0273-2289/99/77–79/0641/$12.00

Financing Biotechnology Projects

Lender Due Diligence Requirements and the Role of Independent Technical Consultants

J. B. Keller and P. B. Plath*

Harris Group Inc., 1999 Broadway, Suite 1500, Denver, CO 80202, E-mail: paul.plath@harrisgrp.com

Abstract

An increasing number of biotechnology projects are being brought to commercialization using conventional structured finance sources, which have traditionally only been available to proven technologies and primary industries. Attracting and securing competitive cost financing from mainstream lenders, however, will require the sponsor of a new technology or process to undergo a greater level of due diligence. The specific areas and intensity of investigation, which are typically required by lenders in order to secure long-term financing for biotechnology-based manufacturing systems, is reviewed. The processes for evaluating the adequacy of prior laboratory testing and pilot plant demonstrations is discussed. Particular emphasis is given to scale-up considerations and the ability of the proposed facility design to accommodate significant modifications, in the event that scale-up problems are encountered.

Index Entries: Biotechnology; commercialization; scale-up; risk assessment; project finance; due diligence.

Introduction

Conventional forms of financing have typically not been available to sponsors of emerging technology processes due to the unwillingness of mainstream banks and institutional lenders to accept technology risks and the marketability of unproven products. Typically, financing the commercialization of new processes has relied upon governmental or private development grants, the backing of a substantial corporate balance sheet or relatively expensive private debt placements or public offerings.

As conventional lenders become more sophisticated and regulatory barriers between commercial banks, investment banks, and insurance companies fall away, new types of financing are becoming available to what

*Author to whom all correspondence and reprint requests should be addressed.

were once considered high risk industries. The most attractive of the new forms of financing is usually referred to as structured finance or project finance. Project finance models have typically been used to finance large public and private infrastructure projects, but their use has been spreading into many industries. Project-based financing is potentially attractive to emerging biotechnology processes and projects because it offers the ability to secure long-term financing at competitive rates with low equity requirements. Project financing, however, relies upon the underlying soundness of the process, the value of the production assets, and the ability to predict production costs and product revenues. The ability to use project financing will require the sponsor to demonstrate the fundamental technical and economic soundness of the process and project.

This paper provides an overview of the specific areas and scope of investigation that is typically required by mainstream lenders in order to provide long-term financing for biotechnology-based manufacturing systems. The paper discusses the process for evaluating the adequacy of laboratory testing and pilot-plant demonstrations. Particular emphasis is given to scale-up considerations and the ability of the proposed facility design to accommodate significant modifications in the event that scale-up or process bottleneck problems are encountered.

Contractual arrangements for the engineering, construction, and testing of facilities are discussed with regard to necessary provisions for cost and schedule control and performance warranties. Environmental permitting requirements and governmental approvals will require a thorough legal and technical review and are of considerable concern to lenders.

Finally, we will provide an overview of the due diligence processes, which lenders and their consultants use to evaluate business plans for projects including: assessing the competitive position, new market entrants, pricing strategies and production costs, patent issues, license and royalty costs, and capital and start-up costs.

The Project Finance Model

Project finance is an asset-based form of structured finance. Project finance relies only upon a defined project asset and revenue stream as the security for the loan. This means that not only the physical assets are pledged as loan security, but also any permits, contracts, inventories, royalties, and production are pledged as collateral. The advantages of a project-based financing include: off-balance sheet financing, asset segregation for liability protection, long debt terms (15 years or more), competitive interest rates, relatively low equity requirements, and access to major banking resources and services. The primary disadvantage to project finance is that the project must be well-developed before financing is placed and the lending institutions will impose substantial due diligence and monitoring requirements. Project finance, therefore, is not well-suited for processes or projects in early stages of development. However, if a new process can

successfully withstand the technical, legal, and financial scrutiny imposed by the lenders, securing a structured project-type financing can give a process the kind of "stamp of approval" that is often necessary to bring emerging technologies to commercialization.

The rest of this paper will discuss at a summary level the scope of the due diligence process typically required to secure financing for an emerging technology project.

Evaluating Technical Risks

In the introduction to this paper we stated that mainstream bank and institutional lenders will not accept technological risks that cannot be well-defined and quantified. Although nearly any new project, whether it be a pipeline, toll road, mine, or manufacturing facility involves some risk of technology failure, most commonly financed projects utilize well-understood technologies with quantifiable risks. Although facilities employing well-proven processes have much more potential to be financed, that is not to say that a plant employing an unproven process cannot be financed. It is just that the hurdle is much higher.

In order to adequately define the technical risks, lenders will require substantial evidence of good, repeatable process laboratory testing and pilot-scale production trials to demonstrate scalability. Lenders will typically hire independent technical consultants to review and challenge the methods and results of laboratory and pilot-plant testing. In some instances, the independent technical consultants will actually perform or direct additional testing in order to demonstrate the repeatability and robustness of the process.

In order to successfully complete the pre-financing due diligence investigation, the independent technical consultants will need to review, verify, and confirm the status of the process and project in the areas of fundamental technology evaluation, scale-up potential, hazard assessment, and commercialization issues.

Fundamental Technology Evaluation

Above all, project lenders and investors must have assurances that the fundamental processes and technologies to be incorporated in the project actually work. This means that the process developers and engineers must be prepared to fully document and defend the laboratory testing and pilot-plant work that has been done. For biotechnology projects, the primary types of studies, tests, or trials that will need to be reviewed by the independent technical consultants include:

1. Feedstock utilization;
2. Product and byproduct yield data;
3. Catalyst and/or enzyme utilization;
4. Batch cycle time studies;

5. Organism viability and resistance to mutation and infection; and
6. Separation and purification procedures.

In addition to the process studies, the independent technical consultants will need to see a great deal of the engineering documentation for the proposed production facilities. Mass and energy balances, process flow diagrams, and the piping and instrumentation diagrams are fundamental information. Specifications for major equipment items also will be examined. The process engineers and/or the process developer probably will be contacted with questions, and intrinsic to the questioning will be an evaluation of the credibility of the process engineers/developer, in addition to the process itself.

Scale-Up Issues

Scale-up is often the greatest single risk in process commercialization. Simply put, bigger is different. Beyond the intuitive understanding we all have for this, there are often harsh realities and substantial engineering challenges in making the transition from shake flasks to 20,000-liter fermenters. Engineers tend to think in linear terms, but nature often is nonlinear. Annoyances in the lab can become insurmountable problems in the full-scale facility. An independent technical consultant will want to see data and documentation showing the scale-up progression from the lab, to the pilot plant, to the commercial scale. As noted previously, additional testing may be requested if the consultant feels that process scale-up has not been demonstrated. As a rule of thumb, scale-ups larger than two orders of magnitude are difficult to defend.

Hazard Assessments

Any new chemical or biological process will require a comprehensive hazard assessment. Biohazards of a proposed process usually can be subsumed under one of the following categories:

1. Pathogenicity, the potential of an organism used in the process to infect man, animals, or plants with disease;
2. Toxicity and allergy associated with an organism or of its products;
3. Problems concerned with the inactivation and disposal of the spent organism;
4. Safety and economic aspects associated with contamination, infection, or mutation of process organism strains; and
5. Safety aspects associated with the industrial use of process organism strains employing recombinant DNA.

Hazard issues can usually be addressed by appropriate use of technical expertise and the regulatory framework in place for the biotechnology field. Some biohazard risks, however, may not be acceptable, in any form, to lenders. We know of no *industrial-scale* process using a pathogenic organism.

Commercialization Issues

Although a process or production facility may be feasible from an engineering perspective, other technical issues may impede commercialization. These issues include patent and license rights, permitting and siting requirements, and public opposition.

If a particular organism or process has been patented or is being developed under license agreements, the limitations and conditions of the patents and licenses must be well-understood. The key questions to be answered include: are the unique aspects of the process well-defined in the patents and are the differences from other similar organisms or processes sufficient to preclude claims of patent infringement; and do license conditions restrict the ability to optimize or expand the process?

Permitting requirements for a large biotech manufacturing facility can be substantial, particularly if the facility will produce large quantities of waste products or require the storage of large volumes of feedstocks and/or intermediate and finished products. In addition, the potential for biological hazards will bring a greater number of federal and state regulatory agencies into the process. Permitting and regulatory approval timetables will be assessed for reasonableness as well as specific permit and reporting requirements. The technical consultant will want to be assured that the proposed design, construction, and operation of the facility will be in accordance with the requirements of various federal, state, and local regulatory agencies having jurisdiction and that the permit requirements are not contradictory or will not unacceptably limit the operation of the facility.

Public opposition can be a substantial risk to the development schedule of a new facility, particularly during the site selection and permitting process. Although most proposed biotech facilities do not have the characteristics that commonly draw adverse public attention (major pollution source, need for large land or water resources, traffic impacts, and so on), the perception of biological hazards, resulting from a spill or accidental release, could delay regulatory approvals or impact site selection. The likelihood for public opposition and the possible impacts to the development schedule and construction costs are another area that could be investigated during the due diligence process.

Evaluating Economic Risks

To a project lender, all risks are ultimately translated into economic risks. These economic risks are generally grouped into four main categories: capital costs, operating expenses, feedstock and fuel costs, and revenue (market) risks.

Capital Costs

Capital cost estimates are carefully scrutinized in emerging technology projects owing to the usual lack of actual cost data to construct other

similar facilities. Technical risks are often translated into capital costs risks either as direct cost impacts to redesign nonperforming aspects of a project or as schedule delay costs. Lenders will usually look to sponsors to mitigate capital cost risks by employing fixed price, turnkey contracting for the basic process and facility construction. The turnkey contractors will be expected to provide schedule and minimum plant performance guarantees backed by liquidated damages, performance bonds, or efficacy insurance. Working capital requirements are usually based on conservative case assumptions for startup durations, slow production ramp-ups, and low initial production efficiencies. Contingency allowances are also likely to be substantial, particularly if strong schedule or performance guarantees cannot be obtained from equipment vendors and contractors. Contingency requirements will be particularly high if any novel or custom process equipment or control systems must be manufactured.

Operating Expenses

Operating expenses, for the purposes of this discussion, generally include labor, maintenance, utilities, waste treatment and disposal, insurance, and general administrative costs. Operating expenses can often be the most difficult area of a proposed project's long-term economics to forecast, due to the lack of any consistent historical data on similar processes and facilities. Frequently, data must be assembled from comparable industries and processes in order to develop reasonable and defendable cost estimates.

Labor costs are typically the single largest fixed operating expense in a manufacturing facility. Labor-cost forecasts should be based on a well-developed staffing plan including an organization chart, shift plans, and position descriptions. A local labor availability and cost survey may also be required if the proposed facility will require either a large number of employees or specialty skills. A hiring and training schedule and cost estimate will also be required to ensure the costs of recruiting, relocating, and training management and production labor force are adequately accounted for in the economic projections.

Maintenance costs can vary dramatically between different processes, so a thorough analysis must be completed of both routine maintenance requirements and periodic long-term overhaul and replacement needs. Routine maintenance expenses, such as consumable parts and materials, will typically be evaluated on a production cost-allowance basis (e.g., $/ton or $/gallon of production). Periodic equipment overhaul and replacement costs forecasts must typically be based on a specific schedule of major vessels, rotating equipment, heat-exchange equipment, and catalysts, which will require inspections, overhaul, or replacement on a long-term scheduled basis. Typically, lenders will require some type of cash-reserve accrual to pay for long-term major maintenance needs.

Waste treatment and disposal costs, whether they are for solid or liquid wastes, can be substantial for large-scale biotechnology facilities, particularly those using primary materials for feedstocks. Liquid and solid

waste-disposal permits or limitations can impose rigorous requirements for detoxification, neutralization, and consolidation of waste products. Lenders will typically require a detailed analysis of waste-treatment costs as part of basic economic forecasts. If off-site disposal of wastes will be significant, agreements should be in place with the landfills, public treatment works, or other receiving facilities that confirm the acceptability of the waste materials and define unit disposal costs.

Insurance costs, both for property loss and business interruption, can also be significant for new technology projects but are often overlooked when developing economic forecasts. If a new process utilizes expensive, custom, or long lead-time equipment, insurance carriers may be unwilling to provide conventional types of coverage at reasonable costs. The lenders may require the services of an insurance consultant to define the availability and cost of an acceptable insurance program for the process and facility. Occasionally emerging technology facilities must utilize specialty carriers (e.g., Lloyd's of London) in order to place the types and levels of insurance required for lenders.

General and administrative costs include legal, accounting, sales and marketing, personnel administration, and general management. General and administrative costs are often difficult to forecast, and as a result frequently result in the large budget variances. Lenders will be just as concerned that the management and administrative functions are as thoughtfully planned as the production functions. Project finance lenders will impose substantial reporting requirements, which will require adequate management and accounting support.

Feedstock and Fuel Costs

If feedstocks and fuel make up a substantial portion of the process operating costs, lenders will require a detailed analysis of the feedstock and/or fuel supplies and pricing projections. Feedstocks and fuels that are broadly traded commodities (such as grains and natural gas) will require less supporting analysis than waste or byproduct materials with limited sourcing options. If the process or project is dependent on a particular feedstock from a particular source, long-term contracts for the supply of the feedstock from that source will likely be required. If the feedstocks are widely available, it may not be necessary to have supplies and pricing locked in with contracts prior to financing, although most lenders will require that specific alternative supplies are identified and some type of hedging arrangements are in place in order to reduce the risk of supply interruptions or excessive price volatility.

Product Sales Revenue

In project finance, the revenue stream from the sale of the products and byproducts is the primary collateral for the loan. Very close scrutiny will be given to the business plan with regard to markets, competition, and

other factors that will influence the quantities and price of the product that can be sold in the marketplace. Project lenders typically will not take much market risk unless the product is a commodity that is openly traded and in which the economic fundamentals are well-understood. Typically, lenders will require a majority of the project revenue to be derived from intermediate to long-term purchase contracts or commitments for the product. If the project will only have one, or very few, primary customers, then the lenders will also need assurances that the proposed customers are viable businesses and can be expected to take the contracted quantities over the term of the contracts. If a significant portion of the revenue will be from short-term or spot market sales, then comprehensive market analysis studies will be required to quantify the depth of the market, competitors, potential new entrants, and other factors that could impact the size of the market or the price of the product.

Summary

Project-type financing may offer emerging technologies attractive financing alternatives for the development and commercialization of new processes and manufacturing projects. Although project finance may be more attractive from a cost standpoint, process and project sponsors will need to be able to support substantial due diligence investigations from the lenders and their technical consultants.

As mainstream commercial banks and institutional investors become more technically sophisticated, they are looking beyond traditional industrial sectors for new business. Many lenders may be eager to consider emerging technology projects; however, not all of them will necessarily be up to the task of fully evaluating the relative risks and merits of a process or project. With an unproven process, the intellectual demands on the lenders and their technical consultants are much greater. If one has an unproven process to finance, the project sponsor should expend some effort assessing the experience, objectivity, and breadth of knowledge of the lenders and their technical consultants before investing too much time and effort with that particular lender. Both the project sponsors and the lenders must be prepared to support an objective, comprehensive due diligence process if the financing, and ultimately the project, are to be successful.