

Canadian Plasma Resources

Offer to Sell Source Plasma to Canadian Blood Services

October 2016

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Canadian plasma for Canadians

Canadian Blood Services (CBS) has stated publicly that it is developing a comprehensive national collection strategy to increase plasma donation in Canada and to reduce Canada's dependence on the United States for the supply of plasma protein products for Canadian patients. We believe that Canadian Plasma Resources (CPR) can make a valuable contribution toward helping CBS achieve its goals.

CPR operates a reimbursed plasma collection centre in Saskatoon, Saskatchewan with additional collection facilities anticipated to be granted licences in Moncton, New Brunswick and Kelowna, British Columbia in 2017. Our business plan calls for 10 centres to be operational by 2021 collecting 400,000 litres of plasma annually. While our primary business objective is to collect Canadian plasma to make finished plasma protein products to treat the medical needs of Canadian patients, CPR can also assist CBS by becoming a supplier of source plasma to CBS.

Accordingly, this is an offer to sell Health Canada licenced source plasma to CBS. We believe it contains the following benefits for Canada;

- Decrease Canada's dependence on plasma from the United States which CBS has recently acknowledged is a considerable and growing risk
- Increase the domestic use of valuable Canadian plasma donations, while creating jobs and economic benefits to the cities where our highly regulated and controlled collections centres are located,
- Provide a new avenue for potential cost savings to CBS

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Canadian Blood Services - Detailed Offer to Sell Tested Source Plasma

Price for Canadian plasma to Canadian Blood Services:

The average value of North American source plasma is US\$155 per liter and ranges from US\$140 to US\$165. The initial 2017 price for CPR source plasma to CBS is \$166.00 per litre in Canadian dollars (approximately US\$125) representing a 20% discount over average contract price and reducing concerns around corrency fluctuations.

Available volumes and scalability:

While open to discussion, CPR is offering the following plasma volumes to CBS:

- Volume per year 2017 15,000 litres
- Volume per year 2018 30,000 litres
- Volume per year 2019 60,000 litros

This initial volume offer is subject to discussion, as collection volumes are scalable. CPR operations, additional centres etc., can be augmented to meet the volume needs of CBS if they are in excess of these initial volumes.

Annual price changes:

Subject to discussion but expected to be in line with CPI

Potential CBS cost savings:

This CPR offer presents to CBS an attractive alternative to commercial product purchases both from the perspective of lowering their dependence of foreign plasma sources and also cost savings.

A price of \$166 per litre or \$133 per (800 ml) unit for source plasma is designed to offer significant cost savings compared the average cost per unit for fresh blood product collection at CBS.

Timeline for offer response:

a response from CBS by Dec 9, 2016 is requested. This offer is open for discussion and negotiation in line with the general conditions and terms outlined herein.

This offer provides estimated savings on IVIG and albumin alone, with the potential for additional savings via other toll tractioned finished products

Assumption 1: 1 litre of plasma yields 4.5 grams of IVIG and 24 grams of albumin.

Assumption 2: cost of IVIG is US\$50 per gram and cost of albumin is US\$2.5per gram.

Assumption 3: toll fractionation prices are 50% of commercial prices; therefore, cost of toll manufacturing IVIG is US\$25 per gram, and cost of toll manufacturing albumin is US\$1.25 per gram.

Cost to purchase commercial PPP's: 4.5gm of commercial IVIG US\$225,00 and 24gm of albumin is US\$60,00.

Total commercial PPP's price is <u>US\$285.00</u>

Cost to purchase Plasma: a litre of CPR Canada plasma US\$125 (The contract between CBS and CPR will be in G\$. The value is converted to US\$ here for comparison purposes)

Total price of GPR plasma and toll PPP's is <u>US\$ 276.50</u>

Background

Canadian Plasma Resources Corporation (CPR) Company Overview:

CPR the corporation: a privately held company established in Toronto, Ontario was issued authorization and an establishment licence as a drug fabricator in December 2014. CPR was then incorporated federally in July of 2015 with headquarters at 300-1222 Quebec Ave in Saskatoon, SK S7K 1V2. CPR's first operational plasma collection centre opened in February 2016 in Saskatoon, Sk.

CPR ownership and capitalization: CPR is owned by three resident Canadians. An initial capitalization of \$9 million will allow CPR to secure licenses and establish the initial three operational plasma collection centres. Additionally \$20 million in funding has been committed by the shareholders for expansion through 2021.

CPR Company Mission: to supply Canadian plasma of the highest quality and reliability for creating treatments that improve and save lives in Canada and around the world.

CPR Company Vision: to increase plasma production in Canada and to reduce dependency on foreign source plasma.

CPR's business plans:

Business Plan Phase 1: CPR will establish a business to collect source plasma in Canada by opening at least ten purpose built centres that are designed, located, built, equipped, staffed and operated in a manner that meets Canadian regulatory requirements, the established international industry association standards, as well as our international human plasma protein fractionation customer requirements. In this phase the ten plasma collection centers will be established in the provinces of Saskatchewan, New



Brunswick, British Columbia, Manitoba and Nova Scotia. These centers will start to collect plasma from healthy donors immediately upon receipt of regulatory approvals.

The first collection centre was officially opened in Saskatoon, SK in February 2016. This will be followed by centers in Moncton, NB and Kelowna, BC in 2017. Opening seven plasma centers in five provinces is the next step in phase one of CPR's plasma project. The rarget is to achieve a plasma collection rate of 400,000 L/year by 2021. The company will be employing approximately 400 people when this target is reached. The collected plasma will ideally be sold directly to CBS and HQ, or processed in our partner fractionation facilities in the US or Germany to manufacture finished products for the Canadian Market.

Business Plan Phase II: CPR is considering establishing a human plasma-protein manufacturing facility for the purpose of producing finished PPPs in Canada, and establishing a vertically-integrated Canadian business to serve Canadian needs. This project will be completed in partnership with Biotest AG. The project can be completed in 4 years and would have a minimum annual production capacity of 400,000 liters to be economically feasible.

Current CPR plasma customers:

CPR has a supply agreement in place with Biotest AC to supply up to 40,000 litre/year of fully tested Canadian plasma for fractionation in their German facilities. While this agreement can be scaled to

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higher volumes, CPR would like to use this agreement as a base for our Canadian business with collection growth fulfilling a plasma supply agreement with CBS and meeting the needs of Canadian patients.

The need for more Canadian plasma:

While Canada is self sufficient in fresh blood components through the very significant network of CBS and Héma-Québec (HQ) collection sites and efforts, Canada is dependent on USA reimbursed donor plasma for most of the plasma protein products (PPPs) used by Canadian patients everyday. The 2014/2015 CBS annual report stated that, "self-sufficiency is not operationally or economically feasible in a volunteer, impaid model, Canadian Blood Services strives to maintain a sufficiency of 30 per cent for Ig."

Globally, more than 75% of plasma for manufacturing PPPs comes from the private plasma industry. There are over 500 specialized reimbursed plasma donation centers located throughout the US and Europe and over 60 fractionation plants across 20 countries, with the largest ones located in the US and Europe but none currently in Canada.

Unlike the drug marketplace, where price increases are almost non existent, the PPP market continues to show growth rates of up to 10% with prices tied in-elastically to supply/demand balances. The CBS recently stated 'The demand for plasma products is rising. Advances in medicine are allowing health-care professionals to better diagnose patients, which can lead to an increased use of products. There are also a rising number of indications for plasma protein products. Finally, there are new markets — like China and India — where use is lower at the moment, but has the potential to increase; even a small percentage increase in those markets could have a significant impact." With many developing countries not able to provide significant sources of domestic plasma, due to endemic viral markets, their large dependency on European and North American plasma sources can only drive up the cost of plasma and PPPs. Canada, with superior regulatory standards and a healthier donor base, is an ideal place to collect source plasma, and can be a significant player in meeting both domestic and global plasma supply needs, but a reimbursed donor model will be required to significantly increase plasma collections.

If the CPR succeeds in collecting an additional 400,000 litres of Canadian plasma, almost 1,800,000 additional grams of Canadian IVIG could be fractionated, significantly reducing Canadian patients' absolute reliance on foreign paid donor plasma for IVIG and several other PPP's. It is this need, both domestically and globally, that makes this offer and the CPR Canadian business plan so important.

Today B out of every 10 Canadian patients using Ig is treated with IVIG brands made from US paid donor plasma.

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Several regulatory approvals have been granted to support this CBS offer:

Canada: Canadian Plasma Resources is authorized and licensed by Health Canada's (HC) Biologics and Genetic Therapies Directorate (BGTD) to collect source plasma for further manufacturing as a blood establishment. This license is required for any establishment that operates plasma collection centres in Canada. Additionally CPR needs provincial licensing in certain jurisdictions depending on the local regulations. For Example in Saskatchewan CPR has obtained a license as a Category IX lab.

An additional benefit of this offer is that local plasma collection means that Health Canada will have direct regulatory oversight on more of the source plasma used in PPPs that are being prescribed to treat Canadian patients.

PPTA: Additionally CPR procedures, approved by Health Canada during the licensing process, comply with the International Quality Plasma Program (IQPP) of the Plasma Protein Therapies Association (PPTA). CPR is working towards becoming a PPTA source member and obtaining International Quality Plasma Program (IQPP) certification.

EU: CPR collection centre in Saskatoon has also been inspected by the German Health Authorities (GHA) and has been deemed compliant. The centre will be certified by the European Union by January 2017.

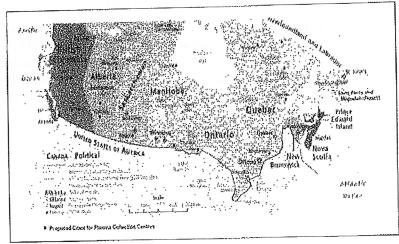
USA: CPR's procedures are also compatible with US FDA regulations, however CPR must obtain a separate license from the FDA. This process will commence after we start operation in our Moncton centre.

Besides the national blood operators, Canadian Plasma Resources and Promeric Plasma Resources are the only two commercial fabricators with Establishment Licenses from Health Canada for source plasma collection.

This CPR offer will not adversely effect CBS collection operations:

While politically sensitive in some regions today, the Canadian precedent for reimbursed plasma was in fact established in Winnipeg, MB over 30 years ago with Cangene reimbursing donors to collect Rh specific plasma for a monoclonal immunoglobin product.

In 2013 Health Canada's public consultation process acknowledged that: "Paying people to donate plasma has not weakened Canada's blood system or the volunteer



donor base and there is no evidence it will. This system is completely voluntary and will remain so. Evidence has shown that the U.S. and other countries with paid plasma donation sites have some of the highest voluntary blood donations in the world."

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There is significant Canadian support for a reimbursed plasma collection model:

While reimbursing donors is an issue in some areas of Canada, it is important to note that many provinces and regions, like, British Columbia, Saskatchewan, Manitoba, New Brunswick, and Nova Scotia are actively embracing the CPR collection model..

Patient support for efforts to collect more Canadian plasma to treat Canadians is clear from statements and publications issued by several patient advocacy groups like Network of Rate Blood Disorders Organization (NRBDO), Canadian Immunodeficiency Patient Organization (CIPO), Canadian Organization for Rate Diseases (CORD), the National Chapter of the Canadian Hemophilia Society (CHS), Hereditary Angioedema (HAE) Canada and Alpha 1 Canada.

Health Canada's granting CPR an operating licence demonstrates their support for this collection model. The Krever Commission recognized: 1) that for some products it may be necessary to offer compensation to these persons for their time and effort in order to attract a sufficient number of donors; and 2) emphasized the need to become self-sufficient in plasma to reduce reliance on the U.S. as a source of plasma.

Provinces and cities understand the economic benefits of a CPR centre:

Plasma production stimulates job creation at many levels in the provincial labour market. CPR employs highly skilled and trained professionals for its operations, including; Certified Phlebotomists, Medical Lab Technologists, Registered Nurses, and Licensed Physicians. It is expected that once fully operational, each collection site will employ a staff of 30 with a payroll of \$1,350,000 injected into the local economy in wages alone.

Even with modest levels of donor reimbursement for their time while donating plasma the annual reimbursement money injected into the local economy could exceed \$1,250,000 per centre.

Rents, taxes and many of the other costs of operating these centres would generate additional economic benefits to the local economy. The ability of CPR to build a network of Canadian collection centres, rather than establishing such centres in countries like the USA, is conditional to a great extent on securing Canadian supply agreements. The capital investment in these centres and the economic benefits for cities and provinces cannot be realized without securing supply agreements such as this with CBS.

Initial CPR collection centre overview:

Saskatchewan collection centre: the first CPR collection centre is located 1222 Quebec Avenue, Saskatoon Saskatchewan and began collecting plasma from donors in Feb 2016. To date over 600 donors have been qualified in the start up months of this centre.

Volume plans/goals: Each centre will be built around a 24 bed model and is expected to collect 15,000 litres of fully tested plasma in the first full year, with annual collections ramping up to 40,000 per year over a 3 year period.

Donation testing and storage: all plasma is frozen below -25 °C within 4 hours of collection using blast freezers. Testing for the following serlogical tests: HIV-1/2 antibodies, HCV antibody and HBsAg as well as NAT testign for: HIV, HAV, HBV, HCV and Parvo B19 is done on every unit

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collected. Additionally donor samples are tested for Syphilis (RPR), Antibody Screen, Total Protein and SPE. These tests are performed at Qaultex in San Antoio, Texas.

Scalability of CPR business: With the first fully licenced and operational centre in place, the model has been established for CPR in Canada. Current business plans are for 10 collection centres but CPR has the resources, flexibility and financial capacity to open sufficient centres in Canada to meet the future demands of customers like CBS.

Staffing: new jobs are being created that are in addition to existing CBS staff. While not currently unionized, CPR offers jobs that are stable with predictable shifts for highly skilled healthcare workers with attractive benefit packages.

Donor profile, screening, eligibility requirements and donation frequency;

Just like at all CBS donation clinics, all CPR donors are fully screened before plasma donations are taken.

Applicant donors must also return to be screened a second time (all 4 layers) between 2 to 16 weeks of the first donation, before the plasma from that donor may be considered for use (this is beyond Health Canada requirements).

On every visit, each donor undergoes four layers of screening. The Donor must 1. Meet the basic donor eligibility criteria. 2. Complete the comprehensive questionnaire. 3. Receive a physical exam performed by a licensed physician or registered muse. 4. Be tested for transmissible disease markers.

Donor relmbursement & retention plans:

CPR is planning to utilize a model proven by the plasma industry in the US and Europe to recruit and retain qualified donors. Experience in Canada and other countries demonstrates that, national self-sufficiency in blood and PPPs cannot be achieved unless plasma donors are compensated for their time. This is due to the large time commitment involved in repeat plasma donations. Each plasma donor can safely donate up to once a week and in order to run an efficient plasma collection business and to ensure the highest level of safety, we need to rely on repeat, qualified donors. CPR's aim is that qualified donors, on average, give plasma, 24 times every year which is comparable to the average donation rate reported by the US plasma industry. Each donation process takes about 1.5 hours and donors will be "compensated" for their commitment and time. This compensation will be non-cash and will not depend on the volume of plasma extracted from the donors. CPR is targeting an average donor compensation equivalent to CDN\$25 for each donation, which is comparable to the values in Germany and Austria

Conclusion

CPR is looking forward to further discussions on terms and conditions for a CBS supply agreement and looks forward to any opportunities to build a strong partnership with CBS. We hope this offer for sale can be a framework for future business opportunities between CBS and CPR.