CONFIDENTIAL

# BLOOD PRODUCTS MANUFACTURING UNIT

## INVESTMENT APPRAISAL

JULY 1984

Director, BPL:
27 July 1984.

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1794

26.7.84.

Information required for Alun Williams.

BLOOD PRODUCTS MANUFACTURING UNIT

Investment Appraisal, July 1984

Following the papers supplied by BPL and CBLA to DHSS concerning the current financial status of the Elstree building development, a request from DHSS (HS2A Division) for further information is dealt with below:-

1. Which option for revenue consequentials of capital spending (RCCS) will be accepted for the investment appraisal?

Answer: The concensus lies with the selection of RCCS at £12.44M per annum as used in option 3/3a presented to DHSS at their Elstree meetings on 12th and 18th June 1984 with BPL and CBLA.

2. What would be the phasing of the capital expenditure?

Answer: Information to be supplied by CBLA. (see Appendix III)

3. What fraction of costs are equipment costs?

Answer: The estimated final costs (EFC) June 1984 showed the equipment costs to be £8.301M against a total EFC of £35,985M. Capital savings of £835,000 were identified at that time and have subsequently been subtracted from the EFC by DHSS, reducing the June figure to £35.15M. The equipment cost is therefore $\frac{7.5}{35.15}$ x 100% = 21.3%. The EFC includes fees.

Matthew Hall cost commentary No. 12, 17th June, places the revised EFC at £35.47M which includes £200,000 for those areas of the contract still at risk to inflation and £134,000 which represented capital costs and fees raised by MCVOs being processed at the time of the June 1984 EFC summary. These areas of risk were drawn to the attention of DHSS at their meeting with CBLA.

4. Capital cost of Quality Control building and Warehousing?

Answer: The attached document (Appendix 1) shows the revised costings for the Warehouse, QC and Engineering building, indicating functional contents and associated areas, together with proportional costs of building to specification per unit area. To maintain the costs within

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the total proposed cash limit for BPL of £38.8M, the following changes have been made:

Warehouse: there will be no -40°C cold room, provision being made by hiring a converted facility from Christian Salvesen. The cost of the building is therefore £1.09M.

QC and Engineering: the engineering facility represents an essential low-cost area and is retained in accordance with the earlier specification.
Quality Control, Quality Assurance and associated services are designed to accommodate Bacteriology, sterile product testing, media preparation, support services of environmental control, coagulation assay, chemistry and biochemistry laboratories, together with offices, data services terminal, filing and regulatory records departments. A sum is included for equipment and, where appropriate, VAT has been allowed for. The existing Virology and Hepatitis Laboratory will be retained, as will the Animal House. The cost of the additional capital buildings and equipment will be limited to £3.35M as summarised in Appendix 1.

5. Current commercial prices of main products were required by Mr. Anguilly for inclusion in the updated investment appraisal.
Attached as Appendix II is a general commentary on this subject which is both significant in terms of its information and relevant to our current situation.

Products for new BPL

| | | | |
|---|---|---|---|
| | Albumin | 10,000 kg @ £2/g | = £20M |
| (OPTION 1) | Factor VIII (intermediate purity) | 100M iu @ £0.12/iu | = £12M |
| (OPTION 2) | " (high purity) | 100M iu @ £0.16/iu | = £16M |
| | Factor IX | 20M iu @ £0.10/iu | = £2M |
| | Ig (im) | 100 kg @ £9/g | = £0.9M |
| | Ig (iv) | 250 kg @ £25 | = £5M |
| | | OPTION 1 | = £39.9M |
| | | OPTION 2 | = £43.9M |

Explanation

Quantities of albumin and factor VIII are in accordance with current manufacturing projections. Thus, factor VIII at 100M iu will meet the

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total projected requirement of the NHS which means that the ongoing theoretical deficit used in the first cost appraisal for imported factor VIII no longer applies.

Factor IX projected requirements have increased to 20M iu and the price of factor IX has been levelled at 10p per unit both for provision to the NHS and for sales of excess. Since the supply of factor IX to the NHS has increased by 5M iu, this has been subtracted from the excess production available for sale which is now 100M iu at 10p per unit.

Intramuscular immunoglobulin remains the same. Intravenous immunoglobulin projections for the NHS have increased to 250 kg priced at £25. This increase is set against the excess available for sale which now becomes 1,000 kg, but this should be realistically priced at £8/g.

For the purposes of investment appraisal, therefore, the revised sale of product should now be

100M iu factor IX at 10p per unit = £10M
1,000 kg intravenous immunoglobulin at £8 per gram = £8M
Total potential sale = £18M.

For the reasons stated above on factor VIII, we do not consider that there will be a need to purchase the additional 10M iu factor VIII. Therefore the purchase of £.75M factor VIII at self-sufficiency no longer relates and should be deleted.

**SUMMARY**

All the information on products and prices is shown in Appendix IV and the Discounted Cash Flow analyses have been repeated with and without the effect of the value of BPL production to the NHS. The DCFs therefore represent revisions of the options 3/3A demonstrated to DHSS and Finance Branch at their Elstree June 18th meeting.

The following points should be noted:

1) In the earlier analysis, product values were simply updated values taken from the 1980 investment appraisal. Product prices both to the NHS and excess product for sale represent realistic and defendable current rates.

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2) BPL capital costs and BPL revenue costs have been revised as shown in Appendix IV, although the plasma supply cost represents an update of the 1980 figure.

3) There is no need to maintain the small residual import cost of factor VIII which has been shown in all previous investment appraisals.

CONCLUSION

The investment appraisal still remains attractive, particularly when the effect of the value of products supplied to the NHS is taken into consideration. Considering that estimates of revenue expenditure and product prices could show significant variation from the values used, there appears to be no significant difference between Option 3/3A (18th June) and the revised Option 3/3A presented at today's date.

**R. S. LANE,**
**Director, BPL.**

**27 July 1984.**

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# Proposal for Warehouse and QC/Engineering Buildings

## 1. Warehouse

a) +4°C Area — Capacity 432 pallets (1200 x 1000mm) for factor VIII, factor IX, Ig normal i/m, Ig normal i/v, specific Ig, reject factor VIII/IX, technical grade product.

b) Ambient Area — Capacity 2160 pallets (1200 x 1000 mm) for finished PPF, water for injection, cartons, containers and other raw materials, together with product awaiting QC release.

c) Chemical store 52 m²

d) Control office 20 m²

e) Movement area 172 m², for unloading, sorting, load preparation etc.

Aggregated, these requirements will be contained in a building of approximately 60m x 30m with height to eaves of some 7m with a low pitch roof giving overall height at ridge of 8 to 8.5m.

Ambient and +4°C areas would be fitted with heavy mobile racking to maximise use of cube and achieve required capacity.

Costs — Budget estimates of elements are as follows:

| | |
|---|---|
| Site preparation | £100,000 |
| Warehouse construction 20,000 ft² @ £20 ft² | 400,000 |
| Cold Room (+4°C) | 200,000 |
| Mobile racking | 150,000 |
| F.L.T. | 18,000 |
| Heating and ventilating | 20,000 |
| S/B generator | 50,000 |
| Services external and internal | 150,000 |
| Total | £1,088,000 |
| VAT on FLT (15%) | 2,700 |
| Total inc. VAT | £1,090,700 |

## 2. QC and Engineering

a) Engineering — Workshops for Machine, Mechanical, Electrical, Instrument and Refrigeration Sections, materials and spare parts storage, Engineers' offices, drawing office and project room, records and clerical office.

Costs 680 m² @ £500 m² = £340,000.

b) QC — To accommodate Bacteriology, Media preparation, Coagulation Assay and Chemistry units, together with offices for QC, QA, data services, filing and statutory records.

Costs 1295 m² @ £1,000 m² = £1,295,000.

c) Equipment

188,000
+ VAT 28,200
£216,200.

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Cost Summary

| | |
|---|---|
| Warehouse (inc. VAT) | 1,090,700 |
| Engineering | 340,000 |
| QC | 1,295,000 |
| Equipment (inc. VAT) | 216,200 |
| Fees @ 15% | 408,100 |
| | £3,350,000 |

To enable costs to meet requirement of overall capital budget of £38.8M, less E.F.C. for Production factory of £35.45M, the animal houses and virology/hepatitis units have been omitted from the QC unit.

GRO-C

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## Current product pricing in the UK, Europe and the United States

In our discussions with DHSS, it was agreed that the product prices used in the investment appraisal should reflect world prices since considerable variations between markets exist.

There is a current albumin shortage in the USA for the following reasons:

In 1979, growth in the industry was projected at 7% per annum, but by 1980, a reduction in clinical demand in USA and West Germany meant that the growth in plasma collection centres needed to be headed off. Fractionation capacity remained static and industry looked to factor VIII and intravenous immunoglobulin for cash supply.

The effect of the world recession further reduced albumin use in 1980-82 since hospital practice in USA was cut back - less money = fewer operations.

However, by 1983 an expansion of albumin uptake had got underway but the panic caused by AIDS interfered. Use of whole blood has fallen by 25% with large-scale redundancy in the American Red Cross. While albumin is preferred instead of whole blood, plasma supply from whole blood has reduced dramatically.

USA industry has responded typically. The primary provision is to the USA and then to the profitable market in Japan. Europe comes last where there is a seller's market. Prices for albumin across the world range from $35 to $65 for ~20g, the higher prices being outside the USA. Additionally in Europe there is a waiting time for delivery.

The lower quality American PPF is available to Europe and it must be remembered that the BPL product is ALBUMIN for comparison purpose. In fact, BPL PPF will be relabelled "Human Albumin" in 1984 to offset market disadvantages from under-description.

At the current meeting of International Blood Transfusion Societies in Munich, a firm price for albumin is not available - a contract is based on competition in the market for available product.

Factor VIII prices reflect similar market forces. Thus the price in Europe varies between 8p per unit and 22p per unit for a product of equivalent quality to NHS intermediate concentrate. England is being used as a clearing house for United States intermediate concentrate not heated to inactivate hepatitis, whilst the move is now taking place to present mainly heat-treated material to satisfy the German market, but at a higher price. The efficacy of heat-treated factor VIII is not proven, although the price of this material will briefly reflect a 25% increase to cope with the loss of yield associated with manufacture. For the purpose of the investment appraisal, it would be realistic to adopt a price of 12p per international unit for intermediate purity factor VIII with a production target of 100M international units.

It should be understood, however, that recent advances in process technology at BPL will permit the bulk of factor VIII issued from the new manufacturing unit to be high purity factor VIII, of which a proportion may be heat treated if this is shown to increase efficacy and safety. The price of high purity material may be realistically rated at 16p per unit and DHSS should decide what figure they wish to incorporate into the appraisal.

Factor IX remains a difficult product to price within the United Kingdom since none is bought. From the Swiss Red Cross figures, it would be appropriate to charge 10p per iu but, of course, there is no certainty that such a price would relate to the UK market were we dependent upon a commercial product. For investment appraisal purposes, the figure of 23p per international unit should be reduced to 10p. However, the production of factor IX in the new BPL will be increased from 15M to 20M international units, based on current usage, with a possible increase to 25M international units.

Immunoglobulin The price for intramuscular immunoglobulin can be retained as quoted in an earlier appendix presented to DHSS; intravenous immunoglobulin is priced at £25/g.

Conclusion With uncertainty in the plasma fractionation market in the United States compounded by the factors set out above, it is clear that the American Blood Resources Association will primarily satisfy American and Japanese needs using the European market to balance its manufacturing

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against total demand and to gain the best financial return to offset the effects of a more competitive home market. European countries having a greater degree of independence through national blood component fractionation will be able to resist American selling pressures better than West Germany where reliance on the commercial component market is almost complete. The effect in the UK of rebuilding the BPL and current increases in output of factor VIII and albumin exact the lowest price for factor VIII in Europe and commercial companies are now withdrawing albumin from the UK for sale in the more profitable markets in the United States and Japan.

As deduced in the original investment appraisal, it is difficult to relate blood component world prices to the UK market, but it is certain that without current potential for fractionation in the UK, imports would carry much higher prices.

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BRIEF SUMMARY OF THE CASH FLOW POSITION DERIVED LARGELY FROM FIGURES SUPPLIED BY MHNE.

The cash required for 1984/5 amounts to £19,032,500 against a cash limit of £12,490,000.

These figures do not include the additional interim capital building projects of Warehousing and QC etc.

## NEW LABORATORY PROJECT

### Estimated Cash Flows/Final Cost as at 26.7.84

| | Payments to MHNE | In House and other expenditure charged to Project | TOTAL |
|---|---|---|---|
| | £ | £ | £ |
| To 31.3.84 | 5,132,267 | 120,557 | 5,252,824 |
| " 30.6.84 | 1,936,592 | 22,898 | 1,959,490 |
| Estimates | | | |
| July-Mar. 84/5 | 17,003,000 | 70,000 | 17,073,000 |
| Apr.-Mar. 85/6 (including retention) | 11,425,000 | 100,000 | 11,525,000 |
| | £35,496,859 | £313,455 | £35,810,314 |

The estimated payments to MHNE are from their sources, presumably at July 1984 prices.

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APPRAISAL OF DEVELOPMENT OPTION FOR THE BPL (JULY 1982)

Attached are the Discounted Cash Flow (DCF) statements with respect to the revised Options 3/3A:

| | |
|---|---|
| Capital Cost | £38.8M |
| Annual Revenue Cost | £12.44M |

using the outputs and prices given in the attached table.
No changes have been made to plasma supply costs.

The Net Present Value (NPV) of the option is:

| | |
|---|---|
| Excluding BPL production of NHS requirements: | £184.15M |
| Including " " " : | (£154.58M). |

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## VOLUMES AND PRICES OF BPL OUTPUT FROM 1987/88

### VALUE OF BPL PRODUCTION TO NHS REQUIREMENTS AT NUNE 1984 MARKET PRICES FROM 1987/88

| | | | | | £ |
|---|---|---|---|---|---|
| Albumin | 10,000 kg | @ | £2.00 per gm | = | 20,000,000 |
| Factor VIII (medium purity) | 100,000,000 | @ | £0.12 per iu | = | 12,000,000 |
| Factor IX | 20,000,000 | @ | £0.10 per iu | = | 2,000,000 |
| Immunoglobulin (im) | 100 kgs | @ | £9.00 per gm | = | 900,000 |
| Immunoglobulin (iv) | 250 kgs | @ | £25.00 per gm | = | 6,250,000 |
| | | | | | £41,150,000 |

### EXCESS OF BPL PRODUCTION AVAILABLE FOR SALE AT COST PRICE FROM 1987/88

| | | | | | |
|---|---|---|---|---|---|
| Factor IX | 100,000,000 iu | @ | £0.10 per iu | = | 10,000,000 |
| Immunoglobulin (iv) | 1,000 kg | @ | £8.00 per gm | = | 8,000,000 |
| | | | | | £18,000,000 |

### BPL PRODUCTION IN YEAR 1986/87 (50% of above) FOR NHS REQUIREMENTS

| | | | | | |
|---|---|---|---|---|---|
| Albumin | 5,000 kgs | @ | £2.00 per gm | = | 10,000,000 |
| Factor VIII (medium purity) | 50,000,000 iu | @ | £0.12 per iu | = | 6,000,000 |
| Factor IX | 20,000,000 iu | @ | £0.10 per iu | = | 2,000,000 |
| Immunoglobulin (im) | 100 kgs | @ | £9.00 per gm | = | 900,000 |
| Immunoglobulin (iv) | 250 kgs | @ | £25.00 per gm | = | 6,250,000 |
| | | | | | £25,150,000 |

**SHORTFALL TO BE BOUGHT-IN = £16,000,000**

### EXCESS OF BPL PRODUCTION AVAILABLE FOR SALE IN 1986/87 AT COST PRICE

| | | | | | |
|---|---|---|---|---|---|
| Factor IX | 40,000,000 iu | @ | £0.10 | = | 4,000,000 |
| Immunoglobulin (iv) | 325 kg | @ | £8.00 per gm | = | 2,600,000 |
| | | | | | £6,600,000 |

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APPRAISAL OF REDEVELOPMENT OPTION FOR THE BLOOD PRODUCTS LABORATORY (JULY 82)
EFFECT OF CHANGES IN CAPITAL COSTS FOR OPTION 3 (400 tonnes FFP) AT JUNE 84 PRICES

TOTAL CAPITAL COST £38.8M. ANNUAL REVENUE EXPENSE £12.44M.

| Financial Year | BPL Capital Cost | BPL Revenue Cost | Plasma Supply Cost | Cost of Bought-in Products | Value of Excess Products | Net Cost of Option | Net Cost Discount @ 5% | Cumulative Discounted Net Cost |
|---|---|---|---|---|---|---|---|---|
| 1982/83 | 1.00 | | | | | 1.00 | 1.00 | 1.00 |
| 1983/84 | 6.00 | | | | | 6.00 | 5.71 | 6.71 |
| 1984/85 | 12.50 | | | | | 12.50 | 11.34 | 18.05 |
| 1985/86 | 16.00 | | | | | 16.00 | 13.82 | 31.87 |
| 1986/87 | 3.30 | 9.33 | 15.04 | 16.0 | ( 6.60) | 37.07 | 30.50 | 62.37 |
| 1987/88 | | 12.44 | 21.33 | | (18.00) | 15.77 | 12.36 | 74.73 |
| 1988/89 | | 12.44 | 21.33 | | (18.00) | 15.77 | 11.77 | 86.50 |
| 1989/90 | | 12.44 | 21.33 | | (18.00) | 15.77 | 11.21 | 97.71 |
| 1990/91 | | 12.44 | 21.33 | | (18.00) | 15.77 | 10.67 | 108.38 |
| 1991/92 | | 12.44 | 21.33 | | (18.00) | 15.77 | 10.17 | 118.55 |
| 1992/93 | | 12.44 | 21.33 | | (18.00) | 15.77 | 9.68 | 128.23 |
| 1993/94 | | 12.44 | 21.33 | | (18.00) | 15.77 | 9.22 | 137.45 |
| 1994/95 | | 12.44 | 21.33 | | (18.00) | 15.77 | 8.78 | 146.23 |
| 1995/96 | | 12.44 | 21.33 | | (18.00) | 23.11 | 12.26 | 158.49 |
| 1996/97 | | 12.44 | 21.33 | | (18.00) | 15.77 | 7.97 | 166.46 |
| 1997/98 | | 12.44 | 21.33 | | (18.00) | 15.77 | 7.59 | 174.05 |
| 1998/99 | | 12.44 | 21.33 | | (18.00) | 15.77 | 7.22 | 181.27 |
| 1999/2000 | (9.17) | 12.44 | 21.33 | | (18.00) | 6.60 | 2.88 | 184.15 |
| | | | | | NPV (NET PRESENT VALUE) | | 184.15 | |

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APPRAISAL OF REDEVELOPMENT OPTION FOR THE BLOOD PRODUCTS LABORATORY (JULY 82)
EFFECT OF VALUE OF BPL PRODUCTION FOR NHS NEEDS ON VARIOUS OPTIONS AT JUNE 84 PRICES

CAPITAL EXPENDITURE £38.8M ANNUAL REVENUE EXPENSE £12.44M

| Financial Year | Net Cost of Option | Value of BPL Production to NHS | Net Cost of Option | Net Cost Discounted @ 5% | Cumulative Discounted Net Cost |
|---|---|---|---|---|---|
| 1982/83 | 1.00 | | 1.00 | 1.00 | 1.00 |
| 1983/84 | 6.00 | | 6.00 | 5.71 | 6.71 |
| 1984/85 | 12.50 | | 12.50 | 11.34 | 18.05 |
| 1985/86 | 16.00 | | 16.00 | 13.82 | 31.87 |
| 1986/87 | 37.07 | (25.15) | 11.92 | 9.81 | 41.68 |
| 1987/88 | 15.77 | (41.15) | (25.38) | (19.89) | 21.79 |
| 1988/89 | 15.77 | (41.15) | (25.38) | (18.94) | 2.85 |
| 1989/90 | 15.77 | (41.15) | (25.38) | (18.04) | (15.19) |
| 1990/91 | 15.77 | (41.15) | (25.38) | (17.18) | (32.37) |
| 1991/92 | 15.77 | (41.15) | (25.38) | (16.36) | (48.73) |
| 1992/93 | 15.77 | (41.15) | (25.38) | (15.58) | (64.31) |
| 1993/94 | 15.77 | (41.15) | (25.38) | (14.84) | (79.15) |
| 1994/95 | 15.77 | (41.15) | (25.38) | (14.13) | (93.28) |
| 1995/96 | 23.11 | (41.15) | (18.04) | ( 9.57) | (102.85) |
| 1996/97 | 15.77 | (41.15) | (25.38) | (12.82) | (115.67) |
| 1997/98 | 15.77 | (41.15) | (25.38) | (12.21) | (127.88) |
| 1998/99 | 15.77 | (41.15) | (25.38) | (11.63) | (139.51) |
| 1999/2000 | 6.60 | (41.15) | (34.55) | (15.07) | (154.58) |
| | | NPV (NET PRESENT VALUE) | | (154.58) | |

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