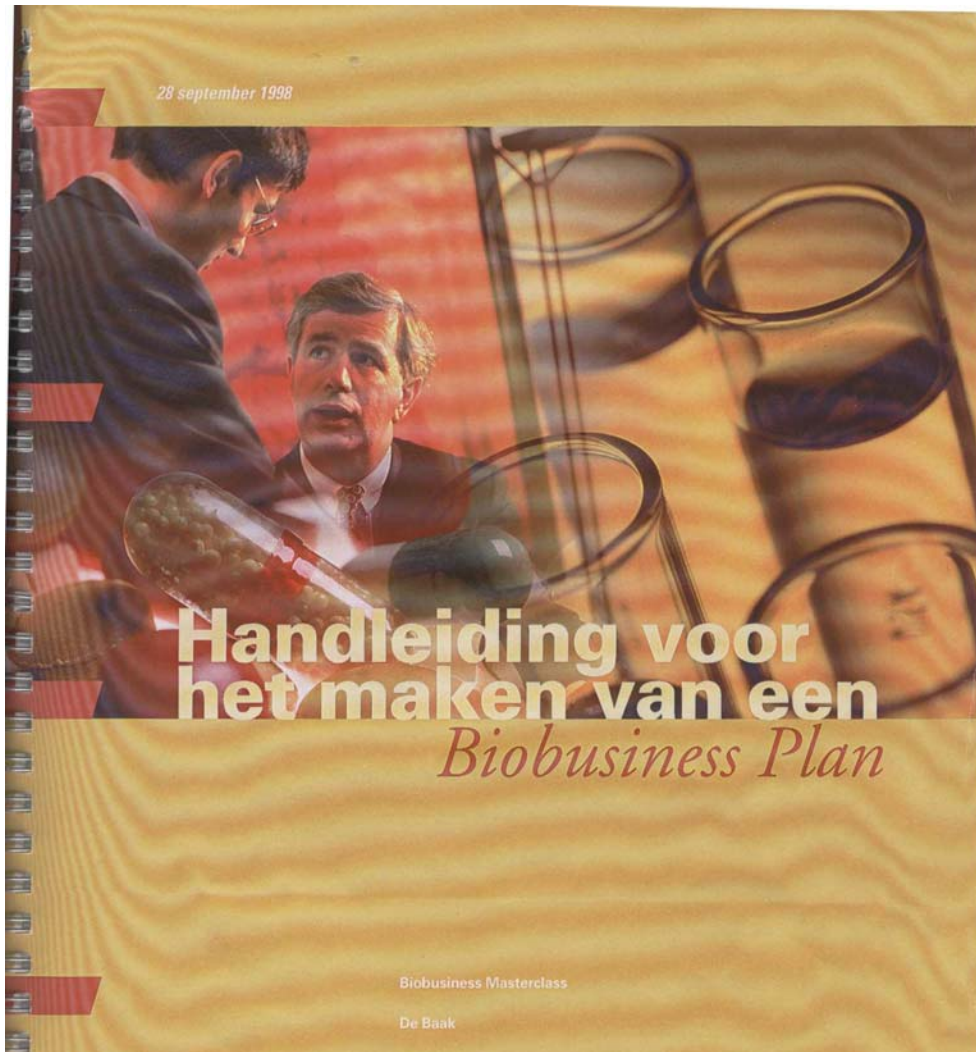


Biobusiness Plan



Ernst & Young

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1 BIOBUSINESS PLANNING

The Strategy Behind It

Producing a bio business plan provides an excellent *opportunity* to consider all the facets of a business or a new venture, challenging feasibility and providing greater confidence in decision-making. The process will also help identify and clarify future financing needs and is a necessary step in raising external finance.

The creation of the business plan stems from the strategy planning process which is the evaluation of a business' or new venture's competitive advantage and opportunities. The business plan will develop in more detail the broad action points derived from strategy planning, establishing corporate goals, setting objectives, evaluating the development/operational environment and producing ways to measure successful achievement of milestones.

For a biotech company, there can be a range of different strategy models. For example, in biopharmaceuticals:

- Virtual company (few employees, mostly outsourced)
- FIPCO (fully integrated pharmaceutical company)
- RIPCO (strategically partnered, royalty based pharmaceutical company)

The model adopted will be designed to fit management's philosophy, the technology rights, the skills of the team and the potential for deals that exist in the selected development area. The chosen model will need to be vigorously challenged if the team is to develop a robust business plan.

A business plan will also be a useful ongoing tool, as it can be used to measure progress and as a basis to communicate between management, staff and existing investors. To achieve this the plan must be kept up to date as the business moves through different stages of its life. To be totally effective management needs to continuously review the overall strategy and ensure that the business plan is always aligned to the current strategy. A company's strategy must also change along with its objectives.

This brochure focuses on the necessary steps to produce a biobusiness plan for the purposes of raising finance, giving guidance on what to include, and how to present the plan. It also incorporates tips which are derived from Ernst & Young's substantial experience in assisting a wide range of clients to produce business plans for many different reasons.

II WHAT IS DIFFERENT ABOUT BIOTECH COMPANIES?

Writing a business plan is never easy. Writing one for a biotech company has additional complications due to the particular characteristics of the industry, some of which we set out below:

- **Technology** capturing and conveying the market potential of new technology is critical. Major technological leaps forward, protected by excellent patents, may be valueless without a clear route to market. Multiple applications from the same technology make it a “platform” from which to build even greater value. An understanding of the potential value of the sales from your technology is critical. It is essential to ensure that ownership of any intellectual property is well protected.
- **Team** often the skills that more technology through proof of principle is not the ones that will be needed to drive towards future milestones and commercial goals. The skills and experience of the team have to fit the strategy imperatives of the business.
- **Timescales** unlike most development stage businesses, biotech companies can take years to get from concept, through proof of principle, to approvals and finally product sales. It is not unusual for this to take 10 years for biopharmaceutical and agricultural biotechnology companies.
- **Strategy** the costs of developing a new drug are high and significant funding is required to develop a marketable product. Companies must have a clear strategy defining when and if they plan to enter collaborative deals in order to gain access to other technology or skills, to help with funding, and in time to provide assistance with marketing and distribution requirements. In the future the company may need to seek access to public equity markets to raise the significant sums required to develop a marketable product. The timing of entry to such markets should be considered at an early stage.
- **Transitions** a biotech company will develop through several stages, as the resource needs for progressing potential products increases and the costs of research trials escalate through the development phases. Major management, cultural and cash requirement changes occur as this happens.
- **Milestones** a journey of several years duration can be difficult to plot. Funders want to know how you will reach your destination. Money is only put at risk if there is clarity about intended usage and milestones, against which progress can be established. Future funding will only happen if milestones are achieved.
- **Value building** in technology terms, in IPR terms, in commercial terms and in overall business terms, you are “building value”. Generally, there are not any sales to support your market assessments; new entrants with competing technology are a constant threat and achieving trial successes doesn’t mean you will definitely have approved products. Still, you must provide a return to original investors and attract new investors by growing the value of the shares in the business.

- **Funding** .often the most difficult cash to find is that which gets a company from concept, through proof of principle and towards the stage when the next plan would have more solid commercial foundations. There are no easy answers to funding this money, but it has to be found by the start-up team if the £'OOOs and £'millions of the later funding rounds are to follow. New routes to funding a biotech business are found each year.
- **Deals** .it is an inevitable that biotech companies will do 'deals'. They do them to acquire technology, to fund developments, share rights/risks, gain distribution rights and speed up the building of a business. Deals are an important source of funds and an end point in the value chain to market. They are not easy to do and doing them is a core skill for the team.
- **Sales** .no matter how hard you try to explain, there will always be a majority of people who don't understand how you can build a biotech business if you are not yet selling anything. The financial community that deals with biotech companies understands why sales are not present in most biotech financial projections, however, that does not mean that they don't think about sales. Indeed, assessing product sales potential is a key skill requiring careful market analysis, scientific advisory networks and business evaluation models.
- **Credibility/Advice** .venture capitalists and other funders take big risks with large sums of money in biotech. They will look very carefully at businesses that appear to have the potential to really create value. In the final analysis though, the team and its scientific and other advisers will need to have very high credentials and be recognised, probably internationally, as experts in their fields. Venture capitalists use such experts to advise them and if a team or plan lacks sufficient credibility, then it is unlikely to receive funding.

The UK remains one of the premier locations for creating and developing a biotechnology venture. Now is the time to seize the opportunity to enter the new venture arena. Delay may lead to that opportunity slipping away, and you may never be the one to create the next Chiroscience, Cortecs or Powderject.

III PREPARING A BIOTECH Business PLAN

1. GETTING STARTED

Guidance on writing the plan depends on the main objective for producing it. We answer the most common questions raised on writing business plans below, but the underlying rule is **WRITE FOR YOUR READER**. This means both writing in language that the reader will understand, and covering the issues that the reader will want to know about.

E&Y TIP

Some 85% of plans are not seriously considered by investors so if the purpose of the plan is to raise finance, it is vital to identify the likely sources of finance at an early stage in order to **WRITE FOR YOUR READER**.

Identify your objectives

Identify the reasons for writing your plan and identify your target audience. Consider what your target audience is likely to know about your business, what else they will want to know and how they will use the information given.

You should also consider whether there are any potential conflicts between what they will want to know and what you want them to know. These potential conflicts need to be considered and resolved before you write the plan.

2. DRAFTING THE PLAN

Who should write the business plan?

A business plan reflects your thoughts and plans for your business, and as such must be written by **YOU**. You may need some help from advisers in challenging your comments and assumptions, deciding on content and overall format, and you may also need assistance in preparing financial projections.

What should the plan cover?

Any plan must include the key areas of the potential market, the technology and intellectual property protection, the management and the financial requirements and returns.

There is no agreed format for biobusiness plans; however, they should follow a logical flow in explaining the ideas, the benefits and the results. To help with this, we have set Out in Section 4 a general outline of what should be covered and how the plan should be structured. In some situations only part of this outline may be appropriate, certain sections may be amalgamated or further separated, but in all cases you should tailor the plan to your specific circumstances.

How long should it be?

There is no definite guideline on the length of your biobusiness plan. You should keep it as short as possible whilst covering the subject adequately, and, to achieve this, much of the detailed information can be relegated to appendices.

How do I maintain flexibility?

To achieve its objectives, the plan needs to be specific. It may be useful to discuss alternative options and the impact they would have, but the plan should be based on management's current preference.

How should it be presented?

Presentation should be entirely aimed at captivating the interest of the reader and ease of reading and understanding. For example, page and paragraph numbers should be used along with cross-referencing, simple graphs and graphics, and colour photographs, if this assists understanding. Binding and covers should be practical and should avoid both amateurish and lavish appearance.

3. PREPARING FINANCIAL PROJECTIONS

The plan needs to include projected profit and loss accounts, balance sheets (including an opening balance sheet), cash flows and the underlying assumptions. The assumptions must be supported by, and consistent with, your descriptions and explanations in the rest of the plan, or the differences explained.

How can Forecast future results?

Forecasting the probable development pattern into the future is a difficult task. It is critical to assess the financing needs and timing of value creation in the business. Development strategy and the extent of collaborative deals will affect the level of future research spending, the level of income and therefore the funding requirements. Projecting future sales specific to research spend on projects may not be appropriate. Supporting your assumptions on the value of potential products by reference to their target markets is essential.

It is recognised by financiers that the environment in which a business operates is subject to changing factors and the assumptions underlying projections must therefore similarly be susceptible to change. Nevertheless, prospective investors will use the projections to gauge whether the investment is capable of meeting their required rate of return.

Should my projections be optimistic?

It is advisable to aim for the middle road and to be as objective and realistic as possible in compiling financial projections. If in doubt, be conservative and discuss potential "up-sides" in the narrative. The problems of estimating future costs are well recognised and it is acceptable to include a contingency in the projections to cover uncertainty.

E&Y TIP

Test the sensitivity of the projections and assess the financial risk implicit in them by assessing the impact of changes in the key assumptions. Key risks are usually related to time spent during each stage of development and in the total time to market, the level of **O** competition, ultimate product pricing, unforeseen costs and the probability of successful product development. Consider your assumptions regarding fixed versus variable costs, and review the impact on your cash requirements.

Should my projections allow for inflation?

It is often argued that inflation on costs should be ignored. Whilst it is certainly easier to ignore inflation, this may prove misleading if the prices of certain key items in the projections are expected to be significantly different to the general rate of inflation. Also, where increases are expected to be significant, an understatement of the funding requirement could arise. In most cases, therefore, we would advise that effects of projected inflation should be built into the projections.

4. WRITING THE PLAN

Produce an outline

Prepare an outline plan based on the objectives and the readers' requirements identified above. Your outline should incorporate the key points to be made for each heading and sub-heading, and the more detailed you make this, the easier the eventual writing of the plan will be.

Having produced an outline, review it for the necessary level of detail required for each section. Consider the sources of supporting information and whether further research is required.

Write your plan

Use the financial projections to ensure that the plan you have in mind is financially viable. Ensure that your assumptions are recorded so they can be justified by explanations in the narrative sections. The narrative sections should address all the issues identified in your outline, and the assumptions made in producing the forecasts.

Review your plan

Review your plan to ensure it adequately addresses key issues, is understandable for the target audience, and that it meets your objectives.

The plan should ideally be reviewed by experienced businessmen or advisers who have some knowledge of the industry and your target audience.

IV OUTLINE CONTENTS AND STRUCTURE

There is no agreed *format* for biobusiness plans. However, they should follow a logical flow in explaining the idea, the benefits and the results. We suggest a general outline below, although, as only part of this outline may be necessary in some situations, certain sections may be amalgamated or expanded. In all cases, you should tailor the plan to your specific circumstances and audience.

A contents list should be included to assist readers in locating specific sections, which should generally include the following:

Executive Summary
Background
Technology and its potential
Market Analysis and Route to Market
Development of products
The Management Team and Organisation
Funding Requirements
Financial Projections
Key Issues Risk Assessment and Sensitivity Analysis
Action Plan and Milestones
Appendices or Exhibits
Each section is dealt with in turn below.

1. EXECUTIVE SUMMARY

This section is important for all plans for third parties as it sets the scene, explains the purpose and summarises the whole plan, enabling it to be read efficiently. It is particularly important when raising finance as potential investors receive many business plans and may make an assessment of your business before reading the main body of the plan. The Executive Summary should summarise the key points of your proposal, including:

- the purpose of the plan
- management's ultimate business goal and the company's distinguishing features which will be critical in achieving this goal
- the business opportunity
- the size and type of market the product is aimed at
- significant product features
- the management team, their experience and how they will realise the opportunity
- critical milestones
- financial projection profile
- key funding stages required and expected growth in value of the company

E&Y TIP

The purpose of your plan will normally be to raise finance, so the Executive Summary must excite investors' interest by highlighting the potential of the technology and the ability of management to realise that potential.

2. BACKGROUND

This should provide a brief summary of the business, the development to date of the technology and the team. The summary should explain how the opportunity was identified, who owns it, the related intellectual property rights and its progress to date.

Any financial highlights for the last three years should be summarised, where applicable, including the highlights for the year to date. Where appropriate, past performance should be analysed and explained.

3. TECHNOLOGY AND ITS POTENTIAL

This section should explain, without technical jargon, you're principal technologies, their applications, and distinguishing features. Detailed technical specifications and any relevant scientific papers are best included as an appendix. The main purpose of explaining technology is for the reader to understand the market potential, any unique selling points and consequently, the business opportunity. It will also be important to give an indication of the extent of the development pipeline.

To demonstrate the distinguishing features, the principal markets and market needs should be highlighted, although they should be discussed in further detail in the following section.

E&Y TIP

Be market led. Distinguish your technology via a (tabular) comparison with competitors or potential competitors by key market factors such as price, time, quality, payback period etc.

We have included a checklist of some of the key factors to consider in appendix 1.

4. MARKET ANALYSIS AND ROUTE TO MARKET

The market analysis section is of critical importance. You cannot assume that everyone sees the potential of your technology or that they will agree with your assessment of that potential. You must clearly identify your understanding of the market, the value of the unmet need and reasons why the products will be purchased. Customers and potential customers need to be identified, and factors such as customer needs and decision factors should be fully explained, and supported by third party comments.

The absolute size of your market or niche should be outlined, or estimated by reference to market information. Where possible, forecast market share needs to be included. The use of external reports or research is critical to strengthen the reader's understanding and belief in the market. It is critical that you highlight any potential competitors and how you will achieve your stated market share in the light of that competition.

You must also be clear on your product development strategy, i.e. will you seek collaborative partners or go it alone during the development process. This will have a major impact on future revenue streams and on the level of resource and skills required within the company during development. It is important for people to understand so that they can evaluate the risks involved in product development.

E&Y TIP

A common mistake is merely to state what profits will result if only a small market share is achieved. Your plan must explain what market share you expect to achieve and how you will achieve it.

The strategic model adopted for the company will be determined largely by the skill sets that exist within or are intended to be built by the company. The development of products and their route to market will need to be understood. If possible, it would be better to outline the most likely distribution channels and the type of deal that you would expect to achieve if a third party takes the product from you for delivery to the market.

E&Y TIP

Demonstrate evidence of an appetite on the part of third parties to do deals in the selected area of the technology and of a dear unmet customer need.

We have included a list of some of the key factors to consider in appendix 2.

5. DEVELOPMENT OF PRODUCTS

All research and development activities are fraught with uncertainty and risk; they are inherently unpredictable. Careful planning, experience and strong management skills are used to contain the risks, to minimise exposures and to maximise probability of timely success. As products develop it will be necessary to complete clinical trials, and deal with regulatory submissions. It is important to outline the proposed strategy for this phase of development in the plan, as this stage is both expensive and requires specialist skills.

Often research teams are switching environments to a small entrepreneurial company and may not have been used to evaluating the progress of research on a commercial basis. It is important to demonstrate a dear view of how research objectives will be achieved.

We have included a list of some of the key factors to consider in appendix 3.

6. THE MANAGEMENT TEAM AND ORGANISATION

By this stage your plan will have demonstrated the potential of your product. But at every stage of your business's development, the investor is investing in people, and you must demonstrate that the management team is able, and likely, to realise that potential.

You should identify your key members of the management team, explaining why they are key and demonstrate the relevance of their skills, previous achievements and experience to their responsibilities.

E&Y TIP

Present the background and skills of the management team that demonstrate that **THEY WILL** make a success of this business.

For example:

The Business Development Director has enjoyed wide experience and success at X Limited and Y Pic, her current employer, where she has been the prime influence in achieving partnering deals on A key products.

It may be useful to provide a current and projected organisation chart, clearly showing responsibility and reporting lines.

E&Y TIP

Recognise any important skill gaps or experience limitations in your management team. These can then be addressed up front with investors.

A checklist of key questions to be covered in this section is given in appendix 4.

7. FUNDING REQUIREMENTS

The extent of immediate and future funding requirements must be identified, along with the uses to which moneys raised will be put. Anticipated sources of funds should also be identified which might include seed/angel funding, venture capital, partnering deals or grants. As noted above, it is important that the business plan is written for the reader. As funding is likely to be the main purpose of the plan, considering the requirements of the target group of investors will be important in determining the content of the plan.

The current financial structure should be stated including details of ownership and current shareholdings.

8. FINANCIAL PROJECTIONS

The assumptions behind your projections are critical, they require thought and must be consistent with the previous narrative. Too much financial information can be worse than too little. Companies must show the key areas whilst detailed financial data may be included in the appendices to the plan. Projected profit and loss statements, balance sheets and cash flows should be given. Quarterly profit and cash flow forecasts should be given for at least the first year and annually thereafter for the period through to profitability. The key assumptions underlying the projections should be given and justified. We have listed some of the key items to include in appendix 5.

E&Y TIP

Test the data using several different assumptions to determine whether the final information is reasonable.

9. KEY ISSUES .RISK ASSESSMENT AND SENSITIVITY ANALYSIS

Produce a summary of the critical success factors of the business, along with its key strengths, weaknesses, opportunities and threats, noting how weaknesses and threats will be dealt with. Any business idea will have risks, and the business plan will have much more credibility if those risks are identified rather than ignored. You should identify the main risks to the business, and show their potential impact on the financial projections. Explain what you will do to limit the risk factors and how you will minimise their impact.

10. ACTION PLAN AND MILESTONES

List in chronological order the key stages necessary to achieve the plan with a note of responsibility for completion, and the current status of each stage.

One of the common failings in putting together a biobusiness plan is to give insufficient attention to the milestones along the path of the development of the business. Link these to key stages, they will usually be important in demonstrating progress and justifying further funding rounds.

Common questions about raising finance

One of the main uses of a biobusiness plan is as an external document to assist in raising finance, which is why we discuss below the most common questions arising from businesses trying to raise finance.

Who should we send the plan to?

Whether the document should be sent to a venture capital house or other investor is determined by the appetite for biotech funding, the use to which the funds are to be put (and therefore the type of funds sought) and the amount that management wishes to raise.

It is important not to flood the Venture Capital market with copies of your plan, and not to waste valuable time by sending it to inappropriate investors.

How should we structure the finance required?

Management teams often feel obliged to suggest a suitable financial structure for the required finance. In practice most investors will wish to make this judgement themselves so as to meet their required rates of return and other investment criteria. Sometimes it is possible to obtain grant and guaranteed bank funding but this can be difficult at the start-up phase. Management should seek professional advice before seeking funding and on offers received.

How long will it take to raise finance?

This depends partly on the nature of the funding proposal - clearly an existing business raising additional finance may do so in far less time than a new project raising venture capital. Typical time scales for the latter range from three to six months or even longer in some cases. However, most venture capitalists are prepared to give an early indication after receipt of the business plan of whether they are seriously interested in pursuing the proposal.

What sort of return will a venture capitalist require?

Venture capitalists invest in unquoted companies, many of which are relatively immature businesses and thus carry considerable risk. To compensate for this venture capitalists seek high returns, typically of 30-60% per annum.

Will investors expect me to sell the business at a later date?

The eventual disposal of the business whether by sale to another party or by flotation, is the most likely way of achieving the capital returns for both investor and management, although certain investors are prepared to invest for longer terms if conditions are right.

The management team can only invest a relatively small amount of capital - how can we retain a significant equity share in the business?

Venture capitalists and other equity investors are familiar **with** this situation - it is a rare exception when management are able to put up more than a minority share of the required funding. Investors are aware of the need to retain the motivation of the management team and will always wish to ensure that they are left with the potential for a return which at least matches that of the venture capitalists, and usually exceeds it.

How much cash will management be required to put up?

There are no definitive rules on this. In principle, the outside investors will look for a significant financial commitment by the founders/management and in absolute terms this will vary according to the wealth of the individuals concerned. Commitment can of course be demonstrated in other ways. For example, time, effort and money spent in bringing a project to the point when it can be presented to outside investors.

What is due diligence?

This is a term which refers to the investigation and appraisal procedures adopted by venture capitalists and others prior to making an investment. Such procedures will extend not only to validating the credentials of the individuals concerned but also to an examination of all other aspects of the project. Scientific/technical specialists are employed to help assess the technologically, market, and intellectual property aspects of a project.

Must I have the full management team in place before approaching investors?

As management has been identified as a critical issue, it is preferable for key managers to be in place before any approach to investors. However, where gaps exist in the management team these should at least be identified and the steps necessary to fill them outlined.

How do I maintain confidentiality?

Where a plan is being produced for external readers, there may be a reluctance to disclose certain information. We recommend that all plans carry a confidentiality clause restricting the use of information therein and that external readers are checked for potential conflicts of interest.

What legal implications exist?

Care should be taken when sending a business plan to individuals to ensure that the provisions of the Financial Services Act are complied with and, in particular, that the document is approved as an investment advertisement when necessary. In addition, it is important to have regard to the Companies Act which requires all offers of securities to the public to be accompanied by a prospectus. Copies of the plan should be controlled and distribution recorded.

HOW ERNST & YOUNG CAN HELP 6

If you would like assistance in producing your biobusiness plan or are looking to raise finance then contact us to discuss your plans.

Ernst & Young is a leading adviser within this sector and has strong contacts with the sources of funding for biotech companies. Through our extensive experience and knowledge of the marketplace, we can usually indicate which institutions are most likely to be interested in your particular proposal, help with submissions and provide advice and guidance on any offers received.

Further we are also able provide advice and guidance on tax structuring. Whilst this may not be an obvious question during the initial planning phase, value creation is one of the key objectives for a biotech company. Considering factors such as potential tax on gains on individual shareholdings at an early stage may lead to significant savings in the future. You can either contact the partner who usually deals with your affairs or any one of the contacts listed at the back of this brochure.

TECHNOLOGY AND ITS POTENTIAL CHECKLIST

- What are the key features of the technology?
- What protection does your technology have?
- What unmet needs does your planned product or service satisfy?
- How do competitors satisfy or fail to satisfy those needs?
- What is the impact of customer buying expected to be on your product or service? (Are changes in methods, or complementary purchases necessary?)
- What is your competitive advantage in terms of customer benefits (e.g. hospitalisation costs, treatment costs etc)
- Are any pharmacoeconomic studies available in your chosen technology area?
- What is the anticipated reaction of competitors to your new product?
- What further research and development is necessary?

MARKET ANALYSIS AND ROUTE TO MARKET CHECKLIST

- What markets are you targeting?
- How big are they now? How big will they be in five or ten years?
- What are the chief characteristics?
- What growth, or changes are shown by third party public reports?
- What are the major trends?
- What barriers to entry are likely?
- Who will be the major customers?
- What companies do you and will you compete with (including future entrants to the market) in each product or service line?
- How do you compare with other competitor companies?
- What is the market share of each existing competitor?
- How far through the development pipeline and commercial sales process will you take the product before handing over to a third party/partner?
- What evidence is there that partnering deals of the nature you intend to do can be done?
- What sort of deal economics do you need to achieve to provide the returns for your funders/your partners?
- Can you yet forecast such deals?

DEVELOPMENT OF PRODUCTS CHECKLIST

- What is the timetable for necessary research and development including testing and regulatory approvals?
- What are the expected costs of development and later, of production?
- What is the critical path of the process and what are the contingency plans for key areas?
- Is there existing or planned pilot plant or full production capacity?
- What capital investment is required?
- What are the key development risks?

THE MANAGEMENT TEAM CHECKLIST

- Who are your key managers?
- What are the individual and global objectives of key management?
- How do you intend to retain or attract and compensate key people (i.e. share options, incentive bonuses etc)?
- What are their skills and, particularly, their achievements and experience, and how does this relate to the success of your venture?
- What management additions do you plan, when, and with what required qualifications?
- Who is on your board of directors?
- What second tier management do you have?
- How many employees do you have and will you require?
- What are your recruitment policies and how will you train new employees?
- Show sample organisational structures both current and projected, if significantly different.
- What levels of remuneration do you or will you offer?
- What are the long-term objectives of management?
- What management information system will support management?
- What business and scientific advisers will management have?
- What key management review process do you anticipate?

THE FINANCIAL PROJECTIONS CHECKLIST

When preparing the profit and loss, balance sheet and cash flow forecasts consider including the following headings:

Profit and loss account Balance sheet Cash flow statement

Income: Fixed assets Cash receipts

royalty cost trading

milestone depreciation interest

sales Stock new equity/loans

Cost of sales Debtors and Cash payments

Expenditure: prepayments Wages and salaries

Cash

R&D costs Bank overdraft Property

Administration Trade creditors Suppliers

Finance Other creditors/accruals Capital expenditure

Property Long term ban Other overheads

Net profit/(loss) Share capital Royalties

Taxation Retained profits Tax .PAYE/NI

-VAT

Profit/(loss) after tax Net cash flow

Opening balance

Closing balance

Ensure that the plan clearly identifies the rate of cash burn, and the timing of future capital injections.

ERNST & YOUNG BIOTECH/LIFE SCIENCES CONTACT PERSONEN

Voor nadere informatie omtrent Moret Ernst & Young's dienstverleningen en ondernemingen in de sectoren "Biotech/Life Sciences" en/of "entrepreneurial growth companies", kunt u zich richten tot:

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