SPEYWOOD LABORATORIES

COMPANY PROFILE

A familial bleeding disorder affecting males and apparent from birth was first recognised in writings in the second century. The name haemophilia dates from 1828 (Hopff) and at that time it was known to be sex linked via symptomless females. It is believed that Queen Victoria was a carrier and via her the condition was inherited by the last children of the Russian Royal Family.

Classic haemophilia results from a genetic defect resulting in a deficiency of Factor VIII one of the blood clotting protein constituents of blood. Speywood Laboratories are a development company engaged in research, production and purification of blood clotting proteins. It is the only producer of Porcine FVIII, which is now becoming the product of choice for the treatment of haemophiliacs with inhibitors and those with acquired haemophilia.

Minor sales of Hyate:C (Porcine Factor VIII) are made on a named patient basis, even though the product is still awaiting a Product Licence from the D.H.S.S. The programme of clinical trials for Hyate:C is extensive. Specialists at The Royal Free Hospital in London, Professor Manucci in Italy plus those in the U.S.A. have already considerable experience with our product. The Medicines Division of the D.H.S.S. have already inspected our product licence application data, and we have good reason to believe that with minor modification it will be acceptable to the Committee on Safety of Medicines. It is projected that the necessary approvals will be obtained in the first half of 1984 for the U.K. and the second half for the U.S.A.

In view of the recent concern over AIDS, American and European Clinicians are eager to obtain an effective therapy for certain haemophiliacs that is not derived from human plasma.

The extraction of Porcine FVIII is achieved by means of an affinity chromatography process employing a polyelectrolyte obtained under licence from MONSANTO. This process has been developed on a laboratory scale for human FVIII, but not so far commercialised. There is however, considerable interest from European fractionators in this process.

Laboratory prepared human FVIII concentrate has been further treated by Dr. Tuddenham at the Royal Free by means of a monoclonal antibody purification system. This material represents a highly purified FVIII pure protein with a molecular weight of 365k. Dr. Tuddenham and the Royal Free team operate under an agreement with Speywood.

The 365k material has been supplied to Genentech with whom Speywood have a joint development agreement for Genetically Engineered FVIII. In return for the U.K. contribution to this research programme, Speywood will receive highly attractive European distribution rights for the recombinant FVIII when available. Considerable development is ongoing in the U.S.A. for a synthetic FVIII, but the Genentech/Speywood team is considered the most advanced.

The original Speywood was founded by David Heath and financed from private sources. It had an interest in certain O.T.C. and Ethical Pharmaceuticals. Its development of clotting agents was financed by the sale of these interests plus the injection of £4 million by B.T.G. and Prutec Ltd. These latter Companies required the appointment of a new Chairman and Mr. D.E.Seymour, the retired Technical Director and Deputy Chief Executive of Smith and Nephew, accepted this position.

In early 1983 J.C.Mottram accepted the position of Chief Executive of Speywood on an interim basis with a brief to re-organise Speywood into a classical U.K. Pharmaceutical Company. Mr. Mottram had recently retired from Smith and Nephew where he had been the Managing Director of the Pharmaceutical Division for many years.

B.T.G. and Prutec have financed the Company up to its present stage of development, but now feel that a new partner should be introduced. In view of the narrow product base the management consider that a Pharmaceutical Partner able to offer resources for medical back-up and marketing would be most suitable. The time is approaching when Speywood should expand internationally and it will be uneconomic to attempt this on the basis of one product.

The current vital statistics of the Company are:-

Accommodation

Speywood occupies leased accomodation on the Wrexham Industrial Estate of 28,000 sq. ft. In 1982 it also operated from a sales office in Nottingham, but this has now been closed and all operations transferred to Wrexham.

Staff

Production, Development and Q.C.	42
Admin, Accounts and Commercial	7
Total.....	49

Performance

£ 000's

		1982		1981
Sales		618		602
Gross Profit		314		193
Indirect Expenses of which		(1621)		(671)
R. & D.	638		146	
Depreciation	98		23	
Other Income Mainly Research Grants		94		226
Loss		1,273		331

The trading results for 1983 will not be materially different from 1982.

However, sales on a named patient basis in August and September have exceeded £100,000 in each month and a recent rationalisation programme has enabled significant economics to be made so effectively reducing nett expenditure to £130,000 per month.

	30 June 1983 £ 000
Fixed assets Cost less depreciation	1109
Stock and WIP	182
Debtors	171
Creditors	459
Total net assets	673

SPEYWOOD FUTURE PROSPECTS

In the immediate future the viability of Speywood depends on obtaining a product licence for Hyate:C and then ensuring that this product becomes the preferred treatment for "Haemophiliacs with Inhibitors". This condition is observed in some 10% - 15% of haemophiliacs. These patients develop inhibitors to human FVIII and therefore demonstrate little response to the standard therapy of FVIII concentrate extracted from human plasma.

In some cases treatment can be achieved with activated prothrombin complexes FIEBA Immuno or AUTOPLEX Hyland but results tend to be unreliable and as these products are derived from human plasma they carry the risk of transmitting Hepatitis and AIDS. The time is now opportune for the commercial exploitation of Hyate:C in view of the current awareness of the dangers associated with products derived from human plasma.

Adequate data exists for a U.K. product licence for Hyate:C and our application is being negotiated through the Medicines Division of the D.H.S.S. The Wrexham premises have already been granted a Medicines Act Licence to manufacture Hyate:C. It is anticipated that we should be able to officially launch the product commercially in the first quarter of 1984.

Speywood is progressing and IND via the FDA in the U.S.A. We are assisted in this work by a local pharmaceutical consultant.

It is apparent that Speywood in 1984 will require technical support to progress its registration in Europe plus a marketing partner to promote Hyate:C world wide. It would be uneconomic for Speywood with only one product to establish an extensive medical department to plan clinical trials and effect product registration. Also a marketing department based on one product would be both expensive and ineffectual.

Given an adequate partner for technical support and marketing Speywood should achieve sales of £6.7 million in 1986 (see attached sales forecast).

SPEYWOOD FUTURE OPERATING COSTS

SPEYWOOD'S nett operating costs in 1984 are projected at £1.7 million. This reduced level of expenditure will be on-going in January 1984 following the economising measures now in hand. The 1984 budgeted expenses allow for a production level of 1 million units per month by December 1984.

It is forecast that production could be doubled in 1985 by using a further abattoir for blood collection and minor improvements to the Wrexham plant. Costs would increase from £1.7 million to £2.3 million and sales from £1.7 million to £3.2 million. The company would then be in profit.

Further expansion to over 30 million units per year would require additional abattoir capacity but would be well within the processing filling and freeze drying facilities of the Wrexham plant. Operating costs could be confined within £3.5 million per year.

One characteristic of Hyate:C production is the high level of fixed expense for the sterile environment, Q.C. and technical back up, but the low cost of consumables and raw materials etc.

MARKETING PARTNERS OPERATING ECONOMICS

A suitable marketing partner for Speywood would already be operating in biologicals and have medical and marketing resources in Europe and possibly the U.S.A., these requirements are most likely to be found in a European or American pharmaceutical company. Providing this company is neither Immuno or Hyland, it will not have a product for treating inhibitor patients and therefore the distribution of Hyate:C will be commercially attractive.

It is proposed that Hyate:C should be sold to the marketing partner at 50% of the agreed price to hospitals, and that this latter price be equivalent to the price of FEIBA which is currently the lowest cost competitor.

Providing the marketing partner has adequate technical and marketing resources he should experience minimal further expense in handling Hyate:C. Certain promotional literature clinical support and conference costs may be additional to his current level of expense but these are unlikely to exceed 10% of sales.

It can be projected therefore that the contribution to profit received by the marketing partner will be:-

	1984	1985	1986
Gross contribution	£1.7 million	£3.4 million	£6.6 million
Nett contribution	£1.2 million	£2.5 million	£5.5 million

These projections are of course dependant on the granting of a Product Licence.

SPEYWOOD AND THE MARKETING PARTNER IN THE LONGER TERM

Any pharmaceutical company relying on a single product is obviously vulnerable. The rate of obsolescence of products in major therapeutic areas is fairly rapid and a lifespan in excess of 7 to 10 years is unusual. However the "haemophiliac inhibitor" market is highly specialised and relatively small so that it will not attract a high level of competitive research activity. Only specialised blood fractionators are likely to work in the area, using human plasma as their raw material. In many ways this is an unsafe and unsatisfactory raw material. It can be projected with confidence that Hyate:C will have a useful role to play for at least 10 years.

The further purification of porcine FVIII is possible and it may be that this material could have a wider application. Technical and clinical development on these lines is on-going.

It is however, predicted that the treatment of Haemophiliacs will some time in the future be revolutionised by the introduction of human FVIII prepared by recombined DNA technique. Speywood have a joint development programme with Genentech for the creation of genetically engineered FVIII. As explained in the introduction, this programme involves the Royal Free and when completed Speywood will have highly advantageous distribution rights in Europe for Genetically Engineered FVIII.

It is not likely that this material will be available on a fully commercial basis before 1990 but it will then be a highly attractive product. A human FVIII prepared synthetically would not have its supply restricted by blood donors or carry the danger of AIDS or Hepatitis. In the Speywood market the current usage of human FVIII is around 500 million units per annum at an average price to hospitals of 10 pence, and Speywood have rights to purchase material from Genentech at 25% of the price to hospitals.

THE SCHEME

The Marketing Partner will have such a dominant role in the company that it is considered they should become a major investor in Speywood. They would also probably require an option for the total purchase of the company at some later date. A two stage transfer is therefore proposed, with the initial investment being related to the company's present worth, but the option taking account of the significant future profits to be derived from Hyate:C and the Genentech Agreement.

Details of the proposal are on the attached schedule.