



CANADIAN PLASMA RESOURCES

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March 6, 2017

## Open Letter to Provincial and Territorial Ministers of Health

Dear Ministers:

### Re: Paid Plasma in Canada and Canadian Blood Services' Source Plasma Collection Plan

According to media reports, Canadian Blood Services (CBS) has recently submitted a funding request to your governments for an additional 100 million dollars to fund the capital costs of establishing 40 new plasma collection centres across Canada.

I am writing to you today for three reasons. First, to highlight several facts that suggest the true cost of CBS' proposed program vastly exceeds 100 million dollars, second; to correct the misleading information being provided to you and the public concerning plasma collection and my company, and third, to share with you the details of our offer to provide CBS with Health Canada licensed Canadian plasma – a proposal they rejected despite the significant cost advantages associated with it.

As you know, CBS purchases pharmaceutical products made from human plasma known as plasma protein products (PPPs) for Canadian patients outside Quebec. PPPs are life-saving drugs on which thousands of our most vulnerable patients rely. Canada is completely dependent on foreign pharmaceutical companies to provide these drugs and only contributes a small fraction of the raw material (human plasma) to manufacture them. Last year CBS spent 645 million dollars purchasing PPPs from these foreign firms. This represented a program spending increase of 27% over the previous year.

Today, only 17 percent of the plasma used in Ig (main driver of the PPP market) comes from volunteer donors in Canada. Most other PPPs have no Canadian plasma content. The rest comes from paid American donors. This is due to cost. Because of the significant time commitment required to be a plasma donor (vs a blood donor), it is far more expensive to find enough volunteer donors than it is to recruit paid donors. The private sector can collect and process a unit of plasma from a paid donor, under the same Health Canada regulatory and licensing requirements, at a fraction of what it costs CBS to collect the same unit of plasma from a volunteer donor. CBS acknowledged this fact when it closed its only dedicated plasma collection facility in Thunder Bay a few years ago. And so because Canada has not had its own private sector plasma industry to date, we have relied on the American private sector and the paid American donor to meet our needs for the last several decades.

CBS' new proposal is to restart the program it recently shut down, and expand it to collect an additional 866,000 units of plasma annually to increase Canada's plasma sufficiency for Immune globulin (Ig) to 50% at the end of seven years. This new plasma would be collected from volunteer donors and shipped to the foreign pharmaceutical companies that currently supply CBS with PPPs.

Give Plasma, Give Life

According to its annual report, last year CBS spent 448 million dollars to collect and manage 758,000 units of blood and plasma. Their new proposal to collect an additional 866,000 units of only plasma, will more than double the total volume of products CBS collects in a year. Anyone familiar with plasma collection procedures knows full well that growing a donor base beyond its current size disproportionately increases costs, and given that plasmapheresis is more complex and time consuming than whole blood collection, it is reasonable to assume that the total costs associated with this new program will significantly exceed the 100 million dollar price tag quoted by CBS.

My company, Canadian Plasma Resources, was formed because we see an opportunity to create a domestic PPP industry in Canada. Our goal is to create a Canadian business that can compete with the foreign companies who supply our health care system today. Our initial business plan is to establish ten collection centres across the country to collect 400,000 litres of plasma and build a fractionation facility to manufacture PPPs. This represents a 400 million dollar investment and 2000 new jobs.

Despite the fact that demand for plasma protein products has been rising rapidly for many years, and that Canada is and has been completely dependent on the United States for decades for our supply, it is only the establishment of Canadian Plasma Resources, and our intent to build an industry here that has prompted CBS to expand its own plasma collection efforts. As far as we can tell, this is due to political pressure exerted by public sector unions who oppose any role for the Canadian private sector regardless of the benefits, and safe blood advocates who reject the undisputed scientific consensus that PPPs manufactured from paid plasma donations are as safe as those manufactured from voluntary donations.

In succumbing to this pressure, CBS is now suggesting that a paid plasma industry is not desirable for Canada, even though their own plan explicitly states that they will continue to rely on the paid American plasma donor for at least half of Canada's supply indefinitely. And let's not forget that aside from the donor issue, foreign companies will continue to supply 100 percent of Canada's finished products absent a Canadian manufacturer. So the question is not whether Canada will rely on paid donors or the private sector, the question is whether those paid donors and companies will forever only be American. That CBS and its unions prefer American suppliers over Canadian options is beyond comprehension.

To support their request for additional funds from you, CBS has made numerous disparaging statements about our company that are inconsistent, unsupported by evidence, and hypocritical. They claim that our Saskatoon facility is depleting the voluntary blood donor pool in that city without offering any evidence to that effect, or acknowledging that they downsized and moved their own blood collection facility and increased the time required between blood donations for female donors. Despite this, in the past, they have noted that the paid plasma company located in Winnipeg has had no impact on voluntary donations in that city.

It has also been claimed that it is not our intent to supply the Canadian market – and that we are simply here to collect plasma and export it for sale on the open market to the highest bidder. This is a ridiculous argument as CBS purchases all of its PPPs on the open market, through competitive tenders, and they are one of – if not the highest bidder – with Canada paying among the highest prices in the world. Why would we invest millions to operate in one of the highest cost jurisdictions in the world if our primary customers are located in lower cost places?

We recently offered to sell source plasma licensed by Health Canada to CBS (that's the raw material, not the finished products which they purchase on the open market) from our facility in Saskatoon. Unfortunately they declined. Even though our offer was 20% below the average US price. CBS purchased over 47 thousand litres of raw plasma from US vendors last year; an increase of 50% over the previous year. I have attached our offer for your information. You will note the substantial difference in cost vs.

what CBS pays its American suppliers. A concern was expressed that CBS might have difficulty using our plasma as it is not registered by the FDA in the United States, where CBS ships raw plasma for processing. This concern was not given as the reason for rejecting our plasma, but addressing it is a simple process and we would be happy to do so should CBS reconsider its decision.

We welcome CBS' new found interest in collecting plasma. Canada is the largest per capita user of PPPs and demand is growing quickly all over the world. So, to ensure security of supply for Canadian patients, we absolutely support any increase in the supply of Canadian plasma, regardless of whether it comes from volunteer or paid donors. But let's be clear - no country has been able to meet its demand for plasma without relying on paid donors. Canada is and will be no different.

We are proud to be licensed by Health Canada, and privileged to have the support of several provinces and most national patient advocacy organizations for our model. We believe this is a great opportunity for Canada and look forward to responding to any questions or concerns you may have.

Sincerely,



Barzin Bahardoust, CEO

Canadian Plasma Resources



CANADIAN PLASMA RESOURCES

# 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

## 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 currency 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 litres

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 fractioned 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 US\$285.00**

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

**Total price of CPR plasma and toll PPP's is US\$ 276.50**

## 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 I:** 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 CPR business plan calls for 10 centres to be operational by 2021, collecting 400,000 litres of plasma annually.

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 target 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 AG 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

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, unpaid 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 markers, 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 8 out of every 10 Canadian patients using Ig is treated with IVIG brands made from US paid donor plasma.

## 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 Prometic 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 immunoglobulin 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."*



## **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 Rare Blood Disorders Organization (NRBDO), Canadian Immunodeficiency Patient Organization (CIPO), Canadian Organization for Rare Diseases (CORD), the National Chapter of the Canadian Hemophilia Society (CHS), Hereditary Angioedema (HAE) Canada and Alpha1 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 serological 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

collected. Additionally donor samples are tested for Syphilis (RPR), Antibody Screen, Total Protein and SPE. These tests are performed at Qaultex in San Antonio, 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 nurse.
4. Be tested for transmissible disease markers.

### **Donor reimbursement & 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.