

**RESTRICTED - POLICY**

**To:** Andrew Laycock  
Alistair Bridges

**From:** Richard Lawes

**Date:** 28 January 2002

**Copies:** SofS  
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PS/PH  
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**US PLASMA SHORTAGE: IMPACT ON BIO PRODUCTS LABORATORY/  
SUPPLY OF BLOOD PRODUCTS TO THE NHS**

1. As you know, we need to take immediate action to secure the supply of blood products for the NHS. The background to the current situation and our options is contained in paragraph 5 onwards.
2. The preferred option identified to secure this supply is to enter into discussions with Life Resources Incorporated (LRI) with a view of securing an option to purchase the company. LRI is a company based in America that is the largest remaining independent supplier of plasma. LRI is the parent company of Diagnostic Chemistries Incorporated (DCI) mentioned in previous correspondence. This is the only one choice available at the moment to secure sufficient plasma supplies for Bio Products Laboratory (BPL) and we are in direct competition for this with the multinational pharmaceutical companies.
3. This option has been discussed in detail with Ministers and Nigel Crisp and both have approved the strategy we have adopted.
4. In our exchange of earlier this month you specifically asked for further information on the following areas:
  - An analysis of the problem, the solutions and any possible impact future technology may have.
  - Costings for the options, identifying the assumptions made
  - Confirmation of the affordability of the scheme.

## Background

5. A short summary of the background information on BPL and its key products is supplied as Annexes A and B.
6. The supply of raw plasma to BPL had been identified as a key resource constraint within the first PA Consulting report on BPL – *Outline Business Case for the future of Bio Products Laboratory* February 2001 - Appendix F Security of Supply of Plasma Products. This was a report originally commissioned with the support of Treasury and PUK to examine the future ownership route for BPL, and recommended a future joint venture with the private sector. Any future decision on the supply of plasma issue for BPL will be taken with reference to the strategic long terms needs of BPL and specifically any impact on the options for its future ownership.
7. Until a validated screening test for vCJD becomes available, or it is proven conclusively that vCJD cannot be transmitted through blood, UK plasma cannot be used in the manufacture of blood products. The latest assumption is that a validated vCJD screening test is at least 3 to 5 years away. Even then, MCA and probably the US FDA would need to undertake time-consuming regulatory checks before BPL could return to using UK plasma. In addition it would take time for NBA to set up the infrastructure to be able to use UK plasma. The DOH is continually monitoring the progress of a screening test and, before any final decision is taken on LRI, the position on the screening test development will be re-evaluated.
8. The use of non-plasma derived products such as recombinants is not currently a viable alternative as there are no such products available for immunoglobulins and this is the major product from BPL. There are recombinant products available for factor VIII and factor IX but these are in short supply and are highly expensive. Ministers have not yet taken a decision around their future use ie whether to replace the plasma derived product. Even if such a decision were taken the earliest the replacement could take place would be 2005/2006. However, current information is that there would still be patients unable to use recombinant products and therefore there would be a continued need for plasma derived factor VIII and factor IX product albeit at reduced levels.
9. Leaving aside the return to UK plasma and/or the introduction of non-plasma derived products there is not one single clear alternative to the purchase of LRI. Broadly the alternatives include securing additional plasma supply and purchasing extra finished product. The former involves BPL purchasing as much ad hoc plasma as possible if it becomes available and for BPL to move quickly to find a commercial partner with a secure plasma supply. Neither of these options can be guaranteed and current market information is that no potential partner has regular surplus plasma. In addition DOH could support the building of new plasma centres in the USA. Again this is not a guaranteed solution and even in the best case scenario our information is that this would only provide a portion of the BPL raw plasma requirement.

10. Based on the best advice available to us, including the information from a meeting held recently by the Primary Immunodeficiency Association with possible alternative suppliers of finished product, it will not be possible for enough product to be purchased at or near the current market prices to begin to replace the output from BPL. The Purchasing and Supplies Agency are aware of the issue but cannot give a formal indication of available volumes and the corresponding prices unless a formal tender is advertised. Any significant shortage of product will have a direct clinical impact. For key groups of patients there are no alternative therapies and lack of treatment for these people is life threatening.
11. An update report was commissioned from PA, *Review of BPL Partnership Options* and published in May 2001, a copy of which was sent to Treasury. This report highlighted the worsening of the raw plasma supply to BPL:  
  
*"Since writing the earlier report, the pressure on securing raw plasma supply for the security supply for the UK market has increased significantly. Due to increasing global demand for US plasma, larger commercial competitors are moving to acquire plasma collection centres in the US, in order to secure supply. This has created an increased risk that BPL will not be able to secure its required amount of source plasma..." (page 1)*
12. Representatives from the DOH first met with the owners of LRI in August 2001 and following internal debate with Ministers a Project Board was established. The Board is chaired by Martin Gorham, Chief Executive of the National Blood Authority with the Public Health (Blood) branch taking the policy lead. The Private Finance Unit is providing support relating to the project management and commercial aspects of the transaction and SOL are providing and co-ordinating legal advice. Chris Hadfield, the Chief Executive of BPL is also present on the board.
13. As part of the internal option appraisal, SOL examined whether a purchase of DCI is within the vires of the DOH. They are of the opinion that the SofS does have the vires to undertake this transaction. A full copy of their advice is attached as Annex C.
14. The National Blood Authority (NBA) then commissioned a further report from PA Consulting to independently assess the options available to BPL to address the security of plasma issue. Their report, containing option appraisals and recommendations, was produced in December 2001. The executive summary to this report is attached as Annex D.
15. The key findings from the report were that the preferred option was heavily dependent upon the key assessment driver used; there were two possible main drivers, security of supply or economic viability.
16. If security of supply was the prime driver then a part purchase (believed to be the most likely LRI option at the time of the report) was considered the preferred option. If economic viability was the prime driver then the preferred

option was to buy raw plasma as it became available on the market with a view to return to UK plasma should a test for vCJD become available within 5 years. Under the economic viability option, should a vCJD test not be available within 5 years the report recommends alternative options should be considered such as the closure of the plant at BPL or pursuing a form of joint venture so that the partner would provide the supply of plasma.

17. The report also recommended that BPL should purchase any available plasma available on the market so that it could remain operationally viable and to retain the options available to BPL.
18. PA were also specifically requested to update their findings from the very first report *Outline Business Case for the future of the Bio Products Laboratory* – analysing the future ownership options of BPL. This is attached as Annex E. This report concluded that the findings of the original Outline Business Case remained valid and;

*“There is no reason to believe that entering into an arrangement for the supply of plasma under any of the options considered in the plasma option report would impair the value of BPL to a JV partner. Indeed the market observations, and BPL’s own view, would suggest that securing plasma supply would increase the value of BPL to a potential JV...”*

19. Ministers were formally consulted on 20 December and they have confirmed that security of supply is the main driver. This meant that the full or part purchase of LRI is confirmed as the preferred option.

#### **Current position**

20. On 21 December 2001, the owners of LRI issued through their advisers, Scura, Rise and Partners LLC (SRP) formal documents of sale. These consisted of an explanatory letter, with a proposed timetable and preferred transaction route accompanied by an information memorandum for Life Resources Incorporated and affiliates.
21. The letter requested a non-binding indication of interest commenting on the proposed transaction structure and the consideration for the purchase to be received. The closing date for receipt of the bid was 18 January 2002.
22. PA Consulting were immediately asked to review their option appraisal based on the new information received from SRP. The outcome of this assessment is attached as Annex F. The advice given was that the findings from the previous report held given the new information and that the purchase of Life Resources Inc (LRI) was the route that provided security of supply. The report does highlight that the earlier assumptions regarding the value of LRI were pessimistic and purchasing the company will be more expensive than anticipated. The favourable NPV of this solution is now dependent on the achievement of proposed growth plans for the company. However this does not change the decision on the way ahead as security of supply is the key objective.



23. A team of advisers was appointed for this work consisting of Simmons and Simmons (legal) and PA Consulting (financial). These advisers were also supported by their respective associates in the United States and they produced the draft offer letter, a copy of which is attached as Annex G. We have yet to receive a formal response.
24. PA Consulting advised that, based on the information available, LRI had a value of between \$60m-\$80m.
25. DOH is aware that the structure as proposed by LRI is not the best commercial solution for DOH. It is, however, as the starting point of negotiations with the owners of LRI, who have made a general offer of sale and will accept the best overall deal they can get. The actual structure of the deal will be developed as a result of considerable further negotiation and the Department and its advisers need to be successful at this stage before the strategy of the next phase is determined.
26. If our letter of interest is successful the future stages of the transaction will be undertaken quickly. For this reason DOH have begun to examine the credentials of advisers for the next stages. We are also seeking advice to prepare for the likely negotiations so that we are prepared to meet any reasonable timetable. In order to maintain LRI as an option to resolve the plasma supply issue we must continue to negotiate with the owners of LRI as long as the option remains strategically and commercially acceptable.
27. Capital funding of £50m in 2001/2002 has been identified for the initial stage of the purchase. This has been found from the DUP. Funding for any additional costs will also be met from within the Department's allocation. If completion is not secured this financial year, it will be carried forward to 2002/2003.
28. We have set aside a budget of £1m for advisory services for 2001/2002. This will include the funding of due diligence. However we would be seeking repayment of due diligence costs from LRI should our bid be unsuccessful. Should the transaction be delayed the budget for the advisers will also be carried forward to 2002/2003.

### **Liabilities**

29. From the information received to date we have not seen evidence of liabilities beyond those expected for a company of this type (eg lease payments). We would look to the due diligence process to provide further assurance on this issue.

## Conclusion

30. It is clear that should we be successful at this stage of the bidding process, we will be forced to move very quickly in the stages up to financial close. If you would like to meet to discuss this further, or have any questions on this submission, please let me know as soon as possible. We will contact you when we hear further from LRI.

Richard Lawes

Room **GRO-C**  
Quarry House  
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**THE BIO PRODUCTS LABORATORY: BRIEF BACKGROUND**

1. BPL is part of the National Blood Authority and supplies plasma-based products (immunoglobulin, albumin, Factor VIII etc) to the NHS in England and Wales. It was set up in 1950 to meet a government commitment to self-sufficiency in plasma fractionation and manufacture of plasma products for the NHS. A second, much smaller plant – the Protein Fractionation Centre – was also set up Scotland.
2. BPL's total budget (measured as total costs, since these exceed revenues) is around £70m pa. It employs around 500 staff.
3. BPL's current plant was built in the mid 1980s still with the intention of achieving national self sufficiency. However, since the introduction of charges to the NHS for blood products in 1989/90, BPL has operated on a commercial basis, in competition with other commercial manufacturers. Unfortunately, as part of a Special Health Authority, it has none of the advantages of its competitors in terms of financial freedoms, investment in developing technologies etc.
4. BPL is currently operating at less than half capacity and has been unable to recover its costs at market prices. It has made a financial loss and received a subsidy from the Department every year except 1994/5 from central funding (around £17m in the current financial year). This deficit was set to improve until the decision was taken in 1998 to source BPL's plasma from the US because of the unknown risks posed by vCJD. Since then the rising costs of US plasma, driven by shortages, and unfavourable exchange rates have put paid to any hope of BPL breaking even in the foreseeable future.
5. The Department also provides BPL with capital funding of around £5m pa.



## **BPL PRODUCT RANGE AND CONTINUITY OF SUPPLY**

BPL supplies a wide range of products to the NHS in England and Wales and in some instances supplies the entire UK needs. The products fall into three main product ranges, namely clotting factors, albumin and immunoglobulins. For the major products in these three groups, there are several alternative suppliers and the trend in some cases is away from plasma derived products to alternatives.

The situation on the major product groups and minor products is as described below.

### **CLOTTING FACTORS**

The major products to treat Haemophilia A and Haemophilia B are Factors VIII and IX. Several suppliers are already supplying licensed products in the UK in direct competition with BPL's products. However, the demand for these plasma derived products is declining as the products of choice are recombinants from three suppliers in the case of Factor VIII, and one supplier in the case of Factor IX. With BPL's current plasma supply, it could only meet around 45% of the UK's Factor VIII needs but has a very large surplus of Factor IX if required to meet any likely any future demand for Factor IX.

It is assumed that BPL sales of plasma derived Factor VIII and IX in the UK will continue to decline to very low levels over the next few years, but product could be diverted from export markets if required as BPL will continue to sell their products to satisfy growing needs in developing countries.

### **Other Clotting Factors**

#### **Factor VII**

BPL offers an unlicensed Factor VII product for a limited number of users in the UK on a named patient basis. Baxter Immuno is the only other supplier, again with an unlicensed product. There are very few users of this product worldwide and it is therefore made available on a compassionate basis. There are other possibilities. Recombinant 7A from Nova Nordisk, which is very expensive and only has a short shelf life. A four factor prothrombin complex, which contains Factor VII in addition to II, IX and X. This is available from a number of European manufacturers although not licensed in the UK.



## Factor XI

BPL makes an unlicensed Factor XI which is supplied to UK patients on a named patient basis and again supply is in very limited quantities overseas under very special circumstances. The only other company to offer Factor XI is LFB in France, but again this product is unlicensed.

## Anti Thrombin III

BPL's product currently has a transitional licence but is likely to be moved to supply on a named patient basis. There is only a small number of users in the UK and there are other products licensed in Europe which could be supplied to the UK on a named patient basis.

## von Willebrand Factor

BPL offers its intermediate purity Factor VIII, 8Y, as treatment for von Willebrands disease, but this product seems to be less effective since the conversion to US plasma and the majority of patients are now treated with Hemate B available from Aventis Behring. The majority of patients are normally treated with DDAVP.

## **ALBUMIN**

BPL provides two grades of albumin, namely 4.5% and 20% solutions. There are several other licensed suppliers of albumin to the UK, but there has recently been a strong move to non-plasma alternatives due to concerns over albumin and there is now a very large worldwide albumin surplus, which means the likelihood of the UK ever running short of product is extremely small.

## **IMMUNOGLOBULINS**

Intravenous polyvalent immunoglobulin is a product with a wide and growing range of uses for which there are in some cases no alternative products available. The UK market is currently supplied by more than six manufacturers but demand is growing and shortages are a common feature. The most important group of patients dependent on this product is that suffering from a range of immune deficiencies. This group of patients currently accounts for between one-quarter and one-third of UK immunoglobulin usage.

### **Specific Immunoglobulins**

#### Anti-D

BPL is currently the major supplier of Anti-D immunoglobulin in the UK with two other licensed suppliers, namely Baxter Immuno and Cangene. There is currently surplus of Anti-D plasma in the USA and no shortage is anticipated over the next few

years at least, so no shortage of the immunoglobulin is expected even allowing for growth in demand for ante-natal prophylaxis.

#### Tetanus

BPL is the major supplier of tetanus immunoglobulin in the UK with Baxter Immuno also offering a licensed product.

#### Hepatitis B

BPL is the sole supplier of a licensed intramuscular product supplied to the PHLS. BPL also supplies an unlicensed intravenous product on a named patient basis, largely used for liver transplantation.

#### Varicella Zoster

BPL is the sole supplier of this licensed product and supplies all of it to the PHLS.

#### Rabies Immunoglobulin

BPL is the only licensed supplier of this product to the UK and supplies the PHLS and the Ministry of Defence.

### **SECURITY OF PRODUCT SUPPLY FROM BPL IF OUTSIDE THE NHS**

There seems no case for any contractual arrangement obliging BPL to make any formal commitment to continuity of supply to the UK for Factors VIII and IX.

In the case of von Willebrand factor, again unless BPL can produce a more effective product which it has in development, there is no case for seeking a contractual commitment.

For the other special coagulation factors, the situation is somewhat sensitive as the products are unlicensed and supplied on a named patient basis. BPL has discontinued supply of such unlicensed products whenever a licensed alternative has become available and would expect the MCA to support such a move. However, it should be possible to cover the supply of these special factors in a contract.

#### Albumin

There is no argument to seek any commitment from BPL to supply the UK market.

#### Immunoglobulin

Intravenous immunoglobulin for immune deficiencies will always be an extremely sensitive area. BPL can be expected to seek to continue to be the market leader in the UK on the assumption that prices are not significantly below those generally available in overseas markets. In those circumstances it would not be unreasonable to require that BPL commit to supply sufficient immunoglobulin to the UK market to meet the

entirety of the immune deficient needs, even though that product may be at any time spread across a wide range of uses. Hence, in the event of severe shortage, that product could be redirected to essential users only. BPL would expect to grow its immunoglobulin business worldwide very substantially over time and hence such an obligation would be decreasingly onerous over time.

#### Other Specific Immunoglobulins

For other than Anti-D, it would seem most logical for there to be a contract between BPL and the PHLS, where BPL is committed to supply the entire needs of the PHLS based on a three year forecast, updated annually. The total value of this contract would be around £3 million a year and some appropriate formula could be devised to control the prices if the PPRS were not deemed appropriate. The PHLS may not wish to get involved in tetanus but if the NHS wants to ensure that product is available and committed, then someone has to make sure that BPL and/or Baxter Immuno make available sufficient product to meet the small needs for the NHS.

In the case of Anti-D, this product is clearly extremely sensitive with demand likely to grow substantially as ante-natal prophylaxis is introduced. Some may view ante-natal prophylaxis as being a bit of a luxury in case of product shortage and hence if a contract were signed to supply, for instance, all the post natal needs, then that would probably be acceptable.

#### **PFC' s POSITION**

In the case of immunoglobulin, both intravenous and specific, it should be remembered that PFC are also suppliers of all but rabies which they purchase from BPL. They could undoubtedly, over a comparatively short period of time, satisfy all the specific immunoglobulin demand although Anti-D might put them under some pressure. They also supply intravenous immunoglobulin to a wide range of users in Scotland and Northern Ireland. So PFC could provide a partial backstop were there any difficulties in supplies from BPL.

R C D Walker  
15 November 2000

ANNEX C

Our Ref: LCB/709/C

BY E/MAIL

Charles Lister  
PH  
Room **GRO-C**  
WEL

From: Ronald Powell SOL COMMERCIAL

Date: 29 January 2002

Copies: Gillian Aitken	SOLC2
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RE: SECURING PLASMA SUPPLIES FOR BPL

1. Thank you for your minute of the 20<sup>th</sup> August 2001. I have discussed the contents of this reply with Gillian Aitken and you may take this reply as coming from us jointly.

2. Before dealing with your specific inquiries I think it wise to remind ourselves of the Secretary of State's general obligations as set out in the early sections of the National Health Service Act 1977. I say this because I am sure that if any court had to look at any arrangement the Secretary of State made, it would bear these opening responsibilities heavily in mind. The provisions I have in mind are, firstly section 1 which says:-

*"It is the Secretary of State's duty to continue the promotion in England and Wales of a comprehensive health service designed to secure improvement –*

*(a) in the physical and mental health of the people of those countries, and*

*(b) in the prevention, diagnosis and treatment of illness,*

*and for that purpose to provide or secure the effective provision of services in accordance with this Act".*

3. It is important to note that this places on the Secretary of State a fundamental **duty**, and he is at risk of being sued for breach of statutory duty or negligence if he fails to carry out that duty. Failing to take steps to secure and adequate supply of blood plasma could well be seen as a breach of this obligation.



4. In addition, section 2 says:-

“Without prejudice to the Secretary of State’s powers apart from this section, he has power –

(a) to provide such services as he considers appropriate for the purpose of discharging any duty imposed on him by this Act; and

(b) to do any other thing whatsoever which is calculated to facilitate, or is conducive or incidental to, the discharge of such a duty”.

5. Here I would draw attention to the power “to do **any other thing whatsoever**”. This wide power, coupled with the obligation in the previous section seems to me, as a starting point, to provide the Secretary of State with a substantial degree of legal cover for any activities that he wishes to undertake which are conducive or incidental to the discharge of his duty under section 1.

6. Because of these overriding obligations, I think a court would be generous in our favour in interpreting any action that we took in this area.

7. The National Health Service Act 1977 s.96(c) (inserted by the Health and Social Care Act 2001, and enforced from the 1<sup>st</sup> August) allows the Secretary of State to form a limited company for the purpose of supplying goods to eg, the National Blood Authority. There is no reason in principle why a limited company so formed, should not own shares in a United States company or become a majority shareholder in such a company, or have a wholly owned subsidiary which is a United States company. On the face of it therefore the proposition suggested by you in paragraph 5(i) of your minute of the 20<sup>th</sup> August is acceptable.

8. So far as the technicalities and timescales are concerned, limited companies can be established very quickly, indeed when last I had anything to do with this area, you use to be able to buy a ready made company off the shelf so to speak and change its name to one that suited you. That process could then take merely a few days. But in practice you might want to take a little more time over that process.

9. In terms then of running the company and the negotiations that might need to take place with DCI to establish the sort of regime that they have been talking about, you will need some specialist advice. Accountants usually are able to take care of ensuring that the requirements of the various Companies' Acts are met as regards the filing of returns, accounts etc, once the company is up and running. You will also need some legal advice I suspect on the more arcane areas of UK and US company law that you might encounter. This is not a field in which this Office has (at least at present – times may change) any expertise but we do have external City solicitors that we can call upon in these areas. The downside from your point of view, is that we in Solicitor's Office are not funded to meet the costs of external solicitors and you would need to ensure that you had funds available for this purpose. But I would be happy to discuss the more practical aspects of the transaction once you have resolved any policy issues.

10. That I think provides the answers to the questions set out in your paragraphs 5(i) and (ii) and it seems therefore unnecessary for us to consider further the questions in 5(iii).

**RONALD POWELL**

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**REPORT BY PA CONSULTING GROUP: 26 NOVEMBER 2001**

**AN APPRAISAL OF PLASMA SUPPLY OPTIONS FOR THE BIO PRODUCT LABOARTORY**

**Executive Summary and Conclusions**

This document is the final report for the BPL Plasma Supply Project undertaken by PA Consulting Group for the National Blood Service.

Of the three main options open to BPL to secure future supplies of plasma, all carry with them a high degree of uncertainty, and therefore risk. Some of the options can only be followed if they are started within the next two to three months, and this therefore places pressure on the need for an early decision. The decision is complex, involving the interplay of financial and policy criteria, and judgement about the future of the plasma derived bio product market. It is not straightforward, therefore, to make a firm recommendation, since the decision would be different depending on the weighting given to the criteria.

In addition, none of the options address the broader fundamental issue of the long term viability of BPL as a stand alone entity, highlighted in our report earlier this year. This means that there remains the need to secure BPL a joint venture partner to provide it with the investment capital to innovate and maintain a portfolio of products that will generate income over the next ten years.

We have considered three plasma supply options in this report, which are essentially to rely on the current business model (option 1B) or to enter into contracts to secure supply (options 2&3)

- **Option 1B - Obtaining plasma "ad hoc" as it is available on the open market, making no investment, other than in plasma**
- **Option 2 - Securing supply through the part purchase of a US plasma supplier,**
- **Options 3 - Securing supply through procuring access to a new group of US plasma collection centres.**

We have also considered, as a baseline, the closure of the plant once current supplies have been exhausted (option 1A).

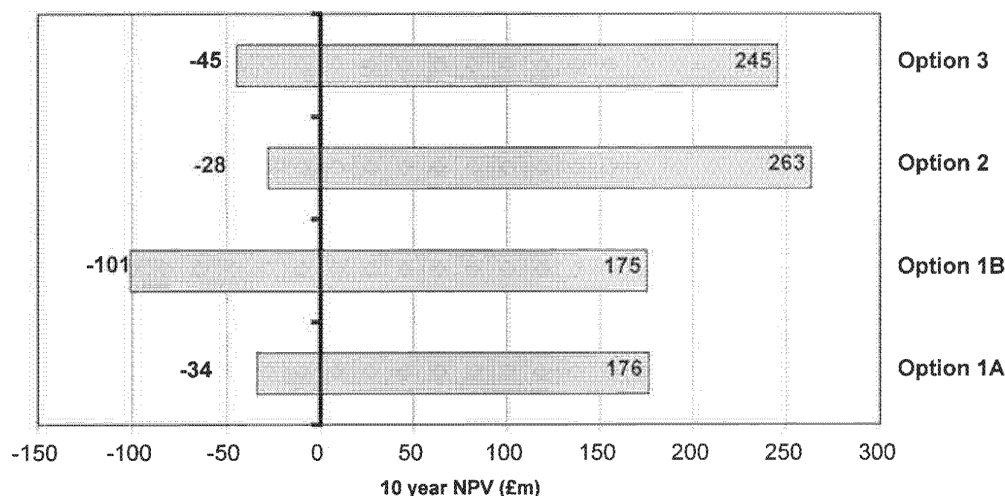
The three option carry different risk profiles. Option 1B, to rely on ad hoc plasma supplies, has the lowest financial risk since it involves minimum up front investment, but is the highest risk in terms of sustainability, since there can be no guarantees of any additional plasma supply. It also carries a negative NPV since the plant will require continuous subsidy at the low levels of operation. The other two options, part purchase of DCI (option 2) and setting up managed centres (option 3) carry less risk of sustainability once the initial deals have been negotiated (options 2 is the more secure in this respect as it relies on plasma from existing centres), but carry higher financial risks. This is that the investment will have no remaining value. In option 2

the investment at risk is £18m. In option 3 the figure is the same, although since it is by way of loan the risk is lower. The base case NPV of both options is positive (£45m).

The risk adjusted profiles of each option are shown in the graph below, and further details of the financial analyses are set out in section 6.



**Option 2 has the most favorable risk profile**  
Projected range of NPVs (millions of pounds)



This summary attempts to set out the results of the analysis, recognising that there may be different criteria applied to judge the decision.

### **Immediate action – fund the purchase of further ad hoc plasma**

Any option open to BPL, other than planning for immediate closure, requires it to maintain operations for between 2 and 5 years. This will require more plasma than its current forward contracts will supply, and there is every indication from our market research that it will be progressively harder to buy plasma in the open market. Any opportunity to purchase plasma, and therefore extend the short-term period of security of supply, should be acted upon and funded. This will allow for a longer operating period under the worse case positions, and provide a contingency should any of the options take longer to put in place that is envisaged.

### **Decision on the longer term options**

Whilst the immediate threat to BPL is the shortage of plasma to maintain operations, the decision as to how to respond to this does need to reflect a longer-term view. It also depends on the relative balance given to sustainability, (essentially “security of supply”) or financial NPV (essentially the best value to the treasury at the lowest risk). These were the two main criteria from the outline business case prepared in January, and we have used them as our most important criteria in this review. Whilst in reality a decision will be based on a combination of these factors, we have summarised the conclusions from each perspective



### **If security of supply is prime driver**

If this is the main driver, then the analysis would suggest that option 2, the part purchase of DCI, is the most reliable option. This is the only option that provides reasonable security over the future supply. The managed centres do not achieve the full volumes that BPL require, and are subject to volume risks that one might expect from the set up of a new enterprise. Reliance on ad hoc purchases of plasma on the open market (option 1B) is also of high risk in terms of supply. There appears to be little spare capacity from a reducing number of independent providers, and there can therefore be no security over regular or sufficient supply.

The DCI option (option 2) would also appear financially the most viable over a 10 year period. It has a positive base case NPV of £45m, and a maximum risk of £18m, equating to the up front investment. The NPV ranges from £34 to 64m (excluding the use of UK plasma) depending on the view taken of the value of the investment (from no value generated to the value doubling over 10 years). By contract, the NPV of managed care centres (options 3) range from £4m to £45m (excluding the use of UK plasma) depending on the scenario.

Option 2's most significant drawback is the level of immediate funding that it requires, and the risk associated with the negotiation of a commercially robust deal, within the timescales required.

For this reason, if the DCI option was pursued, a contingency should be considered. For example, initiating one of the managed centre options to act as fall back should DCI not go ahead. If DCI is signed, this contingency could be aborted, or the rights to the collections center plasma assigned. It may have associated break costs if terminated, but as the centres are developed by way of loan, the main sunk cost would be management and advisor time.

In addition there will be a financial risk to the value of the investment under option 2, both in the normal course of business, and in the event that there is a threat to the US plasma market (either through contamination, or as a vCJD test become available that allows UK plasma become useable again).

### **If economic viability is the prime driver**

Here there are two main objectives

- **To optimise the financial position of BPL in relation to Treasury funding concerns**
- **Whilst minimising risk.**

Under this perspective, the ability of BPL to supply the UK market is still paramount. However, greater weight is given to the financial criteria and lower weight to the risks concerning security of supply.

There is also conflict between the two aspects of the financial criteria. Option 1B has the lowest risk, since there is no up front investment, but also does not achieve a positive NPV. Option 2 (DCI) has the highest NPV (£34m-£64m), but the highest risk

to the investment. We have made an assumption for the purpose of this report that minimising risk is more important than maximising NPV, but this assumption should be verified before any final decision.

The critical judgement here is about whether UK plasma will be viable to process in the future, and within what timescales. The main driver of this will be the availability of a vCJD test that will allow raw plasma to be tested. Current market thinking is within 5 years, although we have also run a more optimistic assumption of 3 years, and a pessimistic scenario where it is not available within the 10 year timescale of this analysis. Contamination of the US plasma supply, e.g. if vCJD becomes prevalent in the US, would have a similar effect, since the choice would be no product, or accept the risk of vCJD, (where UK plasma would then be useable again).

If the judgment is that the test will be available within 5 years then option 1B, a strategy of keeping BPL open through ad hoc plasma purchases, and the lowest financial risk of failure. By conserving stocks and processing a minimum amount to supply part of the UK market, the plant would be available to exploit the UK plasma once it became available. In other words, it may be expensive to maintain BPL over the next few years, and operationally difficult to retain skilled staff at the plant, but this would be compensated by the ability to use UK plasma in the future. This also avoids any risk of capital for the acquisition of US plasma.

The benefit to the UK of being able to process its own plasma would provide a large positive NPV (some £200m over years 6 to 10). This would make all the 1B options positive in NPV terms. It can be argued that the benefit of UK plasma will apply equally to all options, and therefore in itself will not be a distinguishing factor, but clearly it is an important consideration in the judgment about the balance of risk and viability represented by option 1B.

The main risk in option 1B is sustainability, since there can be no guarantee of ad hoc plasma supplies, and the timescale for the test to become available may become extended, with an impact on the ability of BPL to retain skilled staff and maintain normal operations, as well as process plasma. It may become necessary to also pursue option 3 (managed centres) in parallel as a source of additional plasma, if no other source can be found.

If the view is that the test will not be available within 5 years, then other options should be considered, either to close the plant and seek contracts for the supply of product, or to pursue some form of joint venture that would allow BPL to benefit from the immediate value of its asset, ensure that a fractionating plant remains in the UK, and that the entity could continue to supply product, and be available to contract process UK plasma if it should eventually become viable to process.

The reason for this is the risk of reliance on the ad hoc market, which would threaten the viability of BPL, combined with the longer term viability risks referred to at the beginning of this section.

## Next steps

There are four steps that we recommend based on the analysis in this report

- ***Agreement to fund ad hoc purchases of plasma should be sought immediately***
- ***The Project Board should determine the relative importance of the evaluation criteria, and on that basis should make a recommendation as to the option to pursue***
- ***The process for gaining agreement to that recommendation should be confirmed. Option 2 has an immediate timescale, and failure to meet that will risk losing the option. All the options should be acted upon swiftly if BPL is to remain sustainable beyond the next 24 months.***
- ***The PPP options concerning a JV, highlighted in the report issued early this year, should be pursued, since none of the plasma supply options address the issue of the longer term viability of BPL.***

Finally, on the basis of our analysis, we would like to re-emphasise the need for prompt action. Although we have framed the “do nothing” option (1A) as a largely analytical baseline, it should be noted that if effective progress is not made both to develop the potential relationships with US plasma suppliers and to secure additional “ad hoc” plasma, we believe there to be a significant risk that Option 1A, leading to the closure of the plant, may become the only way forward by default.

## **ANNEX E**

**A review to update the conclusions of the PA Consulting report “Outline Business Case for the future of the Bio Products Laboratory”, dated 22 February 2001.**

### **• PURPOSE OF THIS PAPER**

In February 2001, PA Consulting Group published a report (Reference 1) analysing the future ownership options for the Bio Products Laboratory (BPL). The report was written in the context of a rapidly changing market for blood plasma products and its conclusions reflected both the state of that market at that time, as well as necessarily making certain assumptions regarding future trends. Since the publication of the report, a decision still has to be made in progressing the options to secure BPL's future. More recent reports by PA, the first reviewing the likely market interest in a joint venture with BPL (Reference 2) and the second considering the possible options for securing supplies of plasma for BPL (Reference 3) have confirmed that this decision must be made soon to avoid the planning for the organisation's future being compromised by a reducing set of options.

In this context PA has been commissioned to provide a brief update of the Outline Business Case, to determine the degree to which its conclusions regarding the preferred ownership option for BPL are still valid.

This short paper summarises that review and concludes that on the basis of recent work, the recommendations of the OBC appear to remain valid, and that the market conditions, as observed through the two subsequent reviews, have moved in the direction that was anticipated, albeit more rapidly than we envisaged in the first report.

It should be noted that the conclusions of the OBC were made without talking directly to possible Joint Venture partners, a key step in establishing the viability and the detail of any such arrangement, and that the original recommendation that these talks should take place to confirm the findings still stands.

The paper does not constitute investment advice under the 1986 Financial Services Act.

### **• CONCLUSIONS OF THE OUTLINE BUSINESS CASE**

The Outline Business Case prepared by PA Consulting Group in February 2001 considered the various future ownership options that were open to BPL and that would help to secure its long term future. This future was under threat because BPL was operating at an annual deficit of approximately £15M, no longer had long term security over the supply of raw plasma, and had concerns that as a purely public sector body, it would not be able to compete effectively against commercial businesses in the investment in and development of new products.

The OBC considered five options:

- *Single Innovation Joint Venture*; Where a partner helps with the development of a single BPL product or process and the two parties share the benefits



- *Whole Organisation Joint Venture*; The whole of BPL is placed into a new joint venture company, with the third party partner taking all management responsibility. This partner could be from the public or private sectors and there would be no barrier to overseas involvement
- *Contract-out*; The running of BPL is contracted out to a third party who take responsibility for all staff and assets
- *Externalise*; BPL goes into external ownership through a trade sale, MBO or similar arrangement
- *Mutual Ownership*; Department of Health establishes BPL as a mutually owned organisation which passes all unused surplus to the NHS.

Options were evaluated against a number of criteria, with the two primary requirements being

- the retention of a UK-based fractionating facility (that would therefore be able to provide security of supply in blood plasma products for the National Health Service)
- maximising BPL's financial contribution to the UK public sector.

The secondary evaluation criteria were:

- specific needs of major stakeholders
- the ability to deliver the commercial freedom considered necessary for BPL to operate in a commercial and competitive sector.
- implementation complexity and timescale

As a result of the evaluation it was concluded that, although BPL has the potential to be a successful business, its short term financial viability could only be assured if it was able to increase manufacturing throughput. Furthermore, in the medium to long term BPL would have to be able to operate in an increasingly commercial and risky global market place by maintaining a market lead in new product development and exploitation of the future markets (an issue of increasing importance given growing health risks associated with the collection and usage of human blood). Failure to secure the investments required would almost inevitably lead to a downward spiral in both BPL's market share and revenue.

A "Whole Organisation Joint Venture" was considered to be the best option for a viable business, providing security of supply to the NHS and able to access both the investment and commercial expertise necessary.

## • UPDATE OF OBC FINDINGS AND CONCLUSIONS

This short review has revisited the evaluation that led to the selection of the whole organisation joint venture option in the OBC, reconsidering both the individual evaluation criteria and the market context in which the recommendation was made.

The review has not included a detailed re-evaluation and validation of the business case but does draw on relevant work undertaken by PA in the course of preparing Reference 3, analysing BPL's future business case and likely trends in the blood plasma supply market.

In terms of the context for the business case, there is no doubt that the need to act still exists: indeed BPL's options for plasma supply once the existing agreements end have reduced further since the OBC was drafted and arguably the market is becoming even more commercial than was expected at the time of the OBC.

We have reviewed all the key evaluation criteria and assumptions for the option comparison itself. The assumptions and values used to estimate incomes, expenditures and the risks likely to be faced by the business are considered to be stable but this has not been verified as part of this review. On this basis we therefore consider it likely that the results of the financial evaluation in the OBC remain valid. Similarly, there does not appear to have been any change in the factors affecting the assessment of the options against the other primary criterion: the security of supply to the NHS.

Of the three secondary criteria, our original assessment against the needs of BPL's stakeholders also appears to be robust, as does the option's ability to deliver the necessary commercial freedoms. However, this latter criterion has become more important in the context of recent changes to the market. Given that the joint venture option scores well against this criterion, the effect is to strengthen its status as preferred option.

The final secondary criterion concerns implementation complexity and timescale. Although arguably the implementation complexity has increased as a result of the further consolidation of the market, the key issue here is that the implementation complexity (including any interdependencies it may have with the initiative to enter into commercial arrangements to secure further plasma supplies) cannot easily be understood until more formal approaches to the market are made.

A subsequent study to survey market conditions and identify potential partners confirmed that BPL was an attractive partner and that there were a number of businesses that could provide the investment, capability and synergies being sought by BPL.

However the consolidation of the market – reducing the number of possible partners as well as increasing the commercial strength of BPL's competitors – (highlighted in the rapid reduction in the proportion of US plasma now supplied by organisations that are independent from BPL's main competitors) increased the need for urgent action if this option was to remain viable.

## • CONCLUSIONS

On the basis that the underlying requirements prevail - specifically those relating to the need to retain a UK fractionating facility - the Outline Business Case conclusion remains valid.

The market conditions that forced the need to consider future options for BPL, and upon which the original OBC recommendation was predicated, still exist (this has been confirmed in References 2 and 3). Furthermore the consolidation of the market that suggested the need for urgent action to progress the option, has, if anything, occurred even faster than was originally envisaged.

We recommend that BPL make formal approaches to the market with a view to confirming the appetite for a whole organisation joint ventures and which would allow any significant implementation risks to be identified and evaluated. This is also important in the context of any negotiations with plasma suppliers that may be impacted by any movement towards negotiating Joint Venture (JV) options.

There is no reason to believe that entering into an arrangement for the supply of plasma under any of the options considered in the plasma option report (ref 3) would impair the value of BPL to a JV partner. Indeed the market observations, and BPL's own view, would suggest that securing plasma supply would increase the value of BPL to a potential JV partner, although clearly this cannot be confirmed until market soundings are taken.

#### References

1. PA Consulting Group. Outline Business Case for the future of the Bio Products Laboratory. 22 February 2001.
2. PA Consulting Group. Review of BPL Partnership Options. May 2001
3. PA Consulting Group. An appraisal of plasma supply options for the Bio Products Laboratory. Draft Final Report. 26 November 2001.

**Subject** **LIFE RESOURCES INC REFINED PURCHASE APPRAISAL**  
**Restricted – management and commercial**

**To** Richard Lawes

**From** David Fry

**Date** 8 January 2002

### Introduction

PA recently performed an appraisal of plasma supply options for BPL. We have now been asked to update that appraisal, specifically with respect to the “purchase of DCI”, which was considered as option 2 in the original report. This update is in the light of new information provided in an information memorandum issued by Life Resources Inc (LRI), who is also known as DCI. The options considering this new information is therefore referred to as the “LRI option”. This paper is for the purposes of distinguishing between options and does not constitute a valuation of LRI as an investment.

This document should be read as an addendum to the Draft Final Report “National Blood Service, An Appraisal Of Plasma Supply Options For The Bio Products Laboratory”, dated 26 November 2001.

### Summary of previous report

The plasma supply options paper considered three plasma supply options, which were essentially to rely on the current business model (option 1B) or to enter into contracts to secure supply (options 2&3)

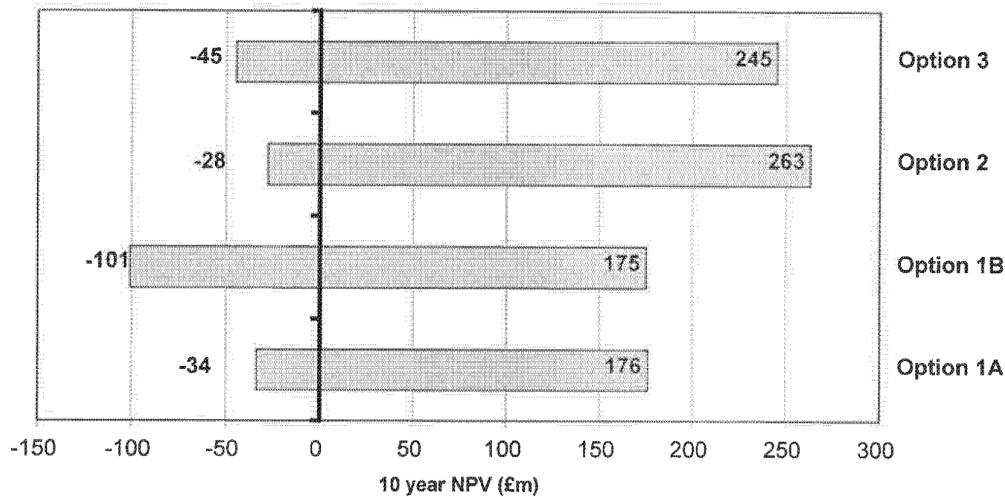
- Option 1B - Obtaining plasma “ad hoc” as it is available on the open market, making no investment, other than in plasma
- Option 2 - Securing supply through the part purchase of a US plasma supplier,
- Options 3 - Securing supply through procuring access to a new group of US plasma collection centres.

The original paper also considered, as a baseline, the closure of the plant once current supplies have been exhausted (option 1A). The risk-adjusted profiles of these options are set out in the following graph, extracted from the previous report.





**Option 2 has the most favorable risk profile**  
Projected range of NPVs (millions of pounds)



The broad conclusion was that all options carried risks, and that none of the options alone would satisfy fully the supply requirements, and thus provide security of supply, with the exception of option 2. Option 2 also carried the more favourable NPV, but there were risks associated with the level of up front investment required.

This broad conclusion remains the same, in the light of the new information provided. The main difference is that the new LRI option requires greater investment (since the whole company is to be purchased), and the favourable NPV is more dependent on achieving growth plans, with its impact both on cash flow and value of LRI at the end of the period appraised.

#### Comparison of LRI Option.

The table below compares the key financial outputs for all the options reviewed in PA's most recent report to BPL as well as the LRI option. These are before risk adjustment.

Option (numbers refer to options in the original report and are discounted at 6%)	Total NPV with residual value of investments	Peak level subsidy required (including investment)	Up front investment required
Option 1A	£(24)m	£26m (Year 1)	£0m
Option 1B	£(25)m	£35m (Year 5)	£0m
Option 2.	£54m	£44m (Year 2)	£18m
LRI Option (15% discount rate)	£10m	£75m (Year 3)	£29m
LRI Option (6% discount rate)	£124m	£75m (Year 3)	£29m
Option 3	£43m	£24m (Year 1)	£8m

The options were originally appraised using the 6% government discount rate. The LRI options has been appraised using this rate, and a rate of 15%, to take account of



the higher risk that is associated with the achievement of the LRI growth plans. Terminal value is taken as the value of the cash flows from year 10 in perpetuity. The NPV return is between £10M and £124m. Using the same underlying risk assumptions as before – the risk adjusted range would be £10M - £324M (Option 2 was £(28)M to £263M). The LRI option protects BPL from the risk of increased plasma price, and the benefit of using UK plasma would still apply. There is therefore a higher potential financial return from this investment, although the range of NPV recognises the fact that the LRI option is more sensitive to the residual value than the original option 2 and to the achievement of growth. The main differences in assumptions are:

- The purchase is for 100% of the company – increasing the overall investment
- There is a requirement for expansion capital - which is factored into this calculation (note it may be possible for LRI to service this by way of a loan – which would increase the NPV to the government)
- The residual value is higher. The terminal value of LRI in year 11 is estimated at £67m, higher than the £51m implied residual value estimated for the original Option 2.

The LRI option includes expansion of the plasma collection business beyond the forecast requirements of BPL. This expansion, if successful, would enhance the value of LRI, but of course carries normal risk associated with business expansion. Appropriate negotiation of consideration for the purchase of LRI could mitigate this by making payment of consideration dependent on the growth of the business. This is mitigated to some extent if the consideration is dependant on achieving performance, since a reduction in value would most likely be accompanied by a reduction in the total consideration paid.

The NPV of the LRI option is also higher than the NPV of Option 3 - Investing in plasma centres and the LRI option has three advantages over that option:

- Because Option 3 involves loans rather than equity investment, no residual value exists in Option 3.
- With all plasma coming from LRI, BPL is less exposed to price risk because price increases feed through to the benefit of LRI and hence BPL in terms of increased cash flow from the investment.
- Option 3 does not provide BPL with security of supply of their full plasma needs in the early years of the period, and retains a risk that the centres will not achieve the levels required over the whole period.

#### Financial analysis

The table below summarises the key changes in the LRI option from the assumptions of the original Option 2 analysis.

Model input	Original Assumption	Refined Assumption	Comments
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Model input	Original Assumption	Refined Assumption	Comments
Upfront investment in LRI	£20m	£59m	Based on the initial estimate of \$27m for 1/3 of the company plus transactions costs. <sup>1</sup>
Percentage of LRI dividend equity purchased	33%	100%	Assumes that only class A stock pay dividends
Further capital outlays	No further capital outlays	Capital outlays for expansion	Assumed to come from equity holder in this model.
Earn out payments	No earn out payments	\$4.2m p.a.	Based on the assumption that 50% of the transaction price will be paid as an earn out over 7 years.
Post-tax annual dividends	£1.4m	Annual LRI cash flow available to acquirer	Based on forecast LRI accounts provided – cash flows available over 10-year period are lower due to expansion capital expenditures.
Plasma supply	Based on forecast plasma supply – meets requirements in all years except year 9 and 10	As required for imports and exports –	BPL buys plasma as required Note we have not adjusted the BPL forecast for plasma production.
Plasma price	\$127/litre	\$127/litre	Assumes no change in plasma price. Note the LRI option is less sensitive to increases in raw plasma price.
Residual value	Assumed the real value doubles over the 10 year period (to £34M for the 1/3 share)	Assumes the real value at year 10 is £67M (15% DCF) to £93M (6% DCF)	This is based on more detailed forecasts of LRI growth, and the fact that the benefit from the growth will be shared with the management of LRI, through earn out.

The financial analysis assumes that the deal will generate no operational efficiencies; all operational cost assumptions for BPL and LRI are unchanged.

There is no impact factored in for price rises that may result from the increase in plasma price if BPL can no longer supply the UK market. We ran a sensitivity on the original option appraisal if prices rose by 5% overall – representing £5m pa in a UK market of about £100M. BPL have produced figures suggesting a much higher impact (£20-30M per annum), and this would clearly depress the NPV of options 1 and 2 still further.

<sup>1</sup> The report included a slightly understated cost of £17m, rather than £20m due to an erroneous calculation of £1.5m transaction costs. This has no impact on any conclusions.

ANNEX G

PRIVATE AND CONFIDENTIAL

Attention of: Mr Denis F Kelly  
Scura, Rise & Partners, LLC  
712 Fifth Avenue  
New York, NY 10019

Private & Confidential  
Subject to Contract and Due Diligence

17 January 2002

Dear Sirs,

I refer to your letter of 21 December 2001 to the Bio Products Laboratory ("BPL"). I am pleased to submit this letter confirming the Department of Health's (the "DOH") interest in purchasing Life Resources Holding Incorporated and its affiliates ("Life Resources"), to provide a preliminary non-binding indication of our valuation and to respond to other matters set out in the "Preferred Transaction Structure" schedule to that letter (together, the "Transaction"). I am authorised to submit this letter and to try to reach mutually acceptable terms rapidly.

Let me say at the outset that I consider that between Life Resources and the DOH we can put in place an arrangement that meets not only the objectives of Martin Silver, Gerald Matlin and Perry Ciarletta (the "Sellers"), but also our own in a way that other prospective acquirers of Life Resources cannot replicate. When I met Martin and Gerald last summer, with Chris Hadfield and Richard Lawes, and discussed our ongoing relationship with them, my team were pleased that the future needs of both parties were so compatible. In particular, I see the DOH as having some unique advantages, such as the following:

- *Our desire to see the current management remain in control of the day to day operational running of Life Resources;*
- *Payment of the consideration would be a UK Government obligation, with the security that this implies;*
- *Funding for the consideration has been identified within the DOH. The funding is not reliant on external, bank finance with the possibilities of extra complexity in negotiations and increased burden of ongoing reporting that often goes with this;*
- *We are prepared to be flexible in structuring the acquisition both to support the Sellers' desire to expand the business and to meet their individual tax planning requirements; and*
- *BPL has no competing US plasma collection business which would otherwise make you sensitive about releasing commercial information in the due diligence process.*

## **Valuation**

Based upon the limited amount of information provided to date in the Confidential Information Memorandum, we are pleased to make an indicative offer of between US\$60 million to US\$80 million for 100% of the stock in Life Resources, on a debt free-basis. Our indicative offer relies on certain key assumptions we have had to make with respect to Life Resources and which we will need to confirm going forward.

As you have proposed, we accept that a portion of the purchase price should be payable through an earnout linked to the achievement of financial and non financial targets. I am prepared to discuss the proportion of consideration and period of this earnout further and remain open to discussing with you alternative structures of paying the purchase price in order to consider the Sellers' tax planning.

The purchase price and earnout would be payable in cash and would be obligations of the UK Government.

## **Other Key Elements**

We would like to emphasise the following aspects of our initial thinking:

- The current management could retain control over the day to day operational running of the business with the services of key individuals secured by long-term employment contracts with an appropriate balance of fixed and performance related remuneration;
- The DOH would require control of the Board of Life Resources in order to protect its investment but the DOH would consider offering the Sellers board representation to allow them to participate in and make significant contribution to the strategic decision making process of Life Resources;
- A long-term supply contract with BPL for a specified annual quantity of plasma at the annual prevailing arm's length market price is envisaged, with surplus plasma being sold to third parties;
- A willingness on the part of the DOH to discuss it providing funding towards the expansion plans of Life Resources. Clearly we will need to gain greater understanding of these plans and the funding that they would require; and
- Our present thinking is that the DOH would acquire 100% of the stock in Life Resources. Our feeling is that the Class B stock complicates the arrangements and that contractual arrangements can be utilised instead. But, we are open to discuss further the thinking behind the Class B Shares.





This letter is a non-binding and preliminary indication of purchase price estimate only and is not to be considered as an offer or commitment on the part of the DOH. This letter is strictly not legally binding on either of us and does not fetter in any way the discretion or actions of the Secretary of State for Health. Neither of us shall have any obligation to the other unless and until a definitive

Transaction agreement (with such terms, warranties, representations and indemnities as are appropriate to a transaction of this nature), mutually satisfactory to each of us, is executed and delivered. Any Transaction is conditional upon approval by the Secretary of State for Health and the completion by the DOH of financial, commercial and legal due diligence to its satisfaction, receipt of such governmental or regulatory approvals as may be required and the reorganisation of Life Resources and its separate affiliates into a structure satisfactory to the DOH.

The DOH requires that no party may make any written or other public disclosures regarding this letter and the fact of our interest in acquiring Life Resources or regarding any information disclosed by the DOH for the purposes of our interest to any person without the prior written consent of the DOH. Before proceeding further the DOH will require as soon as practicable that the parties enter into mutual legally binding confidentiality undertakings in order to protect further the confidentiality of all information supplied or acquired by each party during the course of the negotiations.

The DOH is willing to spend a significant amount of time and effort to achieve a mutually acceptable Transaction that both meets the Sellers' objectives and gives us the legal protection that we need so as to act, and to be perceived as acting, responsibly in the interests of UK taxpayers and to do so on a timely basis. In order to incentivise it to do so, the DOH would need either a period of exclusivity in which to negotiate heads of terms or an indication of the detailed negotiation procedure that is expected to be followed after receipt of initial indicative offers. If a number of parties are to be invited to undertake detailed due diligence we would expect there to be an underwriting of costs for unsuccessful parties. Notwithstanding this, if you consider a face to face meeting in the US or the UK to discuss this letter to be useful, we are ready and willing to make the necessary arrangements.

have discussed this letter with Chris Hadfield of the Bio Products Laboratory and Martin Gorham of the National Blood Authority. It has their enthusiastic support and, like me, they too are keen to reach a successful conclusion to our discussions.

I look forward to hearing your response and hope to progress our discussions in the near future.

Yours faithfully





Charles Lister  
for the Department of Health