which it has replaced).

Such policies establish that the costs arising from internal development, the maintenance expenses or the restructuring costs of intangible assets (including goodwill), which are not specifically identifiable, which have indefinite useful life, or which are connected to an uninterrupted and connected to the entity exercise, must be reported in the income statement (LEV 2001).

The treatment related to the possibility or to the express prohibition of capitalization of some intangible assets is developed in specific documents or interpretations.

The Accounting Principle FAS 2 - Accounting for Research and Development Costs - rules the accounting treatment of the costs of research and development in the financial statements of the enterprises. FASB defines the concepts of "research" and of "development" as it follows:

- **Research**: planned research or critical investigation aiming to the discovery of new knowledges with the hope that these will be useful in the development of a new product or service or a new process or technique, useful to determine a significant improvement of an existing product or process.
- **Development**: the translation of a research discovery or other knowledge in a plan or a project or in a significant improvement of an existing product or process, if effected for the sale or the use. It includes the conceptual formulation, the program and the experimentations of the productive alternatives, the construction of prototypes and the effectiveness of small size plants. It doesn't include the usual or systematic change of the existing products, productive lines, production processes and other in progress operations, even if these changes can represent improvements; it doesn't include besides the market-researches or the activities of products-checking on the market.

FAS 2 offers some examples of activity that typically are included in the activity of research and development and it describes, besides, which expenses have to be reported as activity of research and development.

The activities of research and development are the followings:
- Research laboratories oriented to the discovery of new knowledges.
- Searches turned to the application of new research discoveries or other knowledges.
- Conceptual formulations and programs of possible alternatives of products or trials.
- Research testing or evaluation of alternative products or processes.
- Change of formulas or plain for a new product or process.
- Design, construction and testing of prototypes and models of pre-production.
- Design of tools and forms, involving new technologies.
- Planning, construction and starting up of small plant which is not large enough to be used for the commercial production.
- Engineering activity to improve the design of a product in order to meet the specific functional and economic requests and to be ready for going into operation.

The accounting principle FAS 2 generally assumes that the costs related to the activity of research and development must be reported in the income statement of the exercise when they occur. Therefore, the expenses arising from R&D sustained by a biotech company can never be considered as assets, able to produce future economic benefits.

The same treatment was defined (before the new FAS 141 issued in January 2008) for the research and development intangible assets still in progress acquired through a business combination. Under Fin - 4 (applicability of FASB Statement n° 2 to business combinations accounted for by the purchase method), if identifiable tangible and intangible assets resulting from R&D activities performed by to company that is acquired in to business combination
have no alternative use (such R&D activities macaws referred to in this issue as in-process R&D), they should be written off on given the business combination is consummated.

The new FAS 141 requires, instead, an acquirer to recognize all tangible and intangible research and development assets acquired in a business combination, as was proposed in the 2005 Exposure Draft. Previously, FASB Interpretation No. 4, Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method, required an acquirer to measure and immediately expense tangible and intangible assets to be used in research and development that had no alternative future use. A research and development asset was recognized as such only if it had an alternative future use. The FASB concluded that the requirement to immediately write off assets to be used in research and development activities if they have no alternative future use resulted in information that was not representationally faithful. In addition, eliminating that requirement furthers the goal of international convergence of accounting standards (with IFRS 3).

Therefore, the new FAS supersedes Interpretation 4 and requires research and development assets acquired in a business combination to be recognized regardless of whether they have an alternative future use.

In developing the 2005 Exposure Draft of the new principle, the Board also considered whether it could make further improvements by extending the recognition provisions of this Statement for research and development assets to purchases of in-process research and development assets outside a business combination. At that time, the FASB decided not to do so because the additional time needed to deliberate the related issues would have unduly delayed the issuance the new FAS 141.

Following, the same case of business combination introduced before, accounted for by using the past (FAS 141) US GAAP.

As showed, according to the superseded FAS, the acquirer entity has to write off the intangible assets referable to the activities of research and development in progress at the date of the business combination, (Until 4) and recognise an expense at the date of the acquisition. Subsequently, the continuation of the development is accounted for as a normal expense for research and development in the income statement of the exercise when it occurs.

At the time of the approval for trading, the entity gets economic benefits in terms of revenues from the investments in R&D and above all from the investments produced by the acquisition that are not reported as assets. Such accounting policy involves, under the same conditions, an elevated economic earning because, on one hand, the revenues arising from the sale of the products object of intense activity of research are considered and, on the other hand, the expenses related to the acquisition and development of those assets which generate such revenues, are not reported (trough the amortisation process).

The new FAS shows the same approach of IFRS 3 due to the convergence process.
Tab. 7 Table about the impact of the purchase method (supersedes) in the exploitation of the IPR&Ds in a business combination involving Biotech companies (US GAAP).
6. Empirical evaluation

Effected empirical analysis is set as an objective to verify the importance of the different normative in first place on the economic performance and financial information of the enterprises and subsequently on the variability of the results.

The Analysis has been effected through a sample of companies composed from the largest Global Pharmaceutical Companies. The analysis has allowed to show the different problem list investigated by the present paper:

The twenty largest pharmaceutical companies (source Punkett's Biotech&Genetics Industrial Almanac 2007), can be considered a meaningful sample because:
- all companies develop internally or externally activities relate to the biotech;
- all companies have effected, in the last years, operations of business combination with biotech companies;
- show a relevant R&D activity;
- some adopt IAS/IFRSs others US GAAP.

From the sample two big pharma have been excluded (Takeda Pharmaceutical company LTD and the Daiichi Sankyo co Japanese LTD) because with financial statement not comparable.

The conducted analysis has considered the economic and financial statements of the group for the last exercises available (2005-2006) verifying the following elements:
- relevance of intangibles and goodwill;
- relevance of the IPR&Ds arising from business combination
- activity of R&D

The relevance of the intangibles assets in the financial statement is analysed with the following ratios:
- intangible assets/total assets
- goodwill/total asset
- Intangible asset/equity
- Goodwill/equity

The relevance of the IPR&Ds arising from business combination is analysed with the following ratios:
- IPR&D/asset;
- IPR&D/equity
- IPR&D/income.

The activity of R&D is analysed with the following ratios:
- R&D/income;
- R&D/equity.

Tab. 8 The relevance of the intangibles assets in the financial statement (IAS/IFRS).

<table>
<thead>
<tr>
<th>Intangibles/Total assets</th>
<th>Goodwill/Total assets</th>
<th>Intangibles/Equity</th>
<th>Goodwill/Equity</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLAXOSMITKLINE</td>
<td>15,85 15,00</td>
<td>2,97 2,56</td>
<td>43,16 55,79</td>
</tr>
<tr>
<td>SANOFI-AVENTIS</td>
<td>30,52 34,76</td>
<td>36,61 34,77</td>
<td>113,95 130,54</td>
</tr>
<tr>
<td>BAYER</td>
<td>28,28 13,79</td>
<td>14,72 7,14</td>
<td>123,00 45,40</td>
</tr>
<tr>
<td>NOVARTIS</td>
<td>15,54 10,42</td>
<td>15,67 12,61</td>
<td>25,60 18,14</td>
</tr>
<tr>
<td>ROCHE</td>
<td>7,35 9,04</td>
<td>7,95 8,86</td>
<td>11,68 15,58</td>
</tr>
<tr>
<td>ASTRazeneca</td>
<td>10,38 7,08</td>
<td>3,66 3,84</td>
<td>20,15 12,85</td>
</tr>
<tr>
<td>AKZO NOBEL</td>
<td>2,05 1,63</td>
<td>3,29 2,29</td>
<td>6,15 5,68</td>
</tr>
<tr>
<td>Average</td>
<td>15,71 13,10</td>
<td>12,12 10,30</td>
<td>49,10 40,57</td>
</tr>
</tbody>
</table>

Source: Consolidated Financial Statement
The table shows the relevance of the investments in intangibles and in goodwill in comparison to the total assets and to the total equity. It can be noticed, in the period considered, the growing trend due to operations of business combination. It is also evident the dimension of intangible compared with goodwill (double) due to the possibility to account for IPR&D acquired in a business combination and to capitalize the development costs of internal projects.

**Tab. 9 The relevance of the IPR&Ds arising from business combination (IAS/IFRS).**

<table>
<thead>
<tr>
<th></th>
<th>IPR&amp;D/Total assets</th>
<th>IPR&amp;D/Equity</th>
<th>IPR&amp;D/Income</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLAXOSMITKLINE</td>
<td>6.88</td>
<td>7.21</td>
<td>18.73</td>
</tr>
<tr>
<td>SANOFI-AVENTIS</td>
<td>3.54</td>
<td>3.73</td>
<td>6.01</td>
</tr>
<tr>
<td>BAYER</td>
<td>2.28</td>
<td>3.59</td>
<td>9.91</td>
</tr>
<tr>
<td>NOVARTIS</td>
<td>3.48</td>
<td>1.45</td>
<td>5.73</td>
</tr>
<tr>
<td>ROCHE</td>
<td>5.13</td>
<td>6.90</td>
<td>8.15</td>
</tr>
<tr>
<td>ASTRAZENECA</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>AKZO NOBEL</td>
<td>0.06</td>
<td>0.04</td>
<td>0.19</td>
</tr>
<tr>
<td>Average</td>
<td>3.56</td>
<td>3.82</td>
<td>8.12</td>
</tr>
</tbody>
</table>

Source: Consolidated Financial Statement

In the Tab. 9 the relevance of the IPR&Ds is analyzed with reference to the operations of business combination. It can be noticed that the amount of IPR&D acquired in BC during the years is relevant above all if compared with the income (impact compared with write off).

**Tab. 10 The activity of R&D (IAS/IFRS).**

<table>
<thead>
<tr>
<th></th>
<th>R&amp;D/income</th>
<th>R&amp;D/Equity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2006</td>
<td>2005</td>
</tr>
<tr>
<td>GLAXOSMITKLINE</td>
<td>62.88</td>
<td>65.12</td>
</tr>
<tr>
<td>SANOFI-AVENTIS</td>
<td>100.70</td>
<td>155.96</td>
</tr>
<tr>
<td>BAYER</td>
<td>102.01</td>
<td>144.01</td>
</tr>
<tr>
<td>NOVARTIS</td>
<td>74.27</td>
<td>78.57</td>
</tr>
<tr>
<td>ROCHE</td>
<td>71.85</td>
<td>82.61</td>
</tr>
<tr>
<td>ASTRAZENECA</td>
<td>55.79</td>
<td>93.99</td>
</tr>
<tr>
<td>AKZO NOBEL</td>
<td>74.87</td>
<td>81.16</td>
</tr>
<tr>
<td>Average</td>
<td>77.48</td>
<td>100.20</td>
</tr>
</tbody>
</table>

Source: Consolidated Financial Statement

The table shows the relevance of the activities of R&D compared with the economic result and equity. It is important to underline the large amount even if reduced because of the possibility of capitalization.
Tab. 11 The relevance of the intangibles assets in the financial statement (US GAAP).

<table>
<thead>
<tr>
<th></th>
<th>Intangibles/Total assets</th>
<th>Goodwill/ Total assets</th>
<th>Intangibles/Equity</th>
<th>Goodwill/ Equity</th>
</tr>
</thead>
<tbody>
<tr>
<td>PFIZER</td>
<td>21.20</td>
<td>22.44</td>
<td>18.18</td>
<td>17.94</td>
</tr>
<tr>
<td>JOHNSON &amp; JOHNSON</td>
<td>21.75</td>
<td>10.51</td>
<td>18.91</td>
<td>10.18</td>
</tr>
<tr>
<td>ABBOT LABORATORIES</td>
<td>17.70</td>
<td>16.27</td>
<td>26.12</td>
<td>17.91</td>
</tr>
<tr>
<td>MERCK &amp; CC</td>
<td>2.12</td>
<td>1.16</td>
<td>3.21</td>
<td>2.42</td>
</tr>
<tr>
<td>BRISTOL MYERS SQUIBB</td>
<td>7.24</td>
<td>6.83</td>
<td>18.88</td>
<td>17.14</td>
</tr>
<tr>
<td>WYETH</td>
<td>1.03</td>
<td>0.78</td>
<td>11.38</td>
<td>10.70</td>
</tr>
<tr>
<td>ELI LILLY</td>
<td>0.00</td>
<td>0.00</td>
<td>0.59</td>
<td>0.57</td>
</tr>
<tr>
<td>AMGEN</td>
<td>11.09</td>
<td>12.77</td>
<td>33.45</td>
<td>35.82</td>
</tr>
<tr>
<td>BAXTER</td>
<td>3.27</td>
<td>3.88</td>
<td>11.02</td>
<td>12.19</td>
</tr>
<tr>
<td>SCHERING-PLough</td>
<td>1.78</td>
<td>2.36</td>
<td>1.28</td>
<td>1.32</td>
</tr>
<tr>
<td>GENENTECH</td>
<td>3.21</td>
<td>4.73</td>
<td>8.86</td>
<td>10.83</td>
</tr>
<tr>
<td>Average</td>
<td>9.64</td>
<td>8.17</td>
<td>13.81</td>
<td>12.46</td>
</tr>
</tbody>
</table>

Source: Consolidated Financial Statement

As showed in the tab. 11 above the weight of the intangible assets and the goodwill is extremely relevant and in growth during the considered years because of the business combination operations effected that allow to acquire technology already developed and technology in progress. To this intention it is meaningful to notice that the company under US GAAP rules show an amount of goodwill higher than the analogous ones that use the IAS/IFRSs. This situation could be originated from different factors; it is important however to underline that the non possibility to account for IPR&D (with the past FAS 141) acquired in a business combination could force the management to attribute to them limited value and this consequently increases the value of goodwill.

Tab. 12 The relevance of the IPR&Ds arising from business combination (IAS/IFRS).

<table>
<thead>
<tr>
<th></th>
<th>IPR&amp;D/Total assets</th>
<th>IPR&amp;D/Equity</th>
<th>IPR&amp;D/Income</th>
</tr>
</thead>
<tbody>
<tr>
<td>PFIZER</td>
<td>0.73</td>
<td>1.45</td>
<td>1.17</td>
</tr>
<tr>
<td>JOHNSON &amp; JOHNSON</td>
<td>0.79</td>
<td>0.61</td>
<td>1.42</td>
</tr>
<tr>
<td>ABBOT LABORATORIES</td>
<td>3.49</td>
<td>4.12</td>
<td>8.98</td>
</tr>
<tr>
<td>MERCK &amp; CC</td>
<td>1.71</td>
<td>0.00</td>
<td>4.34</td>
</tr>
<tr>
<td>BRISTOL MYERS SQUIBB</td>
<td>0.00</td>
<td>0.22</td>
<td>0.00</td>
</tr>
<tr>
<td>WYETH</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>ELI LILLY</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>AMGEN</td>
<td>3.26</td>
<td>0.44</td>
<td>5.81</td>
</tr>
<tr>
<td>BAXTER</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>SCHERING-PLough</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>GENENTECH</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>Average</td>
<td>1.66</td>
<td>1.14</td>
<td>4.34</td>
</tr>
</tbody>
</table>

Source: Consolidated Financial Statement

In the tab. 12 are analyzed the relevance of the IPR&Ds acquired in a business combination. It is possible to notice that the amounts are very limited (in absolute value and also comparing them with those of the IAS/IFRS enterprises). Once more such situation can
induce to think that the management of the acquiring company minimizes the value attributed to IPR&D and this increases the goodwill amount.

Tab. 13 relevance of the activity of R&D (US GAAP).

<table>
<thead>
<tr>
<th>Company</th>
<th>R&amp;D/income</th>
<th>R&amp;D/Equity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2006</td>
<td>2005</td>
</tr>
<tr>
<td>PFIZER</td>
<td>39.30</td>
<td>89.75</td>
</tr>
<tr>
<td>JOHNSON &amp; JOHNSON</td>
<td>64.46</td>
<td>64.23</td>
</tr>
<tr>
<td>ABBOT LABORATORIES</td>
<td>131.41</td>
<td>54.00</td>
</tr>
<tr>
<td>MERCK &amp; CC</td>
<td>107.87</td>
<td>83.09</td>
</tr>
<tr>
<td>BRISTOL MYERS SQUIBB</td>
<td>193.50</td>
<td>91.53</td>
</tr>
<tr>
<td>WYETH</td>
<td>74.09</td>
<td>75.19</td>
</tr>
<tr>
<td>ELI LILLY</td>
<td>117.54</td>
<td>152.85</td>
</tr>
<tr>
<td>AMGEN</td>
<td>114.10</td>
<td>62.98</td>
</tr>
<tr>
<td>BAXTER</td>
<td>45.25</td>
<td>55.75</td>
</tr>
<tr>
<td>SCHERING-PLOUGH</td>
<td>191.43</td>
<td>693.31</td>
</tr>
<tr>
<td>GENENTECH</td>
<td>83.91</td>
<td>98.67</td>
</tr>
<tr>
<td>Average</td>
<td>107.72</td>
<td>138.31</td>
</tr>
</tbody>
</table>

Source: Consolidated Financial Statement

The table shows the relevance of R&D expenses. As it can be noticed, in absence the possibility of capitalization, the amount charged to economic account is significant in comparison to the dimension of the income and the equity. It is nevertheless important to underline that the opportunity to capitalize expenses of research and development produces, as a result in the following years, the amortization process with an impact on the performance.

7. Conclusions

The effected analysis has allowed to show some remarkable crucial matters, relevant to the economic and financial communication presented by biotech companies and, in general, by the big pharma performing analogous activities.

As generally shared, the financial statement provides useful information in order to take economic decisions in terms of investment, but not always the accounting policies, such as the International Financial Reporting Standard or the US GAAP, perfectly fit the different typologies of enterprises with very specific business models, as those of the biotech sector, where the trials for the creation of the output "technological invention" involves many exercises and the developed activities are characterized by a strong risk level. It is the combination of these two elements - "time" factor and "risk" factor - that put under pressure the accounting policies in the different contexts. As faced in the present work, the research and development activities, basic point of the existence of the biotech companies, are ruled in different ways. The International Financial Reporting Standard, in case of internal development, allow the capitalization of the expenses only after the satisfaction of specific criterions, that, applied to the sector, defer the moment of recognition and reporting. The US GAAP instead don't allow such possibility and they forbid the capitalization of the costs of R&D. The different treatment and the uncertainties about the correct moment in which the expenses of R&D can be considered as intangible assets, involve sometimes very different results in front of the same conditions, making not comparable between them enterprises that
challenge in a fair way from a scientific point of view. The reason that push to formulate the accounting standards is to share, because it is moved by the necessity of not to make the business performance activity volatile, with reference to intangible assets generally considered more "risky"; nevertheless, it must be underlined that the rigidity in the approach, even if it can be suitable for an "integrated" entity where the value chain starts from the first phases of research and bring to the production and trading of the product, it is not right at all for an enterprise that focuses its business model in a narrow part of the trial (more in details, the part characterized by most of the risk). As showed by the empirical analysis, the application of the principles determines the representation of enterprises in economic unbalance during the whole phase of research and development of their "products" and which are often able to attract financial resources, not because of the information resulting from the financial statements, but because of what cannot emerge from it, that is the "value of the research".

Besides, the "acquisition method" methodology used to account for business combinations (according to IAS/IFRS and the new FAS 141) allows to recognise the fair value of the IPR&Ds creating, as pointed out by the Board (FASB) itself, a different treatment between internally generated assets and acquired assets through a business combination. This can be, and actually the effects are already visible, the cause of a deep distortion in the mechanisms of creation of the intangible assets. The possibility to report in the financial statement only the R&D assets acquired through a business combination, pushes to outsource such R&D activities compared to the internal generation, making to decrease the direct investments of the “big pharma” in the internal research. Such situation, that can also have a remarkable economic and social impact, both positive both negative (and on whose importance those who write about it don’t give an opinion into the matter), should not be artificially determined by accounting principles but, on the contrary, by studies and specific regulations.

After developing these critical considerations on the economic and financial communication of the biotech companies, it is necessary to propose some solutions inspired to make, as long as it’s possible, their financial statements understandable to the purpose of "taking economic decisions". Moreover, it is opportune to specify that the possibility to reach the pointed goals is however subordinate to a quick process of convergence of the different rules (IAS/IFRS, US GAAP, but also other domestic GAAP).

On the point of view of considering the biotech companies as enterprises destined to perpetuate their activity, it is necessary to underline that the economic representation has to take in due consideration the accrual principle: "the effects of transactions and other events are recognised when they occur and reported in the financial statements of the periods to which they relate". It comes from this, the necessity to capitalize the sustained costs of R&D with future utility. As regards that, it is necessary to establish not "subjective" criterions for the evaluation and therefore to provide the certainty of the behaviour of the management to the reader of the financial reports. Such capitalized intangible assets will have to be tested for impairment systematically, using defined tests with strict procedures and formality, and certified by auditor experts in the field.

As regards the IPR&Ds acquired through operations of business combination, the possibility of recognition and reporting has to be, in any case, homogeneous with the treatment used for the internally developed assets.

Finally, large space could be given to the disclosure related to the activities of research and development in progress, with the exploitation of the following information:
- Description of the medicine and the pathologies;
- Phase of experimentation;
- Probability of obtainment of the approval;
- Expected year for trading;
- Potential market;
- Total costs sustained for the experimentation;
- Economic value to completion;
- Results of the impairment test and relevant information.

Such information are all available within the enterprise and they lead the management in the economic and managerial choices and could also be useful to the reader "investor" of the financial report.
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