

Pharmaceuticals and Life Sciences

International Financial Reporting Standards (IFRS)

Issues and Solutions for the Pharmaceuticals and Life Sciences Industries - Vol III

Accounting For Licensing and Development Agreements



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Foreword

One of the big problems life science and biotechnology companies face in order to flourish is the lack of adequate and appropriate long term financing. At the same time, the pharmaceutical industry had been dealing with a number of challenges related to the loss of patent protection and the need to adjust to the new ways of performing research. Often the solution to these problems has been to partner with another company.

Each agreement is unique and may contain very complex clauses. While both US Generally Accepted Accounting Principles (US GAAP) and International Financial Reporting Standards (IFRS) provide guidance on revenue recognition, as yet there is no specific industry guidance as to how these agreements should be accounted for.

This third publication of IFRS Issues and Solutions for the Pharmaceutical and Life Sciences industries has been prepared to stimulate discussion and represents a first step in trying to establish a common platform or framework. Principally written from a revenue recognition standpoint, it considers how both parties should account for an agreement. However, the paper does not intend to provide a formulaic approach to evaluating contracts as each solution should reflect the facts and circumstances of each agreement.

I hope this paper, filled with illustrative examples, is informative, helpful and will encourage consistent financial reporting practices within the Pharmaceuticals and Life Sciences industries.

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01 Introduction

1.1 Background

Over the last 20-30 years there have been many dramatic advances in medical and biological science. These have not only improved man's understanding of the causes and nature of disease and illness but have also enabled the creation of newer, more sophisticated drugs with fewer side effects than ever before. Much work has been performed in this area by life science and biotechnology companies that have been created by scientists and academics to fund the development of this new science. With such complex science the path has been long and hard and while some players have flourished, particularly in the USA, many more have failed along the way. In many cases companies with promising ideas have failed because they have not had access to adequate and appropriate long term financing and/or drug development and marketing expertise.

At the same time, the well established pharmaceutical industry has been dealing with a number of challenges including:

- The blockbusters of the 1980's and early 90's have been losing patent protection leading to dramatic falls in sales and returns
- Old ways of performing research do not seem to bring the same rewards and many companies have suffered from dwindling research productivity and product pipelines
- There has been a dramatic shift in what the public and regulators expect from new drugs and getting a new drug to market is more difficult and costly than ever before.

One solution to these problems has been for pharmaceutical and biotechnology companies to team up. This often involves pharma providing the financial, marketing and development expertise and biotech providing the new drug candidates, targets and cutting edge science. In recent years this has led to the creation of literally thousands of strategic alliances, collaboration agreements and a whole host of other types of arrangements. All major pharmaceutical companies have these types of arrangement and their business development departments are always on the look out for more. The vast majority of biotechnology companies also have them or if they don't, they may well be looking for their first deal.

01 Introduction

These agreements between pharmaceuticals and biotechnology companies are often very complex and last for many years over the different phases of a product's life cycle, all the way from an early stage development project through to a marketed product. Differing levels of risk and reward may be transferred between parties depending on the time in a product's life cycle that an agreement is signed. At one end of the scale an agreement might involve only the provision of research and development (R&D) services, whereas at the other end a transaction might involve risk sharing between parties and several different interrelated components including significant upfront or milestone payments, put and call options, debt and equity or other instruments, plus royalty arrangements.

Given the complexity, it is unsurprising that accounting for these agreements is difficult and subjective. In particular, accounting for revenues earned under these agreements can involve significant judgement as to when the criteria for revenue recognition have been met and to what extent the contract should be separated into components that are accounted for separately. In addition, it is common for agreements to contain significant milestones (substantive or otherwise) and determining the appropriate accounting treatment for these can be problematic and a source of debate between management, their auditors and the regulators. For development stage companies of a small or medium size, the revenues associated with these contracts are often material and the pattern of their recognition can have a significant impact on the pattern of reported profits and losses.

Each agreement is unique and may contain complex clauses and therefore it is difficult to provide a "one size fits all" solution. Each agreement should be evaluated on its own merits and the accounting, whenever possible, reflect the substance and commercial reality of the arrangement.

While both US Generally Accepted Accounting Principles (US GAAP) and International Financial Reporting Standards (IFRS) provide guidance on revenue recognition, as yet there is no specific industry guidance or literature, under either US GAAP or IFRS, as to how these type of arrangements should be accounted for.

1.2 Scope and approach

This discussion paper has been prepared to stimulate discussion and represents a first step in trying to establish a common platform or framework for evaluating licensing and development agreements in the pharmaceutical and biotechnology industries.

While this paper considers how both parties should account for the joint agreement, it is principally written from a revenue recognition standpoint. While this should help all parties in these types of agreements, we envisage it will be of particular interest in providing guidance to small and medium sized pharmaceutical and biotechnology companies whose arrangements contain material license fee income and development milestones.

This paper has not intended to provide a formulaic approach to evaluating contracts since contracts will always require individual and detailed analysis. Rather the aim of the paper is to highlight those factors and themes that should be considered when developing an appropriate accounting treatment for any individual arrangement.

The approach taken in the paper is to identify the general principles, describe how these might apply in practice and then to work through some detailed examples. The paper has taken some features that are common to different agreements. Each scenario is examined by itself and different conclusions could be drawn when it is looked at in the context of a full agreement.

1.3 Risk and reward

One of the functions of licensing and development agreements is to share and diversify development risk. Both companies share the risk of development work and the pharmaceutical company is also able to fill strategic gaps in its development pipeline and gain exposure and access to new technologies and treatments.

Typically the earlier in a product's development that an agreement is signed, the greater the risk that is shared/transferred between the parties and the lower the consideration that will be paid by the pharmaceutical company (particularly upfront consideration).

1.4 Acknowledgements

We would like to thank both Adrian Bennett and Michael Gaull for their contribution to the research and production of this document.

02 General Accounting Principles

2.1 Revenue recognition

Revenue recognition guidance under IFRS is provided principally by International Accounting Standard (IAS) 18 Revenue. IAS 18 provides guidance on revenue recognition for the provision of both goods and services. IAS 11 also provides guidance but specifically in relation to construction contracts and will usually not be applicable to most agreements encountered in the pharmaceutical and biotechnology industries. Its requirements are, however, applied by analogy through IAS 18.21.

Under IFRS, revenue is recognised when it is probable that future economic benefits will flow to the entity and those benefits can be measured reliably. Revenue on sales of goods is only recognised when, inter alia, the significant risks and rewards of ownership have been transferred to the buyer and the seller does not retain either control of the goods, or continuing involvement, to the degree associated with ownership. For services, evidence is required that a service has been delivered by requiring the seller to be able to measure reliably the stage of completion of the transaction.

In the pharmaceuticals industry it is important to assess whether the selling entity has actually delivered something – either transferring the risks and rewards of goods or other assets (e.g. licences) or by providing a service to the buyer.

Service revenues

Agreements will usually encompass the delivery of services at some level, although this may not be immediately self evident from the way the contract is worded. For example, as part of an agreement, a party may agree to perform development work as part of a collaboration rather than providing development services to a third party. Even so, it will often be appropriate to account for revenues during the development phase using a service revenue accounting model.

IAS 18 (para 20) states that when the outcome of a transaction involving the rendering of services can be estimated reliably, revenue associated with the transaction shall be recognised by reference to the stage of completion of the transaction at the balance sheet date. The outcome of a transaction can be estimated reliably when all the following conditions are satisfied:

- The amount of revenue can be measured reliably
- It is probable that the economic benefits associated with the transaction will flow to the entity
- The stage of completion of the transaction at the balance sheet date can be measured reliably
- The costs incurred for the transaction and the costs to complete the transaction can be measured reliably.

The recognition of revenue by reference to the stage of completion of a transaction is often referred to as the percentage of completion method. Under this method, revenue is recognised in the accounting periods in which the services are rendered.

The determination of the stage of completion may be made on either input or output measures and the most appropriate measure will depend on the nature of the contract. The table below shows scenarios where it might be appropriate to use an input or output based measure to determine the stage of completion of services:

Measure	Services	Fees paid
Input	Contract Development Services	On an agreed hourly rate
Output	Enrolling patients into a clinical trial	For each patient recruited into a trial

For general contract development services paid on an hourly rate, it would be appropriate to recognise revenue by reference to the number of hours worked (i.e. using an input measure) since that is the basis upon which the related fees are earned. Other contracts may make reference to outputs such as the enrolment of certain numbers of patients into clinical trials and here recognition based on the number of hours incurred to recruit those patients would not be appropriate since the fees are not earned on that basis.

Costs under these types of arrangements are expensed as incurred and therefore the pattern of cost recognition may be different to revenue recognition.

Milestone payments

Contracts in which milestone payments are received in return for performing a service should be accounted for using the percentage of completion method.

Many agreements make reference to the payment of milestones on completion of certain phases of clinical development. For example an agreement between two parties could be structured as follows:

Milestone Event	£'000
1. Successful completion of phase II clinical trial	5,000
2. Food and Drug Administration (FDA) approval	10,000

In this case, the services that are being delivered are the performance of a clinical trial. However the associated services fees are only payable in the event that the clinical trial is successful (i.e. only a successful outcome to the trial signifies completion of the milestone event). Generally there is a presumption that the outcome of a clinical trial cannot be estimated with certainty and therefore the probability criterion (i.e. that it is probable that economic benefits will flow to the entity) will only be met once the milestone event has occurred (IAS 18.20b). The fee is entirely success based and it is therefore unlikely that an entity will be able to assert that it is probable that any costs incurred to date will be recoverable (IAS 18.28). Therefore, no revenue in respect of these milestones would be recognised until they were successfully completed and the costs would be expensed as incurred.

This type of revenue recognition (i.e. on successful completion of a milestone) is often referred to as the “milestone payment method” and is common in the industry. In reality, it is an application of the percentage of completion method in the sense that:

- The relevant services have been 100% delivered
- The revenues are only recognised when it is probable the economic benefits will flow to the entity i.e. when the milestone event is achieved.

Milestone payment method – key distinction

Any references in this document to the **milestone payment method** are referring to a percentage of completion method where services are being delivered and the service revenues are received in the form of milestones.

This is a **critical** distinction. Many types of contracts contain milestones, including those where there is no obligation to perform services. In such cases, milestones often represent deferred consideration.

To result in revenue, a payment must be substantiated by an outcome; otherwise it may be simply a stage payment.

It is critical to understand whether the party performing services or work under the arrangement is receiving milestone payments and what those payments have been made for. Are the payments for substantive services performed or for something else?

Upfront payments

Many agreements that contain milestone payments also include upfront payments. Upfront payments that have been received without the provision of any goods or services should be deferred and recognised over the relevant contract period. Nothing has been provided in return for the payment; the payment is for services over the entire contract period. Where the milestone payment method is being applied then the upfront payment should be recognised on a basis that is consistent with the services delivered over the contract period. It may be that the services are delivered evenly over the contract period. In such a case the upfront payment should be spread on a straight line basis. If the services are not delivered evenly the upfront payment should be recognised in line with delivery.

Agreements may also make reference to payments for past research and development services however, this is not relevant from a revenue recognition perspective. Immediate recognition of an upfront payment is only appropriate if there is an outright disposal and the criteria for the sale of goods within IAS 18 are met.

Under the milestone payment method, milestones are only recognised as revenue when: they are receivable; they are non-refundable; and provided they are in substance consideration for a completed separate earnings process. The milestone events must have real substance, and they must represent achievement of specific defined goals. This determination is judgmental and may be difficult although the following considerations are important in making that assessment:

- Substantive effort must be involved in achieving each milestone. Each milestone should represent the rendering of a distinct service
- Milestone payments should represent the fair value of the service that has been provided. Factors to consider are:
 - The payment must be reasonable in relation to the effort expended. This evaluation should consider the level, skill and expertise of personnel involved and other costs incurred. Risk may be a factor. For example, it would be reasonable that a larger milestone payment is associated with achievement of a higher risk event as compared to a lower risk event (e.g. the milestone for achieving a successful phase III trial would typically be significantly higher than for a phase I trial)

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- The payment should be considered in relation to other payments in the overall contract with each milestone representing fair value for the effort and associated risk. For example, if an upfront payment is low and the first milestone payment that is “earned” shortly thereafter is much higher, this may indicate that a portion of the milestone payment is a “disguised upfront payment.” A comparison of the milestone payments to each other also should be made. For example, a higher milestone payment for an early-in-the-project target compared to a milestone payment to be received upon achieving a later, more critical and difficult target may indicate an imbalance.
- It would be expected that, considering the above two factors, a reasonable amount of time will have passed between the upfront payment and the first milestone as well as between each milestone. (Note: While in itself the passage of time does not indicate work will have been performed, a lack of time may indicate that it has not)
- Where a contract contains a number of milestone payments an entity should demonstrate that each payment is for a separate service or significant act. If this was not the case and the contract was for a single service then the percentage of completion method would have to be applied to the contract as a whole. This could result in very late revenue recognition with all costs expensed as incurred. Guidance on segmenting a contract into its components is set out in Section 3.

Example – Application of the milestone payment method

Pharmaceutical company Omega contracts with life sciences company Theta. Theta agrees to deliver a library of compounds according to Omega’s specified criteria. In return Omega agrees to pay Theta the following non-refundable amounts:

- LC0.5 million on signing of the agreement
- LC2 million on delivery of a library of 100 compounds which are active against Omega’s targets
- LC1 million when any of the compounds developed by Theta is put into a clinical trial by Omega.

Theta expects to incur costs of LC1.5 million in the development of the library, earning a significant mark-up. There is risk to Theta because if it is unable to deliver the library it will not earn the LC2 million milestone.

It would appear reasonable under the percentage of completion method to recognise revenue based on milestones in this case because:

- The upfront payment is not disproportionate (it appears to provide a measure of working capital for Theta to fund the LC1.5 million of development)
- Theta is providing a distinct service in return for the LC2 million payment that involves substantive effort
- The LC2 million milestone payable is only payable in the event of success and together with the upfront includes a reasonable profit element (LC1 million or 40%) given the risk involved, compared to other similar contracts in the industry

- The final milestone (or milestones) is further contingent consideration payable only if the product is put into a clinical trial (or trials). There is no basis for recognising this until the event is achieved – i.e. in accordance with the milestone payment method
- Theta is not able to ascertain the probability that the library of effective compounds will be delivered until that event occurs
- Given these facts, the LC2 million payment appears to be at fair value in return for the service rendered by Theta.

Revenue should be recognised under IAS 18 by Theta as follows:

- The LC0.5 million upfront is recognised over the estimated period that Theta will develop the library. Thereafter Theta has no ongoing obligations
- The LC2 million milestone would only be recognised when the library of compounds is delivered and Omega accept that the library is active against their specified targets. At this point the service has been rendered and the revenue has been earned
- The LC1 million milestone payable each time a compound entered clinical trials would be recognised when this event occurred.

The costs of LC1.5 million are recognised as they are incurred.

Sale of assets

While agreements will often most appropriately be considered as relating to the sale of services, particularly more complex agreements, there may be occasions when it is more appropriate to consider the transaction as relating to the sale of an asset (e.g. the outright sale or assignment of a license). Although IAS 18 deals with sales of goods and services, similar criteria to sale of goods should be applied to the recognition of revenue from sales of assets. Revenue should only be recognised when all the following conditions have been satisfied (IAS 18.14):

- The entity has transferred to the buyer the significant risks and rewards of ownership of the goods
- The entity retains neither continuing managerial involvement to the degree usually associated with ownership nor effective control over the goods sold*
- The amount of revenue can be measured reliably
- It is probable that the economic benefits associated with the transaction will flow to the entity
- The costs incurred or to be incurred in respect of the transaction can be measured reliably.

* **Note:** This can be a difficult assessment when there is participation in a Joint Development or Marketing Committee (or similar activities), particularly where there may be a casting vote or where one partner adopts a lead role in a particular phase.

Example – Outright sale of a license

Blayo PLC acquired a license to sell a drug BBlocker for LC2,000 in 20X0. In November 20X5 Blayo PLC was forced by regulators to dispose of BBlocker and therefore in December 20X5 it signed an arrangement with Neurex Ltd under which Blayo assigned its license to BBlocker to Neurex for LC10,000. Blayo retained no intellectual property (patents, licenses, etc.) associated with BBlocker and no royalties were payable under the arrangement.

Blayo recognises income/revenue of LC10,000 in its financial statements for the period ended 31 December 20X5 since all risks and rewards associated with ownership of the asset have been transferred and Blayo retains no continuing managerial involvement. The cost of the transaction can be measured reliably and the carrying value of the licence should be de-recognised.

2.2. Risk sharing and onerous contracts

Development agreements may be structured such that the party performing the development incurs short term losses on a development project but has access to future revenues when a product is eventually produced and marketed. The biotech company bears greater risk in developing the product but may receive a greater share of future benefits at a later stage.

Fees to be received after the development period will often not be in return for a service. When considering the expected benefits under the contract (IAS 37.68) the amounts expected over the entire contract should be taken into account and not only those amounts receivable over the development period.

Generally such a company would not have an onerous contract if it had a significant exposure to the risks and rewards of ownership of the asset under development. These rewards may take many different forms including royalties and/or manufacturing fees at greater than commercial rates. The probability of future rewards may be slim, however that is part and parcel of the business of pharmaceutical research and is the risk taken by all companies in performing research and development work. This risk is generally factored into price negotiations such that at the outset of a contract the expected benefits, on a weighted average probability basis, exceed the potential costs of fulfilling the contract [IAS 37.10]. Where any entity has potential future upside under an agreement, the recognition of a provision for an onerous contract may represent a provision for future operating losses and would therefore not be appropriate. An entity should take all facts and circumstances into account when assessing whether or not a contract is onerous.

Certain fixed fee agreements may not include potential upside from royalties or manufacturing fees. These and similar arrangements need to be reviewed carefully each period to determine whether the contract as a whole is expected to be profitable. Where the outcome of the contract cannot be assessed with reasonable certainty, then revenue should only be recognised to the extent that costs are recoverable. If the recoverability of costs can also not be assessed with reasonable certainty, no revenue should be recognised and costs should be expensed as incurred. If the contract is expected to make a loss then that loss should be provided for immediately.

All contracts should be reviewed carefully to understand the nature of risks and rewards of the arrangement and to determine whether there is an onerous contract. Where a company does have an onerous contract, the unavoidable costs under the contract (reduced by the probable fees to be earned) should be recognised as provision. This would be the lower of the cost of fulfilling the contract or any penalties arising from failure to fulfil it.

Example – Onerous contract

Pharmaceutical company Omega contracts with life sciences company Theta. Theta agrees to deliver a library of compounds according to Omega's specified criteria. In return Omega agrees to pay Theta the following amounts:

- LC0.5 million on signing of the agreement
- LC3 million on delivery of a library of 100 compounds which are active against Omega's targets.

Theta is obligated to deliver the library or would be in breach of contract and face penalties.

Revenue on the arrangement would be recognised similar to that in the above example i.e. the upfront payment (LC0.5 million) would be recognised over the period of delivery of the samples and the milestone (LC3 million) would be recognised on successful delivery. However the costs require further consideration:

- At inception, on 1 January 20X6, the contract is expected to take two years to complete and Theta will incur costs of LC2.5 million earning an overall profit of LC1 million
- At 31 December 20X6 the project has overrun and Theta has incurred costs of LC3 million and expects to incur further costs of LC1 million to complete the library. Theta still expects that it will be able to deliver the library.

At the balance sheet date Theta has projected a total loss of LC0.5 million on the contract:

	LC'M
Costs incurred to date	3
Costs to complete	1
Total projected costs	4
Total projected revenues	-3.5
Loss on contract	0.5

This loss would be provided for as at 31 December 20X6 as it is an onerous contractual commitment.

Conversely, if the same agreement allowed Theta to participate in the future success of any compounds then it is unlikely that a provision would be required. For example if the contract included the following additional consideration:

- LC1 million payable to Theta for any library compound used by Omega in a clinical trial.

Under the latter scenario Theta is performing in the expectation that certain of the compounds will enter clinical trials for which it will be paid deferred consideration. Therefore no provision would be required.

03 Components and Separation of Contracts

Identification of the separate accounting components of an arrangement

Individual arrangements may be very complicated. They may be constructed through several different but related contracts or may be within a single contract but covering several phases of the product development life cycle. Arrangements may include some or all of the following: agreement to perform development work, sale of intellectual property licenses, manufacturing agreements, sales and marketing agreements. Likewise, the consideration under the arrangement may take several different forms including: upfront payments, milestones, license fees, royalties and manufacturing fees. These contracts may span many years.

Where this is the case an assessment should be made as to whether it is more appropriate to account for the arrangement as a single transaction or to account for the separately identifiable components in order to reflect the substance of the transaction (IAS 18.13). While IFRS expresses this as a general principle, it does not provide definitive guidance as to how this should be applied in practice and here US GAAP is helpful. The US guidance in EITF 00-21 explains that the different elements of an arrangement can be accounted for separately where the entity can demonstrate:

- The delivered element/component has value to the customer on a standalone basis if sold separately or the customer could resell the delivered item on a standalone basis. This does not require the existence of an observable market
- There is objective and reliable evidence of the fair value of the undelivered element
- If there is a general right of return, delivery of the undelivered element is considered probable and substantially in control of the vendor.

03 Components and Separation of Contracts

These concepts appropriately support the principles in IAS 18 and are illustrated by the following example:

Example – Separating contracts

Company Alpha buys a highly specialised piece of scientific equipment (LC2,000), a standard desk-top PC (LC500) to operate it and an installation and training package (no charge) from supplier Beta. The desk-top PC could be sourced from other suppliers and has a manufacturer's recommended retail price of (LC500) however Alpha chose to purchase it from Beta for convenience. The scientific equipment, training and installation cannot be provided by anyone other than Beta and can be acquired separately from the PC (LC2,000). Customers cannot operate the equipment without installation and training however these services are always provided "free of charge". Beta's year end is 31 December and on December 29 Beta delivers all the equipment to Alpha's premises. The installation and training are scheduled to take place in January. There is no general right of return associated with the PC; however the scientific equipment is subject to a customer acceptance procedure. As at 31 December 20X5 how much revenue should Beta recognise?

Step 1: Identify the separate components of a transaction

This arrangement has two separate components:

1. The desktop PC
2. The scientific equipment, installation and training package.

The desktop PC has been delivered and has value on standalone basis since it could be used as a PC for another purpose other than to operate the scientific

equipment. Objective and reliable evidence of its fair value exists because it could be bought from another supplier and there is a third party manufacturer's list price.

The scientific equipment and the installation and training package form a single unit of accounting because the scientific equipment does not have standalone value to the customer as the customer can neither make use of it nor resell it without training and installation. In addition there is no objective and reliable evidence for the fair value of the installation and training (the undelivered component) since these are always provided free of charge.

Step 2. Determine how the separate components should be accounted for as at 31 December 20X5

Desktop PC

Revenue of LC500 should be recognised in respect of the PC since it meets the revenue recognition criteria in IAS18. The risks and rewards of ownership were transferred on delivery and there is no right of return. The revenue can be measured reliably and it is expected that the customer will pay on normal terms and therefore probable that economic benefits will flow to Beta.

Scientific equipment, installation and training package

No revenue associated with the scientific equipment should be recognised since the significant risks and rewards have not passed until the customer accepts the equipment through the acceptance procedure after delivery of the installation and training.

Generally, if there is objective and reliable evidence of fair value for all units of accounting in an arrangement, the arrangement consideration should be allocated to the separate units of accounting based on their relative fair values (the relative fair value method). This method ensures that any discount is appropriately allocated to the individual elements of the arrangement.

There may be cases in which there is objective and reliable evidence of the fair value of the undelivered items in an arrangement but no such evidence for the delivered items. Where this is the case, the residual method can be used to allocate the arrangement consideration. Under the residual method, the amount of consideration allocated to the delivered items equals the total arrangement consideration less the aggregate fair value of the undelivered items.

Example – The residual method

Epsilon is a manufacturer of bespoke scientific equipment. Delta contracts to acquire, from Epsilon, a piece of their scientific equipment which includes a year of support under the arrangement as standard. The total package sells for LC2,000. After the first year Delta can acquire further annual support at a price of LC250 per year.

Epsilon delivers the scientific equipment to Delta on 31 December 20X6 with a voucher for support for 20X7.

The arrangement has two separate components:

- A piece of bespoke scientific equipment
- The support contract.

There is no objective and reliable evidence for the fair value of the delivered element – the bespoke scientific equipment. However, the support contract is sold separately at an annual price of LC250 and therefore there is objective and reliable evidence of the fair value of the undelivered element.

The consideration is therefore allocated to the deliverables as follows:

	LC
Consideration	2,000
Support contract at fair value	-250
Scientific equipment “residue”	1,750

Provided the normal revenue recognition criteria for goods are met (IAS 18.14), Epsilon should recognise revenues of LC1,750 in its financial statements for the year ended 31 December 20X6. Support revenues of LC250 are deferred and amortised over the year to 31 December 20X7.

The “reverse” residual method (that is, using a residual method to determine the fair value of an undelivered item) is not permitted under US GAAP. Under IFRS there is no specific guidance as to how the different components of an arrangement should be separated and therefore, technically, the reverse residual method is not prohibited. However its use under IFRS would require care to ensure that any revenue recognised was appropriate and any US GAAP-IFRS differences arising had appropriate justification.

04 Agreements and Revenue Recognition

4.1 Contract research and subcontracted development work

Time and materials basis

In the very early stages of product development or when conducting early stage research, it is quite common for pharmaceutical companies (service buyer) to enter into service type arrangements, with biotech or other life science companies (service provider). Under these types of arrangements there is usually very little (if any) transfer of risk and the commercial substance is often that of an outsourcing arrangement. The services provided might include high throughput screening services, synthesis of chemical libraries or drug candidates or analytical services.

The most simple of these arrangements may involve:

- Services being provided on a “time and materials basis” where the hours worked are billed on at an agreed hourly rate; or
- An agreed fee based on an estimate of the number of full time equivalent employees involved in the project.

Generally the service provider is not exposed to any development risk in the form of success based milestones or other contingent fees.

Accounting by the service provider

At each reporting date, revenue should be recognised in accordance with the percentage of completion method in accordance with IAS 18. The most appropriate measure of completion in this case is by reference to the number of hours worked priced at the agreed rate per hour.

Accounting by the service buyer

The cost of the services is accrued for as those services are performed.

04 Agreements and Revenue Recognition

Fixed fees

As an alternative to working on a purely time and materials basis, a service provider may be contracted to deliver an agreed programme of work for a fixed fee. For example a Company (service provider) may be contracted to deliver a chemical library of 100 compounds based on a specific design criterion for a fee of LC100,000. Under this scenario, the service provider is exposed to the risk of “overruns” i.e. incurring costs in excess of the agreed fee.

Accounting by the service provider

At each reporting date, revenue should be recognised in accordance with the percentage of completion method. In the case above, the most appropriate basis to measure the percentage of completion would be based on inputs, i.e. by reference to the cost (time and materials) incurred to date as a percentage of the total costs expected to be incurred in accordance with the following formula:

$$\text{Revenue} = \frac{\text{Total Revenue} \times \text{Costs incurred to date}}{\text{Total project costs}} - \text{Revenue recorded to date}$$

Appropriate adjustments should be made as estimated costs are updated. Measurement according to outputs (i.e. for example based on the number of compounds) would not be appropriate because it would be unlikely

to appropriately reflect the percentage of completion of the work undertaken and the final creation of the library would likely be the only measurable output. The compounds are likely to be delivered in a single batch, therefore an output based measure would lead to recognition of no revenue until the work was 100% complete.

If the outcome of the contract cannot be estimated reliably, revenue is recognised only to the extent that costs are recoverable. If at any time the total costs expected to be incurred under the contract exceed the total revenues to be earned under the contract, then an onerous contract exists and a provision for losses on contracts should be recorded in accordance with IAS 37. The provision is recorded at the date the contract becomes onerous and would be utilised over the remaining period of the contract.

Accounting by the service buyer

The costs of the services are accrued for as those services are performed.

Other considerations – Straight-line service fee recognition

While generally under IFRS it is appropriate to recognise revenue on a percentage of completion basis, there may be scenarios when this is not appropriate. Consider a Company that provides ad hoc consultancy services over for a fixed period of time with no specified deliverables or fixed time commitment. Determining the percentage of completion under this scenario and the revenue to be recognised may not be possible. Therefore IAS 18.25 requires that when services are performed by an indeterminate number of acts over a specified period of time, revenue should be recognised on a straight-line basis over the specified period unless, there is evidence that some other method represents better the stage of completion.

4.2 Licensing and development agreements

A typical agreement

While there is no such thing as a typical agreement, since they are all unique and have their own nuances, there are certain general features and terms that recur in different agreements. Agreements are usually constructed to share in the risks and rewards through participation in a specific development project or compound which has been developed to a certain stage by one party to the agreement.

The extent to which those risks and rewards are transferred from one party to another will often depend on the stage of development of the asset and the particular business strategies of the parties to the agreement. Generally, the more advanced a product is in its clinical developments, the less transfer of risk and reward. As a drug is developed and passes through clinical trials it is “de-risked” from a development perspective. Therefore the party that holds the exclusive rights to the asset when an agreement is entered into will be able to retain a greater proportion of the upside as the risk of product failure diminishes.

The various scenarios considered in the analysis below are between a large fully integrated pharmaceutical company (Pharma Co.) and a smaller early stage biotech or pharmaceutical company (Biotech Co.).

4.2.1. Pharma Co. performs development work

Large pharmaceutical companies regularly in-license products, at various stages of development, from smaller pharmaceutical and biotech companies. For example, a fairly typical scenario between a large pharmaceutical company (Pharma Co.) and a biotechnology company (Biotech Co.), where Biotech Co. has successfully developed a drug for Syndrome Q through phase II trials, could be structured as follows:

- Pharma Co. is to fund and perform all phase III clinical development work on a drug developed by Biotech Co.
- There is a joint development committee that oversees the development of the product and through which all strategic decisions regarding the product are decided. The committee has equal numbers of representatives from each company
- Biotech Co. retains the patents and underlying intellectual property associated with the product, but grants a license to Pharma Co. to manufacture, sell and market the product in the USA for the treatment of syndrome Q
- Biotech Co. retains the right to sell the product in the rest of the world.

This type of agreement could be entered into by a specialist antibody biotechnology company that had the research expertise to create specific antibody drugs but did not have the resources to fund the drugs' development through expensive phase III clinical trials or the experience and resources to manufacture quantities of the drug for a global market or to sell and market the drug.

The consideration payable by Pharma Co. under such an agreement could include:

- An upfront payment of LC10 million on signing the contract
- Milestone payment of LC20 million on FDA approval
- Royalties payable on net sales of 15%
- Sales milestone of LC20 million payable in the first year that annual sales exceed LC500 million.

The upfront payments and milestones are non-refundable in the event that the contract is cancelled once the payments have been made.

Accounting by Biotech Co.

Biotech Co. has licensed the rights to its product in the USA however, it has retained a residual interest in the product; it will receive royalties on product sales in the USA, it participates in a committee that determines how the product should be developed and has retained the rights to sell the product in all territories outside the USA. Biotech Co. also owns all the intellectual property underlying the product and has only granted a license in respect of a specific indication. The question is whether the rights it has retained mean that there is no sale of a license.

Upfront payment

When the contract is signed, it is clear that economic benefit will flow to the entity and the revenue is measurable. However it is rather less clear whether the other criteria in IAS 18 (para 14) have been met namely:

- Whether “the entity retains neither continuing managerial involvement to the degree usually associated with ownership nor effective control over the goods sold.”
- Whether “the significant risks and rewards associated with ownership have been transferred”.

While Biotech Co. has retained certain rights and has not disposed entirely of the underlying asset, it is clear that a license has been sold. Pharma Co. has an exclusive license to sell the product in the US and to determine the most appropriate way to do that. Biotech Co. may earn a royalty on those sales but it has no ability to influence those sales or how they are made (although the contract may require Pharma Co. to use its best efforts to sell the product). In addition, Biotech Co. has no significant obligations under the contract and is not required to perform clinical development work. Biotech Co. has a seat on a development committee although it is a protective right that it enjoys and it has no obligation to attend meetings or any other substantive obligations. Biotech Co. therefore appears to have retained no substantive rights or obligations in respect of the licence to develop the product and to sell it in the USA.

Since Biotech Co. is performing no development work, the upfront and milestone payments represent consideration/deferred consideration for the sale of the license to develop the product and then to sell the product for the treatment of Syndrome Q in the USA. The payment should be recognised in accordance with IAS 18 (para 14) when it is receivable.

Biotech Co. should also consider whether all of the payments apparently received for the sale of the licence relate to that asset. It should examine whether there is evidence that the fair value of the undelivered item (share of royalties) are at fair value, to give evidence of whether the sale of the licence is at fair value. If the royalty rates were sacrificed to obtain a higher upfront payment (or milestones) then the payment should be deferred and amortised over the life of the agreement.

Milestone payment

The most significant difference between the upfront payment and the milestone is that the milestone is contingent on FDA approval. Once that contingency is met then the milestone should be recognised as revenue on the same basis as the upfront payment. The milestone payment relates to the sale of the license but its receipt is not probable until approval is obtained and so it should not be recognised at the initial transaction date, in accordance with IAS 18.14(d).

Royalties

The royalties should be accrued as revenue/income in line with the underlying sales made by Pharma Co. i.e. they are not recognised in advance since the amounts cannot be measured reliably.

Sales milestone

The sales milestone should be assessed to determine whether in substance it represents deferred consideration for the license or whether in substance it represents an upfront royalty payment.

If the milestone is for the achievement of significant sales thresholds e.g. LC1 or LC0.5 billion of sales and the royalty rates appear to be at fair value, then it is appropriate to record the milestone as income in a single tranche, when its receipt is probable and it meets the criteria for recognition under IAS 18. This is because in substance, it represents additional contingent consideration for the license.

If the milestone levels do not appear to represent a significant sales threshold and the royalty rates appear low then deferral may be appropriate.

Accounting by Pharma Co.

Upfront and milestone payments

In substance the upfront and milestone payments made by Pharma Co. represent consideration for the license to sell the product in the USA.

Under IAS 38 (para 33) these payments are capitalised as intangible assets regardless of the fact that the product has not yet received FDA approval. For acquired intangible assets, it is always assumed that the asset meets the probability criteria for asset recognition since the asset's fair value reflects market expectations about the probability that the future economic benefits embodied in the asset will flow to the entity. In other words, the effect of probability is reflected in the fair value measurement of the intangible asset.

The cost of the intangible asset will include any milestone payments (including the sales milestones). However, those payments should only be recognised when they become probable. The payment, and the related asset, should be recognised when the risks and rewards of the intangible asset are transferred to Pharma Co.

The intangible asset should not be amortised until available for use i.e. following final FDA approval. It should be tested for impairment annually up to the time it is available for use.

Royalties

The royalties should be accrued as a cost of sale in line with the underlying sales. Until the underlying sales are made, the royalty receipts cannot be reliably measured.

Sales milestone

The sales milestone should be accrued in accordance with IAS 37 and recorded when it is probable that it will be paid. The payment represents contingent licence fee consideration (because the royalties are at fair value) and therefore the other side of the entry increases the cost of the intangible asset. In order to demonstrate that the milestone is probable, the product will need to have been launched and there should be a sufficient track record of sales to have a reasonable expectation that the milestone will be reached.

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4.2.2 Biotech Co. performs development work - The milestone payment method

Identifying the party who is performing work

In the previous section we discussed the recognition of revenue by Biotech Co. where ostensibly Biotech Co. had no significant ongoing obligations and certainly no obligation to perform any development work. Under these types of arrangements, milestones were usually considered to represent deferred consideration for a license.

In the following section we discuss situations where payments are received by a biotech company which is also performing clinical trials or development work i.e. providing services. This is quite different to the situation in the above section where we were considering milestones as deferred consideration.

In this section we will consider how income might be recognised where services are provided under a collaboration agreement and explore the use of a method of accounting known as the milestone payment method. As outlined in section 2.1, this method represents a form of percentage of completion accounting which may be applied under certain circumstances.

Biotech Co. performs development work funded by Pharma Co.

Biotech Co. may be a fairly well established company that has the expertise to perform clinical trials. However, they may not have sufficient finance to fund a particular trial and will look for a partner to share in the cost of developing the product and also assist in selling the product in certain territories. Consider an agreement that has the following features:

- Pharma Co. agrees to fund (or partly fund) clinical development work from phase III through to FDA approval
- Biotech Co. is responsible for performing clinical trials and obtaining FDA approval
- Biotech Co. grants Pharma Co. a license to manufacture, sell and market product.

This type of agreement could be entered into by a specialist antibody biotechnology company that had niche expertise in the creation of specific antibody drugs but did not have the resources to fund a drug's development through expensive clinical trials, or the experience and resources to manufacture quantities of the drug for a global market or sell and market the drug.

The consideration payable by Pharma Co. under such an agreement might comprise:

- An upfront payment of LC10 million (in consideration for work performed to date on the drug)
- Milestone of LC20 million payable upon successful completion of a phase III trial
- Milestone of LC10 million on FDA approval
- Royalties payable on sales of 25%
- Biotech Co. expects to incur costs of LC60 million in performing the phase III trial. Pharma Co. will not make further payments in the event that further trials are required or the actual costs of the phase III trial exceed the projected cost.

Accounting by Biotech Co.

In substance, what is happening is that Pharma Co. is making payments to (i) fund a portion of the future development of the drug and (ii) to acquire a license to sell, market and distribute the product. The deal has been structured in such a way that Pharma Co. is funding two-thirds of the drug's future development (LC40 million out of a total of LC60 million). Since Biotech Co. is contracted to develop the drug, it is in substance providing development services for the income it is receiving as well as selling a license to sell, market and distribute the product.

Biotech Co. must consider the most appropriate way to recognise the upfront and milestone payments. The first method it may consider is the milestone payment method and in doing so, it must assess the milestones against the criteria outlined earlier.

In aggregate the upfront payments and milestones equate to funding of much of the development work on the compound. The milestones are also at risk and Biotech Co. only receives them if the output of its work is 100% complete and successful. Biotech Co. has also assessed the royalty rate against other agreements and believes

they are at fair value. This analysis has also been based on an overall assessment of the net present value of the project and its future sales to both parties. Under this scenario it appears reasonable to apply the milestone payment method.

Upfront payment

On initial signing of the agreement Biotech Co. has not fulfilled any of its obligations under the agreement and therefore the upfront payment should be deferred and recognised over the development period. Providing the royalty rates (and any manufacturing/supply agreement) have been priced at fair value then it is appropriate to recognise the upfront payment over the period to filing the drug with the FDA, since in substance the payment is part payment for the cost of development.

If there has been a trade off between the upfront payment (or milestones) and the downstream royalty or the prices in the supply agreement then it may be appropriate to defer a portion or all of the upfront payment over the entire life of the agreement.

Milestones

Substantive effort and considerable cost will be incurred in completing the phase III trial and getting FDA approval. The consideration happens to be split between the two different milestone events however, that is likely more for the benefit of Pharma Co. in further de-risking the project since the final LC10 million is only payable on FDA approval.

The milestones are therefore recognised when earned and receivable i.e. on achievement of each of the milestone events since until that point they cannot be assessed as being probable due to the inherent uncertainty as to whether they will be achieved. Until that point, income should not be recognised.

If there has been a trade off between the upfront payment (or milestones) and the downstream royalty or the prices in the supply agreement then it may be appropriate to defer the milestones payment over the entire life of the agreement.

Royalties

Royalties should be recognised as revenue/income as earned in line with the underlying sales.

Onerous contract considerations

While Biotech Co. is only receiving LC40 million in terms of development funding in return for undertaking a project which it estimates will cost LC60 million, there is no onerous contract since there is further consideration (i.e. royalties) if the product comes to market. The two parties are sharing the cost of development and expect to share in the future upside of the product.

If Biotech Co. was contracted to complete a trial (for whatever reason) and believed it probable the trial would fail, then it may be appropriate to record a provision for an onerous contract.

Accounting by Pharma Co.

Upfront and milestone payments

The upfront and milestone payments are in part consideration for the license and in part Pharma Co.'s share of the cost of funding the development of the asset.

Under IAS 38 (para 33) these payments are capitalised as intangible assets regardless of the fact that the product has not yet received FDA approval. For acquired intangible assets it is always assumed that the asset meets the probability criteria for asset recognition since the asset's fair value reflects market expectations about the probability that the future economic benefits embodied in the asset will flow to the entity. In other words, the effect of probability is reflected in the fair value measurement of the intangible asset. It is

important to note that while Pharma Co. is funding much of the development of the asset, this is not internal development expenditure (or outsourced research and development).

The payments should be recognised when they become payable i.e. on signing for the upfront payment or in the case of the milestone on FDA approval.

The intangible asset should not be amortised until available for use i.e. following final FDA approval.

Royalties

Royalties should be accrued for in line with the underlying sales and recorded as a cost of sale.

4.2.3 Biotech Co. performs development work – Alternatives to the milestone payment method

Under certain circumstances, the use of the milestone payment method will not be appropriate. Consider the same example as above but instead the consideration payable by Pharma Co. comes in the following form:

- Upfront payment of LC2 million
- Milestone at start of phase III of LC24 million
- Development fees of LC4 million payable in four LC1 million tranches phased over the development period
- Milestone of LC10 million on FDA approval
- Royalties payable on sales of 25%.

A phase II trial has recently been completed with a successful outcome and intention to proceed to phase III trials.

Accounting by Biotech Co.

Development phase – upfront, milestones, development fees

While the upfront and milestone payments under the arrangement are the same (i.e. LC40 million), it is not possible to directly link the payments made to the work actually performed under the agreement. In addition much of the funding is received in advance. The milestone payment method is therefore not appropriate because the pattern of payments does not reflect the services provided.

In this scenario, another way of applying the percentage of completion is required. The most appropriate way is to recognise revenue as the **lower** of (i) the actual non-refundable cash received under the contract and (ii) the result achieved using a percentage of completion model:

$$\text{Revenue} = \frac{\text{Actual costs incurred to date}}{\text{Estimated total cost to be incurred}} \times \text{Total (development) payments receivable under contract}$$

This method spreads the consideration receivable under the contract (in the development phase) in line with services delivered, and allows for the fact that some payments are contingent and should not be recognised until the contingency has lapsed i.e. revenue can only be recognised to the extent that non-refundable cash has been received.

Royalties

Royalties should be recognised as revenue/income as earned in line with the underlying sales.

Accounting by Pharma Co.

Upfront fee and milestone at start of phase III

Since the phase II trial has been completed with positive results then, in substance, there is no significant distinction between the upfront fee and this milestone at the inception of phase III. In signing the agreement both parties are expecting to proceed with phase III development and the contract is a mechanism for funding that development. Therefore they are both upfront payments although there may be a slight timing difference in when they are actually paid.

Under IAS 38 (para 33), these payments are capitalised as intangible assets regardless of the fact that the product has not yet received FDA approval. For acquired intangible assets, it is always assumed that the asset meets the probability criteria for asset recognition since the assets fair value reflects market expectations about the probability that the future economic benefits embodied in the asset will flow to the entity.

The payments should be recognised when they become payable i.e. on signing or when phase III starts.

The intangible asset should not be amortised until available for use i.e. following FDA approval.

Development fees

Pharma Co. does not own any original intellectual property at the outset of the arrangement and is making various payments to purchase a license and marketing agreement. The payments that are being made have been staged so that Biotech Co. can use the consideration to fund the development of the product.

There is a general presumption under IAS 38 that payments made to a third party in acquiring an intangible asset should be capitalised. Pharma Co. also needs to assess whether any element of this deal represents, in substance, internal development expenditure. In this

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case, the payments are structured such that it appears, from Pharma Co.'s perspective, that the payments are all consideration to acquire the license. The development fees should therefore be capitalised.

Royalties

Royalties should be accrued as a cost of sale in line with the underlying sales.

4.2.4 Biotech Co. performs development work – Other alternatives to the milestone payment method

In addition to the milestone payment method and the modified percentage of completion model, there are two other methods that can be used to account for payments received under licensing and development agreements. These are the contingency adjusted performance model and the contract term deferral method.

The contingency adjusted performance model

Revenue related to each payment is recognised over the entire contract performance period, starting with the contract's commencement, but not prior to the removal of any contingencies for each individual milestone.

Under this method, the upfront payment and each achievement of a milestone is accounted for individually. The cost of the total effort to complete the expected research and development activities is estimated from the contract's commencement date. Once a contingency is removed and the customer is obligated to make a payment, the cost of the effort that has been incurred to date (since the contract's commencement) is divided by the total expected research and development costs (from the contract's commencement to the end of the development arrangement), and revenue is recognised for that milestone to the extent of the ratio of performance to date, less revenue previously recognised. The remainder is spread over the remaining performance period, based on a similar calculation.

Example – Contingency adjusted performance model

Consider the following example of an agreement signed on the 1 July 20X6:

- Pharma Co. agrees to fund (or partly fund) clinical development work from phase III through to obtain FDA approval
- Biotech Co. agrees to perform clinical trials and file for FDA approval
- Biotech Co. grants Pharma Co. a license to manufacture, sell and market the product.

Pharma Co. agrees to pay:

- LC5 million upfront on signing the contract
- LC1 million on agreeing the phase III trial study protocol
- LC3 million on recruitment of 100 patients into the trial
- LC10 on filing for FDA approval
- Royalty of 25% on sales.

The contract is not expected to be loss making for Biotech Co. when it is assessed during 20X6 and 20X7.

At 31 December 20X6 Biotech Co. has achieved the first two milestones and has incurred 20% of the total costs it expects to incur in the trial. The revenue to be recognised is calculated as follows:

Payment received LC	% Complete	Total to be recognised LC	Recognised previously LC	P&L LC
5	20%	1	0	1
1	20%	0.2	0	0.2
				1.2

Revenues of LC1.2 million would be recognised in the period ended 31 December 20X6 and LC4.8 million deferred at that date.

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At 31 June 20X7 Biotech Co. has achieved the third milestone and has recruited over 100 patients into the trial. In addition, it is estimated that the company has now incurred 30% of the total costs to be incurred on the trial. Revenue to be recognised in the six months to 31 June 20X7 would be calculated as follows:

Payment received LC	% Complete	Total to be recognised LC	Recognised previously LC	P&L LC
5	30%	1.5	1	1
1	30%	0.3	0.2	0.1
3	30%	0.9	0	0.9
			1.2	1.5

Revenue of LC1.5 million would be recognised in the 6 months to 30 June 20X7, with LC6.3 million deferred at the balance sheet date.

This method leads to a “catch-up” effect in respect of the later milestones. For example, milestones received when the project is almost 90% complete result in the immediate recognition of 90% of the milestone rather than its recognition being spread over the remaining 10% of the costs to be incurred.

The contract-term deferral method

Under this method, each time a payment (whether an upfront or milestone payment) is received, it is deferred and amortised over the remaining contract period (probably the period of the development agreement). This method takes no account of the costs (or effort) already incurred and assumes all payments are for future performance and there is no “catch-up” effect as in the ‘contingency adjusted performance model’. This method is not appropriate under IFRS because it does not recognise revenue in accordance with the criteria of IAS 18.

Consistency of application

The choice of a particular method of accounting will largely be driven by the facts and circumstances of any given agreement. In making this assessment it is important that a company is consistent in its decision making process and the manner in which it applies the accounting treatments.

4.2.5. Other considerations

Multiple phases of development

A development agreement may span several phases of clinical development (e.g. phases II and III). In addition, there may be an option at the end of a particular phase to exit the arrangement. This can lead to the question as to whether a contract should be accounted for as a single unit or whether there is more than one accounting unit.

As discussed previously, IFRS does not provide explicit guidance as to how or whether a contract should be treated as more than one accounting unit. Again, US GAAP and EITF00-21 provide useful guidance and would require, in order to separate the phases of the development contract into separate units of account, demonstration that (i) the delivered phase of development has stand alone value to the customer and (ii) there is evidence of the fair values of the undelivered phases of the contract.

While a drug in an intermediate development phase cannot be sold to patients (i.e. all phases up to and including phase II), it could be argued that the completion of intermediate development phase has standalone value to the parties to a licensing contract since there is a market for partially developed drugs. A careful analysis of the particular facts and circumstances at the inception of the contract will be necessary. The following factors may indicate that it is appropriate to separate different phases of development and account for each phase as a separate component:

- The drug is a new chemical entity (NCE) and at the inception of the development contract there is considerable uncertainty whether a second, subsequent phase of development will be possible until the results of the first clinical trial are available
- The margins on different phases of development are at fair value and represent a reasonable return for the effort involved and phase of development

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- There is a realistic expectation that the development candidate could be out-licensed at the end of an intermediate development phase (e.g. end of phase II). This may be less likely to be the case for a product in a niche or speciality class or therapeutic area
- There is no binding commitment on either party to continue with development
- The party providing the development services is not uniquely qualified to perform the development work and the clinical trial.

Such analysis is subject to professional judgement and should be carried out for each contract. It should be clearly documented and built on principles, so that management are able to respond to regulators and auditors.

Where the separate components of a contract are accounted for separately, revenue should be recognised for each service based on its fair value.

Obligations

Contracts may contain certain obligations which require Biotech Co. to perform tasks or services which can preclude or impact the revenue recognition of development milestones. This can be the case even where it might otherwise appear reasonable to recognise revenue based on the payment receivable for the milestone achieved.

Consider an example where Biotech Co. receives a LC20 million milestone for the FDA approval of a drug it licensed to Pharma Co. Biotech Co. has no further development work to perform and has assessed the milestone as being reflective of a significant service delivered to Pharma Co. that should result revenue being recognised in respect of the amount of the milestone. It would appear that Biotech Co. should recognise the milestone as revenue when it becomes receivable. However, what happens when the same arrangement requires Biotech Co. to make “marketing contributions” or deliver “free samples” when the product is launched?

Analysis is required to determine how significant the obligations are and whether they preclude revenue recognition. It may be appropriate to conclude that many of the ongoing obligations are attached to the manufacturing contract and are contingent on successful development. This could include marketing contributions and patent defence costs that would not be incurred absent a marketable product. Revenue recognition on the development phase of the contract may or may not be affected by these obligations.

Assessing obligations

The assessment of different types of obligations that may arise under a contract requires judgement. There are a number of factors that should be considered as a minimum when forming that judgement:

- Is the obligation substantive or perfunctory? This requires an assessment as to whether the obligation is significant to the delivery of the main service or product, whether it is incidental and of little consequence from a revenue recognition perspective. For example, an agreement to answer another party’s questions about a compound they had purchased could be viewed as part of normal good relationship management (i.e. perfunctory) whereas an agreement to supply 500 million free sample tablets would appear to be a substantive obligation.

If the obligation is substantive then further consideration is required:

- Is the obligation a separate component or deliverable under the terms of the contract? If the obligation is a separate component/deliverable then revenue equal to the fair value of that deliverable/component should be deferred until the risks and rewards associated with that component have been transferred in accordance with IAS 18 (i.e. the product or service has been delivered)
- If a specific obligation is not a separate component or deliverable under the terms of the contract, then it needs to be considered to which component it is attached. Revenue associated with a component which includes an unfulfilled obligation may preclude any revenue recognition at all.

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Post development phase obligations

It is quite common for agreements to contain post development phase obligations. Some examples of these and their usual significance on revenue recognition are shown below:

Obligation	Significance
Marketing contributions	Significant
Cost sharing agreement	Significant
Supply of free samples	Significant
Supply of clinical trial materials	May be significant
Provision of services, employees, management	May be significant
Participation in a steering committee	May be significant
Provision of information	Typically insignificant
Patent defense	Typically insignificant
Assist orderly hand-over	Typically insignificant

Assigning these obligations to a specific phase (or component) of the contract can require judgement. Factors to consider include:

- The future timing of any obligations relative to the receipt of the milestone (e.g. a commitment to pay a marketing contribution immediately following receipt of a milestone may indicate a transaction without commercial substance, for example a “round-trip” transaction)
- Expected outflows for the commitment in relation to the expected benefits
- Normal industry and company practice
- Participation of the obligated party in a joint-steering committee and or other contractual mechanism that influences or controls spending
- Whether the obligation meets the definition of a liability under IAS 37.

Deferral of all or a portion of the payments is likely to be appropriate until the contract is complete when there are significant obligations that appear to be “linked” to the milestone payment and for which further payments at fair value are not received. Where this is the case, the guidance on multiple element contracts should be applied.

4.3 Sales and Manufacturing Agreements

Often licensing and development agreements will be signed at the same time as, and linked to, a sales and/or manufacturing agreement.

This might be the case where a niche biotech company has specialist manufacturing capabilities that a large pharmaceutical company does not possess; for example, in the production of certain niche antibody drugs where biotech has certain patented proprietary production techniques. Under these arrangements, a biotech company might agree to provide bulk antibody drug (i.e. before packaging) at an agreed price per dose.

Alternatively, the biotech company may have aspirations of becoming a fully integrated pharmaceutical company with its own sales force. It may agree to retain the rights to sell the product in certain territories or enter a co-marketing or co-promotion arrangement. Other types of arrangement may require one party to provide ongoing marketing support.

The key consideration with these types of arrangements is that in order for the amounts receivable under the contract in the development phase to be treated as a separate unit of accounting, the amounts receivable in the manufacturing phase should be priced at fair value. Demonstrating that these elements of the arrangement are at fair value could be done by comparison with other similar arrangements, for example by reviewing the manufacturing margins earned by Biotech Co. or competitors on sales of similar antibody products.

At fair value

If the various royalties and contract manufacturing sales are assessed to be at fair value then they should be accounted for as they arise under IAS 18.

Not at fair value

If the sales/manufacturing agreement is not at fair value, then some or all of the upfront payments/milestones on the development phases will need to be deferred and recognised over the period of the manufacturing agreement.

05 Example Solutions

The discussion and examples in the preceding sections have attempted to provide a useful framework for analysing licensing and development agreements. However it is important to bear in mind that all agreements are unique and require careful analysis on a case by case basis to determine the most appropriate accounting treatment. Such analysis requires careful consideration of the commercial substance of the arrangement and not just the legal form. For example, it will often be important to consider the financial models that have underpinned the commercial negotiation of any arrangement.

We have outlined in this section some example contracts with solutions as to how they might be accounted for. These are designed to illustrate the relevant thought processes and how one might go about analysing individual contracts. They are not intended to be used as stock answers to be applied to seemingly similar arrangements. They focus on illustrating common features. Different outcomes may result when the feature is examined in the context of an entire contract.

In each example, we have assumed that this is the first commercial arrangement between the two contracting parties.

5.1 Out-licensing of a product in development phase to a marketing partner (example 1)

Background

Silicon Tech is a biotechnology company that has successfully developed a novel protein, for the treatment of Syndrome Y, through to completion of phase II trials. Silicon Tech has signed a licensing and marketing agreement with pharmaceutical marketer Germanium to fund product development of the product. Germanium has acquired a license to sell, market and distribute the product in the USA. Silicon Tech will continue to develop the product and will have all product rights outside of the USA. The financial terms are:

- Germanium will pay a non-refundable upfront fee of LC15 million
- Germanium will pay a milestone of LC10 million on approval of the drug by the FDA
- Silicon Tech will earn a royalty of 20% on product sales in the Territory
- The estimated cost of the phase III trial is LC22.5 million. Germanium will not make further payments in the event that further trials are required or the actual costs of the trial exceed the projected cost.

Silicon Tech and other comparable companies earn royalties of 15-25% on other novel proteins they have developed. Syndrome Y is not an area of unmet medical need and would not command any significant premium in royalties.

Solution**Silicon Tech**

The milestones are similar to others in comparable contracts. Within the context of the agreement, the payments are proportionate to the cost of development and milestones are only payable on the 100% completion of a significant substantive event. The royalty is comparable with that on other novel protein treatments.

The royalties are assessed as being at fair value. Management concludes that the development phase of the agreement should be treated separately from the remainder of the agreement.

The agreement qualifies for the milestone payment method and Silicon Tech should recognise the upfront payment over the term of the development agreement to the expected date of filing its regulatory submission to the FDA. The milestone payment for FDA is a substantive milestone which should be recognised when the milestone criteria are met.

Any royalties should be recognised when earned.

At the outset of the agreement, Silicon Tech is only guaranteed to receive LC15 million of the total cost of the trial of LC22.5 million. However, Silicon does not have an onerous contract because:

- Future milestone receipts and royalties are expected to exceed the cost of development if the product is successful
- Silicon Tech has entered into the contract on the basis that the expected benefits are greater than the costs of fulfilling the contract. The expected benefits take account of the probabilities of the trials being successful or not.

Germanium

The upfront and milestone payment are capitalised as the acquisition of a separate intangible asset by Germanium. In substance, Germanium is paying to acquire a license to the drug and to help fund its development.

Under IAS 38 (para 33) these payments are capitalised as intangible assets regardless of the fact that the product has not yet received FDA approval. For acquired intangible assets, it is always assumed that the asset meets the probability criteria for asset recognition since the assets fair value reflects market expectations about the probability that the future economic benefits embodied in the asset will flow to the entity.

The payments do not represent internal development expenditure since Germanium did not own the original IP to the protein and is not taking on risk in the funding of further development.

No amortisation should be charged until the asset is available for use and then it should be amortised over its estimated useful life, typically until the end of its patent life. The asset should be tested at each reporting date for impairment until available for use and amortisation begins.

The royalties should be accrued as cost of sales as the related sales of protein X are recognised.

5.2 Out-licensing of a product in development phase to a marketing partner (example 2)

Background

Boron Bio is a biotechnology company that has successfully developed a synthetic protein for the treatment of Disease B through to completion of phase II trials. Boron has signed a licensing and marketing agreement with pharmaceutical company Molybdenum to help fund the continued development of the product. Boron Bio grants a license to Molybdenum to sell, market and distribute the product globally. Boron Bio will continue to develop the product. The financial terms are:

- Molybdenum will pay a non-refundable upfront fee of LC8 million
- Molybdenum will pay development fees of a maximum of LC12 million over the period of the phase III trial
- A milestone of LC4 million on successful completion of the phase III trial
- A milestone of LC1 million on approval by the FDA
- Boron Bio will earn a royalty of 30% on product sales.

The estimated cost of the phase III trial is LC22.5 million.

Boron Bio and other comparable companies earn royalties of 20-25% on other synthetic proteins they have developed. Disease B is an area of unmet medical need.

Solution

Boron Bio

The payments under the development agreement of LC25 million represent in substance LC22.5 million of development costs plus a success fee of LC2.5 million. If the product fails in development then Boron Bio is exposed to costs of LC2.5 million (being the upfront and development fees in total of LC20million less development expenses of LC22.5million).

The royalty of 30% is higher than other products because Disease B is an area of unmet medical need. If analysis of the premium suggests the royalty rate is at fair value then the royalty element of the contract should be separated from the development phase.

There is no clear correlation between the milestones arising on the work performed and the associated risk. In addition, there are development fees payable which indicate that the milestone payment method is probably not appropriate.

The development agreement should be accounted for using a modified percentage of completion method. Revenue should be recognised on the basis of percentage of costs incurred multiplied by total estimated receipts (LC25 million), but restricted to the amounts earned under the agreement (cash received and receivable).

At the outset of the agreement Boron Bio is only guaranteed to receive LC20 million of the total cost of the trial of LC22.5 million. However, Boron Bio does not have an onerous contract because:

- Future milestone receipts and royalties are expected to exceed the cost of development if the product is successful
- Boron Bio has entered into the contract on the basis that the expected benefits are greater than the costs of fulfilling the contract. The expected benefits take account of the probabilities of the trials being successful or not.

Any royalties should be recognised when earned.

Molybdenum

Molybdenum has agreed to pay up to LC25 million to buy into the risks and rewards of protein A, which was originally developed by Boron Bio.

There is a general presumption under IAS 38 that payments made to a third party in acquiring an intangible asset should be capitalised. While that is the general case, Molybdenum also needs to assess whether any element of this deal represents, in substance, internal development expenditure. In this case the payments are structured such that it appears from Molybdenum's perspective the payments are all consideration to acquire the license albeit it is likely Boron Bio will use the cash received to fund development. The various upfront payments and milestones should therefore be capitalised.

Amortisation starts when the asset is available for use and the asset should be amortised over its estimate useful life, usually the end of its patent life. It is tested at each reporting date for impairment until available for use.

The royalties should be accrued as the related sales of protein B are recognised.

5.3 Out-licensing of a product in a development phase to a marketing partner (example 3)

Background

Pharmaceutical company Argon has developed a novel compound Beta for the treatment of disorder Gamma through completion of phase I trials. Compound Beta is a highly novel structure and there is no data available on similar compounds. Disorder Gamma is not an area of unmet clinical need but there is significant market potential as existing treatments have significant side effects.

Argon has signed a licensing and marketing agreement with HeliumPharma. HeliumPharma has been granted an exclusive license to sell, market, distribute and manufacture the product for distribution in the USA.

HeliumPharma has agreed to pay:

- An upfront payment of LC2 million
- Phase II development fees of LC12 million
- A milestone of LC25 million at the beginning of phase III trials
- A milestone of LC5 million on enrolment of the last patient into the clinical trial
- A milestone of LC15 million on approval of the NDA by the FDA
- Royalties of 20% on the marketed product.

Argon will carry out the development work of Compound Beta and the cost of the phase II trial is estimated to be LC25 million. The cost of the phase III trial is estimated at LC60 million.

Either party can cancel the agreement at the end of phase II if the results are unfavourable. Each party has an option to assign their interest to another party if the results are favourable.

Analysis shows that royalties on products out-licensed at a similar stage would typically be in the range 10-15%. For products with significant “blockbuster” potential (sales in excess of LC10 million), royalties up to 20% are payable.

Solution

Argon

The royalties payable are greater than for products out-licensed at a similar stage due to the novel nature of the product and its potential. A royalty rate of 10% is comparable with rates for products with the greatest potential and is therefore assessed as being at fair value.

The two phases of development should be treated as separate elements since there is significant risk that phase III may not go ahead and each party has an option to exit the arrangement or assign their interest to a third party. The various payments and fees in the development phase do not qualify for the milestone payment method as some do not require substantive effort. There is no clear linkage between the payments and the related risk.

At the outset of the agreement, Argon is only guaranteed to receive LC14 million of the total cost of the trial of LC25 million. However, Argon does not have an onerous contract because:

- Future milestone receipts and royalties are expected to exceed the cost of development if the product is successful
- Boron Bio has entered into the contract on the basis that the expected benefits are greater than the costs of fulfilling the contract. The expected benefits take account of the probabilities of the trials being successful or not.

The upfront payment and the phase II development fees should be recognised as revenue as the related costs are incurred i.e. on a percentage of completion basis.

The payments receivable under phase III, once both parties commit to proceed, should be accounted for on a percentage of completion basis. The final milestone will only be recognised once it becomes receivable.

Royalties receivable under the contract should be recognised as revenue when earned.

HeliumPharma

HeliumPharma does not own any original intellectual property at the outset of the arrangement and is making various payments to purchase a license and marketing agreement. The payments that are being made have been staged so that Argon can use the consideration to fund the development of the product.

There is a general presumption under IAS 38 that payments made to a third party in acquiring an intangible asset should be capitalised. While that is the general case, HeliumPharma also needs to assess whether any element of this deal represents in substance internal development expenditure. In this case, the payments are structured such that it appears from HeliumPharma's perspective the payments are all consideration to acquire the license albeit it is likely that Argon will use the cash received to fund development. The various upfront payments and milestones should therefore be capitalised.

Royalties incurred under the agreement should be expensed as the related sales are recognised.

5.4 Out-licensing of a development phase drug to a development partner (example 4)

Background

Drug discovery boutique Tungsten has developed a novel compound Theta which it has successfully taken through phase I clinical trials. Tungsten does not have the expertise or resources to take the product through large scale clinical trials or sell and market the product. It has, therefore, out-licensed Theta to Gold Therapeutics who in turn have agreed to pay:

- An upfront fee of LC5 million
- A milestone of LC5 million if phase II is successful
- A milestone of LC20 million if the product receives FDA approval
- Royalties of 5% on net sales.

Royalty rates for similar out-licensing arrangements at this stage of development have royalty rates between 4-6%.

The milestones are non-refundable and there are no ongoing obligations attached to any of them.

Gold Therapeutics is responsible for all development activity and ultimate sales and marketing of the product. Gold Therapeutics has absolute right to market, sell and distribute the product in any indication, in any territory in the world and can grant sub-licenses without the consent of Tungsten. The license terminates when the final valid patent over Theta expires.

Theta has no ongoing involvement in the development or marketing of the drug.

Solution

Tungsten

Tungsten has effectively sold/assigned its interests in Theta to Gold Therapeutics, although it retains a residual interest in the product in the form of a future royalty. The patents may reside with Tungsten but all rights and control of the product have been granted to Gold Therapeutics.

The upfront payment and the subsequent milestones paid by Gold Therapeutics are contingent assignment/license fee income. Given that the royalties appear to be at fair value, the payments should be recognised once they become receivable (i.e., when the milestone is met) since Theta has no ongoing obligations under the arrangement.

Any related intangible assets that Tungsten has on its balance sheet should be de-recognised because, in substance, there has been an outright sale with a corresponding gain or loss on disposal.

Royalties should be recorded as revenue when receivable.

Gold Therapeutics

The upfront and milestone payment made to Tungsten meet the definition of an intangible asset. They represent payments to acquire the rights to Theta and should be capitalised. The asset should not be amortised until it is available for use, but tested for impairment at each reporting date. Once available for use the asset should be amortised over the period to the expiry of the last valid patent.

Gold Therapeutics should expense all its own internal development expenditure associated with the product.

Royalties should be accrued as a cost of sale as the underlying sales are recognised.

5.5 Out-licensing of a late stage development product to a marketing partner (example 5)

Background

Mid-tier biopharmaceutical company Krypton has successfully developed its product Omega through phase II trials. It has started its phase III trial and to date has incurred LC10 million of the total estimated LC50 million that the trial will cost. Part way through the trial Krypton signs an agreement with pharmaceutical company Radon to out-license the product.

Radon will pay:

- LC10 million upfront payment, labelled as for past services
- LC15 million milestone on FDA approval
- Royalties of 25% on net sales.

The royalty rate is in the middle of a range for comparable products out-licensed at a similar point in time.

Solution

Krypton

The upfront payment and milestone comprise approximately 50% of the cost of developing the product. Provided the components appear to be at fair value they should be recognised in accordance with the milestone payment method. The upfront payment should be deferred and recognised over the development period. The milestone payment has significant risk attached to it and should be recognised as income once FDA approval is achieved.

The costs incurred prior to the signing of the development agreement are irrelevant from a revenue recognition perspective.

At the outset of the agreement Krypton only expects to receive 50% of the cost of the trial.

However, Krypton does not have an onerous contract because:

- Future milestone receipts and royalties are expected to exceed the cost of development if the product is successful
- Krypton has entered into the contract on the basis that the expected benefits are greater than the costs of fulfilling the contract. The expected benefits take account of the probabilities of the trials being successful or not.

Radon

Radon should capitalise the upfront and milestone payments as an intangible asset and amortise them over the contractual license period. Amortisation should begin after FDA approval is received.

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