CONFIDENTIAL  
Exhibit 10.32  
CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN  
THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN  
OMITTED AND FILED SEPARATELY WITH THE  
SECURITIES AND EXCHANGE COMMISSION PURSUANT TO  
RULE 24B-2 OF THE SECURITIES EXCHANGE  
ACT OF 1934, AS AMENDED  
MANUFACTURING and SERVICE CONTRACT  
For Commercial and Developmental Products  
This document hereinafter the “AGREEMENT” is made effective as of December 20, 2005 (the “Effective Date”), by Pharmion, Inc., a corporation organized and existing under the laws of Delaware, with its principal office at 0000 00xx Xxxxxxx, XX 00000 (hereinafter “CUSTOMER”), and Ben Venue Laboratories, Inc., a corporation organized and existing under the laws of Delaware, with its principle office at 000 Xxxxxxxxxx Xxxx, Xxxxxxx, Xxxx, 00000 (hereinafter “BVL”).  
WITNESSETH  
WHEREAS, CUSTOMER is active in the pharmaceutical business and is the owner of all rights or licensee of all rights to certain proprietary technical information, patents and patent applications relating to the PRODUCT(s) included in Attachment(s) A — PRODUCT Supplements, which are attached here to and maybe be amended in writing upon mutual agreement of the parties, (hereinafter “PRODUCT”); and  
WHEREAS, BVL provides services to the pharmaceutical industry as a contract manufacturer which supplies its customers with sterile finished dosage forms which it has converted from materials supplied by those customers and/or supplied by BVL and provides developmental services for sterile dosage forms, and  
WHEREAS, CUSTOMER and BVL desire to formalize their relationship through this AGREEMENT for the development and MANUFACTURE of PRODUCT; and  
WHEREAS, BVL possesses the requisite expertise, personnel and FACILITIES for the development, MANUFACTURE and supply of finished sterile dosage forms of the PRODUCT and is willing to provide development services, MANUFACTURE of such PRODUCT(S) on a contract basis to CUSTOMER;  
NOW, THEREFORE, in consideration of the foregoing and of the mutual covenants and conditions herein contained, CUSTOMER and BVL agree as follows:  
Page 1 of 38 BVL — PHARMION Manufacturing and Service Agreement  
 CONFIDENTIAL  
Index of Agreement  
Section 1 — Definitions  
Section 2 — Description of Work  
Section 3 — Manufacturing Facilities  
Section 4 — Volumes and Second Source  
Section 5 — Forecast and Purchase Orders  
Section 6 — Price and Payment  
Section 7 — Quality Agreement  
Section 8 — Indemnification  
Section 9 — Confidentiality  
Section 10 — Term and Termination  
Section 11 — Notices  
Section 12 — Waiver  
Section 13 — Assignment  
Section 14 — Governing Law  
Section 15 — Force Majeure  
Section 16 — Title of Materials  
Section 17 — Debarment  
Section 18 — Entire Agreement  
Section 19 — Severability  
Section 20 — Independent Contractor  
Section 21 — Amendments  
Section 22 — Headings  
Section 23 — Review by Legal Counsel  
Section 24 — Recalls  
Article 25 — English Language  
ATTACHMENTS  
Attachment A — PRODUCT Supplements  
Attachment B — Purchase Order Requirements  
Attachment C — Storage Fees  
Attachment D — Documents Supplied with BATCH Release  
Attachment E — Quality Agreement  
Attachment F — Customer Supplied Equipment  
Page 2 of 38 BVL — PHARMION Manufacturing and Service Agreement  
 CONFIDENTIAL  
ARTICLE 1 — DEFINITIONS  
1.1 Active pharmaceutical ingredient hereinafter “API”, shall mean bulk supplies of the pharmacologically active compounds listed for the PRODUCT(S) included in Attachment(s) A, which CUSTOMER will provide to BVL in bulk form, from time to time, for the sole purpose of MANUFACTURING and/or DEVELOPMENT of the PRODUCTS for CUSTOMER.  
1.2 “AFFILIATE” shall mean (1) any corporation or business entity fifty percent (50%) or more of the voting stock or voting equity interests of which are owned directly or indirectly by a party; or (2) any corporation or business entity which directly or indirectly owns fifty percent (50%) or more of the voting stock or voting equity interests of a party; or (3) any corporation or business entity directly or indirectly controlling or under control of a corporation or business entity as described in (1) or (2).  
1.3 “AGENCY” or “AGENCIES” shall mean the U.S. Food and Drug Administration (hereinafter the “FDA”) Canadian Health Protection Branch, European Agency for Evaluation of Medicinal Products, hereinafter the “EMEA” and/or any successor organization of any such entity and any other government regulatory authority involved in granting approvals for the MANUFACTURING of the PRODUCTS for any TERRITORY, as such other AGENCIES are mutually agreed upon by the parties in writing.  
1.4 “BATCH” shall mean a standard quantity of PRODUCT for each MANUFACTURE expressed in units as defined in Attachment(s) A of this agreement.  
1.5 “cGMP” shall mean all laws and regulations relating to the MANUFACTURING of PRODUCT(S), including, but not limited to, the Current Good Manufacturing Practices as specified in the United States Code of Federal Regulations, the EU Good Manufacturing Guidelines and any other applicable laws, guidelines and/or regulations. In the event of conflict Current Good Manufacturing Practices as specified in the United States Code of Federal Regulations specifically as defined by 21 Code of Federal Regulation Sections 210, 211, et seq. will prevail.  
1.6 “CALENDAR QUARTER” shall mean shall mean each period of three full consecutive calendar months ending March 31, June 30, September 30 and December 31, as the case may be.  
1.7 “COMPOSITION” shall mean any components and/or raw materials that are used in the MANUFACTURING of PRODUCTS as listed in ATTACHMENT(s) A, hereto.  
1.8 “DELIVERY” shall be FCA FACILITY (Incoterms 2000) as per CUSTOMER’S instructions required on PURCHASE ORDERS.  
1.9 “EQUIPMENT” shall mean the equipment described in the BVL Master BATCH Record which is owned or leased by BVL or owned and leased by the CUSTOMER, included in Attachment F—(Customer Supplied Equipment List) and will be used by BVL for MANUFACTURING of PRODUCTS in accordance with the terms and conditions of this  
Page 3 of 38 BVL — PHARMION Manufacturing and Service Agreement  
 CONFIDENTIAL  
AGREEMENT.  
1.10 “FACILITY” or “FACILITIES” shall mean BVL’S FACILITY located at 000 Xxxxxxxxxx Xxxx, Xxxxxxx, Xxxx and all other BVL FACILITIES used in the MANUFACTURING of PRODUCTS; provided that such other FACILITIES have been agreed upon by the parties in writing in advance.  
1.11 “FIRM ORDER” shall mean a binding commitment, as established by a PURCHASE ORDER by CUSTOMER to have a BATCH as defined in Attachment(s) A of PRODUCT(S) MANUFACTURED by BVL hereunder.  
1.12 “IMMEDIATE/IMMEDIATELY” shall mean within twenty-four (24) hours.  
1.13 “INVESTIGATION” shall mean a detailed and thorough review of any atypical or MANUFACTURING deviation (or any other matter requiring review pursuant to the terms of this AGREEMENT) documented in a written report, approved at a senior management level. Each such written report shall include, without limitation, a detailed description of the atypical event, deviation or other matter, all steps taken to review such atypical event, deviation or other matter, a root cause analysis, what other lots of CUSTOMER PRODUCT were affected, if any, the proposed and/or taken corrective actions with applicable timelines and a recommendation for permanent correction.  
1.14 “MANUFACTURE / MANUFACTURING/ MANUFACTURED” shall mean all operations of BVL in the production, packaging, labeling, warehousing, quality control testing, including in-process, release and stability testing when applicable, release and shipping of PRODUCTS to meet the SPECIFICATIONS for the PRODUCTS.  
1.15 “NDA” shall mean New Drug Application.  
1.16 “PRODUCT(S)” shall mean the final packaged dosage forms listed separately in each Attachment(s) A to this agreement.  
1.17 “PROMPT/PROMPTLY” shall mean within thirty (30) days.  
1.18 “PURCHASE ORDER” shall mean a written form submitted by CUSTOMER to BVL authorizing the MANUFACTURE of the PRODUCT or other services as specified on the form, which references this agreement, or a quotation number provided by BVL or other document provided by BVL outlining the services to be performed and the price to be paid for each service listed on the PURCHASE ORDER according the PURCHASE ORDER requirements contained in Attachment B.  
1.19 “SPECIFICATIONS” shall mean the specifications, SOP’s and quality standards for PRODUCT(S) contained or referenced in the Master BATCH Record for each PRODUCT or as otherwise mutually agreed to in writing by the parties in accordance with standard procedures of BVL.  
Page 4 of 38 BVL — PHARMION Manufacturing and Service Agreement  
 CONFIDENTIAL  
1.20 “TERRITORY” shall mean all countries of the world.  
Page 5 of 38 BVL — PHARMION Manufacturing and Service Agreement  
 CONFIDENTIAL  
ARTICLE 2 — DESCRIPTION OF WORK  
2.1 CUSTOMER shall at its own expense supply BVL with sufficient quantities of API and CUSTOMER supplied COMPOSITION needed for the MANUFACTURE of the PRODUCT as specified in the forecast and supporting PURCHASE ORDERS, in order to meet CUSTOMER’S requirements for commercial and/or developmental quantities of PRODUCT in finished dosage form. CUSTOMER supplied COMPOSITION shall be delivered to BVL at least four weeks in advance of the scheduled MANUFACTURING date.  
2.2 Pursuant to subsequent provisions of this AGREEMENT, BVL shall MANUFACTURE CUSTOMER’S requirements for commercial and clinical quantities of PRODUCT in finished packaged dosage form as defined in Attachment(s) A. Such PRODUCT shall meet the SPECIFICATIONS. Subject to BVL’S prior written consent, such consent not to be unreasonably withheld, CUSTOMER may, from time to time, change SPECIFICATIONS, which may be subject to new pricing provided by BVL to CUSTOMER.  
2.3 Upon CUSTOMER’S request and at its expense BVL will perform development work on the PRODUCT(s) per outlined proposals that are submitted to CUSTOMER by BVL based on information provided to BVL by CUSTOMER and that are agreed upon by both parties in writing via a PURCHASE ORDER for the service referencing the Quotation Number provided.  
2.4 Upon written request BVL will provide CUSTOMER with a written proposal to provide services for preparing summary reports of all BATCH MANUFACTURING during a calendar year to be used by CUSTOMER in preparing its Annual Report for the product. CUSTOMER will confirm its acceptance of proposal via a non-cancelable PURCHASE ORDER authorizing BVL to commence such service.  
ARTICLE 3 — MANUFACTURE  
3.1 BVL represents that it has obtained, and will maintain at its sole cost and expense throughout the term of this AGREEMENT, all relevant non PRODUCT specific approvals required (so far as they are made known to BVL) by the AGENCIES for its MANUFACTURING FACILITIES and that its MANUFACTURING FACILITIES conform, and will throughout the term of this AGREEMENT conform, to the applicable cGMP and conform, or will conform, to similar requirements of all AGENCIES having jurisdiction over the MANUFACTURE of the PRODUCT at any time during the term of this AGREEMENT. No change affecting any government submission or approval required for the PRODUCT, either foreign or domestic, shall be made without prior written consent of CUSTOMER and in accordance with the Quality Agreement Attachment E of this AGREEMENT between both parties. Further, BVL will, at its sole cost and expense, obtain and maintain all non PRODUCT specific licenses, permits, certifications and approvals from any other local state, or federal governmental authorities which are or may become necessary for the MANUFACTURE of the PRODUCT. No changes to BVL’S MANUFACTURING FACILITIES, equipment, testing procedures, validation, suppliers of raw materials and components, or documentation systems that are specific to the PRODUCT shall be made without the prior written consent of  
Page 6 of 38 BVL — PHARMION Manufacturing and Service Agreement  
 CONFIDENTIAL  
CUSTOMER, unless required by an AGENCY, in such case BVL will notify CUSTOMER.  
3.2 BVL warrants that PRODUCT delivered to CUSTOMER pursuant to this AGREEMENT shall conform with the SPECIFICATIONS, and be in compliance with all applicable laws and regulations, and be in compliance with all regulatory requirements of AGENCIES, in the event of conflicting laws and regulations, compliance will be referenced by the then current 21 Code of Federal Regulation Sections 210, 211, et seq .  
3.3 All documents and updates with regard to the MANUFACTURE of the PRODUCT which are required by any AGENCY shall be provided by BVL, and BVL shall submit to all inquiries and inspections by any such AGENCY. All PRODUCT specific documents provided by BVL to any AGENCY shall be provided to CUSTOMER, in advance if feasible, and in no case shall such documents be provided to CUSTOMER no later than five (5) business days after such documents are provided to any AGENCY. BVL shall promptly notify CUSTOMER of all scheduled AGENCY inspections concerning the PRODUCT, whereupon CUSTOMER shall have the right to be present for such inspection. Any and all redacted written communications from any AGENCY pertaining to or affecting the PRODUCT shall be provided to CUSTOMER no more than five (5) business days after such communications are received by BVL. CUSTOMER shall provide BVL with copies of all regulatory agency approvals for PRODUCT(S) for both clinical studies and commercial use, in addition CUSTOMER shall provide BVL with two year advance plans for all planned filings with any AGENCY.  
3.4 For all routine commercial and/or special BATCH MANUFACTURE, BVL will conduct all MANUFACTURING and development operations required for the MANUFACTURE of the PRODUCT. Dispensing operations are to be performed using appropriate safety measures and containment techniques as dictated by current health, safety and environmental regulations, laws, AGENCY rules and regulations, and industry standards, provided such safety measures and containment techniques are harmonized.  
ARTICLE 4 — VOLUMES & SECOND SOURCE  
4.1 BVL shall supply CUSTOMER with CUSTOMER’S requirements of clinical and commercial PRODUCT in accordance with the terms of this AGREEMENT and for the TERRITORY. CUSTOMER will purchase from BVL and BVL will supply to CUSTOMER the quantities of the PRODUCT listed in Attachment A for the TERRITORY pursuant to the terms of the AGREEMENT and subject to the limitation in Article 5.  
4.2 CUSTOMER appoints BVL as the principal supplier for its requirements of those PRODUCT(S) listed in ATTACHMENT A(s). Principle supplier shall mean that CUSTOMER will procure from BVL at least 65% of its total requirements for all TERRITORIES for the PRODUCT(s). CUSTOMER may qualify at its discretion and cost other Third-Party contractors as it deems necessary to ensure uninterrupted supply and/or regulatory approvals in its TERRITORY, such quantities will not be included in Attachment(s) A. BVL and CUSTOMER acknowledge that quantities provided in forecasts in accordance with this AGREEMENT shall represent at least 65% of the total demand for PRODUCT by CUSTOMER on an annual basis.  
Page 7 of 38 BVL — PHARMION Manufacturing and Service Agreement  
 CONFIDENTIAL  
CUSTOMER may qualify a second source of supply other than BVL and may secure PRODUCT(S) from that second source. However, no Confidential Information, as defined in Article 9, disclosed there under by BVL to CUSTOMER shall be disclosed to such second source, it being understood that any PRODUCT specific information contained in the Master Batch Record is not confidential to BVL and may be disclosed to the second source.  
4.3 In addition CUSTOMER can qualify a second source principal supplier of PRODUCT(S) for TERRITORY if (i) BVL has materially failed to meet CUSTOMER’S orders for a period of more than three (3) consecutive months on accepted PO’s and said orders have been placed according to the terms of this AGREEMENT, or (ii) BVL has committed to an anticipatory breach of this AGREEMENT, or (iii) a Force Majeure has occurred which CUSTOMER reasonably believes will affect BVL’s ability to supply PRODUCT for a period of at least three (3) months (iv) BVL is non-Compliant with the regulations required to MANUFACTURE PRODUCT and is unable to cure such non-compliance. In the case of a Force Majeure, any of the above four types of occurrences or other material failure, both parties agree that CUSTOMER may use a second source as a principal supplier to supply all or some of the CUSTOMER’S needs until BVL is able to recommence production; provided that both parties shall agree upon a date to resume such production for CUSTOMER in an orderly manner. BVL shall assist CUSTOMER in transferring the MANUFACTURING Process to a Third-Party Contractor by providing technical assistance and documentation as necessary at mutually agreed upon fees provided.  
ARTICLE 5 — Forecasts and Purchase Orders  
5.1 Forecasts and Purchase Orders  
CUSTOMER and BVL shall cooperate in estimating and scheduling the MANUFACTURING of PURCHASE ORDERS. The annual quantity contained in forecast will be divided into individual BATCH PURCHASE ORDERS evenly distributed over the course of any 12 months period, provided that the total quantities ordered by these PURCHASE ORDERS meets the requirements of Article 5. BVL and CUSTOMER may upon written mutual agreement plan production to accommodate varying monthly demand for the PRODUCT.  
5.1.1 Five Year Planning Forecasts  
CUSTOMER will determine its good faith projected five year PRODUCT MANUFACTURE needs, and the initial forecast for each PRODUCT will be included in Attachment A for each presentation of the PRODUCT. The format of the forecast will be outlined in Attachment A.  
The first five-year forecast will be incorporated in Attachment A for each presentation of the PRODUCT to be MANUFACTURED under this AGREEMENT. The five-year forecast will be updated at least annually by CUSTOMER, which will be due by February 28 each year.  
In the event the updated five-year forecast represents an increase of greater than [...\*\*\*...] in any given year included in the prior year five-year forecast or [...\*\*\*...] over the last year planned in the previous forecast, then the updated forecast will be subject to acceptance by BVL based on available capacity. BVL shall confirm its rejection of the quantities for the first two years of  
Page 8 of 38 BVL — PHARMION Manufacturing and Service Agreement  
\*\*\* Confidential Treatment Requested  
 CONFIDENTIAL  
each annual update to the five year forecast which are in excess of such [...\*\*\*...] increase by written notice to CUSTOMER within one hundred and eighty (180) days after receipt of CUSTOMER’s annual update to the 5 year forecast.  
5.1.2 Rolling 12 Month Forecast  
One Hundred and Twenty (120) days in advance of the first day of each calendar quarter CUSTOMER will provide BVL with a 12 month rolling forecast for all presentations of the PRODUCT(S) included in Attachment(s) A. The first three (3) months or first calendar quarter will be considered FIRM ORDERS for which CUSTOMER will provide PURCHASE ORDERS for each BATCH of production required. BATCHES are defined in the PRODUCT Description incorporated in Attachment(s) A.  
5.1.3 Additional Services  
In the event that CUSTOMER request or an AGENCY requires additional services in support of PRODUCT(S), BVL will provide CUSTOMER with a proposal for such services. BVL will provide such services only upon receipt from CUSTOMER of a binding PURCHASE ORDER referencing the proposal number provided for the required service.  
5.3 It is BVL’S responsibility to maintain a sufficient inventory of BVL supplied COMPOSITION from mutually approved vendors, to meet the forecast. It is CUSTOMER’S responsibility to supply API or CUSTOMER COMPOSITION as indicated in Attachment(s) A. CUSTOMER will coordinate with BVL Materials Management Department according to BVL SOP’s on the specifics related to each shipment of API to BVL. BVL will be responsible to receive, sample, store and maintain the inventory at BVL. At the beginning of each month BVL will provide a standard monthly inventory report of CUSTOMER COMPOSITION. BVL will notify CUSTOMER IMMEDIATELY when the amount of CUSTOMER supplied materials available at BVL reaches the minimum quantity of material as agreed by both parties.  
5.4 Manufacturing Capacity — Obligation of BVL MANUFACTURE and of CUSTOMER to Purchase PRODUCT(S)  
5.4.1 BVL shall be obligated to MANUFACTURE PRODUCT only (i) in accordance with quantities forecasted by CUSTOMER in accordance with this Article 5, or (ii) as accepted by BVL for increased forecasts which require BVL’s acceptance pursuant to Section 5.1.1 hereof.  
5.4.2 In the event that CUSTOMER does not order at least [...\*\*\*...] of the quantities of the PRODUCTS forecasted by CUSTOMER for the [...\*\*\*...] in the initial or subsequent five year forecast (as such forecasts may be modified from on an annual basis by CUSTOMER as provided in this Article 5), then BVL shall provide written notice to CUSTOMER of such failure. If CUSTOMER does not within [...\*\*\*...] after the date of such notice place orders for a. quantity of the PRODUCTS necessary to satisfy at least [...\*\*\*...] of such forecasted quantities, then CUSTOMER shall be obligated to pay BVL a fee [...\*\*\*...]) for the quantities of the PRODUCTS not ordered during the relevant [...\*\*\*...] period to satisfy such [...\*\*\*...] requirement. Fees payable pursuant to this Section 5.4.2 shall be due on a monthly  
Page 9 of 38 BVL — PHARMION Manufacturing and Service Agreement  
\*\*\* Confidential Treatment Requested  
 CONFIDENTIAL  
basis in installments in accordance with the schedule of deliveries of the PRODUCTS that should have occurred in accordance with the then-current forecast.  
5.4.3 In the event of early termination of this AGREEMENT by CUSTOMER for any reason other than breach of this AGREEMENT by BVL then CUSTOMER shall be obligated to pay BVL a fee equal to [...\*\*\*...] for quantities of the PRODUCTS each BATCH not ordered for the remaining [...\*\*\*...] period up to the termination date of the AGREEMENT forecasted, but not MANUFACTURED during that period.  
5.4.4. The payment of fees by CUSTOMER to BVL pursuant to this Section 5.4 shall not apply (i) if CUSTOMER is entitled to qualify a supplier pursuant to Section 4.3 hereof, or (ii) BVL is in breach of this Agreement.  
ARTICLE 6 — PRICE & PAYMENT  
6.1 Price and Shipment  
6.1.1 The prices to be paid by CUSTOMER for the services and/or quantities of PRODUCT purchased pursuant to Article 5 of this AGREEMENT are specified in Attachment A(s) — PRODUCT Supplements or in quotations provided to CUSTOMER and confirmed by CUSTOMER’S PURCHASE ORDERS.  
6.1.2 All prices are FCA (Incoterms 2000), Ben Venue FACILITIES.  
6.1.3 CUSTOMER is responsible for all shipment cost, shipping charges will be paid directly by CUSTOMER.  
6.2 Price Adjustments  
6.2.1 Annual Price Adjustments  
Prices are subject to adjustment on an annual basis by BVL for the next succeeding year. BVL shall notify CUSTOMER of price adjustments for each presentation of the PRODUCT included in Attachment(s) A by October 31 of each year for the following year beginning Jan 1.  
The Annual Price adjustment shall be automatically calculated [...\*\*\*...] for the Producers Price Index for Pharmaceutical commodity code [...\*\*\*...].  
In the event that average for the Producers Price Index for Pharmaceutical commodity code [...\*\*\*...] is negative in any year, then the price will remain unchanged for the subsequent year.  
6.2.2 Price Adjustment on PRODUCT or Process SPECIFICATION Changes  
BVL reserves the right to adjust prices based on changes to the SPECIFICATIONS for the PRODUCT or Process regardless of the event or action causing the SPECIFICATIONS change, including but not limited to changes in inspection, packaging and labeling. All changes to the  
Page 10 of 38 BVL — PHARMION Manufacturing and Service Agreement  
\*\*\* Confidential Treatment Requested  
 CONFIDENTIAL  
SPECIFICATIONS and prices shall be mutually agreed to in writing by BVL and CUSTOMER.  
6.2.3 Prices for Developmental Services and Developmental MANUFACTURE  
Pricing for Developmental Services and Developmental MANUFACTURE will be provided to CUSTOMER in written proposals provided to CUSTOMER by BVL based on the services requested. CUSTOMER will confirm acceptance of the proposals by way of issuance of a PURCHASE ORDER referencing the quotation number provided on the proposal.  
6.3 Payment  
The purchase price for PRODUCT or services shall be paid to BVL no later than thirty (30) days after the date of BVL’S invoice to CUSTOMER. BVL will issue an invoice at such time that BVL’S Quality Control Department has completed its testing, found the PRODUCT suitable to be shipped and has shipped the documents identified in Attachment D or upon completion of other services as described in proposals. CUSTOMER may request that a BATCH be shipped before CUSTOMER release i.e., shipment in Quarantine. In the event a Quarantine shipment is made BVL will invoice on the shipment day. CUSTOMER will notify BVL in writing that a lot can be shipped in Quarantine and BVL will make all effort to honor this request.  
In the event of nonpayment of balances without reasonable cause within forty-five (45) days of the invoice date, CUSTOMER agrees to pay BVL a monthly late payment charge equal to one and one-half percent (1.5%) of the unpaid balance. Should unpaid balances extend beyond 60 days after an invoice has been issued, BVL reserves the right to require CUSTOMER to pay one-half (1/2) of the price for each BATCH at the time of PURCHASE ORDER issuance and the remaining one-half (1/2) of the price prior to the delivery of those BATCHES until all unpaid balances, including interest charges, have been paid. Should unpaid balances extend beyond 90 days BVL reserves the right to terminate this AGREEMENT unless cured by CUSTOMER within 30 days of notice, or may cease production and/or service performance until cured. CUSTOMER notify BVL in writing within 30 days of the invoice date that CUSTOMER is disputing payment of the invoice and the reason for such dispute.  
6.4 Payment for Non Validated Services or Production and Obsolete Materials  
CUSTOMER will be required to pay BVL for all PRODUCT MANUFACTURED during any period when any MANUFACTURING Process and Testing Procedures have not been fully developed and validated, regardless of whether the PRODUCT is accepted or rejected by the CUSTOMER unless such rejection is due to the gross negligence of BVL.  
CUSTOMER will be required to pay BVL for all packaging components and raw materials which were purchased by BVL for use specifically in the MANUFACTURE of the PRODUCT covered by this AGREEMENT should any of the BVL supplied COMPOSITION become obsolete due to the action of CUSTOMER or any AGENCY.  
6.5 Cancellation Fees  
Page 11 of 38 BVL — PHARMION Manufacturing and Service Agreement  
\*\*\* Confidential Treatment Requested  
 CONFIDENTIAL  
CUSTOMER will pay a cancellation fee equal to [...\*\*\*...] of the price of the BATCH if cancellation or postponement is made four (4) weeks in advance of the scheduled MANUFACTURING date. If cancellation or postponement is made less than four (4) weeks in advance of the scheduled MANUFACTURING date, CUSTOMER is responsible for payment of the full price of the scheduled MANUFACTURE of the BATCH(ES).  
6.6 Storage Fees  
CUSTOMER is responsible for storage charges as specified in Attachment C for PRODUCT stored for more than one month beyond BVL’S release. Short-term storage of PRODUCT in BVL’S warehousing FACILITIES beyond one month must receive prior approval from BVL. Such approval will be granted only on a space-available basis.  
6.7 Stability Program  
During the term of the this AGREEMENT and upon CUSTOMER request and BVL agreement, BVL will conduct and support, at CUSTOMER’S expense, all stability studies in progress or planned (e.g. NDA annual stability studies) as of the Effective Date until such studies are concluded. CUSTOMER shall be responsible for all costs of conducting any stability studies. Stability Program cost will be covered in a separate quotation provided by BVL to CUSTOMER based on the agreed upon protocol. CUSTOMER may also make arrangements for stability work to be performed at a facility other than BVL at CUSTOMERS expense.  
6.8 Inspection, Packaging and Labeling.  
CUSTOMER shall be responsible for and bear all costs associated with the design, development, quality release and Regulatory Approval of all labeling and packaging materials for PRODUCT. CUSTOMER shall perform its design, development, quality release and Regulatory Approval obligations hereunder in a timely manner sufficient for BVL to satisfy its MANUFACTURE obligations hereunder for the PRODUCT. Labeling and packaging developed by CUSTOMER will conform to labeling and packaging SPECIFICATIONS mutually agreed to in writing. Any change in the inspection, labeling and packaging SPECIFICATIONS will be evaluated by BVL for cost impact and BVL reserves the right to issue a price quotation pursuant to Article 6.  
ARTICLE 7 — QUALITY  
7.0 All items relating to the Quality Operations are incorporated in Attachment E — Quality Agreement.  
ARTICLE 8 — INDEMNIFICATION  
8.0. CUSTOMER hereby holds harmless and indemnifies BVL its employees, officers and affiliates against any and all claims, losses, liabilities, lawsuits, proceedings, costs and expenses, including, without limitation, reasonable attorneys’ fees, and the cost of recalls, resulting from, arising out of or in connection with injuries and/or death resulting from, arising out of or in connection with any use of the PRODUCT, including, without limitation, claims based on  
Page 12 of 38 BVL — PHARMION Manufacturing and Service Agreement  
\*\*\* Confidential Treatment Requested  
 CONFIDENTIAL  
negligence, warranty, strict liability or any other theory of PRODUCT liability or violation of any applicable laws or regulations, (collectively, “Claims”) except to the extent that such injuries or violations were the result of BVL’S negligence or willful misconduct in the MANUFACTURE of PRODUCT according to the terms of this AGREEMENT. If any Claim shall be made against BVL as to which this indemnification applies, BVL shall IMMEDIATELY inform CUSTOMER thereof of any claim which will be brought against BVL and/or CUSTOMER and in such case BVL shall not take any step nor conduct any legal proceeding before consulting and obtaining CUSTOMER’S written confirmation. At BVL’S request, CUSTOMER and/or its insurers shall assume direction and control of the defense against such claim, including, without limitation, the settlement thereof at the sole option of CUSTOMER or its insurer. BVL may, at its option and expense, have its own counsel participate in any proceeding, which is under the direction and control of CUSTOMER. BVL shall cooperate with CUSTOMER and its insurer in the disposition of any such matters. In addition, BVL may at any time relieve CUSTOMER of its responsibilities under this paragraph 8.0 as to any other claim.  
8.1 BVL hereby holds harmless and indemnifies CUSTOMER against any and all Claims resulting from, arising out of or in connection with negligence or willful misconduct of BVL in the MANUFACTURE of PRODUCT according to the terms of this AGREEMENT. If any claims shall be made against CUSTOMER as to which this indemnification applies, CUSTOMER shall IMMEDIATELY inform BVL thereof and at CUSTOMER’S request, BVL and/or its insurers shall assume direction and control of the defense against such claim, including, without limitation, the settlement thereof at the sole option of BVL or its insurer. CUSTOMER may, at its option and expense, have its own counsel participate in any proceeding, which is under the direction and control of BVL. CUSTOMER shall cooperate with BVL and its insurer in the disposition of any such matters. In addition CUSTOMER may at any time relieve BVL of its responsibilities under this paragraph as to any other claim.  
8.2 CUSTOMER and BVL will, at their own cost and expense, obtain and maintain in full force and effect, during the term of this AGREEMENT, Commercial General Liability insurance, written on the standard approved Policy Form, and Blanket Contractual Liability, with limits of liability of not less than $5,000,000 Combined Single Limit Bodily Injury and Property Damage covering its duties and obligations under the AGREEMENT. Said policy or policies of insurance shall include the other party as an Additional Insured. The limit of liability may be provided through a combination of Primary, Excess/Umbrella or Self-Insured Retention. In addition both parties shall maintain Workers Compensation Insurance.  
8.3 Reimbursement for Loss of Customer Supplied COMPOSITION  
BVL agrees to reimburse CUSTOMER up to a maximum of [...\*\*\*...] per BATCH pro-rated over the usable portion of the BATCH if applicable, for any loss of CUSTOMER supplied COMPOSITION (API or components / excipients) for each BATCH that does not meet SPECIFICATIONS and therefore can not be released, provided that the loss of such materials can be proven to be caused by, a.) the failure of BVL to follow procedures, B.) or BVL is negligent, or C.) there is willful misconduct on the part of BVL. In addition to this payment, BVL will be responsible for all MANUFACTURING fees incurred during the MANUFACTURE of the failed BATCH, pro-rated over the usable portion of the BATCH  
Page 13 of 38 BVL — PHARMION Manufacturing and Service Agreement  
\*\*\* Confidential Treatment Requested  
 CONFIDENTIAL  
if applicable.  
ARTICLE 9 — CONFIDENTIALITY  
9.1 The terms of this Confidentiality section are mutual between BVL and CUSTOMER as either a Disclosing Party or Receiving Party as the case may be.  
9.2 The Disclosing party will provide to the Receiving party certain information including but not limited to, data, reports, patents, patent applications, trade secrets, or the like concerning any scientific, technical, financial, trade, or business information applicable to the PRODUCT, including the contents of this AGREEMENT, the Confidential Information. The Receiving party agrees to protect and keep confidential all Confidential Information and all notes of information obtained pursuant to this Agreement. The Receiving Party agrees that it shall limit its use of the Confidential Information to performing certain services as mutually agreed to in writing by the Parties. The Receiving Party also agrees that it shall not use any Confidential Information, directly or indirectly, for its own benefit or that of any person, firm or corporation other than the Disclosing Party. All information exchanged regardless of format shall be considered Confidential Information.  
9.3 The Receiving Party agrees and acknowledges that the Confidential Information to be disclosed to it pursuant to this Agreement constitutes unique and valuable commercial and proprietary information of the Disclosing Party. Accordingly, the Receiving Party shall not duplicate, disclose, or discuss any such Confidential Information to or with third parties, without the prior written consent of the Disclosing Party. Except that the Receiving Party may disclose Confidential Information received by it under this Agreement only to those of its directors, officers, employees, agents, and consultants who have a need to know such Confidential Information in the course of the performance of their duties with respect to the purposes of this Agreement and who are bound by written agreement to protect the confidentiality of such Confidential Information in accordance with the terms hereof.  
9.4 Notwithstanding anything to the contrary herein, the Receiving Party shall not be obligated to maintain the confidentiality of any information provided to it under this Agreement which:  
a. Is already in the public domain at the time of disclosure to it, or  
b. at any time after disclosure to the Receiving Party becomes public knowledge through no fault of the Receiving Party; or  
c. is disclosed to the Receiving Party by any third party who is free to make such disclosure; or  
d. is disclosed by the Receiving Party with the prior written consent of the Disclosing Party, or  
e. is information which the Receiving Party can establish was in it’s possession prior to  
disclosure or was subsequently and independently developed by employees of or on behalf of  
the Receiving Party without use, direct or indirect, of Confidential Information protected by  
this Agreement; or  
f. is required to be disclosed pursuant to a requirement of law, subject to provisions outlined in Item 9.8 of Article 9 of this agreement.  
Page 14 of 38 BVL — PHARMION Manufacturing and Service Agreement  
 CONFIDENTIAL  
9.5 The confidential undertakings and agreements of the Receiving Party shall survive termination or expiration of this AGREEMENT. Promptly upon termination of this AGREEMENT and request of the Disclosing Party, the Receiving Party shall return to the Disclosing Party all originals and copies of documents or written materials (including electronic notes or documents) of the Disclosing Party containing any Confidential Information and any notes or written materials created by the Receiving Party or summaries thereof containing any Confidential Information of the Disclosing Party or other Confidential Information in its possession. This AGREEMENT shall not be construed as a grant of any right or license to the Receiving Party with respect to Confidential Information or the Disclosing Party’s Product or as a requirement to either party to enter into any further arrangement with respect to Confidential Information or the Disclosing Party’s Product.  
9.6 The confidentiality obligations of this AGREEMENT shall be maintained for a period of five years beyond the expiration or termination of this AGREEMENT.  
9.7 Provided all obligations of this agreement are maintained, the parties understand and acknowledge that the other may now market or have under development products which are competitive with products now offered or which may be offered by the other, and the parties’ communications hereunder will not serve to impair the right of other to develop, make, use, procure, or market products or services now or in the future which may be competitive to those offered by the other party nor for the parties to disclose any planning or other information to the other.  
9.8 Notwithstanding any provision herein to the contrary, in the event that any Receiving Party hereafter becomes obligated by mandatory applicable law, regulatory rule or judicial or administrative order to disclose Confidential Information or any portion thereof, to any third party, governmental authority or court, the Receiving Party shall IMMEDIATELY notify the Disclosing Party thereof of each such requirement and identify the Confidential Information so required thereby, so that the Disclosing Party may seek an appropriate protective order or other remedy with respect to narrowing the scope of such requirement and/or waive Receiving Party’s compliance with the provisions of this AGREEMENT. The parties will consult with each other and cooperate fully on the provisions of this Agreement to be redacted in any filings made by CUSTOMER with the United States Securities and Exchange Commission or as otherwise required by applicable law.  
9.9 Both parties agree that should this AGREEMENT be breached, money damages would be inadequate to remedy such a breach. As a result, the non-breaching party shall be entitled to seek, and a court of competent jurisdiction may grant, specific performance and injunctive or other equitable relief as a remedy for any such breach of this Agreement. Such remedy shall be in addition to all other remedies, including money damages, available to a non-breaching party at law or in equity.  
9.10 Upon request, each party shall return all copies of the Confidential Information to the other party, except for a single copy to be kept by its legal counsel in its confidential file for the  
Page 15 of 38 BVL — PHARMION Manufacturing and Service Agreement  
 CONFIDENTIAL  
purpose of determining compliance with its obligations of this agreement.  
9.11 Neither party will issue any press release or other public announcement relating to any activities involving the other party without the prior written consent of the other party, except where such announcements are required by law or regulation. The parties will use all reasonable efforts to consult with the other and cooperate with respect to wording of any such announcement. PRODUCT labeling (primary, secondary, insert) and government filings may indicate that the PRODUCT has been MANUFACTURED for CUSTOMER by BVL.  
9.12 New techniques, inventions, processes and know-how (hereinafter “New Developments”) that are useful in the MANUFACTURING, using or selling of the PRODUCT may be developed by BVL during the performance of this AGREEMENT. To the extent CUSTOMER’S Confidential Information is the principle basis for any such New Development, then CUSTOMER shall have ownership of such New Development, and BVL shall have a non-transferable, non-exclusive, royalty-free, worldwide, perpetual, license to make, use and sell New Development so long as BVL’S use does not compromise CUSTOMER’S Confidential Information. Notwithstanding the grant of such license, BVL shall not use such New Development or CUSTOMER’S Confidential Information to compete, or assist third parties to compete directly with CUSTOMER in the sale of PRODUCT. BVL agrees to cooperate in the filing and prosecution of all New Development patent applications owned by CUSTOMER, but CUSTOMER shall bear all associated expenses. As to New Developments that may be developed by BVL during the performance of this AGREEMENT and do not involve CUSTOMER’S Confidential Information, BVL grants CUSTOMER a royalty-free, irrevocable, worldwide, transferable and sub-licensable non-exclusive license to make, have made, use or sell the New Development in connection with PRODUCT.  
ARTICLE 10 — TERM  
10.1 This AGREEMENT shall become effective on the date first stated above and, except as otherwise provided herein, shall be in effect for an initial term of five (5) years. So long as this AGREEMENT is in force, it shall be automatically renewed for additional terms of two (2) years each, unless one party shall elect to terminate this AGREEMENT by notice thereof to the other party in writing at least twenty-four (24) months prior to expiration of the then existing term.  
10.2 Each party agrees to meet within [...\*\*\*...] prior to the end of the [...\*\*\*...] of this AGREEMENT, and at the end of each subsequent [...\*\*\*...] period thereafter, to review the terms of this AGREEMENT and to make any changes which both parties agree are required to: (i) be in compliance with cGMPs and legal & business understandings that may have occurred during the interim; (ii) accommodate changing PRODUCT and MANUFACTURING demands; and (iii) any other changes that may be required in the development or MANUFACTURE of the PRODUCT. This Review Meeting will have no other effect on the other terms of Article 10.  
10.3 Either party may terminate this AGREEMENT for a material breach by the other party by giving the breaching party written notice, specifying the breach relied on, and giving the breaching party three (3) months to cure such breach. If the default has not been cured at the end of the three (3) month period, then, upon notice thereof to the breaching party by the other, this  
Page 16 of 38 BVL — PHARMION Manufacturing and Service Agreement  
\*\*\* Confidential Treatment requested  
 CONFIDENTIAL  
AGREEMENT shall terminate. Termination for breach will have no effect on performance obligations or amounts to be paid which have accrued up to the effective date of such termination.  
10.4 In the event of any proceedings, voluntary or involuntary, in bankruptcy or insolvency, by or against CUSTOMER or BVL, or the appointment with or without the parties’ consent of a receiver for either party, the other party shall be entitled to terminate this AGREEMENT without any liability whatsoever. Such termination shall not effect any claim for damages available to the terminating party.  
10.5 In event of termination, transition will be conducted in such a manner as to not cause inconvenience to either party. Should termination be initiated by BVL, BVL shall notify CUSTOMER in writing of its desire to so terminate; provided, however, that termination by BVL shall not be effective until CUSTOMER has located and arranged for continuation of MANUFACTURE of PRODUCT with another supplier, and further provided that such termination procedure shall not extend beyond two (2) years from BVL’S written notice of termination to CUSTOMER. The parties will cooperate during such period to continue any such ongoing project. In the event of notice of such early termination by BVL, BVL shall perform such functions reasonably necessary or required in connection with the orderly wind-down of any active Project as required by the terms of this AGREEMENT or federal, state, or local laws or regulations, including applicable AGENCY regulations. In the event of termination by BVL, CUSTOMER shall pay BVL for MANUFACTURING and other services completed up to the actual date of such termination within thirty (30) days of CUSTOMER’S receipt of all results, reports, data, samples, and other deliverables to be provided pursuant to this AGREEMENT, reduced by all prior payments made by CUSTOMER for said services and production. In the event the funds received by BVL prior to such termination exceed costs incurred to the date of termination, BVL shall refund the difference to CUSTOMER within thirty (30) days after the effective date of termination.  
10.6 CUSTOMER shall have the right to terminate this AGREEMENT upon twenty four (24) months written notice to BVL in the event CUSTOMER is purchased by, or CUSTOMER enters into a licensing, partnership, joint venture, or marketing and distribution AGREEMENT with, a third party which has the interest and capability to supply finished parenteral dosage forms for the PRODUCT, or with ninety days written notice when a AGENCY does not license the PRODUCT for marketing, the AGENCY withdraws marketing approval, or CUSTOMER otherwise terminates the commercial sale of PRODUCT in all TERRITORIES. If CUSTOMER terminates pursuant to either provision, CUSTOMER shall reimburse BVL for any purchases of special materials used for PRODUCT that cannot be canceled, unless these materials can be utilized by BVL on other projects. The reimbursement shall be made within thirty (30) days upon receipt by CUSTOMER of an invoice itemizing the material costs. BVL agrees to transfer to CUSTOMER any materials for which CUSTOMER has paid under this provision. Termination under this provision shall have no effect on payment obligations that have accrued up to the effective date of termination. CUSTOMER shall have no further obligations to BVL.  
10.7 BVL may elect to terminate this AGREEMENT under the circumstances set forth below after giving CUSTOMER notice and an opportunity to cure in accordance with the provisions of  
Page 17 of 38 BVL — PHARMION Manufacturing and Service Agreement  
 CONFIDENTIAL  
Section 10.3 if (i) CUSTOMER fails to provide a Forecast and PURCHASE ORDERS at a required time; (ii) CUSTOMER fails to pay undisputed invoices within 120 days of invoice date. Termination under this option shall have no effect on the parties’ obligations that were incurred prior to termination.  
ARTICLE 11 — NOTICES  
Any and all notices or other communications required or permitted under this AGREEMENT must be in written form, and be deemed to have been given upon receipt of telefax to the notified party (followed by hard copy of documents) addressed to the party to be notified as listed in the beginning of this AGREEMENT, or to such other address as either party shall have heretofore specified in a notice to the other in the manner herein provided.  
If to BVL:  
Ben Venue Laboratories, Inc.  
000 Xxxxxxxxxx Xxxx  
Xxxxxxx, Xxxx 00000  
Attn: General Manager, Contract Manufacturing Services  
FAX 000-000-0000  
With Copy To:  
Ben Venue Laboratories, Inc.  
000 Xxxxxxxxxx Xxxx  
Xxxxxxx, Xxxx 00000  
Attn: President & COO  
FAX 000-000-0000  
If to CUSTOMER:  
Pharmion Corporation  
0000 00xx Xxxxxx Xxxxx 000  
Xxxxxxx, XX 00000  
Attn: Vice President and General Counsel  
FAX 000-0000000  
With Copy To:  
Pharmion Corporation  
Attn: Vice President Global Manufacturing  
0000 X. 000xx Xxxxxx  
Xxxxxxxx Xxxx, XX 00000  
Page 18 of 38 BVL — PHARMION Manufacturing and Service Agreement  
 CONFIDENTIAL  
FAX 000-000-0000  
ARTICLE 12 — WAIVER  
No failure on the part of either party to exercise, and no delay in exercising, and no course of dealing with respect to, any right, power or privilege under this AGREEMENT shall operate as a waiver thereof, nor shall any single or partial exercise of any right, power or privilege under this AGREEMENT preclude any other or further exercise thereof or the exercise of any other right, power or privilege.  
ARTICLE 13 — ASSIGNMENT OF AGREEMENT  
Neither this AGREEMENT, nor any rights or obligations hereunder, may be assigned by either party hereto, EXCEPT to an affiliate or a purchaser of all or substantially all of the stock or assets of either one of the parties, without the prior written consent of the other party, which shall not be unreasonably withheld. Any subsequent assignee, purchaser, or transferee shall be bound by the terms of this AGREEMENT. Any attempted assignment that does not comply with the terms of this Article 13 shall be void and of no further force or effect.  
ARTICLE 14 — GOVERNING LAW  
This AGREEMENT will be governed and construed in accordance with the laws of the State of Delaware.  
ARTICLE 15 — FORCE MAJEURE  
No party shall be liable for a failure or delay in performing any of its obligations under this AGREEMENT if, but only to the extent that such failure or delay (directly or indirectly) is due to causes beyond the reasonable control of the affected party, including (i) acts of God; (ii) fire, explosion, or unusually severe weather; (iii) war whether declared or undeclared, invasion, riot or other civil unrest; (iv) enactment or change of laws and regulations by any AGENCY or Government, conflict of laws or regulations by any AGENCY or government, orders, restrictions, actions, embargoes or blockages; (v) national or regional emergency; and (vi) injunctions, strikes, lockouts, labor trouble or other industrial disturbances (regardless of the reasonableness of the demands of labor); (vii) acts of terrorism, provided that the party affected shall PROMPTLY notify the other of the force majeure condition and shall exert reasonable efforts to eliminate, cure or overcome any such causes and to resume performance of its obligations as soon as possible.  
ARTICLE 16 — TITLE OF GOODS  
Title to and risk of loss of the bulk API and waste, in process and in PRODUCT, shall remain with CUSTOMER.  
ARTICLE 17 — DEBARMENT  
Page 19 of 38 BVL — PHARMION Manufacturing and Service Agreement  
 CONFIDENTIAL  
Neither party shall use in any capacity persons, or the services of, persons that are debarred, are on the Debarment List, or that have been convicted of actions that could lead to debarment as described in Section 306(a) and (b) of the Federal Food, Drug, and Cosmetic Act.  
ARTICLE 18 — ENTIRE AGREEMENT  
This AGREEMENT, together with the Attachments identified herein that shall form part of this AGREEMENT, constitutes the entire understanding between the parties and is intended as a final expression of their agreement and as a complete statement of terms and conditions thereof, and shall not be amended except in writing signed by an authorized representative of each party and specifically referring to this AGREEMENT. If there is any inconsistency between this document and any other writings, which are referred to or are incorporated herein, or any PURCHASE ORDERS, invoices, or other documents relating to the PRODUCT, the terms and conditions of this document shall take precedence. This AGREEMENT supersedes any previous agreements or arrangements between the parties and any customary practice of the parties at variance with the terms hereof.  
ARTICLE 19 — SEVERABILITY  
In the event any provision of this AGREEMENT is held to be invalid or unenforceable, the valid or enforceable portion thereof and the remaining provisions of this AGREEMENT will remain in full force and effect.  
ARTICLE 20 — INDEPENDENT CONTRACTOR  
Neither party shall have the right to control the activities of the other in the performance of this AGREEMENT and each shall perform as an independent contractor, and nothing herein shall be construed to be inconsistent with that relationship or status. Under no circumstances shall the employees or agents of one party be considered employees or agents of the other. This AGREEMENT shall not constitute, create, or in any way be interpreted as a joint venture, partnership, or formal business organization of any kind.  
ARTICLE 21 — AMENDMENTS  
No provision of this AGREEMENT or the Attachments attached hereto may be modified or supplemented, except by an instrument in writing signed by BVL and CUSTOMER.  
ARTICLE 22 — HEADINGS  
The Article headings appearing herein are included only for the convenience of reference and are not intended to affect the interpretation of any provision of this AGREEMENT.  
ARTICLE 23 — REVIEW BY LEGAL COUNSEL  
Each of the parties agrees that it has read and had the opportunity to review this AGREEMENT  
Page 20 of 38 BVL — PHARMION Manufacturing and Service Agreement  
 CONFIDENTIAL  
with its legal counsel. Accordingly, the rule of construction that any ambiguity contained in this AGREEMENT shall not be construed against the party or its representative who drafted this AGREEMENT or any portion thereof.  
ARTICLE 24 — RECALL  
In the event (a) any AGENCY or governmental authority issues a request, directive, or order that PRODUCT be recalled, or (b) a court of competent jurisdiction orders such a recall, or (c) the parties reasonably determine after consultation with each other that PRODUCT should be recalled (Recall), the parties shall take all appropriate corrective action. CUSTOMER shall also retain the right to conduct a PRODUCT recall for safety reasons CUSTOMER deems significant. In the event that PRODUCT is recalled or that CUSTOMER is required to disseminate information regarding PRODUCT(S) covered by this AGREEMENT, CUSTOMER shall so notify BVL and, not later than may be required to permit CUSTOMER to meet such obligations, BVL shall provide CUSTOMER with such assistance in connection with such recall as may reasonably be requested by CUSTOMER. BVL will only be financially responsible for the costs of any recall for which its actions or negligence are directly responsible and in accordance with the terms and limits specified in Section 8.3 BVL shall not be responsible for any loss of profit, sales or consequential damages due to recalls.  
ARTICLE 25 — ENGLISH LANGUAGE  
This AGREEMENT, all schedules, attachments, and exhibits hereto, and all reports, documents and notices required hereunder, referred to herein or requested by the parties, in connection with this AGREEMENT shall be written in the English language. Except as otherwise required by applicable law, the binding version of all of the foregoing shall be the English version.  
Page 21 of 38 BVL — PHARMION Manufacturing and Service Agreement  
 CONFIDENTIAL  
IN WITNESS WHEREOF, the parties hereto have executed this AGREEMENT by their duly authorized representatives as of the dates set forth below:  
 For: Ben Venue Laboratories, Inc.   
 Signature:  
 /s/ XXXXXX XXXXXX Date: 12-19-05   
 Xxxxxx Xxxxxx   
 President and COO   
 For: CUSTOMER   
 Signature:  
 /s/ XXXXXX XXXXXXXXX Date: 12-14-05   
 Name:  
 Xxxxxx Xxxxxxxxx   
 Title:  
 COO/Ex. V.P.   
 Page 22 of 38 BVL — PHARMION Manufacturing and Service Agreement  
 CONFIDENTIAL  
Attachment A1  
1.) Product Descriptions  
BVL Project Code: [...\*\*\*...] Pharmion Project Code:  
 PRODUCT Description (INCLUDING   
PACKAGING DESCRIPTION FOR EACH BATCH   
END ITEM NUMBER FROM THE SAME BVL End Item BVL Nude Vial CUSTOMER Size/Order   
NUDE VIAL) Number Number Item Number Quantity   
[...\*\*\*...]  
 [...\*\*\*...] [...\*\*\*...] [...\*\*\*...]   
[...\*\*\*...]  
 [...\*\*\*...] [...\*\*\*...] [...\*\*\*...]   
[...\*\*\*...]  
 [...\*\*\*...] [...\*\*\*...] [...\*\*\*...]   
[...\*\*\*...]  
 [...\*\*\*...] [...\*\*\*...] [...\*\*\*...]   
 Page 23 of 38 BVL — PHARMION Manufacturing and Service Agreement  
\*\*\* Confidential Treatment Requested  
 CONFIDENTIAL  
Attachment A1  
Azacitidine  
2.) Azacitidine PRODUCT TESTING SPECIFICATIONS  
 PRODUCT Description (INCLUDING PACKAGING BVL Final   
DESCRIPTION FOR EACH END ITEM NUMBER FROM BVL End Item BVL Nude Product Specification   
THE SAME NUDE VIAL) Number Vial Number Number   
 Azacitidine, 100mg lyo in a 30ml vial, labeled vial in unit carton with insert, 14 unit cartons shrink wrapped  
 [...\*\*\*...] [...\*\*\*...] [...\*\*\*...]   
Azacitidine, 100mg lyo in a 30ml vial, unlabeled bulk packaged  
 [...\*\*\*...] [...\*\*\*...] [...\*\*\*...]   
 Page 24 of 38 BVL — PHARMION Manufacturing and Service Agreement  
\*\*\* Confidential Treatment Requested  
 CONFIDENTIAL  
Attachment A1  
Azacitidine  
3.) Materials supplied by Pharmion and BVL  
For: Azacitidine, 100mg lyo in a 30ml vial, labeled vial in unit carton with insert, 14 unit cartons shrink wrapped BVL End Item Number [...\*\*\*...]  
 BVL Item Number ITEM DESCRIPTION SUPPLIED BY CUSTOMER SUPPLIED BY BVL  
[...\*\*\*...]  
 [...\*\*\*...] X  
[...\*\*\*...]  
 [...\*\*\*...] X  
[...\*\*\*...]  
 [...\*\*\*...] X  
[...\*\*\*...]  
 [...\*\*\*...] X  
[...\*\*\*...]  
 [...\*\*\*...] X   
[...\*\*\*...]  
 [...\*\*\*...] X  
[...\*\*\*...]  
 [...\*\*\*...] X  
[...\*\*\*...]  
 [...\*\*\*...] X  
[...\*\*\*...]  
 [...\*\*\*...] X  
[...\*\*\*...]  
 [...\*\*\*...] X  
Page 25 of 38 BVL — PHARMION Manufacturing and Service Agreement  
\*\*\* Confidential Treatment Requested  
 CONFIDENTIAL  
Attachment A1  
Azacitidine  
3.) Materials supplied by Pharmion and BVL  
For: Azacitidine, 100mg lyo in a 30ml vial, unlabeled bulk packaged  
BVL End Item Number [...\*\*\*...]  
 BVL Item Number ITEM DESCRIPTION SUPPLIED BY CUSTOMER SUPPLIED BY BVL  
[...\*\*\*...]  
 [...\*\*\*...] X  
[...\*\*\*...]  
 [...\*\*\*...] X  
[...\*\*\*...]  
 [...\*\*\*...] X  
[...\*\*\*...]  
 [...\*\*\*...] X  
[...\*\*\*...]  
 [...\*\*\*...] X   
[...\*\*\*...]  
 [...\*\*\*...] X  
[...\*\*\*...]  
 [...\*\*\*...] X  
[...\*\*\*...]  
 [...\*\*\*...] X  
Page 26 of 38 BVL — PHARMION Manufacturing and Service Agreement  
\*\*\* Confidential Treatment Requested  
 CONFIDENTIAL  
Attachment A1  
Azacitidine  
4.) FORECAST  
4.1 Five Year Forecast — to be submitted by Pharmion to BVL on an annual basis by February 28 each year for the following 5 years (for example by February 28, 2005 BVL will receive from Pharmion the 5 year forecast for 2006 through 2010), BVL will supply Pharmion with an electronic copy of the five year forecast form. The following represents the understandings of the parties with respect to the estimated volumes to be associated with this AGREEMENT for the next five years.  
 BATCH   
PRODUCT BVL End Item Size/Order 2005 2006 2007 2008 2009  
Description Number Quantity Batches Batches Batches Batches Batches  
Azacitidine, 100mg  
lyo in a 30ml vial,  
labeled vial in  
unit carton with  
insert, 14 unit  
cartons shrink  
wrapped  
 [...\*\*\*...] [...\*\*\*...] [...\*\*\*...] [...\*\*\*...] [...\*\*\*...] [...\*\*\*...] [...\*\*\*...]  
Azacitidine, 100mg  
lyo in a 30ml vial,  
labeled vial in  
unit carton with  
insert, 14 unit  
cartons shrink  
wrapped  
 [...\*\*\*...] [...\*\*\*...]   
Azacitidine, 100mg  
lyo in a 30ml vial,  
unlabeled bulk  
packaged  
 [...\*\*\*...] [...\*\*\*...] [...\*\*\*...] [...\*\*\*...] [...\*\*\*...] [...\*\*\*...]  
Azacitidine, 100mg  
lyo in a 30ml vial,  
unlabeled bulk  
packaged  
 [...\*\*\*...] [...\*\*\*...]   
Note: Above forecast is based on annual vial requirements assuming a theoretical [...\*\*\*...] batch. Annual vial requirements can be produced with a smaller vial batch size provided that the equivalent number of total vials are delivered annually.  
Page 27 of 38 BVL — PHARMION Manufacturing and Service Agreement  
\*\*\* Confidential Treatment Requested  
 CONFIDENTIAL  
Attachment A1  
Azacitidine  
4.2 Rolling 12 month Forecast — to be provided Quarterly by Pharmion to BVL. BVL will provide Pharmion with an electronic copy utilizing Microsoft Excel of the following form for submission, which will include 12 monthly periods for forecasting. Pharmion shall provide the rolling 12 month forecast 120 days in advance of the first day of the next Calendar Quarter.  
The following is for representation of the format only.  
 Batch   
PRODUCT BVL End Item Size/Order   
Description Number Quantity Month 1 Month 2 Month 3 Month 4 Month 5  
 Azacitidine, 100mg  
lyo in a 30ml vial,  
labeled vial in  
unit carton with  
insert, 14 unit  
cartons shrink  
wrapped  
 [...\*\*\*...] [...\*\*\*...]   
Azacitidine, 100mg  
lyo in a 30ml vial,  
labeled vial in  
unit carton with  
insert, 14 unit  
cartons shrink  
wrapped  
 [...\*\*\*...] [...\*\*\*...]   
Azacitidine, 100mg  
lyo in a 30ml vial,  
unlabeled bulk  
packaged  
 [...\*\*\*...] [...\*\*\*...]   
Azacitidine, 100mg  
lyo in a 30ml vial,  
unlabeled bulk  
packaged  
 [...\*\*\*...] [...\*\*\*...]   
Page 28 of 38 BVL — PHARMION Manufacturing and Service Agreement  
\*\*\* Confidential Treatment Requested  
 CONFIDENTIAL  
Attachment A1  
Azacitidine  
5.) Pricing for Azacitidine  
BATCH PRICING  
 Effective From [...\*\*\*...]  
 BVL Nude BATCH Price Per BATCH for  
 Vial BVL End Item Size/Order End Item with No Split  
PRODUCT Description Number Number Quantity Pack-outs  
Azacitidine, 100mg  
lyo in a 30ml vial,  
labeled vial in  
unit carton with  
insert, 14 unit  
cartons shrink  
wrapped  
 [...\*\*\*...] [...\*\*\*...] [...\*\*\*...] [...\*\*\*...]  
Azacitidine, 100mg  
lyo in a 30ml vial,  
labeled vial in  
unit carton with  
insert, 14 unit  
cartons shrink  
wrapped  
 [...\*\*\*...] [...\*\*\*...] [...\*\*\*...] [...\*\*\*...]  
Azacitidine, 100mg  
lyo in a 30ml vial,  
unlabeled bulk  
packaged  
 [...\*\*\*...] [...\*\*\*...] [...\*\*\*...] [...\*\*\*...]  
Azacitidine, 100mg  
lyo in a 30ml vial,  
unlabeled bulk  
packaged  
 [...\*\*\*...] [...\*\*\*...] [...\*\*\*...] [...\*\*\*...]  
All other configurations/quantities/ packaging splits will be quoted separately upon request by Pharmion to BVL. The above prices are for full BATCH quantities packaged as described.  
Page 29 of 38 BVL — PHARMION Manufacturing and Service Agreement  
\*\*\* Confidential Treatment Requested  
 CONFIDENTIAL  
Attachment B  
Information to be provided on each Purchase Order  
 1. BVL end item number  
2. BVL PRODUCT description  
3. BATCH Size in vials from Quotation or as described in Attachment A  
4. Number of Batches  
5. Delivery Date (Date for BVL to release the lot and deliver product & batch record)  
6. BVL Quotation Number if Product/Service not included in Attachment A, or Reference this  
AGREEMENT Date  
7. Delivery Address  
8. Shipping requirements & Instructions (temperature, dedicated trucks, preferred carrier, overnight etc.) Contact name for Preferred Carrier, Temperature Monitors, Ship on BVL  
Release or Hold for Customer Authorization to Ship.  
9. Billing Address  
10. Special Instructions for Specific Batch  
 (Examples)  
 “Annual Stability Batch”  
 “Process Validation Batch”  
 “Special Sampling Instructions mutually agreed to and included in Batch Record”  
11. Customer Lot# and Expiration Date if Applicable  
Page 30 of 38 BVL — PHARMION Manufacturing and Service Agreement  
 CONFIDENTIAL  
Attachment C  
MONTHLY STORAGE FEES  
Effective through [...\*\*\*...]  
BVL has limited storage capacity. Therefore, customers are expected to have their PRODUCT(S) shipped to them no later than 30 days after BVL Quality Operations has released their PRODUCT and has shipped the documents identified Attachment D to CUSTOMER. Should unforeseen events lead to a request by a customer for storage beyond this 30 day grace period, the customer must request such storage by BVL in writing at least 15 days before the initial 30 day grace period has expired. The request will be granted only if BVL has sufficient storage capacity to accommodate the request. Then, the following terms will apply.  
Monthly storage fees are assessed on a per lot basis, and begin to accrue 30 days following the BVL release date of the BATCH by BVL’S Quality Operations Dept. BVL will request a separate PURCHASE ORDER be issued for the storage charges. These charges listed below will be reviewed and updated annually.  
Monthly Storage Charge — per square foot per month  
 Room Temperature Storage.  
 $ [...\*\*\*...]   
Refrigerated Storage  
 $ [...\*\*\*...]   
Freezer Storage  
 $ [...\*\*\*...]   
Minimum Storage Charge — per lot per month  
 Room Temperature Storage.  
 $ [...\*\*\*...]   
Refrigerated Storage  
 $ [...\*\*\*...]   
Freezer Storage  
 $ [...\*\*\*...]   
Page 31 of 38 BVL — PHARMION Manufacturing and Service Agreement  
\*\*\* Confidential Treatment Requested  
 CONFIDENTIAL  
Attachment D  
Documents to be supplied by BVL to Pharmion as part of BATCH release  
1.) BVL Certificate of Analysis  
 2.) BVL Certificate of Compliance  
 3.) Copies of the executed BATCH Record  
 4.) Raw Material C of A’s generated by BVL used in the lot (Part of Batch Record)  
 5.) Reports documenting deviations and investigations (Part of batch record)  
 6.) Out Of Specification Results and investigations (Part of batch record)  
NOTE: Raw analytical data, Environmental data (Airborne particulates, Pressure differential between MANUFACTURING rooms and the other data BVL is monitoring) is not copied or otherwise provided to a customer except that these data can be inspected as part of scheduled or for cause audits by the customer.  
Page 32 of 38 BVL — PHARMION Manufacturing and Service Agreement  
 CONFIDENTIAL  
ATTACHMENT E  
QUALITY AGREEMENT  
By and between Ben Venue Laboratories Inc. and Pharmion Inc.  
DEFINITIONS SHALL BE THE SAME AS THOSE CONTAINED IN THE MANUFACTURING AND SERVICE AGREEMENT.  
E.1 Licensure of PRODUCT(S) in TERRITORIES  
CUSTOMER is responsible for Licensure of the PRODUCT in all TERRITORIES.  
CUSTOMER is responsible to insure that all filings with any AGENCY are consistent with the SPECIFICATIONS for the PRODUCT.  
BVL will be responsible for contacting CUSTOMER to discuss changes which impact the MANUFACTURING license(s) for any TERRITORY. CUSTOMER will be responsible for applying for any necessary variation to the MANUFACTURING license(s) to allow production of the PRODUCT(S).  
CUSTOMER will be responsible for informing the appropriate regulatory authorities of any future variation to the Manufacturer’s License and for accordingly informing BVL of any such variations that may affect the MANUFACTURE of the PRODUCTS.  
E.2 Maintenance of PRODUCT License(s)  
CUSTOMER will be responsible for insuring that the BVL’S Master Batch Record,  
SPECIFICATIONS and SOP’s relevant to the MANUFACTURING of the PRODUCT comply with the License(s) of all Territories.  
CUSTOMER shall provide BVL with copies of all approvals by all AGENCIES for use of the PRODUCT in clinical trials and commercial distribution in all TERRITORIES. CUSTOMER shall also advise BVL of all planned filing at least 2 years in advance or as soon as such information is known by CUSTOMER.  
E.3 PRODUCTION AND CONTROL  
BVL will ensure that its production and quality control comply with the SPECIFICATIONS.  
BVL and CUSTOMER undertake to provide the other with all reasonable information and assistance so that the both parties can discharge their responsibilities under this AGREEMENT.  
Page 33 of 38 BVL — PHARMION Manufacturing and Service Agreement  
 CONFIDENTIAL  
E.4 Date of Manufacture and Expiration Dating  
The shelf-life and storage conditions of the PRODUCTS will be in accordance with the  
requirements of the License(s). The format for Date of MANUFACTURE and expiration date of the PRODUCTS will be as specified on the PURCHASE ORDER provided by CUSTOMER or as contained in the SPECIFICATIONS whichever is applicable. Each BATCH will have a unique lot number in accordance with the SPECIFICATIONS and BVL SOP’s.  
E.5 Retained Samples  
CUSTOMER shall retain sufficient samples of the labeled and secondary packaged  
PRODUCT as required to be in compliance with all License(s).  
E.6 Packaging Items and Raw Materials — COMPOSITION  
BVL is responsible for arranging supply of the BVL COMPOSITION as specified in Attachment(s) A. BVL COMPOSITION will be in accordance with the SPECIFICATIONS mutually agreed to by BVL and CUSTOMER. API and CUSTOMER COMPOSITION will be provided by the CUSTOMER as specified in Attachment(s) A and in accordance with the SPECIFICATIONS.  
E.7 PRODUCT Analysis and Sampling Plan  
The Sterility, Bacterial Endotoxin and the Particulate testing will be carried  
out by the BVL in accordance with the approved methods, SPECIFICATIONS and BVL SOP’s. BVL will take samples from MANUFACTURE and perform analytical release testing according the SPECIFICATIONS or in the event analytical release testing is performed by an outside laboratory or the CUSTOMER, BVL will deliver to the outside laboratory or the CUSTOMER samples for analytical release testing, in accordance with the instructions contained in the SPECIFICATIONS.  
E.8 Stability Testing  
CUSTOMER will be responsible for arranging the Stability testing of the PRODUCTS.  
All stability samples will be taken as described in the SPECIFICATIONS for the PRODUCT.  
E.9 Finished PRODUCT Release — Responsibilities for Release of PRODUCT  
BVL will provide CUSTOMER with a Certificate of Analysis, a BVL formatted Certificate of  
Compliance, signed by BVL’S QA Representative, for the operations carried out by BVL  
and a copy of the executed BATCH record for the PRODUCT. CUSTOMER is responsible for the release of  
the PRODUCT for further packaging, distribution, sale, or for use within the TERRITORIES.  
E.10 Complaints  
Page 34 of 38 BVL — PHARMION Manufacturing and Service Agreement  
 CONFIDENTIAL  
It is expected that most complaints and inquiries will be received by CUSTOMER.  
CUSTOMER and BVL will inform each other in writing of all quality related complaints and CUSTOMER will, where appropriate, provide BVL with returned samples for examination and investigation. Potentially serious complaints will be communicated to BVL IMMEDIATELY by CUSTOMER. BVL will investigate all complaints PROMPTLY and will provide CUSTOMER with a written report. In the case of a potentially serious complaint BVL will make an initial response within 3 working days, however, it is accepted that completion of an investigation may take longer. CUSTOMER will be responsible for correspondence with all complainants.  
E.11 Recall of Batches  
The decision to recall a BATCH is the responsibility of CUSTOMER. The nature and urgency of a recall will be decided following discussions (where appropriate), between the CUSTOMER and BVL. Once the decision to recall a BATCH has been taken, the recall will be initiated by CUSTOMER. CUSTOMER will inform BVL of any action that is required of it. CUSTOMER will be responsible for contacting and discussing the nature of the recall with the relevant regulatory AGENCIES. Assistance may be required from BVL on technical matters. CUSTOMER will update BVL as to the progress of the recall.  
E.12 Serious Incidents  
If a serious incident, such as sterility assurance failure, occurs relating either to the  
PRODUCT MANUFACTURED for CUSTOMER, or other products, which are produced using the same FACILITIES as those used for the PRODUCTS and where such an incident could impact the CUSTOMER’S PRODUCT, BVL will inform CUSTOMER.  
E.13 INSPECTIONS  
Any deficiencies noted during an inspection of BVL’S FACILITIES by an AGENCY, which relate directly to the PRODUCT or its MANUFACTURING must be brought to the attention of CUSTOMER. BVL will IMMEDIATELY notify CUSTOMER of all PRODUCT specific AGENCY inspections.  
E.14 WAREHOUSING  
The PRODUCT(S) will be stored at BVL under conditions contained in the SPECIFICATIONS and in accordance with BVL’S SOP(S).  
E.15 SUB-CONTRACTING  
BVL will not subcontract to a third party any of the work entrusted under this AGREEMENT other than what is agreed to in the SPECIFICATIONS, without CUSTOMER’S prior evaluation, and written approval of the sub-contractor and sub-contract agreements.  
Page 35 of 38 BVL — PHARMION Manufacturing and Service Agreement  
 E.16 CONTROL AND SUPPLY OF INFORMATION  
Documentation to be supplied with batches — Attachment D  
For each BATCH of finished PRODUCT, BVL will provide CUSTOMER with a Certificate of  
Analysis, a BVL formatted Certificate of Compliance signed by BVL’S QA Representative, for the  
MANUFACTURE by BVL and a copy of the executed BATCH records.  
E.15 Retention of BATCH Documentation  
The BATCH records consisting of MANUFACTURING, packaging, analytical, control, release and delivery documentation, data and records for each BATCH of PRODUCT will be maintained by BVL in a secure location for a period of 7 years.  
E.16 Finished PRODUCT Post Marketing Surveillance  
Post marketing surveillance will be the responsibility of the CUSTOMER.  
E.17 Quality Defects  
If PRODUCT in any MANUFACTURE fails to comply with the SPECIFICATIONS, either upon receipt or during the shelf-life of the PRODUCT, CUSTOMER will formally contact BVL in writing. BVL will carry out a formal investigation according to BVL SOP’s of its operations and report its findings in full to CUSTOMER in writing. Decision on final disposition of PRODUCT will be jointly agreed by BVL and CUSTOMER.  
E.18 Right to Observe, Inspect and Audit  
CUSTOMER and any third-party consultant appointed by CUSTOMER shall have reasonable access to observe and inspect BVL’S FACILITIES and SOP’S with respect to the PRODUCT(S), including all analytical and MANUFACTURING documentation related to the PRODUCT(S) upon reasonable prior notice to and scheduling in advance by BVL. Any such CUSTOMER appointed third-party consultant must be pre-approved by BVL, although such approval shall not be unreasonably or untimely withheld. Upon scheduling in advance, CUSTOMER shall have the right to one annual audit and at such other times as mutually agreed upon by the parties for cause to (i) observe, inspect and audit the manner in which BVL conducts MANUFACTURE of CUSTOMER PRODUCT(S), (ii) inspect BVL’S FACILITIES and records relating to BVL’S quality and other controls related to its MANUFACTURE of the PRODUCT(S), and (iii) observe and audit the books and records of BVL relating to the existence, safeguard, use and maintenance by BVL of the CUSTOMER COMPOSITION. BVL shall make such books and records available to CUSTOMER for review. Information provided during audits will be limited to technical information related to the MANUFACTURE of PRODUCT(S) no financial information is provided for auditing.  
CUSTOMER employees and CUSTOMER’S consultants who inspect BVL’S FACILITIES shall at all times comply with BVL’S rules, regulations and SOP’s relating to their inspection and CUSTOMER assumes responsibility for the presence and actions of its employees on BVL’S  
Page 36 of 38 BVL — PHARMION Manufacturing and Service Agreement  
 CONFIDENTIAL  
premises. Quality Audits are limited to one per calendar year and will be scheduled in advance with BVL’S Quality Operations Department.  
CUSTOMER shall PROMPTLY provide BVL with a written report of all audit findings. BVL shall PROMPTLY provide CUSTOMER with a written response to all audit observations with corrective actions when appropriate.  
E.19 — Annual Product Review and Annual Reports  
CUSTOMER shall be responsible for the Annual Product Review and Annual Reports required by any AGENCY.  
Page 37 of 38 BVL — PHARMION Manufacturing and Service Agreement  
 CONFIDENTIAL  
Attachment F  
CUSTOMER Supplied Equipment  
None  
Page 38 of 38 BVL — PHARMION Manufacturing and Service Agreement