UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): August 18, 2020 (August 13, 2020)

CytoDyn Inc.
(Exact name of registrant as specified in its charter)

Delaware	**000-49908**	**83-1887078**
(State or other jurisdiction of incorporation)	**(SEC File Number)**	**(I.R.S. Employer Identification No.)**

1111 Main Street, Suite 660 **Vancouver, Washington**	**98660**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (360) 980-8524

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
None	**None**	**None**

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On August 13, 2020, director David F. Welch, Ph.D. informed the Board of Directors of CytoDyn Inc. (the "Company") that in light of increasing personal and professional commitments, he would not be seeking re-election to the Board of Directors at the 2020 annual meeting. Dr. Welch's term will expire effective upon the conclusion of the 2020 Annual Meeting of Stockholders. Dr. Welch's decision not to stand for re-election was not a result of any disagreement with the Company. The Company thanks Dr. Welch for his service and dedication during his tenure as a member of the Board.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The Company is re-filing the Distribution and Supply Agreement between CytoDyn Inc. and American Regent, Inc., which was filed as Exhibit 10.16 to its Annual Report on Form 10-K filed on August 14, 2020, because the exhibit was missing the legend on the first page of the exhibit indicating that certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Exhibit No.	Description
10.1	Distribution and Supply Agreement between CytoDyn Inc. and American Regent, Inc. dated July 2, 2020*

* Certain confidential portions of this Exhibit were omitted by means of marking such portions with asterisks because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CytoDyn Inc.

August 18, 2020

By: */s/ Michael D. Mulholland*
Name: Michael D. Mulholland
Title: Chief Financial Officer

EXHIBIT 10.1

Certain identified information has been excluded because it is both not material and would likely cause competitive harm if publicly disclosed.

DISTRIBUTION AND SUPPLY AGREEMENT

This Distribution and Supply Agreement (this **"Agreement"**) is entered into as of July 2, 2020, (the **"Effective Date"**) by and between American Regent, Inc., a New York corporation having an address at 5 Ramsey Road, Shirley, New York, 11967 (**"American Regent"**), and CytoDyn, Inc., a Delaware corporation having an address at 1111 Main Street, Suite 660, Vancouver, Washington 98660 (**"CytoDyn"**). American Regent and CytoDyn are each referred to herein individually as a **"Party"** and together as the **"Parties"**.

RECITALS

WHEREAS, CytoDyn owns the rights to certain know-how and intellectual property to manufacture and supply the Product (defined below) in the Territory (defined below);

WHEREAS, American Regent has experience in the distribution, marketing and sale of pharmaceutical products in the Territory; and

WHEREAS, CytoDyn desires to grant American Regent, and American Regent desires to accept, the exclusive license to distribute and sell the Product in the Field (defined below) subject to the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the foregoing and the covenants and promises contained in this Agreement, the Parties agree as follows:

1. DEFINITIONS

Unless specifically set forth herein, the following terms, whether used in the singular or the plural, shall have the respective meanings set forth below.

1.1 "Adverse Event" means any untoward medical occurrence in a patient or clinical investigation subject who is administered a Product that has at least a reasonably possible causal relationship with the treatment for which a Product is used. An untoward medical occurrence can include any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of a Product and may include a pre-existing condition that worsened in severity after administration of a Product.

1.2 "Affiliate" means, with respect to any Party, any other Person directly or indirectly controlling or controlled by, or under direct or indirect common control with, such Party. For purposes of this definition, a Person shall be deemed to "control" any other Person if it owns or controls a sufficient interest in the voting equity (or other comparable ownership if the other Person is not a corporation) such that it can direct, order or control the actions of such other Person. For the purposes of this Agreement, any company in the Daiichi Sankyo family of companies shall not be considered an Affiliate of American Regent hereunder.

1.3 "Agreement" has the meaning set forth in the Preamble of this Agreement.

1.4 "American Regent" has the meaning set forth in the Preamble of this Agreement.

1.5 "American Regent Indemnitees" means American Regent and each of its respective Affiliates, subsidiaries, equity holders, directors, managers, officers, employees, trustees, representatives, consultants, sublicensees, agents, successors and permitted assigns.

1.6 "**Applicable Laws**" means all applicable statutes, ordinances, regulations, codes, rules, or orders of any kind whatsoever of any governmental authority in the Territory, including without limitation the Federal Food, Drug, and Cosmetic Act (21 U.S.C. ch. 9 § 301 et seq. ("**the Act**")), the Generic Drug Enforcement Act of 1992 (21 U.S.C. § 335a et seq.), the Prescription Drug Marketing Act, the Anti-Kickback Statute (42 U.S.C. § 1320a-7b et seq.), the Health Insurance Portability and Accountability Act of 1996, the Federal False Claims Act (31 U.S.C. §3729-3733), the Department of Health and Human Services Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers, released April 2003, the Antifraud and Abuse Amendment to the Social Security Act, the AMA guidelines on gifts to physicians, the Securities Act of 1933 and the Securities Exchange Act of 1944 (together with all rules promulgated thereunder (including rules of Official Bodies)) as well as any state laws impacting the promotion of pharmaceutical products, including any state anti-kickback/fraud and abuse related laws, all as amended from time to time.

1.7 "Business Day" means any day other than a Saturday, a Sunday, or a day on which banks in the State of New York are required or authorized to close.

1.8 "**Change of Control**" means with respect to a Party, the occurrence of any of the following: (a) the sale of all or substantially all of such Party's (or such Party's controlling Affiliate's) assets or business relating to this Agreement; (b) a merger, reorganization or consolidation involving such Party (or such Party's controlling Affiliate) in which the voting securities of such Party (or such Party's controlling Affiliate, as applicable) outstanding immediately preceding thereto cease to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (c) a Person, or group of Persons, acting in concert acquire, directly or indirectly, more than fifty percent (50%) of the voting equity securities or management control of such Party (or such Party's controlling Affiliate, as applicable), in one or a series of related transactions.

1.9 "Commercially Reasonable Efforts" means exercising such reasonable efforts and diligence in accordance with a Party's reasonable business, legal, medical and scientific judgment and accordance with the efforts and resources such Party would use for a pharmaceutical product which is of similar market potential, at a similar stage of its product life, taking into account the competitiveness of the marketplace, the proprietary position of the product and the profitability of the product.

1.10 "Competing Product" means any biopharmaceutical drug product labeled for treating Coronavirus Disease 2019 (COVID-19) that targets against the CCR5 receptor as an active moiety, alone or in combination with other ingredients and is therapeutically interchangeable with the Product.

1.11 "Confidential Information" means with respect to a Party all confidential Intellectual Property and confidential or proprietary information relating to the business and affairs of a Party or any of its Affiliates that are disclosed by or on behalf of a Party to the other Party and all information derived therefrom, including financial information, business opportunities, information relating to pharmaceutical products of any nature in any form; provided, however, that **"Confidential Information"** shall not include any information that (a) was already in the public domain at the time of disclosure; (b) becomes part of the public domain through no action or omission of the receiving Party after disclosure to the receiving Party; (c) was already known to the receiving Party, other than under an obligation of confidentiality to the disclosing party, at the time of the disclosure by the other Party; (d) was independently discovered or developed by the receiving Party without the use of Confidential Information belonging to the disclosing Party as shown by pre-existing proof, or (e) was disclosed to the receiving Party, other than under an obligation of confidentiality to which a Third Party was subject, by a Third Party who had no obligation to the disclosing Party not to disclose such information to others, as shown by independent proof.

1.12 "**Cost of Goods Sold**" means [***]. CytoDyn's 2020 estimates of Cost of Goods Sold for the Product are set forth in Exhibit A, attached hereto.

1.13 "CytoDyn" has the meaning set forth in the Preamble of this Agreement.

1.14 "CytoDyn Indemnitees" means any of CytoDyn and its Affiliates, subsidiaries, equity holders, directors, managers, officers, employees, trustees, representatives, consultants, sublicensees, agents, successors and permitted assigns.

1.15 "CytoDyn Product" means a subcutaneous injectable biopharmaceutical drug product that contains CytoDyn's Leronlimab (a humanized monoclonal antibody (also known as PRO 140) targeting against the CCR5 receptor) as the only active pharmaceutical ingredient but not labeled for treating COVID-19 sold by the CytoDyn Product Distributor.

1.16 "CytoDyn Product Distributor" any party, including CytoDyn or a licensed and/or authorized Third Party, commercializing the CytoDyn Product in the Territory.

1.17 "Effective Date" has the meaning set forth in the Preamble of this Agreement.

1.18 "FDA" means the United States Food and Drug Administration or any successor agency which issues a Regulatory Approval for the Marketing of a Product in the United States.

1.19 "Field" means distribution, marketing, offering to sell and selling the Product for the treatment of COVID-19.

1.20 "Firm Order" means a binding, non-cancelable agreement to purchase Product as evidenced by a purchase order, sales acknowledgement or other evidence to purchase Product in writing and delivered to CytoDyn by American Regent and accepted by CytoDyn in accordance with Section 6.2.

1.21 "First Commercial Sale" means with respect to a Product, the first commercial sale of the Product by American Regent to a Third Party in the Field in the Territory in final dosage form packaged for use by end-users, other than for testing purposes and/or sale for experimental purposes, promotional purposes, compassionate use programs, named patient programs, test market purposes, or similar purposes.

1.22 "current Good Manufacturing Practices" or "cGMP" means at any time the quality systems and good manufacturing practices as set forth in 21 C.F.R. (Parts 210 and 211) and any other Applicable Laws, directives, rules, regulations, guides and guidance in existence in the Territory at that time.

1.23 "Intellectual Property" means all patents, copyrights, trademarks, service marks, service names, trade names, internet domain names, e-mail addresses, applications or registrations for any of the foregoing, or extensions, renewals, continuations or re-issues thereof, or amendments or modifications thereto, brandmarks, brand names, trade dress, labels, logos, know-how (including the Product Know-How), show-how, technical and non-technical information, trade secrets, formulae, techniques, sketches, drawings, models, inventions, designs, specifications, processes, apparatus, equipment, databases, research, experimental work, development, pharmacology and clinical data, software programs and applications, software source documents, Third Party licenses, and any similar type of proprietary intellectual property right vesting in the owner and/or licensee thereof pursuant to the Applicable Laws of any relevant jurisdiction or under any applicable license or contract, whether now existing or hereafter created, together with all modifications, enhancements and improvements thereto.

1.24 "Latent Defect" means a defect that existed at the time that title to Product passed to American Regent which could not have been detected by American Regent utilizing American Regent's usual and customary inspection procedures for incoming finished product intended for distribution in the Territory, which in any event will be in accordance with American Regent's cGMP obligations.

1.25 "Losses" has the meaning set forth in Section 10.1.

1.26 "Manufacture" means to make Product in compliance with cGMP, including to process, prepare, make and Test the raw materials used in the preparation of Product and to Test a Product prior to release for Packaging, filling, packaging, labeling, and preparation of Product for shipment, in each case in a finished dosage form ready for administration to humans, and **"Manufacturing"** has a corresponding meaning.

1.27 "Market" means to distribute, market, offer to sell and/or sell for purposes of a commercial sale, and **"Marketing"** has a corresponding meaning.

1.28 "NDC Number" means the National Drug Code number, which is a unique 10-digit, 3-segment number that is a universal product identifier for drugs in the United States that identifies the labeler/vendor, the product and the trade package size.

1.29 "Net Profit" means an amount equal to the [***] of the Product less (i) the [***], and (ii) the [***].

1.30 "Net Profit Split" [***].

1.31 "Net Sales" means the total gross sales of the Product (number of units shipped times the invoice price per unit) by American Regent, its sub-licensees and Affiliates to independent third party customers, less the following deductions incurred, allowed, paid, accrued, or specifically allocated, to the extent actually taken by such third party customers on such sales: (a) [***] of gross sales in the Territory to cover cash discounts given by American Regent; (b) reasonable estimates for customary trade discounts, quantity discounts, credits, rebates, charge backs, and fees (including without limitation those to group purchasing organizations, managed-care entities, wholesalers, and government agencies, including without limitation Medicare and Medicaid); (c) reasonable estimates for allowances or credits to customers on account of retroactive price reductions or returns (including without limitation wholesaler and retailer returns), billing adjustments, bid defaults, shelf stock adjustments, promotional payments, or other similar allowances affecting the Product or on account of retroactive price reductions affecting the Product; (d) sales and excise taxes, customs, and any other taxes, all to the extent added to the sale price and paid by the selling party and not refundable in accordance with Applicable Law and without reimbursement from any third party (but not including taxes assessed against the income derived from such sale); (e) government fees based on the sale of the Product, including any fees due or made pursuant to the Patient Protection and Affordable Care Act; (f) reasonable estimates for allowances and credits to third parties on account of rejected, damaged, returned or recalled Product; (g) royalties payable to third parties in connection with the sale of the Product in the Territory; (h) prompt pay discounts paid to customers; and (i) other specifically identifiable amounts that have been credited against or deducted from the Product's gross sales and are substantially similar to those credits and deductions listed above. Notwithstanding anything to the contrary, the calculation of Net Sales shall be made in accordance with American Regent's standard practices for other pharmaceutical products, consistently applied.

1.32 "Official Body" means any national, federal, state or local government or government of any subdivision thereof, or any parliament, legislature, council, agency, authority, board, commission, self-regulatory authority, department, bureau or instrumentality thereof, or any court, tribunal, grand jury, mediator or arbitrator, whether foreign or domestic, in each case having jurisdiction in the relevant circumstances.

1.33 "Package" means to package and label Product for Marketing and "**Packaging**" has a corresponding meaning.

1.34 "Person" means any individual, partnership, limited partnership, joint venture, syndicate, sole proprietorship, company or corporation with or without share capital, unincorporated association, trust, trustee, executor, administrator or other legal personal representative or other entity or Official Body.

1.35 "Product" means a subcutaneous injectable biopharmaceutical drug product labeled for treating COVID-19 that contains CytoDyn's Leronlimab (a humanized monoclonal antibody (also known as PRO 140) targeting against the CCR5 receptor) as the only active pharmaceutical ingredient. For clarity, Product excludes any intravenous or infusible biopharmaceutical drug product.

1.36 "Product Know-How" means the data, information, expertise, trade secrets, manufacturing, mixing and production procedures, technical assistance, and shop rights, known to in the possession of or licensed to CytoDyn or its Affiliates, whether generally known to others or not, and relating to the Manufacturing, Packaging, Marketing and/or Testing of Product, including:

(a) characteristics, selection of properties and data relating to materials, such as excipients, used or useful in the Manufacturing, Packaging and/or Testing of Product;

(b) techniques, equipment and methods used or useful in the Manufacturing, Packaging or Testing of Product;

(c) equipment and data relating to the Manufacturing, Packaging or Testing of Product; and

(d) all *in vivo* or clinical, pharmacology, toxicology, safety and efficacy data, formulary submissions, pharmaco-economic data, and other such information useful or required in preparing applications for or obtaining or maintaining Regulatory Approval and/or for the Manufacturing, Packaging, Marketing and/or Testing of Product.

1.37 "Product Liability Claim" means any Third-Party claim involving any actual or alleged death or bodily or emotional injury arising out of or relating to any Product sold in the Territory.

1.38 "Product Technology" means collectively Product Know-How and all other Intellectual Property in or to the Product.

1.39 "Quality Agreement" means the mutually agreed Quality Agreement to be entered into by and between American Regent and CytoDyn, or a CytoDyn Affiliate, in accordance with Section 4.4.

1.40 "Recall" has the meaning set forth in Section 5.2(a).

1.41 "Regulatory Approval" means all approvals or authorizations granted by the FDA for the Marketing of a Product in the Territory.

1.42 "Regulatory Requirements" means all applicable Regulatory Approvals, licenses, registrations, cGMPs, and authorizations and all other requirements of the FDA in relation to Product, including each of the foregoing which is necessary for, or otherwise governs, the Manufacture, Marketing, Packaging and Testing of Product in the Territory.

1.43 "Sales, Marketing and Distribution Costs" means [***] to compensate American Regent for its direct costs associated with selling, marketing and distributing the Product (including the costs of obtaining the NDC Number).

1.44 "Specifications" means the specific requirement under a Biologics License Application ("**BLA**") approved by the FDA to govern the quality and integrity of the Product, including, but not limited to, procedures, formula, process, testing method, etc.

1.45 "Supply Interruption" has the meaning set forth in Section 6.4.

1.46 "Tax(es)" means, with respect to American Regent, all federal, state, local, county, foreign and other taxes or government charges constituting sales, use, transfer, value added, customs, duty or excise taxes payable by American Regent in connection with the importation or sale of Product.

1.47 "Term" has the meaning set forth in Section 9.1.

1.48 "Territory" means the United States of America, including its territories, possessions, districts, protectorates and commonwealths.

1.49 "Test" means to test a product or its ingredients prior to release for further processing or for shipping and Marketing in compliance with Applicable Law and **"Testing"** has the corresponding meaning.

1.50 "Third Party" means any Person, other than CytoDyn, American Regent or their respective Affiliates.

2. DISTRIBUTION RIGHTS

2.1 American Regent Distribution in the Field.

(a) Upon and subject to the terms and conditions of this Agreement, and upon FDA approval of the BLA for the Product in the Field, CytoDyn hereby appoints American Regent as the sole and exclusive authorized distributor in the Field in the Territory, with the right to subcontract to its subcontractors, to sell and distribute the Product in the Field in the Territory.

(b) Under the exclusive appointment set forth in Section 2.1(a), American Regent shall obtain exclusively from CytoDyn the Product for Marketing in the Field in the Territory. CytoDyn shall exclusively supply the Product (even to CytoDyn itself) to American Regent for Marketing by American Regent in the Field in the Territory in accordance with the terms of this Agreement.

(c) CytoDyn shall not sell, directly or indirectly through a distributor, any Product bearing an American Regent NDC number.

2.2 Retention of Rights. For the avoidance of doubt, CytoDyn retains all rights to the Product Know-How and Intellectual Property worldwide. CytoDyn retains the right to market, distribute and sell the Product during the Term outside of the Field or outside the Territory, by itself and/or through its Affiliates and/or Third Parties.

2.3 Restrictions on Marketing of Product. From and after the Effective Date, American Regent shall not Market or export the Product outside the Field in the Territory, or Market or export the Product to any Person who, to the knowledge of American Regent intends, or is likely to, Market or export the Product outside the Field in the Territory.

2.4 Covenant Not to Market Competing Product. From and after the Effective Date and during the Term of this Agreement, American Regent shall not Market a Competing Product in the Field in the Territory.

3. MARKETING

3.1 Marketing Obligations. American Regent shall, at its sole costs, use Commercially Reasonable Efforts to Market the Product in the Field in the Territory, including, without limitation, directing the methods of sale and distribution, organization and management of sales and Marketing and pricing in accordance with the terms and conditions of this Agreement.

3.2 Pricing.

(a) American Regent shall solely set the resale prices for the Product in the Field in accordance with Applicable Laws. American Regent shall be responsible for allowing credit for sales returns in connection with the sale of a Product to its customers according to its established procedures for other products. American Regent shall have sole responsibility for deciding distribution related decisions, including, but not limited to, issues concerning market launch, final customer pricing and customer contracts. Within ninety (90) days after the First Commercial Sale, the Parties shall conduct a business review meeting, either in person or telephonically, to discuss market conditions, supply estimates and expected Product trends.

3.3 NDC Number. American Regent shall submit drug listing information to the FDA with respect to American Regent being the distributor of the Product. American Regent shall only distribute and sell Product bearing an NDC Number that reflects American Regent as the distributor and seller thereof. Within fourteen (14) days after the Effective Date, or such other time period mutually agreed by the Parties in writing, American Regent shall obtain an NDC Number for each packaging configuration of the Product. American Regent shall have thirty (30) days after the Effective Date to conduct additional diligence on the use of its NDC Number on the Product packaging and it may terminate this Agreement with fifteen (15) days written notice in the event it determines that there is an unacceptable risk to American Regent in using its NDC Number.

3.4 Rebate; Processing.

(a) American Regent shall only be responsible for those federal, state and local government and private purchasing, pricing or reimbursement programs with respect to the

Product sold by American Regent, including taking all necessary and proper steps to execute agreements and file other appropriate reports and other documents with governmental and private entities. American Regent shall be solely responsible for payment and processing of all rebates, whether required by contract or local, state or federal law, for the Product sold by American Regent.

(b) Upon the written request of American Regent, CytoDyn agrees to provide to American Regent information and data in its possession that American Regent could not otherwise reasonably obtain but must provide to any state or federal government regulators (including without limitation Centers for Medicare and Medicaid Services) pursuant to government-mandated price reporting requirements for the Product (such requirements, "**Pricing Regulations**", and such information and data, and the similarly required customer information in subsection (c) below, collectively "**Compliance Information**"), including, as applicable, aggregate sales and rebate transaction data, average manufacturer price and best price calculations, other data or information regarding sales or pricing (both on and off-invoice) of the Product or CytoDyn Product, and method(s) used for generating the foregoing information, subject to the following conditions:

(i) No later thirty (30) days before the end of a calendar quarter, American Regent shall request in writing the required Compliance Information for that calendar quarter and allow CytoDyn up to fifteen (15) days to provide the requested Compliance Information;

(ii) American Regent shall use all Compliance Information only for compliance with Pricing Regulations and not any other purpose, particularly (but not limited to) set or attempt to set its resale price or its rebate, discount or other incentive amount offered to its customers, sub-distributors, suppliers, or competitors of CytoDyn or American Regent;

(iii) American Regent may disclose the Compliance Information only to its employees and agents who are primarily responsible for American Regent's compliance with Pricing Regulations (collectively, "**Representatives**"), in each case who (A) need to know such Compliance Information to perform its Pricing Regulations obligations, (B) are not involved in any activities related to price setting or negotiation with any other customers, suppliers, or competitors of CytoDyn, and (C) are bound in writing by restrictions regarding disclosure and use of the Compliance Information no less restrictive than those set forth herein;

(iv) American Regent shall be fully liable for any breach of its obligations herein by its Representatives; and

(v) CytoDyn warrants that to its knowledge, all Compliance Information provided to American Regent will be complete and accurate in all material respects. In the event that American Regent discovers, through a routine audit, reconciliation, its compliance program or otherwise, that any government price reporting has been miscalculated or other data provided to American Regent regarding the sales or pricing of the Product in the Territory are inaccurate, it shall notify CytoDyn immediately of such circumstance and shall work with CytoDyn to ensure that proper pricing information is provided to American Regent as soon as possible, but in no event later than thirty (30) days after the end of the calendar quarter in which such inaccuracy is discovered.

(c) In the event that American Regent is required to access Compliance Information to fulfill required reporting obligations pursuant to Pricing Regulations for the Product, and upon written request, CytoDyn shall disclose to American Regent a comprehensive list of customers to whom the CytoDyn Product is directly sold by the CytoDyn Product Distributor, and CytoDyn shall (i) identify mutual customers (wholesalers or other customers that are buying both the American Regent labeled Product from American Regent and the CytoDyn Product from the CytoDyn Product Distributor, and (i) ensure that such mutual customers are segregating the CytoDyn Product from the Product sold by American Regent. Such customer information shall also be Compliance Information hereunder. If American Regent reasonably believes that any mutual customers are charging American Regent fees for services contemplated in any agreements between a mutual customer and the CytoDyn Product Distributor, the Parties shall cooperate to confirm such, and in such a case, American Regent shall not be responsible for paying such fees for service. Rather, the CytoDyn Product Distributor shall work with American Regent to promptly correct such invoices and, if not corrected, the CytoDyn Product Distributor shall be responsible for all outstanding customer fees related to its sales of the American Regent labeled Product.

(d) With respect to rebates that American Regent is obligated to pay pursuant to any government (Federal Medicaid or state assistance) rebate programs for amounts charged to an American Regent NDC Number ("Government Rebates"), American Regent shall be responsible for the processing, handling and payment of all such Government Rebates relating to the Products labeled with an American Regent NDC Number. American Regent shall not be responsible for any reporting obligations associated with the CytoDyn Product.

(e) For the avoidance of doubt, (i) the CytoDyn Product Distributor shall assume all obligations to honor and fulfill the payment of chargeback claims, administrative fees, indirect sales rebates, and all other rebates or fees associated with an indirect sale of the CytoDyn Product through a wholesaler outside the Field with respect to Products labeled with the CytoDyn Product Distributor's NDC Number; (ii) the CytoDyn Product Distributor shall be responsible for all required government reporting of CytoDyn Product sold by the CytoDyn Product Distributor; and (iii) all other payments made to customers for sales of the CytoDyn Product sold by the CytoDyn Product Distributor, or audits submitted from customers, shall be the sole responsibility of the CytoDyn Product Distributor.

3.5 Promotional Materials. American Regent shall not use any promotional materials in connection with the marketing, sale or distribution of the Product without CytoDyn's prior written approval other than (a) the labeling for the Product approved by CytoDyn in accordance with Section 6.5, and (b) after the First Commercial Sale, introduction announcements to the trade, bill sheets and American Regent's on-line product catalog; provided that any such promotional materials shall not contain any information other than the name of the Product, the available packaging configurations, and pricing and delivery terms. CytoDyn shall not make any statement that is inconsistent with the information contained in (a) or (b) in this Section. For purposes of this Agreement, "promotional materials" means all labeling and advertising materials as defined in the Act and the regulations of the FDA thereunder.

3.6 Sampling. American Regent shall not distribute any samples of the Product to any Third Party.

3.7 Reports. CytoDyn shall promptly keep American Regent fully informed of all governmental and regulatory requirements, activities and plans of the FDA including any changes thereto of which it becomes aware which materially affect, or are reasonably likely to materially affect, the sales or distribution of the Product in the Field in the Territory.

4. REGULATORY MATTERS

4.1 Regulatory Responsibilities. CytoDyn will, at its own cost, continue to own and maintain the applicable Regulatory Approvals necessary to Market the Product in the Territory. CytoDyn shall be responsible for all regulatory and safety reporting requirements associated with ownership of the Regulatory Approvals, including without limitation, Adverse Event reporting and annual reporting and pharmacovigilance activities in the Territory. American Regent shall assist CytoDyn at its sole expense by providing customer service, complaint handling and pharmacovigilance systems to support commercialization of the Product as set forth in Section 4.3. The Parties shall bear their own costs associated with the regulatory and safety reporting.

4.2 Pricing. American Regent shall be responsible for dealing with pricing issues relating to price ceilings and reimbursement for the Product in the Field and it shall share such decisions and related information with CytoDyn. American Regent shall be responsible for all government price reporting for sales of the Product in the Field.

4.3 Monitoring Adverse Events and Quality Complaints. Both Parties shall comply fully with all applicable Adverse Event reporting recommendations under Applicable Laws and agree to exchange such information as may be necessary to achieve that end and to ensure that both Parties are completely informed regarding Adverse Events with the Product, provided that CytoDyn, as the owner of the BLA for the Product, shall be solely responsible for all medical questions for the Product and for all Adverse Event reporting to the FDA in relation to the Product. In order to enable CytoDyn to comply with its regulatory reporting responsibilities, American Regent shall use reasonable efforts to inform CytoDyn of all adverse events as promptly as practical, but no later than forty-eight (48) hours of receiving information on such Adverse Event and at such time shall forward to CytoDyn all Adverse Event information received by it and all other information as required by CytoDyn by notice in writing to American Regent. The Parties shall negotiate in good faith and use Commercially Reasonable Efforts to enter into a mutually agreed Safety Data Exchange Agreement promptly after the Effective Date which will set out the policies, procedures and standards by which the Parties will coordinate and implement the pharmacovigilance procedures.

4.4 Quality Agreement. The Parties shall negotiate in good faith and use Commercially Reasonable Efforts to enter into the Quality Agreement promptly after the Effective Date which Quality Agreement will set out the policies, procedures and standards by which the Parties and any Affiliates will coordinate and implement the operation and quality assurance activities and regulatory compliance objectives contemplated under this Agreement with respect to Product. To the extent there are any inconsistencies or conflicts between this Agreement and the Quality Agreement, the terms and conditions of this Agreement shall control unless specifically otherwise agreed to in writing by the Parties.

4.5 Cooperation. Without limiting the foregoing, each of CytoDyn and American Regent shall provide to each other in a timely manner all information which the other Party reasonably requests regarding the Product in order to enable the other Party to comply with all Applicable Laws applicable to the Product in the Territory. Each of CytoDyn and American Regent shall provide to the other or if applicable, directly to the FDA, any assistance and all documents reasonably necessary to enable the other to carry out its obligations under this Article 4. In general, requests for cooperation should be responded to by the other Party within three (3) Business Days and both should make responsible efforts to ensure cooperation is maintained to ensure completion of the given project.

5. PRODUCT QUALITY AND PRODUCT RECALLS

5.1 Product quality inquiries other than Adverse Events.

(a) Each Party shall submit to the other Party, within forty-eight (48) hours of receipt any complaints or issues that question Product quality (other than Adverse Events) received by that Party or any of its Affiliates or, in the case of American Regent, to which that Party must respond, together with all evidence then available and all other information relating thereto subsequently obtained or produced by either Party.

(b) Each of American Regent and CytoDyn shall promptly notify the other of any notice of non-compliance with any Applicable Laws applicable to Product or the Packaging of Product, received from any Official Body, and of any request for or initiation of any inspection of any facility of either CytoDyn or American Regent, or any Affiliate of CytoDyn or American Regent.

5.2 Product Recall.

(a) CytoDyn shall be responsible, at its sole expense, for serialization of the Product. American Regent, at its sole expense, will maintain or cause to be maintained such records of its sales of the Product, as are necessary to permit a recall, market withdrawal or field correction of a Product including any inventory withdrawal in connection with any of the foregoing (each a **"Recall"**).

(b) Each Party shall promptly (but in any case, not later than twenty-four (24) hours of receipt) notify the other Party in writing of any information which indicates a Recall of any Product may be necessary, any safety or regulatory concerns, or any order, request or directive of a court or the FDA requesting or requiring a Recall.

(c) To the extent permitted by circumstances, the Parties will confer before initiating any Recall. If the Parties do not agree on the need for or the extent of such a Recall, either Party may authorize the Recall.

(d) With respect to Recalls agreed on by both Parties, American Regent shall manage, in accordance with CytoDyn's oversight and direction, the carrying out of such Recalls of Product sold by it in accordance with Applicable Laws. In the event CytoDyn materially impedes American Regent's efforts to Recall the Product, American Regent shall have the right to terminate this Agreement with [***] written notice to CytoDyn.

(e) If any Recall is required primarily and substantially because of failure of a Product to conform to the Specifications already existing at the time title is transferred to American Regent or as a result of a material breach of CytoDyn's obligations, as confirmed by a mutually acceptable Third Party laboratory, including a Latent Defect that is shown to have existed at the time of such title transfer, CytoDyn will be responsible for only the direct costs of such Recall (including reimbursement to American Regent and its Affiliates for their direct, out-of-pocket costs and expenses incurred during such Recall). In such event, CytoDyn shall supply to American Regent free of cost and expense replacement Product for any removed Product.

(f) If any Recall is required primarily or substantially because of failure of a Product to conform to the Specifications after title is transferred to American Regent or in circumstances caused by the negligence, mistake, fault, error or omission of American Regent, its Affiliates or subcontractors, including any breach by American Regent of a representation, warranty or covenant hereunder, American Regent will be responsible for the direct costs of such Recall (including reimbursement to CytoDyn and its Affiliates for all of their direct out-of-pocket costs and expenses incurred during such Recall) and the Transfer Price of all Products removed from American Regent's inventory.

(g) If any Recall is required under circumstances not covered in Section 5.2(e) or (f) above, the Parties will equally share the direct costs of such Recall, including direct out-of-pocket costs and expenses related to such Recall.

(h) Without limiting the foregoing, each Party will cooperate fully with the other Party in connection with any Recall efforts.

6. PURCHASE PRICE AND SUPPLY OF PRODUCT

6.1 Supply of Product.

(a) CytoDyn will be responsible for the Manufacture of the Product. American Regent shall purchase from CytoDyn all of American Regent's requirements for the Product in the Territory during the Term, pursuant to Firm Orders submitted by American Regent to CytoDyn from time to time in accordance with Section 6.2.

(b) CytoDyn shall supply all Product to American Regent for distribution in the Territory in the Field during the Term in full and on time, and in accordance with the terms and conditions of this Agreement.

(c) The terms and conditions of this Agreement shall control the Manufacture and supply of Product by CytoDyn to American Regent, and no terms or conditions contained in any purchase order, acknowledgment, invoice, bill of lading, acceptance or other pre-printed form issued by any Party shall have any force or effect to the extent they are inconsistent with or modify the terms and conditions of this Agreement.

6.2 Forecasts, Orders.

(a) Initial Firm Orders. Within [***] after FDA approval of the BLA for a Product, American Regent shall deliver to CytoDyn its initial six (6)-month order for delivery of the Product. Within [***] of CytoDyn's receipt of the initial order, CytoDyn shall notify American Regent whether it accepts or rejects such initial order (in its discretion) and the applicable Transfer Price and, in case of rejection, CytoDyn shall notify American Regent of the quantities of a Product that CytoDyn can accept for such initial order and the applicable Transfer Price. Once CytoDyn accepts the initial order, such initial order shall be construed as the "**Initial Firm Order.**"

(b) No Forecasts. American Regent shall not be required to provide forecasts for the supply of the Product in the Field. It shall purchase Product by providing Purchase Orders. Notwithstanding the foregoing, the Parties shall meet and confer at least once every calendar month to discuss the business issues generally related to the supply and Marketing of the Product (including anticipated demand and supply of Products).

(c) Firm Orders. American Regent shall place orders for a Product in writing (each a '**Purchase Order**") and CytoDyn shall, within ten (10) Business Days of receipt of a Purchase Order, confirm in writing whether a given Purchase Order has been accepted and the Transfer Price applicable to such Purchase Order. CytoDyn shall use Commercially Reasonable Efforts to accept all Purchase Orders which are provided to CytoDyn in accordance with the terms and conditions of this Agreement. All accepted Purchase Orders are Firm Orders.

(d) Delivery Against Firm Orders. Delivery on each Firm Order, including the Initial Firm Order, will take place [***] after CytoDyn has provided written notice to American Regent that such Firm Order has been accepted. CytoDyn shall deliver against each such Firm Order in accordance with this Section 6.2 (including with respect to the delivery dates and quantities set forth therein); provided that notwithstanding anything to the contrary contained herein (a) CytoDyn shall have satisfied its obligations with respect to delivery date if the actual delivery date is [***] of the desired delivery date set forth in the applicable Firm Order (or such other date as agreed to by the Parties), and (b) CytoDyn shall have satisfied its obligations with respect to quantity of Product if the actual quantity of Product Manufactured and supplied is within plus or minus [***] of the quantity of Product set forth in the applicable Firm Order.

(e) Terms and Conditions of Firm Orders. Each Firm Order shall be in the form acceptable to CytoDyn and shall specify (a) the quantities and format (if applicable) of Product ordered, (b) shipping instructions and destination(s), and (c) the requested date of delivery (provided that there shall be no more than one (1) delivery date in any thirty one (31)-day period and the delivery date is consistent with the provisions of Section 6.2(g) herein). Firm Orders shall not be made in any other form of document other than that prescribed by this Agreement unless the Parties mutually agree otherwise in writing. Any term or condition of a Firm Order that is different from or contrary to the terms and conditions of this Agreement shall be void. Except as

contemplated herein, all Firm Orders shall be non-cancelable by either Party and American Regent shall be obligated to pay the Transfer Price for the Product supplied to American Regent. CytoDyn agrees to use its commercially reasonable efforts to comply with unplanned changes in Firm Orders.

(f) Maximum Capacity. Subject to a schedule to be agreed upon by the Parties at the time of the Initial Firm Order, CytoDyn will use Commercially Reasonable Efforts to supply the Product in accordance with its current manufacturing capacity and operational strategy and it shall be entitled to reject any portion of a Firm Order that CytoDyn believes will exceed its anticipated maximum capacity for a given calendar year set forth in the applicable schedule (when aggregated with all prior Firm Orders previously submitted for such calendar year).

6.3 Continuity of Supply. If CytoDyn is unable to supply any Product to American Regent pursuant to Section 6.2 for thirty (30) days or more after the anticipated date of delivery specified in a Firm Order, to the location specified therein, or if CytoDyn is unable to deliver on a timely basis at least [***] of the amount covered by Firm Orders issued by American Regent pursuant to Section 6.2(d) for [***] or more consecutive orders, (whether as a result of cGMP issues, a Force Majeure event, failure to meet quality standards, or otherwise) (individually or collectively a "**Supply Interruption**"), then at any time such Supply Interruption is continuing and CytoDyn holds less than one week of any dosage of saleable Product inventory, American Regent may declare a Supply Interruption by providing CytoDyn with a notice that a Supply Interruption has occurred. In the event that circumstances arise that may give rise to a potential Supply Interruption, the Parties will work collaboratively in good faith to avoid a Supply Interruption and in such connection CytoDyn agrees to use Commercially Reasonable Efforts to provide American Regent with the same or greater percentage of Product for its Firm Orders, as the percentage of Product it provides to any other distributor of Product outside the Territory with respect to its Firm Orders. If there is no resolution of this matter, American Regent's sole remedy shall be to terminate this Agreement.

6.4 Packaging Configuration. American Regent shall sell the Product with CytoDyn's labeling and packaging, bearing American Regent's NDC Number, and clearly identifying American Regent solely as the distributor of the Product. [***] after receiving FDA approval of its own labeling and packaging for the Product, CytoDyn shall supply American Regent with copies of CytoDyn's approved labeling and packaging for the Product. CytoDyn's labeling and packaging shall identify CytoDyn's manufacturer of the Product. [***] after American Regent's receipt of such labeling, American Regent shall provide to CytoDyn proposed camera ready artwork for the labeling and packaging for the Product American Regent will sell, which shall be consistent with the labeling and packaging of the Product provided by CytoDyn, with the addition of the American Regent's NDC Number obtained pursuant to Section 3.3. The American Regent labeling and packaging for the Product shall be subject to the prior approval of CytoDyn, which approval shall not be unreasonably withheld or delayed. CytoDyn shall only be obligated to supply to American Regent the Product in mutually agreed upon packaging configurations, including, but not limited to pallet level aggregation for serialization. Any changes to the packaging and labeling of Product requested by American Regent shall require the prior written consent of CytoDyn, which approval shall not be unreasonably withheld or delayed. If CytoDyn consents to such changes, such changes shall be effected at American Regent's sole cost and expense.

6.5 Serialization.

(a) Connectivity. CytoDyn and American Regent connectivity between American Regent's and CytoDyn's L4 (vendor supported) systems is required to be established and validated prior to the first production lot of Product for sale by American Regent. This connectivity testing confirms that the EPCIS (Electronic Product Code Information Services) file containing the lot information can be successfully transferred from American Regent to CytoDyn. American Regent uses IRIS as its L4 system. Any updates made to the AS2 (a specification about how to transport structured business-to-business data securely and reliably over the Internet) need to be communicated directly to either Party. Using its L4, CytoDyn will generate and provide the serial numbers for the smallest unit of sale and aggregate the Serialized Shipping Container Codes (SSCCs) and pallet to American Regent's L4.

(b) Lot Numbering/Expiration Dates. CytoDyn shall make arrangements for and implement the imprinting of lot numbers and expiration dates on the packaging of Product shipped. Such lot numbers and expiration dates shall be affixed on the Product packaging and on the shipping carton of Product as is required by cGMPs and consistent with the Specifications. Electronic on-line verification of the lot number, expiration date, and serialization will be performed by CytoDyn.

(c) Product Identifier and Serial Numbering. If required by Applicable Law, CytoDyn shall make arrangements for the imprinting of the product identifier, i.e., global trade identification number (GTIN) and serial number on the packaging of each Product shipped. Such product identifier and serial number shall be affixed on the Product packaging and on the shipping carton of each Product as required by cGMPs and consistent with the Specifications. Electronic on-line verification of the product identifier and serial number will be performed by CytoDyn.

(d) Data Carrier Printing and Encoding. If required by Applicable Law, CytoDyn shall make arrangements for the imprinting of the data carrier, i.e., 2D data matrix or barcode, on the packaging of Product shipped. Such data carrier shall encode the lot number, expiration date, Product identifier and serial number. Such data carriers shall be affixed on the Product packaging and on the shipping carton of each Product as required by cGMPs and consistent with the Specifications. Electronic verification of the data carrier will be performed by CytoDyn.

6.6 Method of Delivery of Product. Product shall be shipped and delivered DDP to American Regent's facility in Shirley, NY and/or New Albany, OH (Incoterms® 2010).). American Regent shall advise CytoDyn in writing at least fifteen (15) days in advance of the scheduled shipping date specified in the applicable Firm Order of the carrier to be used to ship Product to American Regent. CytoDyn shall cause such carrier to comply with all Applicable Laws, and the Product storage and shipping requirements, for the shipment of Product. CytoDyn shall determine the appropriate carrier if CytoDyn receives no direction from American Regent at least fifteen (15) days in advance of the scheduled shipping date specified in the applicable Firm Order to use a particular carrier. CytoDyn shall be responsible for providing temperature-controlled transport for the Product, along with verifiable data through temperature tails to support that the Product was not exposed to excursions during transport. Title and risk of loss to Product shall pass to American Regent immediately upon such delivery.

6.7 Acceptance, Rejection and Revocation of Acceptance.

(a) CytoDyn shall be responsible for Product test procedures for quality assurance, including Product storage and shipping requirements, before Product is released to American Regent. CytoDyn shall provide a certificate of analysis and other documents (collectively, the "**COA**") as set forth in the Quality Agreement, in such forms as the Parties shall agree upon, for any Product batch delivered to American Regent hereunder certifying that such Product have been Manufactured, Packaged and shipped in compliance with the Specifications, cGMPs and all other applicable Regulatory Requirements and with an expiry date of not less than twelve (12) months from the date of shipment.

(b) American Regent shall inspect or shall cause to be inspected all shipments of Product promptly upon receipt. American Regent may reject any Product which does not conform to the Specifications, or the shipping and storage requirements for the Product, at the time of receipt at American Regent's location. American Regent shall make any such rejection in writing, within ten (10) days of the later of the receipt of the COA or the Product at the facility designated by American Regent in the applicable Firm Order (the "**Stipulated Rejection Period**"), to CytoDyn, and shall indicate the reasons for such rejection (the **"Rejection Notice"**).

(c) If American Regent has not delivered a Rejection Notice within the Stipulated Rejection Period, American Regent shall be deemed to have accepted that shipment of Product. Once American Regent has accepted or has been deemed to have accepted a shipment of Product, and except with respect to Latent Defects discovered by American Regent or American Regent's customers after the expiration of the Stipulated Rejection Period, American Regent may not exercise any rights to subsequently reject such shipment under this Section 6.7.

6.8 Rejection Procedures.

(a) After CytoDyn receives the Rejection Notice, it will evaluate process issues and the reasons given by American Regent for the rejection. CytoDyn shall use Commercially Reasonable Efforts to promptly notify American Regent whether it agrees with the basis for American Regent's rejection, but in no event shall such notice be given later than thirty (30) days of CytoDyn's receipt of a Rejection Notice. If CytoDyn does not so notify American Regent within thirty (30) days of receipt of the Rejection Notice as to whether it agrees with the basis of American Regent's rejection, CytoDyn shall be deemed to be in agreement therewith.

(b) If CytoDyn agrees with or is deemed to agree with the basis for American Regent's rejection, CytoDyn shall use Commercially Reasonable Efforts to promptly replace, at no cost to American Regent, such rejected Product.

(c) If CytoDyn disagrees with the basis for American Regent's rejection specified in the Rejection Notice: (i) CytoDyn shall use Commercially Reasonable Efforts to promptly replace such rejected Product; (ii) no payment shall be due with respect to the replacement Product until it is determined which Party shall bear the burden of such cost hereunder; and (iii) the Parties shall submit samples of the rejected Product to a mutually acceptable Third Party laboratory, which shall determine whether such Product meets the

Specifications and, as part of this process, may also carry out a full investigation of the Manufacturing process for such Product if the Third Party laboratory reasonably believes such an investigation is necessary to resolve the disagreement. The Parties agree that the determination of the Third-Party laboratory, after it has assessed the retention samples and following any full investigation of the Manufacturing process it conducts, shall be final and determinative. If the Third-Party laboratory determines that the retained samples meet the Specifications, the rejection by American Regent is unjustified, and American Regent shall promptly pay CytoDyn for any replacement Product and, if the Product can no longer be distributed, Transfer Price on the rejected Product. If the Third-Party laboratory determines that the relevant shipment of Product does not meet the Specifications, CytoDyn shall not invoice American Regent for the replacement Product. The Party against whom the Third-Party laboratory rules shall also bear the fees charged by the Third Party laboratory in connection with resolution of the disagreement, including all out-of-pocket costs of investigating the Manufacturing process.

(d) At CytoDyn's election and upon authorization from CytoDyn, American Regent shall destroy the rejected Product promptly and provide CytoDyn with certification of such destruction unless CytoDyn elects to have the Product returned, in which event American Regent shall cooperate in arranging such return. The party against who the Third-Party laboratory rules shall pay the cost of destroying or returning the Product.

(e) Notwithstanding any of the other provisions in this Agreement and without limiting any other provision herein, American Regent agrees that the remedies set forth in this Section 6.8 are American Regent's sole and exclusive remedies with respect to the rejection of Product.

6.9 Prices and Payments.

(a) Transfer Price. The price payable by American Regent (the "Transfer Price") for all Product delivered hereunder shall be [***]. The Transfer Price shall be paid to Cytodyn by American Regent at the time American Regent pays the [***] owed to CytoDyn with respect to such calendar quarter.

(b) Adjustment to Transfer Price. CytoDyn shall use commercially reasonable efforts to reduce its Manufacturing expenses for the Product. CytoDyn shall conduct annual review on the costs of all materials and API required to Manufacture the Product. In the event that the cost of materials decreases by more than [***], CytoDyn shall reduce the Transfer Price accordingly. In the event there is a change in the Manufacturing requirements applicable to the Manufacture of the Product pursuant to this Agreement or an increase in CytoDyn's cost structure for the Manufacture of the Product (including with respect to any materials used to Manufacture the Product) of more than [***], CytoDyn shall promptly notify American Regent and the Transfer Price shall be adjusted by CytoDyn to reflect such increase.

(c) American Regent shall be responsible for the payment of any duties, levies or Taxes applied to the sale of Product in the Territory by any relevant Tax authority.

(d) Any payments to be made hereunder and which have not been made by the due date, shall accrue interest at any rate equal to the lower of (a) a floating annual rate of [***] above the commercial prime rate as published in the Wall Street Journal on the first Monday of each month, or (b) the highest rate permitted by law; provided that payments of such interest shall not constitute a remedy to a material breach for purposes of terminating this Agreement under Section 9.2. Additionally, American Regent shall be responsible for all reasonable attorneys' fees, witness fees and court costs and other costs incurred by CytoDyn to recover amounts owing to it hereunder.

(e) American Regent shall make all payments contemplated by this Agreement in U.S. Dollars and to such address as CytoDyn may from time to time direct in writing to American Regent.

6.10 Net Profit Split. American Regent shall pay CytoDyn an amount equal to [***] of the Net Profits from American Regent's sales of the Product for each calendar quarter during the Term, and any selloff period under Section 9.4 after the Term. To the extent the Net Profit is negative in any particular calendar quarter or quarters, American Regent shall be entitled to accrue and set off such shortfall against any positive Net Profit generated in any subsequent calendar quarter or quarters. Each Party shall have the right to terminate this agreement with thirty (30) days written notice in the event that the Net Profit for American Regent's sales of the Product are negative for two (2) or more consecutive calendar quarters.

6.11 Reporting and Payment.

(a) Not later than thirty (30) days after the end of each calendar quarter, through and including the calendar quarter in which all rebate and chargeback amounts on Product sold during the Term and any applicable selloff period under Section 9.4 are finally reconciled, American Regent shall:

(i) deliver to CytoDyn a written report that specifies in detail the breakdown of individual components of the Net Sales that were used to calculate the Net Profit with respect to such calendar quarter, as well as the Net Profit calculation; and

(ii) pay to CytoDyn the Net Profit split amount owed to CytoDyn with respect to such calendar quarter.

(b) Prior to May 21 every year during the Term, American Regent will use good faith efforts to provide CytoDyn with American Regent's actual and estimated forecasted sales of Product, and estimated Net Profit through to May 31, for CytoDyn's use for its end of year reporting requirements.

6.12 Audit. American Regent shall keep and retain complete and accurate records pertaining to the disposition of the Product and amounts payable under this Agreement for each calendar year or part thereof during the Term in sufficient detail to permit CytoDyn to confirm the accuracy of all payments made or due hereunder for a period of three (3) years following the applicable calendar year or part thereof. CytoDyn shall have the right to appoint an independent

internationally recognized audit firm, reasonably acceptable to American Regent, to audit the books of account of American Regent in order to determine whether American Regent has properly reported and accounted for any fees or payments due to CytoDyn pursuant to this Agreement. The appointed audit firm may perform audits during regular business hours, not more than once in any calendar year during the Term and upon reasonable prior notice to American Regent. CytoDyn shall bear the audit fees, unless such Third Party auditor determines that the amount actually due CytoDyn, in the aggregate, exceeds the amounts paid or deemed paid by American Regent hereunder by the lower of [***] or [***], in which case American Regent shall bear the audit fees. American Regent shall forthwith pay any amounts discovered to be due pursuant to an audit together with interest from the date payment was originally due at a rate equal to the lower of (a) a floating annual rate of [***] above the commercial prime rate as published in the Wall Street Journal on the first Monday of every month calculated monthly or (b) the highest rate permitted by law. The results of the audit shall be final and binding upon the Parties.

6.13 Facility Audits.

(a) American Regent and/or its nominee shall have the right to conduct an audit of any manufacturing site at which the Product is being Manufactured during business hours upon ten (10) Business Days prior written notice to CytoDyn not more than once per calendar year during the Term of this Agreement, unless either Party, the FDA or any Third Party raises any questions about the quality of a Product which could have a material detrimental effect on the sales or use of a Product, in which case American Regent's audit right shall not be subject to the foregoing limitation until the specific issue in question has been resolved, and CytoDyn shall promptly supply to American Regent all data and results relating to all Testing performed in connection with the issue in question. CytoDyn shall be responsible for its own costs, and those of its contract manufacturers, for a first audit by American Regent hereunder. American Regent shall bear the fees and costs of any subsequent audit, including the fees and costs payable by CytoDyn to any Third-Party subcontractor that Manufactures the Product.

(b) CytoDyn and/or its nominee shall have the right to conduct an audit of the facilities and records of American Regent relating to the Marketing, Testing, and storage of the Product and of any correspondence between American Regent and the FDA related to the Product or such facilities, during business hours upon reasonable prior written notice to American Regent not more than once per any twenty-four month period during the Term of this Agreement, unless any Official Body reasonably believes that American Regent may be in material breach of its obligations under Article 3 or Section 4.4 or Applicable Laws governing the Marketing of Product that could have a material detrimental effect on the sales or use of the Product, in which case CytoDyn's audit right shall not be subject to the foregoing limitation until the specific issue or question has been resolved, and American Regent shall promptly supply to CytoDyn all data and results relating to all Testing performed by American Regent on the Product.

7. INTELLECTUAL PROPERTY

7.1 Ownership of CytoDyn Intellectual Property. CytoDyn shall retain all of its rights, title and interest in and to all Product Technology, copyrights, and all other industrial and Intellectual Property embodied in or which covers the Product, in each case which is owned, held,

or licensed by it as of the Effective Date or thereafter or developed, created or discovered by it or on its behalf during the Term, subject to the rights granted in this Agreement. Except as otherwise expressly provided in this Agreement, American Regent has and shall have no right, title or interest in any Intellectual Property owned by or licensed by CytoDyn relating to the Product including the Product Technology.

7.2 Ownership of American Regent Intellectual Property. American Regent shall retain all of its right, title and interest in and to any Intellectual Property owned by American Regent. For clarification purposes, the Parties agree that nothing herein grants, or constitutes an agreement or obligation to grant, to CytoDyn, or any of their Affiliates or other Third Party any right, title or interest in, to or under any Intellectual Property owned by American Regent.

7.3 Notice of Patent Infringement.

(a) Information Concerning Infringement. If either Party shall learn of (i) any claim or assertion that the Manufacture, Marketing, Packaging or Testing of a Product, or the use of the Product Technology or other Intellectual Property related to a Product infringes, misappropriates or otherwise violates the Intellectual Property rights of any Third Party, or (ii) the actual or threatened infringement, misappropriation or other violation by any Third Party of the Product Technology or other Intellectual Property related to a Product, then the Party becoming so informed shall as soon as reasonably practicable, but in all events within fifteen (15) Business Days thereof, notify the other Party of such claim or assertion, or actual or threatened infringement, misappropriation or other violation.

(b) Potential Infringement. In the event either CytoDyn or American Regent learns of any Third-Party patents which may cover the Manufacturing, Marketing, Testing or Packaging of a Product in the Territory, such Party will promptly notify the other Party. The Parties agree to confer in good faith regarding such potential infringement risk and to explore reasonable alternatives for avoiding such risk and to provide such information to each other as either Party may reasonably request.

7.4 Infringement of Product Technology by a Third Party. In the event that any Party becomes aware of any Person infringing or potentially infringing the Product Technology, whether by direct or indirect infringement, or by misappropriation of Product Technology, it shall promptly notify the other Party. CytoDyn shall notify American Regent within thirty (30) days of such notice, whether CytoDyn wishes to commence, at its own expense, an infringement action against any Person infringing or allegedly infringing the Product Technology, including actions for direct or contributory infringement or misappropriation of Product Technology. American Regent shall cooperate with CytoDyn as reasonably requested, at CytoDyn's expense. Any and all amounts recovered with respect to such an action shall be retained by CytoDyn.

8. CONFIDENTIALITY

8.1 CytoDyn's Information. Except as provided in Section 8.3 or elsewhere in this Agreement, American Regent shall maintain all Confidential Information provided by CytoDyn to American Regent, whether in writing, electronically, orally or through access to CytoDyn's

premises, in strict confidence. Such information shall remain the property of CytoDyn, and American Regent shall not use the same for or on behalf of any Person or entity other than CytoDyn or make use of any such information except as permitted by this Agreement without the express prior written approval of CytoDyn.

8.2 American Regent's Information. Except as provided in Section 8.3 or elsewhere in this Agreement, CytoDyn shall maintain all Confidential Information provided by American Regent to CytoDyn, whether in writing, electronically, orally or through access to American Regent's premises, in strict confidence. Such information shall remain the property of American Regent, and CytoDyn shall not make use of any such information except as permitted by this Agreement without the express prior written approval of American Regent.

8.3 Exceptions. The covenants of the receiving Party contained in Section 8.1 and Section 8.2 shall not apply to Confidential Information (a) that the receiving Party can reasonably demonstrate by competent proof is required to be disclosed by Applicable Law or a court or other Official Body pursuant to (i) regulatory filings; (ii) prosecuting or defending litigation; or (iii) complying with Applicable Law and orders or decisions of any Official Body having jurisdiction; or (b) disclosed to Affiliates who agree to be bound by similar terms of confidentiality. Notwithstanding any provision herein to the contrary, nothing herein shall prevent or prohibit any disclosure of any information concerning this Agreement (A) required under Applicable Laws and the rules and regulations of any stock exchange or market system on which any Party's securities are or may be traded, (B) by either Party in connection with an Approved Transaction (as defined below), where prospective parties or the other party or parties to such Approved Transaction have entered into confidentiality agreements with the Party concerning such Confidential Information, (C) to either Party's financial advisors or legal advisors who have agreed to the limitations on disclosure contained herein and/or (D) to investment bankers and/or financing sources in connection with bona fide financing transactions involving either Party or an Affiliate. For the purposes of this Agreement, each of the following shall constitute an **"Approved Transaction"**: (i) the issuance by either Party of securities in connection with any financing transaction or public offering, and/or (ii) a merger, consolidation or other similar transaction involving either Party (i.e., wherein another entity acquires all or substantially all of that Party's equity interests or assets or a merger or consolidation or similar transaction wherein securities of the post transaction entity will be issued to the other party). If a Party is required or permitted to make a disclosure of the other Party's Confidential Information pursuant to this Section 8.3, it will use Commercially Reasonable Efforts to (I) limit the scope of the Confidential Information disclosed and the number of persons to whom such Confidential Information is disclosed, in each case to the minimum extent required to address the reason such disclosure is permitted hereunder and (II) secure confidential treatment of such Confidential Information and comply with any applicable provisions of Section 12.7.

8.4 Survival. This Article 8 shall survive termination of this Agreement for a period of five (5) years.

9. TERM AND TERMINATION OF AGREEMENT

9.1 Term. The term of this Agreement shall commence on the Effective Date and continue for three (3) years from the date of the First Commercial Sale (the **"Initial Term"**). The

Parties may mutually agree in writing to renew the Agreement for one additional one (1) year period (the **"Renewal Term"**, if applicable, and together with the Initial Term, subject to early termination pursuant to Section 9.2 the **"Term"**) provided that if American Regent does not wish to renew it must provide CytoDyn at least six (6) months written notice to CytoDyn prior to the expiry of the Initial Term.

9.2 Termination.

(a) Material Breach. A Party shall have the right to terminate this Agreement upon prior written notice to the other Party for material breach of this Agreement by the other Party (which includes any failure by American Regent to pay amounts when due to CytoDyn in accordance with the terms of this Agreement). Any notice of material breach shall specify the breach in reasonable detail. Unless otherwise provided in this Agreement, the termination shall be effective thirty (30) days after receipt of the written notice, unless the breaching Party cures the breach within that thirty (30) day notice period, or, if such breach is incapable of cure within such thirty (30) day period, the breaching Party has commenced good faith efforts to cure such breach within such thirty (30) day period and cures such breach within three (3) months after the receipt of the notice of material breach.

(b) Termination by CytoDyn. After the First Commercial Sale occurs, CytoDyn shall have the right to terminate this Agreement at any time in its sole discretion by giving six (6) months advance written notice to American Regent.

(c) Termination by American Regent. Notwithstanding anything contained herein to the contrary, American Regent shall have the right to terminate this Agreement:

(i) upon six (6) months advance written notice to CytoDyn (a) if, following due diligence and/or a quality inspection of the manufacturing facility associated with the Product, it determines that the distribution of the Product by American Regent should not be pursued, subject to the cure provisions of Section 9.2(a) above, or (b) if there is an unresolved Supply Interruption pursuant to Section 6.4.

(ii) immediately upon written notice to CytoDyn if (a) pursuant to Section 3.3, American Regent determines there is an unacceptable risk of using American Regent's NDC Number on the Product labeling, (b) if both the mutually agreed Quality Agreement and the Safety Data Exchange Agreement have not been executed by the Parties within forty five (45) days of the Effective Date, (c) any patent or trade secret infringement alleged by a Third Party (except any company in the Daiichi Sankyo family of companies) against American Regent resulting from American Regent's Marketing of the Product survives motion to dismiss or has not been resolved six (6) months after American Regent first receives written notice of the alleged infringement, (d) any regulatory authority in the Territory requires the cessation of sale or distribution of the Product, (e) pursuant to Section 5.2(d), or (f) there is a negative Net Profit for the Product for two (2) consecutive calendar quarters pursuant to Section 6.10.

(d) Bankruptcy and Insolvency. A Party shall have the right to terminate this Agreement in the event that a court of competent jurisdiction declares the other Party insolvent or

bankrupt, or a bankruptcy proceeding is commenced against the other Party or the other Party files a proposal, assignment for the benefit of creditors, arrangement, composition or seeks similar relief under any Applicable Law or the other Party is in receivership, in which case termination shall be effective upon written notice to that effect.

(e) Termination Due to Change of Control. In the event of a Change of Control of American Regent (or American Regent's controlling Affiliate) during the Term, American Regent shall deliver a written notice of such Change of Control to CytoDyn within thirty (30) days of the Change of Control event. At any time within ninety (90) days after the earlier of CytoDyn's receipt of the notice of such Change of Control, or the date CytoDyn otherwise becomes aware of such Change of Control, CytoDyn may terminate this Agreement upon ninety (90) days written notice to American Regent.

9.3 Accrued Rights, Surviving Obligations. Termination or expiration of this Agreement shall not affect any accrued rights of either Party or payments otherwise owing. Without limiting the foregoing, the terms of Sections 3.4, 4.3, 4.5, 6.11, 6.12, 9.3, 9.4, 9.5; Article 1 (to the extent needed to interpret any surviving Articles or Sections) and Articles 5, 7, 8, 10, 11, and 12 shall survive termination or expiration of this Agreement.

9.4 Transitional Matters.

(a) Upon expiration or termination of this Agreement, at CytoDyn's option, either (a) all Firm Orders previously submitted by American Regent prior to the effective date of termination or expiration shall be cancelled, or (b) all Firm Orders previously submitted by American Regent prior to the effective date of termination or expiration shall remain in effect, and CytoDyn shall supply Product, and American Regent shall purchase such Product under such Firm Orders, in accordance with the terms of this Agreement; provided, however, that to the extent CytoDyn elects to continue to fill such Firm Orders, American Regent shall be required to pre-pay the [***] for all such Product (which payment shall be made within [***] after American Regent's receipt of notice of CytoDyn's election to fill such Firm Orders).

(b) Upon expiration or termination of the Agreement, American Regent may, where permitted by Applicable Law, sell Product then in its inventory for a period of [***] thereafter, which [***] period may be extended for up to an additional [***] months but only to the extent CytoDyn has not granted a Third Party an exclusive distribution right to such Product in the Territory, all in accordance with the terms of this Agreement. Promptly after the expiration of the periods set forth in the previous sentence, American Regent will, at its cost, destroy any unsold Product remaining in its inventory and will provide appropriate evidence of such destruction to CytoDyn or, at CytoDyn's request, return the inventory to CytoDyn at CytoDyn's cost and provided CytoDyn pays American Regent the Transfer Price with respect to such inventory. In addition, all information and materials relating to Product, will, at CytoDyn's request, promptly be delivered to CytoDyn, at CytoDyn's cost of delivery, CytoDyn will have the right to cancel any Firm Orders placed by American Regent which were accepted by CytoDyn prior to such termination, and which require delivery of Product after the date of termination.

(c) Upon termination, American Regent and CytoDyn shall at their own expense use Commercially Reasonable Efforts to ensure that the continuity of patient care is not disrupted. In addition, American Regent will remain responsible for returned Product Marketed by American Regent during the Term and the sell-off period specified under Section 9.4(b), and CytoDyn will be responsible for returned Product not Marketed by American Regent. For the purpose of identifying the responsible party, Product will be tracked via lot numbers.

9.5 Effect of Termination. Upon any termination of this Agreement, except to the extent required for the purposes of Section 9.4, (i) all licenses and rights granted to American Regent hereunder shall immediately terminate and (ii) all rights, properties and interests granted by CytoDyn to American Regent shall immediately revert to and become fully vested in CytoDyn and American Regent shall return to CytoDyn all copies of documents regarding a Product and all Confidential Information supplied by CytoDyn.

10. INDEMNITY

10.1 Indemnification by CytoDyn. CytoDyn agrees to and hereby does indemnify, defend and hold the American Regent Indemnitees harmless from and against all losses, claims, damages, costs and expenses, including reasonable attorneys' fees (including, without limitation, those resulting from a Third Party claims, actions, or proceedings) (collectively **"Losses"**) to the extent arising from: (a) the breach of any representation, warranty, covenant or obligation hereunder by CytoDyn or its Affiliates, (b) any negligent act or omission, or willful misconduct by CytoDyn or its Affiliates; (c) the failure of a Product sold to American Regent to conform to the Specifications (whether the failure is patent or latent) or any Product Liability Claims, in each case because of conditions existing at the time title of such Product is transferred to American Regent, (d) any claims of infringement or misappropriation of any Third Party's patent or trade secret rights.

10.2 Indemnification by American Regent. American Regent agrees to and hereby does indemnify and hold the CytoDyn Indemnitees harmless from and against all Losses arising from claims of negligent distribution of Product by American Regent or any of its agents.

10.3 Procedure. This Section 10.3 describes the procedure for indemnification of Losses for the Third-Party claims. With respect to Losses relating to the claim of a Party hereto, the procedures provided in Article 10 shall govern. The Party seeking indemnification for third party claims under Sections 10.1 or 10.2 (the **"Indemnified Party"**) shall promptly notify the other Party (the **"Indemnifying Party"**) in writing of all matters which may give rise to the right to indemnification hereunder; *provided, however*, that failure to promptly give the notice provided in this Section 10.3 shall not be a defense to the liability of the Indemnifying Party for such claim, but the Indemnifying Party may recover any actual Losses arising from the Indemnified Party's failure to give such prompt notice. The Indemnified Party shall not admit any liability with respect to, or settle, compromise or discharge any such matter covered by this Article 10 without the Indemnifying Party's prior written consent (which shall not be unreasonably withheld). The Indemnifying Party shall have the right, with the consent of the Indemnified Party (which shall not be unreasonably withheld), to settle all indemnifiable matters under this Article 10 related to claims by Third Parties. In connection with any claim giving rise to indemnity under this Article 10 resulting from or arising out of any claim or legal proceeding by a Person other than the Indemnified

Party, the Indemnifying Party at its sole cost and expense may, upon written notice to the Indemnified Party and an acknowledgement of its indemnity obligations hereunder, assume the defense of any such claim or legal proceeding. If the Indemnifying Party assumes the defense of any such claim or legal proceeding, the Indemnifying Party shall select counsel reasonably acceptable to the Indemnified Party to conduct the defense of such claims or legal proceedings and, at the Indemnifying Party's sole cost and expense (which costs and expenses shall not be applied against any indemnity limitation herein), shall take all steps necessary in the defense or settlement thereof. The Indemnified Party shall be entitled to participate in (but not control) the defense of any such action, with its own counsel and at its own expense, and shall be entitled to any and all information and documentation relating thereto. If the Indemnifying Party does not assume (or continue to diligently and competently prosecute) the defense of any such claim or litigation resulting therefrom in accordance with the terms hereof, the Indemnified Party may, at the Indemnifying Party's expense, defend against such claim or litigation in such manner as it may deem appropriate, but may not settle such claim or litigation without the consent of the Indemnifying Party, which consent shall not be unreasonably withheld. The Indemnified Party will cooperate reasonably with the Indemnifying Party in its efforts to conduct or resolve such matters, including by making available to the Indemnifying Party relevant documents and witnesses. The Indemnified Party and the Indemnifying Party shall keep each other informed of all settlement negotiations with Third Parties and of the progress of any litigation with Third Parties. The Indemnified Party and the Indemnifying Party shall permit each other reasonable access to books and records and shall otherwise cooperate with all reasonable requests of each other in connection with any indemnifiable matter resulting from a claim by a Third Party.

10.4 Indemnification Not Sole Remedy. Each Party hereby acknowledges that the indemnification provided under thisArticle 10 shall in no manner limit, restrict or prohibit (unless liability is otherwise expressly limited by the terms of this Agreement) either Party from seeking any recovery or remedy provided at law or in equity from the other Party in connection with any breach or default by such other Party of any representation, warranty or covenant hereunder, including injunctive relief.

10.5 Insurance. American Regent shall maintain insurance (including product liability insurance) with respect to its activities under this Agreement regarding the Product in such amount as such party customarily maintains with respect to similar activities for its other products, but not less than such amount as is reasonable and customary in the industry. American Regent shall maintain such insurance for so long as it continues its activities under this Agreement, and thereafter for so long as such party customarily maintains insurance for itself covering similar activities for its other products. CytoDyn will have in force prior to the First Commercial Sale and shall maintain in good standing throughout the Term of this Agreement and for a period of three (3) years thereafter, product liability insurance policies in respect of the Product(s) with an internationally recognized insurer or insurers licensed to do business in the Territory in an amount not less than [***] per occurrence, and [***] in the aggregate, on such terms and conditions as are customary in the industry. Upon written request, CytoDyn shall provide written proof of such insurance to American Regent.

11. REPRESENTATIONS, WARRANTIES AND COVENANTS; LIMITATIONS OF LIABILITY

11.1 Representations, Warranties and Covenants.

(a) Organization and Authority. Each Party represents and warrants that it (i) is duly organized, validly existing and in good standing under the Applicable Laws of the jurisdiction of its organization, (ii) is qualified to do business in each other's jurisdiction in which the conduct of its business requires such qualification including the Territory, (iii) is in compliance with all Applicable Laws, relating to its business and assets, and (iv) is not in material default of its memorandum or articles of association, its certificate of incorporation or by-laws or all other constituent documents as the case may be, except in the case of (ii) and (iii) where such failure to qualify or be in compliance would not have a material adverse effect on the business and assets of such Party or the performance of this Agreement by such Party.

(b) Due Authorization and Enforceability. Each Party represents and warrants that (i) it has full authority to execute, deliver and perform its obligations under this Agreement, (ii) that this Agreement has been duly executed and delivered by such Party, and constitutes the legal, valid and binding obligations of such Party and is enforceable against such Party in accordance with its terms, and (iii) that the execution, delivery and performance of this Agreement will not violate, be inconsistent with or result in a default under or creation of lien or encumbrance under (except as specifically contemplated by this Agreement) (A) the memorandum or articles of association, certificate of incorporation or by-laws or other constituent documents, as the case may be, of any Party and/or its Affiliates, (B) any material agreement, contract, license understanding or instrument binding upon or affecting such Party or its properties or assets, whether express, implied, written or oral, or (C) any Applicable Laws affecting either Party or its properties or assets, except where such violation would not have a material adverse effect on the business and assets of such Party.

(c) Product Handling. Each Party covenants that it will and will cause its agents to, comply with all Applicable Laws relating to the warehousing, storage, Manufacturing, Marketing, Packaging and Testing of Product applicable to such Applicable Laws and will ensure that all required approvals are in effect and will maintain such approvals in good standing.

(d) Rights to Grant. CytoDyn represents and warrants that it has the sole, exclusive and unencumbered right to grant the rights herein granted to American Regent, and that neither CytoDyn, nor any other Person, has granted any option, license, right or interest in or to the Product in the Field to any Third Party which could conflict with the rights granted by it under this Agreement in the Territory.

(e) No Claims. CytoDyn represents, warrants and covenants that as of the Effective Date there are no proceedings currently pending or, to the knowledge of CytoDyn, threatened against, CytoDyn or any of its Affiliates, relating to or otherwise arising from (i) Product Liability Claims or claims for death or bodily injury relating to any Product, or (ii) infringement, misappropriation or other conflict with any intellectual property or other rights of any Person relating to any Product, or (iii) the Marketing or Manufacture of any Product.

11.2 No Other Warranties. Except as set forth in this Article 11, CytoDyn neither assumes, nor authorizes any Person to assume, any liability for any warranty in connection with the Product, and all liabilities of CytoDyn or any other Person in respect of the Product shall be subject to the limitations as provided under this Article 11. The warranties of CytoDyn set forth in this Article 11 are in lieu of all other warranties, express or implied, and specifically, without limitation, CytoDyn disclaims any implied warranty of merchantability or fitness for a particular purpose.

11.3 Quality Assurance Representations, Warranties and Covenants.

(a) CytoDyn, and its Affiliates engaged in the performance of the actions contemplated hereby, including the Manufacture, sale and delivery of Product hereunder, hereby represents, warrants and covenants to American Regent that all Product that CytoDyn or its Affiliates Manufactures, supplies and delivers under and pursuant to this Agreement will:

(i) conform to the Specifications at time of shipment to American Regent;

(ii) be free and clear from all liens, encumbrances and defects of title, other than those that arise directly as a result of actions taken by American Regent; and

(iii) comply with the requirements under the cGMP standards, the Regulatory Approvals and any other Applicable Law in the Territory, and will not, at the time of such delivery, (A) be adulterated or misbranded, or (B) be an article which may not, under the provisions of the Act, be introduced into interstate commerce.

(b) American Regent shall be responsible for storing Product under appropriate conditions as specified in labeling and for distribution in full compliance with the applicable cGMP standards, the Regulatory Approvals and the Applicable Law.

(c) American Regent shall not, in bad faith, disrupt or cause the disruption of the supply of Product into the marketplace in the Territory.

(d) CytoDyn shall at all times during the Term, be in current compliance with, all Regulatory Approvals as may be required to Manufacture and/or to supply the Product pursuant to this Agreement, and, as of the Effective Date.

(e) Each Party represents and warrants that neither it nor any of its Affiliates, directly involved with the performance of this Agreement has been debarred under subsections (a) or (b) of Section 306 of the Act, as amended, 21 U.S.C. Section 335a(a) and (b) or comparable foreign regulation, has been excluded, debarred, suspended or otherwise ineligible to participate in a federal, provincial, or state health care program, (e.g., Medicare or Medicaid) or government procurement or non-procurement program or comparable foreign programs (a "**Program**"). Moreover, if any Party or any of its Affiliates, directly involved with the performance of this Agreement is subsequently excluded, debarred or otherwise ruled ineligible to participate in a Program, such Party agrees to immediately notify the other Party of such debarment, exclusion or suspension. Each Party shall also immediately notify the other Party in the event the notifying

Party or any of its Affiliates, directly involved with the performance of this Agreement has been proposed for exclusion from participation in any Program or charged with a criminal offense which, if convicted, would result in mandatory or discretionary exclusion in any such Program.

(f) Each Party represents and warrants that it did not and will not knowingly use in any capacity the services of any person debarred under the Act or comparable foreign regulation or excluded, debarred, or otherwise ineligible to participate in any Program in connection with its performance of this Agreement.

11.4 Limitation of Liability. Except a Party's indemnification obligations or breach of Section 8, in no event shall either Party or its Affiliates be liable to the other for any indirect, incidental, punitive or special damages, including loss of profits, goodwill or revenue, data or use, incurred by the other Party, however caused and on any theory of liability, arising in any way out of this Agreement. Notwithstanding anything to the contrary contained herein, American Regent's maximum liability under this Agreement, subject to Section 10.2, shall not exceed [***].

12. MISCELLANEOUS

12.1 Force Majeure. The Parties shall not be liable for the failure or delay in performing any obligation under this Agreement (except for the payment of money) if and to the extent such failure or delay is due to (a) acts of God, (b) weather condition, fire or explosion, (c) war, terrorism, invasion, riot or other civil unrest, (d) any governmental laws, orders, restrictions, actions, embargoes or blockades, (e) national or regional emergency, (f) injunctions, strikes, lockouts, labor trouble or other industrial disturbances, (g) shortage of adequate fuel, power, materials, or resources, or (h) any other event which is beyond the reasonable control of the affected Party (each such event, a "**Force Majeure**"); provided that the Party affected shall promptly notify the other of the Force Majeure condition and shall use Commercially Reasonable Efforts at its cost (except, for clarity, for any such costs of CytoDyn which would be allocated to the Transfer Price) to eliminate, cure or overcome any such causes and to resume performance of its obligations. In no event shall American Regent's inability to pay the amounts due under this Agreement be deemed a Force Majeure event and a Force Majeure event shall not excuse American Regent from its obligation to make payments, when due, under this Agreement.

12.2 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware and the trademark and patent laws of the United States, without reference to any rules of conflict of laws. The United Nations Conventions on Contracts for the International Sale of Goods, as well as any other unified laws or regulations relating to the conclusion and implementation of contracts for the international sale of goods, shall not apply. The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement or a breach thereof.

12.3 Consent and Waiver Regarding Services of Process, Personal Jurisdiction and Jury Trial In any action, suit, arbitration or proceeding to enforce the rights of either Party under this Agreement or otherwise arising out of this Agreement or from any acts, omissions or activities of either Party arising from or related in any way to this Agreement or the transactions contemplated hereby or related in any way to the Product, each Party, by execution and delivery of this

Agreement, expressly and irrevocably consents to the service of any complaint, summons, notice or other process relating to any such action, suit, arbitration or proceeding by delivery thereof to it by hand or by any other manner provided for in Section 12.5 hereof. Each Party hereby expressly and irrevocably waives any claim or defense in any such action, suit, arbitration or proceeding based on any alleged lack of personal jurisdiction, improper venue, forum non conveniens or any similar doctrine or theory. IN ADDITION, EACH PARTY HEREBY IRREVOCABLY WAIVES ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY SUIT, ACTION OR OTHER PROCEEDING ARISING OUT OF OR RELATED TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.

12.4 Entire Agreement; Amendments. This Agreement, including the Schedules hereto, sets forth the entire terms of the supply and distribution arrangement between the Parties hereto and, except as otherwise set forth herein, supersedes and terminates all prior agreements and understandings between the Parties regarding the subject matter hereof. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

12.5 Notice. When a Party is required or permitted to give notice under this Agreement, the notice shall be in writing, shall be sent by email, nationally recognized express delivery service, or delivered by courier or personal delivery (with evidence of receipt where feasible) and shall be deemed to be given upon receipt of the other Party. Unless otherwise specified in writing, the mailing addresses of the Parties shall be as set forth below.

For CytoDyn:

CytoDyn Inc.
1111Main Street
Suite 660
Vancouver, Washington 98660
Attention: Nader Pourhassan
Email: npourhassan@cytodyn.com

With a copy (which shall not constitute notice) to:

General Counsel
(Same Mailing Address)
Email: legalnotices@cytodyn.com

For American Regent:

American Regent, Inc.
5 Ramsey Road
Shirley, New York 11967
Attention: Head of Business Development
Email: businessdevelopment@americanregent.com

With a copy (which shall not constitute notice) to:

Vice President and General Counsel
(Same Mailing Address)
Email: legalnotices@americanregent.com

12.6 Assignment; Change of Control. Except as provided in this Section, this Agreement may not be assigned or otherwise transferred, nor may any rights or obligations hereunder be assigned or transferred, by either Party, whether in a merger, sale of stock, sale of assets or other transaction, without the written consent of the other Party. Notwithstanding the foregoing, (i) CytoDyn may, without American Regent's consent, assign this Agreement and its rights and obligations hereunder in whole or in part to (a) a CytoDyn Affiliate or (b) to a Third Party in connection with a Change of Control of CytoDyn and (ii) subject to Section 9.2(e), American Regent may, without CytoDyn's consent, assign this Agreement and its rights and obligations hereunder to a Third Party in connection with a Change of Control of American Regent. Any permitted assignee shall assume all assigned obligations of its assignor under this Agreement. Any attempted assignment not in accordance with this Section shall be void. Notwithstanding the foregoing, in the event of a Change of Control of American Regent, CytoDyn shall have the right to require American Regent (including the Person who acquired American Regent in the Change of Control, if any), to adopt procedures as reasonably requested by CytoDyn to prevent the disclosure of all CytoDyn Confidential Information beyond American Regent personnel having access to and knowledge of CytoDyn Confidential Information prior to the Change of Control and to control the dissemination of CytoDyn Confidential Information disclosed after the Change of Control. The purposes of such procedures shall be to strictly limit such disclosures to only those personnel having a need to know CytoDyn Confidential Information in order for American Regent to perform its obligations under this Agreement and to prohibit the use of CytoDyn Confidential Information for competitive reasons against CytoDyn (and its Affiliates) products, including the use of CytoDyn Confidential Information for the development or commercialization of competing products in the event of a Change of Control of American Regent. This Agreement shall be binding on, and inure to the benefit of, each Party, and its permitted successors and assigns.

12.7 Public Announcements. Neither Party shall make any voluntary publicity releases, interviews or other dissemination of Confidential Information concerning the Product, this Agreement or its terms, or either Party's performance hereunder, to communication media, financial analysts or others without the prior written approval of the other Party, which approval shall not be unreasonably withheld. Notwithstanding the foregoing, (a) CytoDyn may comply with its legal or regulatory disclosure obligations upon prior written notice to American Regent; and (b) upon written notice to American Regent, CytoDyn may make a mutually agreeable publicity release that mentions American Regent upon the execution of this Agreement, the FDA approval of the Product in the Field, or first sale of the Product by American Regent, *provided, however*, that American Regent shall have not less than three (3) Business Days to review and comment on such disclosures and filings, unless a shorter period is necessitated by securities laws, any such comments provided shall be reasonably accepted by CytoDyn and American Regent shall not unreasonably withhold, delay or condition its review and comments on such disclosures.

12.8 Severance. If any Official Body having jurisdiction over either CytoDyn or American Regent declares any Article or part thereof invalid or any such Official Body deems any Article or part thereof to be contrary to any Applicable Laws, then such Article or part thereof shall be deemed stricken from this Agreement in that jurisdiction. To the extent possible the Parties shall revise such invalidated Article or part thereof in a manner that will render such provision valid without impairing the Parties' original intent.

12.9 Non-Waiver. The failure of a Party in any one or more instances to insist upon strict performance of any of the terms and conditions of this Agreement shall not be construed as a waiver or relinquishment, to any extent, of the right to assert or rely upon any such terms or conditions on any future occasion. Except as otherwise specified, all rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be a limitation of any other remedy, right, undertaking, obligation or agreement.

12.10 Further Assurances. Each Party hereto agrees to execute such further documents and take such further steps as the other Party reasonably determines may be necessary or desirable to effectuate the purposes of this Agreement.

12.11 Disclaimer of Agency. This Agreement shall not constitute either Party the legal representative or agent of the other Party, nor shall either Party have the right or authority to assume, create, or incur any Third Party liability or obligation of any kind, express or implied, against or in the name of or on behalf of another except as expressly set forth in this Agreement. None of a Party's directors, officers, agents or employees shall be considered employees agents or legal representatives of the other Party for any purpose.

12.12 Construction. The language in all parts of this Agreement shall be construed, in all cases, according to its fair meaning. The Parties acknowledge that each Party and its counsel have reviewed and revised this Agreement and that any rule of construction to the effect that any ambiguities are to be resolved against the drafting Party shall not be employed in the interpretation of this Agreement. The words "hereof," "herein," "hereto" and "hereunder" and words of similar import, when used in this Agreement, shall refer to this Agreement as a whole and not to any particular provision of this Agreement. The terms defined in the singular shall have a comparable meaning when used in the plural, and vice versa. Whenever used herein, the words "include," "includes" and "including" shall mean "include, without limitation," "includes, without limitation" and "including, without limitation," respectively. The masculine, feminine or neuter gender and the singular or plural number shall each be deemed to include the others whenever the context so indicates.

12.13 Counterparts. This Agreement shall become binding when any one or more counterparts hereof, individually or taken together, shall bear the signatures of each of the Parties hereto. This Agreement may be executed in any number of counterparts, including by facsimile, each of which shall be deemed an original as against the Party whose signature appears thereon, but all which taken together shall constitute but one and the same document.

12.14 Consents in Writing. Any consents or approvals required hereunder from a Party must be in writing.

12.15 Set-offs. No Party may set-off against any payments owing hereunder without the written consent of the other Party.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties hereto have duly executed this Agreement as of the date first written above.

AMERICAN REGENT, INC.

By: /s/ Ken Keller
Name: Ken Keller
Title: President & CEO

CYTODYN, INC.

By: /s/ Nader Pourhassan
Name: Nader Pourhassan
Title: Chief Executive Officer

[SIGNATURE PAGE TO DISTRIBUTION AND SUPPLY AGREEMENT]

EXHIBIT A

CYTODYN'S 2020 ESTIMATES FOR COST OF GOODS SOLD

AGC/Ajinomoto: $[***] per 700 mg dose ($[***] / vial).

Samsung: $[***] per 700 mg dose ($[***] / vial).

[***] will be adjusted on an annual basis based on [***].