BUSINESS BRIEFS

* In its quarterly earnings report, CHINA BIOLOGIC PRODUCTS said it continued to experience strong demand for its products during the three months ended March 31, 2011. China Biologic Products is a Delaware corporation with plasma collection and fractionation operations in China, including, among others, the Guizhou and Beijing provinces. The company reported the following operating performance results:

- Sales increased by 27.2%, to $34,470,822;
- Gross profit increased by 23.9%, to $25,159,224; and
- Net income decreased 40.8%, to $6,308,975

Human albumin (20%, 10% and 25% concentrations) is China Biologic’s top-selling product, accounting for approximately 57.2% of total revenues. Its price declined by 4.9% during the quarter ended March 31.

By contrast, most of China Biologic’s other plasma-derived products recorded price increases in 2010:

- The price of intravenous immune globulin (IVIG), which contributed 30.2% to overall sales, increased by 4.2%;
- The price of hepatitis B immune globulin, which contributed 6.4% to overall sales, increased by 25.2%;
- The price of rabies immune globulin, which contributed 2.2% to overall sales, increased by 14.8%, and
- The price of tetanus immune globulin products, which contributed 3.4% to overall sales, increased 2.7%, all as compared to the same period in 2010.

The price increases in immune globulin products were attributed to a short supply of this product category, while the albumin price decrease was due to the continued growth in albumin imports during the first quarter of 2011.

Sales volumes of albumin, IVIG and tetanus immune globulin increased by 63.2%, 85.5% and 68.5%, respectively, for the three months ended March 31, as compared to the same period in 2010. At the same time, sales volumes of hepatitis B and rabies immune globulin products decreased by 46.9% and 82.7%, respectively, over this period, due to the lack of raw material to manufacture these hyperimmune immunoglobulins.
A preliminary assessment of data from a 1,000-subject pivotal trial of NABI BIOPHARMACEUTICALS’ NicVax (Nicotine Conjugate Immunotherapeutic) showed that subjects treated with NicVax quit smoking at a similar rate of approximately 11% as subjects who received placebo. The primary endpoint of the study was the abstinence rate at 12 months as measured from week 37 through week 52. Abstinence was evaluated by self-reported cigarette consumption and exhaled carbon dioxide.

“We are clearly surprised and deeply disappointed with the results of this first NicVax Phase III trial,” a senior Nabi official said. “We are in the process of assessing the reasons for these unexpected data, as we await the results of the second Phase III trial.” The price of Nabi’s common shares plummeted nearly 70% immediately after the Rockville, Maryland-based company reported that its flagship investigational agent in the first of two confirmatory Phase III clinical trials.

The Gulf Cooperation Council (GCC), which contracts for most of the plasma derivatives requirements of Kuwait, Oman, United Arab Emirates, Qatar and Bahrain, recently awarded Pharmaceutical Tender “SGH #33.” This tender was administered by the Saudi Ministry of Health, as was the case for earlier tenders, and not by NUPCO, a large Saudi pharmaceuticals drug distributor that was to take over this operation some time ago. Awards, quantities and prices of key plasma products were reported as follows:

<table>
<thead>
<tr>
<th>Product</th>
<th>Quantity</th>
<th>CIF Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albumin 20%, 50 ml &amp; PPF (per gram)</td>
<td>~7 metric tons</td>
<td>$3.30-3.48</td>
</tr>
<tr>
<td>IVIG (2.5 gram vials)</td>
<td>Approx. 120,000</td>
<td>$126.50</td>
</tr>
<tr>
<td>Factor VIII, plasma-derived (price per IU)</td>
<td>12.7 million IUs</td>
<td>$0.247</td>
</tr>
<tr>
<td>Factor IX Concentrate (per IU)</td>
<td>4.9 million IUs</td>
<td>$0.210</td>
</tr>
<tr>
<td>Recombinant Factor VIIa (1.2 gram)</td>
<td>-</td>
<td>$729.17</td>
</tr>
<tr>
<td>Fibrinogen 2 grams, 100 mL</td>
<td>-</td>
<td>$470.00</td>
</tr>
<tr>
<td>Hepatitis B Ig, IM, 2 mL (200-250 IU/mL)</td>
<td>-</td>
<td>$71.00</td>
</tr>
<tr>
<td>Rho(D) Immune Globulin (200-300 mcg/vial)</td>
<td>5,534 vials</td>
<td>$48.50</td>
</tr>
<tr>
<td>Rabies Immune Globulin, 2 mL (150 IUs/vial)</td>
<td>-</td>
<td>$61.00</td>
</tr>
<tr>
<td>Tetanus Immune Globulin, 2 mL (250 IUs/vial)</td>
<td>-</td>
<td>$12.83</td>
</tr>
</tbody>
</table>

The successful bidders included BPL (factor VIII), CSL BEHRING, and OCTAPHARMAMA (albumin, coagulation factors, intravenous immunoglobulin, etc). The quantity and prices of the previous tender were published in the October 2010 issue of International Blood/ Plasma News.
According to the Marketing Research Bureau’s newly released market research report, *The Plasma Proteins Market in the United States*, total sales of plasma proteins reached $4.8 billion, a 3.2% increase over 2009. The three top competitors, BAXTER HEALTHCARE, CSL BEHRING and TALECRIS BIOТЕРАПЕУТИКС, had an aggregate share of 79% of the market. When including recombinant factors, the market reached $7.4 billion, up 3.4% from 2009.

Intravenous and subcutaneous immune globulin products collectively represented 59% of total plasma products revenues, while albumin and plasma-derived factor VIII remained unchanged at 8% and 4%, respectively.

Approximately 42.3 million grams of intravenous and subcutaneous immune globulin products were sold in 2010, an 8% increase from 2009. This was equivalent to 138 kilograms per million population, one of the world’s highest levels. Unit sales of albumin increased 7% between 2009 and 2010, reaching about 129 metric tons, or 416 kilograms per million population.

The 2010 factor VIII market (recombinant and plasma-derived), without including von Willebrand factor complex, was estimated at slightly over two billion international units, a 3% increase from the previous years. Recombinant factor VIII products accounted for close to 90% of U.S. factor VIII unit sales. Overall, factor VIII consumption was 6.9 international units per capita.

The economic recession had a relatively limited impact on 2010 sales of plasma and recombinant proteins, in part because they serve patient populations for which limited or no alternatives exist and because they are commonly required for life-saving or life-critical uses. Together with patient advocacy groups, such as the NATIONAL HEMOPHILIA FOUNDATION (NHF) and the IMMUNE DEFICIENCY FOUNDATION (IDF), the PLASMA PROTEIN THERAPEUTICS ASSOCIATION (PPTA) successfully advocated on behalf of patients and the fractionators to exempt plasma-derived therapeutics from certain government and private health insurance provisions aimed at reducing drug costs by shifting more of the burden to patients and thus restricting access to care.

In 2010, slightly over 18 million liters of plasma (source and recovered) were collected in the U.S., down nearly 9% from the previous year. The measures taken in recent months by fractionators – which own and operate more than 95% of the country’s plasma collection centers – to reverse the upward trend in collections produced some results and began deflating plasma inventories.

*JOHNSON & JOHNSON* reports that, since its 2008 acquisition of Jerusalem-based OMRIX BIOPHARMACEUTICALS, the number of countries in which its *EVICEl* surgical fibrin sealant is licensed increased from one (Israel) to 10 countries by the end of 2009, and now is available in 21 countries.
Announcement

The Marketing Research Bureau is pleased to announce the completion and availability of the following report:

THE PLASMA PROTEINS MARKET IN THE UNITED STATES - 2010

(Formerly known as “The Plasma Fractions Market in the United States”)

This report is a comprehensive market analysis of the therapeutic plasma and recombinant proteins sold in the U.S. through mid-2011. It provides 2010 sales data and historical trends, in units, dollars and market shares by manufacturer. Regulatory, economic and health care issues impacting the market are also discussed. The following topics are covered in the report:

- Plasma Collections and Fractionation
- Overview of the Plasma Fractions Market
- Intravenous, Subcutaneous and Intramuscular Immune Globulins (polyvalent & specific)
- Albumin and Plasma Protein Fraction
- Factor VIII and Factor IX (plasma-derived and recombinant),
- Activated Prothrombin Complex and Recombinant Factor VIIa
- Other plasma-derived therapeutic proteins:
  - Alpha-1 Antitrypsin
  - Antithrombin III
  - Fibrinogen
  - C-1 Esterase Inhibitor
  - Protein C
  - Factor XIII
  - Fibrin Sealants
  - Thrombin
- Product Distribution Channels
- Profiles of the major U.S. Fractionators

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The U.S. albumin market reached its highest-ever unit volume in 2010, with more than 9.9 million equivalent units sold by manufacturers to distributors and hospital end-users, according to The Marketing Research Bureau’s newly released research report, ALBUMIN 2015: A U.S. Market Profile and Forecast of Albumin Demand Through the Year 2015. For this report, MRB conducted surveys of general anesthesiologists, cardiac anesthesiologists, critical care specialists and other key albumin users. Extensive secondary research data were also captured to develop a profile of albumin and synthetic colloid usage patterns and emerging trends.

Nearly 75% of U.S. demand for 5% and 25% albumin products in 2010 was generated by medical uses, with the balance attributable to major cardiac and non-cardiac surgeries. Important shifts in the albumin usage mix forecasted between 2010 and 2015 will particularly reflect anticipated changes in demand from cardiac surgery and general surgery, as well as therapeutic plasma exchange and certain other key medical uses.

HOSPIRA’S low-molecular weight hetastarch product, Voluven, has captured about 20% of the U.S. hetastarch market, despite its four-fold higher average selling price than conventional 6% hetastarch in saline. Still, more than twice as many respondents to a survey of general anesthesiologists indicated that they now use more albumin and less hetastarch than they did three years ago than those who say they now use more hetastarch and less albumin.

BLOOD & BIOTECHNOLOGY

An FDA advisory panel has recommended approval of icatibant (JERINI US, a subsidiary of SHIRE HUMAN GENETIC THERAPIES) for the treatment of acute attacks of hereditary angioedema (HAE) in adult aged 18 years and older. The panel agreed that the data provided by Jerini US convincingly showed that subcutaneous injections of icatibant, a selective bradykinin beta-2 receptor antagonist, was beneficial and safe in the treatment of this rare and sometimes fatal disorder. HAE is characterized by intermittent, unpredictable attacks of angioedema in various parts of the body, including the throat, abdomen and extremities. It is caused by a defect in the C1-esterase inhibitor protein, which blocks the first component of the complement system.

Panel members endorsed the fact that icatibant can be self-administered, similarly to the way epinephrine is given for anaphylactic shock. “The severity of the disease makes a compelling reason why patients need to be able to self-inject,” one panel member said. “It doesn’t make sense that these patients have to go to a medical facility to get their treatment for their acute angioedema attacks; it’s not safe to do that,” he added. Jerini US plans to market icatibant as Firazyr.
* In a Proposed Rule, the U.S. Centers for Medicare and Medicaid Services (CMS) has announced that it plans to remove its requirement that healthcare providers maintain the hemoglobin level at a minimum of 10 g/dL in patients with end-stage renal disease (ESRD) on chronic kidney dialysis. In late June the FDA amended the prescribing information for two recombinant human erythropoiesis-stimulating agents (ESAs) -- AMGEN’S Epogen and JOHNSON & JOHNSON’S Procrit – to warn physicians about increased risks of serious adverse cardiovascular events with administration of ESAs at any dose in this patient population.

For patients with chronic kidney disease (CKD) on dialysis, the revised ESA product labeling now recommends initiation of ESA treatment only when the hemoglobin level is less than 10 g/dL; if the hemoglobin level approaches or exceeds 11 g/dL, physicians are advised to reduce or interrupt the dose of ESA. For other CKD patients, physicians are now advised to reduce or interrupt the dose of ESA if the hemoglobin level exceeds 10 g/dL, and to use the lowest possible dose of ESA sufficient to reduce the need for red blood cell transfusion.

CMS has published its Proposed Rule, which includes discussion of how ESA will be reimbursed under the ESRD Prospective Payment System, in the July 8 issue of the Federal Register. Public comments will be accepted by the agency until August 30.

* Sangamo BioSciences has announced the publication of a “groundbreaking preclinical study demonstrating permanent functional correction of the gene that causes hemophilia B by the systemic delivery of zinc finger nucleases (ZFNs).” The Richmond, California-based biotechnology firm’s ZFNs had previously been shown to induce a site-specific double-stranded break (DSB) at a target locus, but it was unclear whether ZFNs could induce DSBs and stimulate genome editing at a clinical meaningful level in vivo.

In this work conducted by investigators at the University of Pennsylvania and the Children’s Hospital of Philadelphia, a single systemic administration of ZFNs and a donor sequence in a mouse model of hemophilia permanently corrected a defective human gene encoding factor IX, resulting in restoration of normal clotting times in the animals.

“ZFN-mediated gene-editing provides a new approach to monogenic disease and circumvents the problems of traditional gene-addition strategies that result in random insertion that may lead to malignancy or other unintended consequences. Genome editing also reinstates the wild-type sequence under the control of the endogenous regulatory sequences, assuring restoration of this critical aspect of normal gene expression,” the study’s senior investigator said. This report appears in the July 14 issue of the journal Nature.
Injections of autologous CD34+ stem cells reduced reported angina episodes and improved exercise tolerance in patients with chronic, severe refractory angina, according to results of a Phase II prospective, double-blind, randomized controlled trial conducted at 26 U.S. centers. Stem cells were collected using BAXTER INTERNATIONAL’S Isolex cell separation and collection system; Baxter also sponsored this trial in a long-term collaboration with researchers at Northwestern University.

In a total of 167 patients, either one or two injections were distributed into sites of ischemic, viable myocardium with a NOGA mapping injection catheter. Weekly angina frequency was significantly lower in the low-dose group than in placebo-treated patients at both six months (6.8 ± 1.1 versus 10.9 ± 1.2, $P = 0.02$) and 12 months (6.3 ± 1.2 versus 11.0 ± 1.2, $P = 0.035$). Angina rates in the high-dose group were also lower than placebo-treated patients, but not significantly.

Similarly, improvement in exercise tolerance was significantly greater in low-dose patients than in placebo-treated patients at six months (139 ± 151 versus 69 ± 122 seconds, $P = 0.014$) and 12 months (140 ± 171 versus 58 ± 146 seconds, $P = 0.017$) and greater as well in the high-dose group, but again not significantly. Previous preclinical studies of autologous CD34+ stem cells have shown an increase in capillary density and improved cardiac function in models of acute and chronic myocardial ischemia. More than 850,000 persons in the U.S. experience refractory angina that has not responded to other therapeutic options, according to some estimates. This study was reported on July 7 in Circulation Research.

**RESEARCH AND DEVELOPMENT**

KAMADA announced that it has initiated a Phase I/II clinical trial of its intravenous alpha-1 antitrypsin (AAT) product for the treatment of type 1 diabetes, also called juvenile-type diabetes. The Israeli Ministry of Health has approved the study protocol to evaluate the safety and efficacy of the product, which is marketed in the U.S. for the treatment of hereditary emphysema by Baxter BioScience under the brand name GLAS-SIA.

“Scientific studies on the subject as well as the quality of preclinical trial results to date are very encouraging. Kamada intends to publish an interim report on the trial in early 2012 and the final report later in 2012,” a senior company official said in a news release.
Resuscitation of experimental hemorrhaged pigs in hypovolemic shock with fresh frozen plasma (FFP) with or without red blood cells reduced post-resuscitation blood loss (PRBL) by 52% to 70% compared to resuscitation with high-molecular-weight hydroxyethyl starch in a balanced electrolyte solution (*HEXTEND*; HOSPIRA). In a carefully designed study conducted at the U.S. Army Institute of Surgical Research, eight anesthetized, instrumented animals underwent a controlled hemorrhage of 24 mL/kg at a rate of 100 mL per minute, followed by splenic injury followed by uncontrolled bleeding for 15-minutes.

PRBL following infusion of four different blood component combinations – FFP, fresh whole blood, a 1:1 mix of FFP and red blood cells and a 1:4 mix of FFP and red blood cells – ranged from 5.5 to 8.6 mL/kg over a five-hour post-injury period. In contrast, PRBL was significantly higher following infusion of the same volume of *HEXTEND* (17.9 ± 2.5 mL/kg). PRBL with lactated Ringer’s solution (11.5 ± 2.5 mL/kg) was not significantly different from *HEXTEND* or blood components.

All fluids produced similar changes in hemodynamics, oxygen delivery and oxygen demand. However, compared with other fluids, *HEXTEND* produced greater hemodilution and reduced coagulation measures, which the investigators attributed to an indirect dilutional effect or a direct hypocoagulable effect. They concluded that, in relation to *HEXTEND* (which is now used routinely in U.S. combat operations), blood products used as an initial resuscitative fluid reduced PRBL from noncompressible injury, preserved coagulation and provided sustained volume expansion. This research was published in *Transfusion*.

High-dose intravenous immunoglobulin (IVIG) may offer relief for patients with sensorimotor neuropathy or nonataxic sensory neuropathy associated with primary Sjögren’s syndrome, according to a study by French researchers reporting in *Arthritis Care & Research*. A retrospective analysis revealed that, of 19 Sjögren’s patients with a median duration of neuropathy of nine years, all five with sensorimotor neuropathy, all four with nonataxic sensory neuropathy and a sole patient with conduction block improved or stabilized on IVIG therapy. In contrast, only two of nine patients with ataxic neuropathy improved, and four worsened. Symptoms remained stable in the remaining three patients. All patients received 2 g/kg of IVIG per month in divided doses for a median of seven months. Response was assessed using the Modified Rankin Scale and a global evaluation by the practitioner. After four to 12 months of treatment, five patients were able to have their IVIG infusions spaced to every two or three months. Ten of 13 patients who required corticosteroids were able to reduce their prednisone dosage from an average of 15 mg daily before IVIG to 10 mg daily with IVIG therapy.

“Symptomatic treatment should be tested in patients with Sjögren’s syndrome without necrotizing vasculitis-related neuropathy,” the investigators concluded. “Further studies are necessary to investigate the optimal number of IVIG courses necessary to definitively assess the efficacy or the failure of the treatment.”
BAXTER INTERNATIONAL and HALOZYME THERAPEUTICS have announced top-line results of a Phase III study of “HyQ,” an investigational “facilitated” subcutaneous immunoglobulin (SCIG) product for use in patients with primary immunodeficiency disorders who require IgG replacement therapy. A Biologics License Application (BLA) for “HyQ” was recently submitted to the U.S. FDA. Subcutaneous administration is facilitated by pre-administration of recombinant human hyaluronidase, an enzyme that increases dispersion and absorption of the infused antibodies. This allows a larger dose to be administered in a single session; study participants received their infusions every three to four weeks.

A total of 89 patients were enrolled in this prospective, open-label study at 15 centers in the U.S. and Canada, which evaluated the tolerability and effectiveness of “HyQ” administered at a single site for the prevention of infections. The acute serious bacterial infection rate was 0.025 per patient per year, far below the required efficacy threshold of 1.0 infections per patient per year. The most frequently reported adverse events were infusion site reactions (20% of infusions), headache (3%), fatigue (1%) and pyrexia (1%).

An extension study will further evaluate “HyQ” administration to patients through March 2012. Baxter plans to present results from the Phase III study by the end of 2011. In addition to the U.S. regulatory submission, Baxter expects to file for approvals in Europe and Canada in the coming months.

Administration of large boluses of either 5% albumin or 0.9% saline solution on admission to the hospital was associated with higher mortality in African children with shock and life-threatening infections than for children who received no fluid bolus, according to a large randomized study by the Kenya Medical Research Institute (KEMRI)--Wellcome Trust Research Programme.

At time of admission to a hospital in Uganda, Kenya or Tanzania, a total of 3,141 of a planned 3,600 children with severe febrile illness and impaired perfusion were randomized to receive boluses of 20 to 40 mL of 5% albumin or saline, or no fluid bolus before the study was halted by the data and safety monitoring committee. All children received appropriate antimicrobial treatment, intravenous maintenance fluids and supportive care.

The 48-hour mortality was 10.6% (111 of 1050 children) in the albumin bolus group, 10.5% (110 of 1047 children) in the saline bolus group, and 7.3% (76 of 1044 children) in the control group. There was no difference in the relative risk (RR) of death between albumin and saline bolus groups (RR = 1.0; 95% confidence interval, 0.78 to 1.29; \( P = 0.96 \)). But the RR of death between combined saline and albumin bolus groups and no-bolus control group was 1.45 (95% CI, 1.13 to 1.86; \( P = 0.003 \)).

(continued on page 175)
Most deaths (87%) occurred before 24 hours. The results were consistent across centers and across subgroups according to the severity of shock and status with respect to malaria, coma, sepsis, acidosis and severe anemia. “The results of this study challenge the importance of bolus resuscitation as a lifesaving intervention in resource-limited settings for children with shock who do not have hypotension and raise questions regarding fluid-resuscitation guidelines in other settings as well,” the authors concluded. This report was published in the June 30 issue of *The New England Journal of Medicine*.

**PLASMA FRACTIONATION NOTES**

*For the 2011-2012 fiscal year, CSL BEHRING’S *Privigen* intravenous immunoglobulin and *Vivaglobin* subcutaneous immunoglobulin products are expected to account for 35% of CANADIAN BLOOD SERVICES’ therapeutic immunoglobulin supply, according to a recent CBS update. BAXTER HEALTHCARE’S *GAMMAGARD* products will account for 14% and Ig products manufactured by TALECRIS BIOtherapeutics (now *GRIFOLS*) will account for 51% of overall Ig product volume.*

For the first quarter, CBS has issued Ig products in the following proportions: Baxter (11.7%), CSL Behring (26%) and Talecris (62.3%). At these distribution ratios, CBS expects supply of Talecris-manufactured products to become tight by the end of this summer. CBS has been informed by Talecris that deliveries of the 20 gram vial size of *IGIVnex* will be below planned levels between July and December 2011; additional 10 gram *IGIVnex* will be supplied to maintain overall inventory coverage.

For the period from April 1, 2011 to March 31, 2012, CSL Behring’s *Alburex* will constitute approximately 65% of CBS’ supply of 5% human albumin. This product is only being delivered in 500 mL bottles, while *Plasbumin* from Talecris is being supplied only in 50 mL and 250 mL bottles.

*GRIFOLS has opened its new corporate head offices in Sant Cugat del Valles in Barcelona. With its recent acquisition of TALECRIS BIOtherapeutics, Grifols is now the third largest plasma derivative manufacturer in the world, with a presence in more than 90 countries and wholly-owned subsidiaries in 24 countries.*

The group’s new corporate head offices, at a site known as Tioparc, include three separate buildings, connected at the basement level, with a total surface area of 45,900 square meters.
**PRODUCT SAFETY UPDATE**

* Pathogen-reduced platelets were associated with a significant \( p < 0.05 \) reduction in one- and 24-hour post-transfusion corrected count increments (summary mean difference 3260; 95% confidence interval, 2450-4791 and 3315, 95% CI, 2027-4603, respectively) as well as a significant increase in overall and in clinically significant bleeding complications, according to a meta-analysis of five randomized controlled trials of hematology-oncology patients.

“Introduction of pathogen reduction technologies in their current stage of development would result in an increase in mild and moderate (albeit not severe) bleeding complications, which the transfusion medicine community must explicitly tolerate to reap the benefits from pathogen reduction,” the study’s author conclude. His findings appear in the journal *Transfusion*.

* Boston-based IMMUNETICS has won a three-year, $2.4 million Phase 2 Small Business Innovation Research (SBIR) grant from the U.S. National Institute of Allergy and Infectious Diseases (NIAID) to help bring its confirmatory test for Chagas’ disease to clinical trials. The company’s immunoblot test is designed to identify antibodies to the parasite \( T. cruzi \), which is endemic in Latin America and often goes undiagnosed for years before symptoms appear.

Currently, the screening tests used for Chagas’ disease rely on radioimmunoprecipitation (RIPA) testing for confirmation, a method that Immunetics says is beyond the capability of many testing laboratories. Collaborators in clinical trials to evaluate this new screening test include BLOOD SYSTEMS RESEARCH INSTITUTE, AMERICAN RED CROSS and the U.S. Centers for Disease Control and Prevention (CDC).

**NEW PRODUCTS**

* InTec Products’ (Xiamen, China) *ABO & RhD Blood Grouping Kit* uses unique visual testing technology to detect ABO and RhD blood groups based on the immune response principle of antigens and antibodies. This kit is suitable for on-site blood collection, medical laboratory testing, and urgent pre-transfusion testing, according to the company.

The *ABO & RhD* kit rapid, accurate results and offers detection of ABO and RhD blood groups simultaneously in a single test without any additional equipment. At 2°C to 30°C, the kit can be stored for up to two years. For more information, visit www.intecasi.com.
RECENT U. S. PATENTS

* Antibodies Binding to the A2 Domain of FVIII and Inhibiting Coagulation Activity. #7,858,089. Assigned to Life Sciences Research Partners VZW (Leuven, Belgium). An isolated human monoclonal antibody of the IgG isotype, or an antigen-binding fragment thereof, which specifically binds to the A2 domain of factor VIII, wherein additional structural features are defined in the patent.

* Methods for Prolonging Survival of Platelets Using UDP-Galactose. #7,858,295. Assigned to Velico Medical, Inc. (Beverly, MA). A method for increasing the storage time of platelets, involving contacting an isolated population of platelets with an amount of at least one glycan modifying agent selected from the group consisting of UDP-galactose and a UDP-galactose precursor with an enzyme that converts a UDP-galactose precursor to UDP-galactose in an amount effective to reduce the clearance of the population of platelets.

* Preparation of a Platelet-/Nucleated Cell Concentrate from Bone Marrow or Blood. #7,858,296. Assigned to Smith & Nephew, Inc. (Memphis, TN). A method of preparing a cell concentrate, starting with a physiological fluid comprising platelets, plasma, nucleated cells and red blood cells and combining a hypotonic fluid with the physiological fluid, then continuing with filtration through first and second filtration devices.

* Polymer-Factor VIII Moiety Conjugates. #7,858,749. Assigned to Nektar Therapeutics (San Francisco, CA). A conjugate comprising a factor VIII polypeptide covalently attached to one, two, three or four water-soluble polymers via degradable linkage wherein (i) the factor VIII polypeptide is selected from the group consisting of factor VIII, factor VIIIa, factor VIII:C, factor VIII:vWF and B-domain deleted factor VIII, and (ii) the water-soluble polymer is selected from the group consisting of poly(alkylene oxide), poly(vinyl pyrrolidone), poly(vinyl alcohol), polyoxazoline, and poly(acryloylmorpholine).

* Mutants of the Factor VII-Activating Protease and Detection Methods Using specific Antibodies. #7,863,009. Assigned to CSL Behring GmbH (Marburg, Germany). A method for detecting autoantibodies against Factor VII Activating Protease (FSAP) and/or one or more FSAP mutants formed by the exchange of one or more amino acids in a body fluid sample from an individual, which comprises letting the body fluid sample react with FSAP and/or FSAP mutants which are fixed to a solid support, washing the solid support, and detecting antibodies bound to the support.
* Hydroxyethylstarch. #7,863,260. Assigned to B. Braun Melsunger AG (Melsunger, Germany). A pharmaceutical formulation for use in at least one of maintaining normovolemia, improving macro- and microcirculation, improving nutritive oxygen supply, stabilizing hemodynamics, improving volume efficiency, reducing plasma viscosity, increasing anemia tolerance, and performing hemodilution, the formulation comprising a hydroxyethylstarch comprising an average molecular weight of greater than or equal to 500,000, a molar substitution of from 0.25 to 0.5 and a C2/C6 ratio of from 2 to below 8, wherein the hydroxyethylstarch in the formulation is in a concentration of up to 20%.

* Process For Removing Fibronectin from Plasma Fractions. #7,863,420. Assigned to Biotest AG (Dreieich, Germany). A process for the production of a composition containing at least one coagulation factor, said process consisting of steps that involve (i) adjusting the pH of a plasma fraction to a value between pH 4.7 and pH 5.3 so as to form a precipitate comprising 70% to 99% of the initial amount of fibronectin and a supernatant containing at least one coagulation factor; (ii) removing the fibronectin precipitate formed in step (i) to thereby yield a composition containing at least one coagulation factor; and (iii) purifying the at least one coagulation factor from the composition obtained in step (ii), therein steps (i) and (ii) are performed at a temperature that ranges from 20°C to 25°C.

* Polymer-Factor VIII Moiety Conjugates. #7,863,421. Assigned to Nektar Therapeutics (San Francisco, CA). A conjugate comprising a water-soluble polymer covalently attached to a factor VIII polypeptide via a thiol group of a cysteine residue contained within the factor VIII polypeptide, wherein the factor VIII polypeptide is selected from the group consisting of factor VIII, factor VIIIa, factor VIII:C, factor VIII:vwWF and B-domain deleted factor VIII, and wherein the water-soluble polymer is selected from the group consisting of poly(alkylene oxide), poly(vinyl pyrrolidone), poly(vinyl alcohol), polyoxazoline, and poly(acryloylmorpholine).

* Method of Treating Anemia by Administering IL-1RA. #7,867,481. Assigned to Amgen Inc. (Thousand Oaks, CA). A method of treating anemia in a mammal, comprising administering a therapeutically effective amount of a pharmaceutical composition comprising an interleukin-1 (IL-1) inhibitor to the mammal wherein the IL-1 inhibitor is IL-1Ra.

* Monoclonal Antibodies to Respiratory Syncytial Virus and Uses Therefor. #7,867,497. Assigned to Vanderbilt University (Nashville, TN). A purified nucleic acid molecule encoding a heavy chain variable region whose sequence is specified in the patent.
* **Induction of Tolerance by Oral Administration of Factor VIII and Treatment of Hemophilia. #7,867,974.** Assigned to The United States of America as represented by the Department of Health and Human Services (Washington, D.C.). A method for increasing hemostasis in a subject having hemophilia A in which clotting factor VIII is deficient and wherein the subject does not have factor VIII inhibitors, comprising orally administering a therapeutically effective amount of factor VIII in water sufficient to induce oral tolerance and supply exogenous factor VIII to the subject, wherein the factor VIII is not present in a liposome.

* **Reversibly Inactivated Acidified Plasmin. #7,871,608.** Assigned to Talecris Biotherapeutics, Inc. (Raleigh, NC). A method of treating a subject suffering from a disorder susceptible to improvement with plasmin, comprising administering a therapeutically effective amount of a composition comprising a reversibly inactivated, acidified plasmin, the plasmin being substantially free of a plasminogen activator; and a low buffering capacity buffer; wherein the composition is a solution suitable for pharmaceutical use that can be raised to physiological pH by adding no more than about 5 volumes of serum to the solution relative to a volume of the solution.

* **Humanized Antibodies That Recognize Beta Amyloid Peptide. #7,871,615.** Assigned to Janssen Alzheimer Immunotherapy (Little Island, County Cork, Ireland) and Wyeth LLC (Madison, NJ). A purified humanized antibody which specifically binds beta amyloid peptide, or antigen-binding fragment thereof, whose structure is specified in the patent.

* **Recombinant Antibodies for Treatment of Respiratory Syncytial Virus Infections. #7,879,329.** Assigned to Symphogen A/S (Lyngby, Denmark). An anti-RSV (respiratory syncytial virus) antibody, or antigen binding fragment thereof, whose structure is described in the patent.

* **Ultra-High Yield Intravenous Immune Globulin Preparation. #7,879,331.** Assigned to Plasma Technologies, LLC (Kiawah Island, SC). A method of extracting IgG from an amount of cryo-poor plasma, comprising providing a cryo-poor plasma, physically separated from a cryoprecipitate; salting the cryo-poor plasma to produce a first intermediate with a total salt content of more than 10% wt/wt; centrifuging the first intermediate to produce a first supernatant and a first paste; salting the first supernatant to produce a second intermediate with a total salt content of at least 21% wt/wt, wherein the salt concentration of the second intermediate is greater than the salt concentration of the first intermediate; centrifuging the second intermediate to produce a second supernatant and a second paste; and de-salting the second paste to produce a product containing the IgG.
MEETINGS

August 15-18, 2011
National Pharmacy Purchasing Association Conference
Tropicana Hotel
Las Vegas, Nevada
Tel: 858-851-6373
Email: Info@PharmacyPurchasing.com
Website: www.PharmacliyPurchasing.com

September 22-23, 2011
Seventh WFH Global Forum
Safety and Supply of Treatment Products for Bleeding Disorders
Montreal, Canada
Tel: +1 (514) 875-7944
Email: wfh@wfth.org
Website: www.wfh.org

October 13-15, 2011
Latin American Society for Immunodeficiencies (LASID)
and The International Patient Organization
For Primary Immunodeficiencies (IPOPI)
Hotel Fiesta Americana Reforma
Mexico City, Mexico
Tel: +52 55 5663 2803
Email: info@intermeeting.com.mx
Website: www.intermeeting.com.mx

October 23, 2011
PPTA Business Forum 2011
Manchester Grand Hyatt
San Diego, CA
Tel: 202-789-3100
Fax: 410-263-2298
Email: ppta@pptaglobal.org
Website: www.plasmaproteinforum.com

November 10-12, 2011
63rd Annual Meeting
National Hemophilia Foundation (NHF)
Chicago, IL
Tel: 212-328-3700
Email: handi@hemophilia.org
Website: www.hemophilia.org

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