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) September 28, 2009

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

Colorado	000-49908	75-3056237
(State or other jurisdiction of incorporation	(Commission File Number)	(IRS Employer of identification No.)

1511 Third Street, Santa Fe, NM 87505
(Address of Principal Executive Offices) (Zip Code)

(505) 988-5520
(Registrant's telephone number, including area code)

(Former Name or Former Address, if Changed Since Last Report)
227 E. Palace Ave, Suite M, Santa Fe, NM 87501

Check the appropriate box below if the Form 8-K filing is intended to be simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

[ ] 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))

Item 8.01 Other Event

CytoDyn has entered into an agreement to provide financial support and free GMP product to Massachusetts General Hospital for the purpose of conducting an ex-vivo study of Cytolin(R), the Company's lead drug. The study will enroll 10 adults with early HIV infection and 10 healthy controls, each of whom will be required to participate for six months. This study, which is intended as a prelude to an in vivo study, will take advantage of the state-of-the-art laboratories available at Massachusetts General Hospital to confirm, and perhaps sharpen, the previously demonstrated role of killer T cells in causing the

wholesale loss of CD4 T cells in humans infected with HIV, as well as the mechanisms of action responsible for the clinical benefits seen in patients treated with Cytolin(R).

The Principal Investigator for the study is Eric S. Rosenberg, MD, an Associate Professor of Medicine in the Infectious Diseases Division of Massachusetts General Hospital and a prominent researcher specializing in HIV/AIDS. The study is being initiated by the Principal Investigator, who designed the study protocol, and is being sponsored by Massachusetts General Hospital.

The costs associated with this study are estimated to be approximately $316,000 of which 50% or $158,000 has already been paid to Massachusetts General Hospital by CytoDyn, along with a $2,500 fee for the Institutional Review Board (IRB). The company has raised all the capital required for this study through a company offering of preferred shares.

This agreement with Massachusetts General Hospital is a departure from the Company's previously announced strategy for developing Cytolin(R) and from the traditional model of drug development under which clinical studies are conducted strictly for the purpose of demonstrating the safety and efficacy of a new drug. However, management believes that because of new economic and regulatory realities, it is in the interests of CytoDyn to support this study sponsored by Massachusetts General Hospital, which is intended to confirm, and perhaps sharpen, the scientific breakthrough underlying Cytolin(R).

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
10.1	Clinical Trial Agreement between CytoDyn, Inc. and The General Hospital Corporation

SIGNATURE

Pursuant to the requirements of 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.

Date: September 29, 2009

/s/ Allen D. Allen

Allen D. Allen

THE GENERAL HOSPITAL CORPORATION
CLINICAL TRIAL AGREEMENT
(Investigator-Initiated)

This Clinical Trial Agreement ("Agreement") is made as of the 28 day of September, 2009 ("Effective Date") between CytoDyn, Inc., a publicly traded corporation organized under the laws of Colorado with its principal place of business at 1511 Third Street, Santa Fe, New Mexico 87505 ("Company"), and The General Hospital Corporation d/b/a Massachusetts General Hospital, a not-for-profit corporation organized under the laws of Massachusetts with its principal place of business at 55 Fruit Street, Boston, MA 02114 ("Institution"), each referred to herein individually as a "Party" and collectively as the "Parties."

The Parties to this Agreement share a common mission of improving the public health by engaging in research for the purpose of discovering and making available to the public new and improved medical drugs, devices, procedures, and information. In connection with this mission, Institution, through Eric Rosenberg, M.D. ("Principal Investigator"), having particular expertise and opportunity, proposes to provide, and Company desires to have, further research conducted on Company's drug described below.

Accordingly, for good and valuable consideration, the sufficiency of which is hereby acknowledged, the Parties agree as follows:

Section 1: Study Performance
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1.1 Conduct of Study in Accordance with Protocol; Priority of Terms. Subject to the initial and continuing approvals described in Section 1.2 below, Institution, through Principal Investigator, agrees to conduct an ex-vivo study of Cytolin(R) brand of S6FI monoclonal antibodies ("Study Drug") in accordance with the study protocol entitled "An observational study to determine the in-vitro immunologic and virology activity of Cytolin," attached to this Agreement as Exhibit A and herein incorporated by reference ("Study"). The Parties agree that the Study will be performed in strict accordance with the Study protocol entitled above, and any subsequent amendments thereto (the" Study Protocol"). In the event of any conflict between the Protocol and the provisions of the main body of this Agreement, the Protocol shall govern with respect to scientific and subject consent issues, and the provisions of the main body of this Agreement shall govern with respect to all other issues. In the event of any conflict between the Study informed consent form and the provisions of this Agreement with respect to any commitment by Company to cover costs associated with subject injuries, the broader commitment (the commitment that is more protective of human subjects) shall control.

1.2 Study Review and Approvals. The Study shall be conducted by personnel, agents, vendors, or consultants of Institution under the direction of the Principal Investigator at Institution or additional facilities with the prior approval and ongoing review of all appropriate and necessary review authorities. Institution, through Principal Investigator, shall provide Company with written evidence of review and approval of this Study by Institution's Institutional Review Board ("IRB") prior to the initiation of the Study and shall inform Company of the IRB's continuing reviews of the Study promptly after each such review takes place, which shall be at least once per year. Initiation of the Study Protocol shall not begin until IRB approval

is obtained. In accordance with the obligations under the Food and Drug Administration Amendment Act of 2007 ("the Act"), Company agrees to fully register this Study with the public registry clinicaltrials.gov before enrollment of the first patient at Institution and comply with all of the Act's requirements thereafter.

1.3 Completion of the Study. For purposes of this Agreement, Company and Institution shall consider the Study to be complete and concluded at all sites at such time as the occurrence of final data lock or earlier termination

by a Data Safety Monitoring Board or as otherwise specified in the Protocol ("Study Conclusion").

1.4 Provision and Use of Study Drug. Company shall be responsible for providing and delivering to Institution, at no charge, such quantities of the Study Drug in bags for in vitro use as needed for conducting the Study in accordance with the Study Protocol, along with the results of safety testing for the lot of Study Drug provided, and conducted according to currently published standards. Institution acknowledges receipt of the latter. Company understands that Institution and Principal Investigator are relying on timely delivery of the Study Drug in order for Institution to perform its obligations under this Agreement. Institution understands that the ability of the Company to provide the drug depends upon Institution providing shipping and delivery requirements. Institution, through Principal Investigator, will safeguard such Study Drug with the degree of care used for its own property and shall return or otherwise dispose of any remaining Study Drug at the Study Conclusion in accordance with the Study Protocol. Institution and Principal Investigator shall not use any Study Drug for any purpose other than the Study, unless otherwise agreed. Company represents and warrants that it is in compliance with federal, state, and local laws and regulations relating to the manufacture and formulation of any investigational drug and to other materials supplied, and with other applicable legal requirements.,

1.5 Compliance with Applicable Laws and Regulations. Parties agree to conduct the Study in accordance with all applicable local, state, and federal laws and regulations.

Section 2: Material Subject Information
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2.1 Company agrees to notify Principal Investigator in writing promptly and at least within fifteen (15) days of information (such as Study results) that could affect the safety or medical care of current or former subjects, affect current subjects' willingness to continue participation, influence the conduct of the Study, or alter the IRB's approval. Company and Institution shall comply with their respective reporting requirements to regulatory authorities, including, for example, the Food and Drug Administration, the Office for Human Research Protections, and other authorities as required. Institution, through the Principal Investigator and/or IRB as appropriate, shall be responsible for informing subjects of the above important information they learn from Company in accordance with the IRB-approved informed consent form and Company shall not contact them. No other provision of this Agreement shall be construed to override the provisions of this Section 2.1.

Section 3: Study Data/Results
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3.1 Provision of Data/Results; Provision of Abstracts/Manuscripts].

(a) Institution shall own the data resulting from the Study. Institution shall provide copies of the data produced in the performance of the Study to Company. Company may use the Study data in accordance with Section 3.2.

(b) All data from laboratory analyses for Institution's Study subjects which are performed off-site, and all other subject-specific data generated by Company or its agents for Institution's Study subjects, if Institution does not receive such data directly from the off-site laboratory or other source, shall be provided by Company to Institution upon the Study Conclusion. If the Study is blinded, Company shall also provide the randomization codes for Institution's Study subjects upon the Study Conclusion.

3.2 Use of Data/Results. Institution shall comply in all material respects with all applicable federal, state and local laws and regulations regarding the privacy of individually identifiable health information (including

its collection, use, storage, and disclosure), including, but not limited to, the Health Insurance Portability and Accountability Act of 1996 ("HIP AA") and the regulations promulgated thereunder, as may be amended from time to time. Company agrees to collect, use, store, and disclose individually identifiable health information collected or produced in the Study only for the purpose of the Study and related studies (that is, other studies of the Study Drug, alone or in combination with other drugs, or other studies that relate to the medical condition or disease area under investigation in the Study), and for the purpose of complying with applicable law, provided that all such uses are disclosed in the IRB-approved informed consent form. If Institution's IRB-approved informed consent form so states, Company may use information that is not identifiable under any applicable U.S. laws for any research and development purpose. Company will use all reasonable efforts to protect the privacy and security of individually identifiable health information and will require its business partners to do so also. Company will not contact any Study subjects, unless permitted by the informed consent form. No other provision in this Agreement shall be construed to override the provisions of this Section 3.2.

3.3 Use of Specimens/Tissue. Company will collect, use, store, and disclose any specimens/tissue it receives only in accordance with the Protocol and informed consent form, and in any event will not collect, use, store, or disclose any individually identifiable health information attached to or contained within the specimens/tissue in any manner that would violate Section 3.2 of this Agreement.

Section 4: Publication
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4.1 Principal Investigator shall be free to publish the data/results from the Study in accordance with this Section 4.1.] Principal Investigator shall be free to publish the data/results of the Study subject only to the provisions of Section 8 regarding Company's Proprietary

Information. The Institution shall require Principal Investigator to furnish Company with a copy of any proposed publication prior to submission for publication, at least thirty (30) days prior to submission for manuscripts and at least seven (7) days prior to submission for abstracts. Company shall be entitled to review such proposed publications solely for the purpose of identifying Company Proprietary Information, which shall be removed from the publication upon Company's request; and to identify any patentable Inventions, which shall be addressed as described below; and to provide any other comments Company desires to provide, provided that Principal Investigator shall have no obligation to address any such additional comments. At the expiration of such thirty (30) day or seven (7) day period, Principal Investigator may proceed with submission for publication provided that any identified Company Proprietary Information has been removed; and provided further that upon notice by Company that Company reasonably believes a patent application claiming an Invention (as defined in Section 5) should be filed prior to such publication, in Institution's discretion such submission shall be delayed for up to an additional thirty (30) days or until any patent application or applications have been filed, whichever shall first occur. In no event shall the submission of such publication of results be delayed for more than sixty (60) days for manuscripts and for more than thirty-seven (37) days for abstracts from the date such proposed publication was provided to Company; at the end of said sixty (60) or thirty-seven (37) days, the Principal Investigator shall be free to publish such results as proposed.

Section 5: Inventions/Intellectual Property
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5.1 The Principal Investigator and any other investigators (hereinafter "Institution Investigator") who shall conceive and reduce to practice an invention, solely or jointly, in the performance of the Study as outlined in the Protocol (hereinafter referred to as "Invention") shall promptly report such Invention to Institution and shall assign all of his or her rights,

title and interest in the Invention to Institution. Institution shall promptly advise Company in writing of each Invention disclosed to Institution and shall discuss with Company whether a patent application or applications (hereinafter referred to, together with any patents issued thereon, as "Patent Rights") pertaining to such Invention should be filed and in which countries. In the event of joint inventorship between Company personnel and Institution Investigator, Company personnel shall assign all of their rights, title and interest in the Invention ("Joint Invention") to Company, and Institution Investigator shall assign all of their rights, title and interest in the Joint Invention to Institution, and the Joint Invention will be deemed to be jointly owned. If both parties mutually agree that Patent Rights should be filed, applications assigned solely to Institution shall be filed by Institution, and applications owned jointly by Institution and Company shall be filed as mutually agreed upon by the parties. In the event Company is not interested in having Patent Rights filed with respect to a particular Invention, Company shall advise Institution of such fact within ninety (90) days from the date on which the Invention was disclosed to Company by Institution and Institution shall be free to file and prosecute Patent Rights on such Invention (including Institution's rights in any Joint Invention) at its own expense and to license such Patent Rights to any other party.

5.2 All patent costs pertaining to any Patent Rights filed by mutual agreement of Company and Institution, including preparation, filing, prosecution, issuance and maintenance costs, shall be borne by Company.

5.3 As to any Patent Rights assigned in whole or in part to Institution and filed by mutual agreement of the parties, Company shall have for the three (3) months next following the filing of such Patent Rights in the United States Patent and Trademark Office the option to negotiate a world-wide, royalty bearing, exclusive license under the rights assigned by an Institution Investigator to Institution therein with the right to sublicense. It is understood that Institution will reserve the right to use any Invention for research, clinical and educational purposes, and that if federal funding has supported the Invention, Company's license will be subject to the rights, conditions and limitations imposed by United States law with respect to Subject Inventions (as defined in 35 U.S.C. Section 202 et seq., as amended), including without limitation the royalty-free non-exclusive license granted to the United States Government with respect to such Subject Inventions (see 35 USC Section 202 et seq., as amended, and regulations pertaining thereto).

5.4 This option is to be exercised by written notice to Institution during said three month period and the negotiation, during the three (3) months next following such notice, of a license agreement containing license terms standard for agreements between universities and industry including without limitation clauses providing for payment of reasonable royalties and other compensation to Institution, objective, time-limited due diligence provisions for the development, commercialization and marketing of a product embodying the Invention and product liability indemnification and insurance requirements which are acceptable to Institution's liability insurance carrier. In the absence of such notice by Company and agreement on license terms, Institution may grant a license to such Patent Rights to any other party.

5.5 All information given to Company by Institution in accordance with Sections 5.1, 5.2, 5.3, and 5.4 will be held in confidence by Company so long as such information remains unpublished or publicly undisclosed by Institution.

Section 6: Use of Name
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6.1 Except for disclosure by Institution of Company's support for the Study in publications, for purposes of recruitment/consent of Study subjects, and by either Party for purposes of meeting any applicable requirements for the registration of the Study or of Study results with a publicly accessible or other clinical trial registry, and for satisfying the Company's obligation to report its financial commitments to Institution in cash or in kind and related material events in an 8K filed with the Securities and Exchange Commission

within four days of the date this Agreement is executed, neither Party to this Agreement shall use the name of the other Party or of any staff member, employee, student, or agent of the other Party or any adaptation, acronym or name by which the other Party is commonly known, in any advertising, promotional or sales literature or in any publicity without the prior written approval of the Party or individual whose name is to be used., which approval shall not be unreasonably withheld.

Section 7: Study Records
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7.1 Institution shall make Study records (including minimum necessary portions of

medical records) available to Company representatives upon reasonable request for comparison with case report forms. Any audits conducted by Company will be undertaken in conjunction with Institution, at reasonable times and with reasonable prior notice, and pursuant to guidelines established by Institution in order to assure patient confidentiality. Each of Company and Institution shall retain records of the Study, including in Institution's case either the original or a copy of all volunteer consent forms, in conformance with federal regulations applicable to it. . Institution shall also make such records available upon request for review by representatives of the U.S. Food and Drug Administration. Company acknowledges that Company may not direct the manner in which Institution fulfills its obligations to permit inspection by governmental entities. It shall not be a breach of this Agreement for Institution to comply with the demands and requests of any governmental entity in accordance with Institution's judgment or to fail to inform and consult with the Company before complying with such demand or request.

Section 8: Proprietary Information
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It is anticipated that in the performance of this Agreement, Principal Investigator, Company and Institution may need to disclose to each other information, which is considered confidential. The rights and obligations of the parties with respect to such information are as follows:

8.1 "Disclosing Party" shall mean a party that discloses Proprietary Information (as defined in paragraph 8.2 below) under this Agreement. "Receiving Party" shall mean a party that receives Proprietary Information under this Agreement.

8.2 "Proprietary Information" refers to information of any kind, other than data from or results of the Study, which is obtained by Receiving Party from Disclosing Party, which, by appropriate marking, is identified as confidential and proprietary at the time of disclosure. In the event that Proprietary Information must be provided visually or orally, obligations of confidence shall attach only to that information which is confirmed by Disclosing Party in writing within thirty (30) working days as being confidential.

8.3 Period of Restriction. For a period of five (5) years after the Effective Date of this Agreement and indefinitely with respect to any individually identifiable health information, institutional billing information and institutional financial information disclosed by Institution to Company, Receiving Party agrees to use reasonable efforts, no less than the protection given their own confidential information, to use Proprietary Information received from Disclosing Party and accepted by Receiving Party only in accordance with this Section 8.

8.4 Use of Proprietary Information. Receiving Party agrees to use Disclosing Party's Proprietary Information solely for the purposes of conducting the Study, obtaining any required review of the Study or its conduct, or ensuring proper medical treatment of any patient or subject. Receiving Party agrees to make Proprietary Information available only to those personnel and

agents at Receiving Party and those consultants and vendors who require access to it in the performance of this Study and to inform them of the confidential nature of such information.

8.5 Release of Proprietary Information. Except as provided herein, Receiving Party

agrees to keep all Proprietary Information confidential unless Disclosing Party gives specific written consent for release.

8.6 Notice of Unauthorized Disclosure. Receiving Party shall notify, and shall require any recipient to notify, Disclosing Party of any disclosure not authorized hereunder of which it becomes aware. In such situations, Receiving Party shall take and shall require each such recipient to take reasonable steps to prevent any further disclosure or unauthorized use.

8.7 Exclusions. No Receiving Party shall be required to treat any information as Proprietary Information under this Agreement in the event:

(i) it is publicly available prior to the date of the Agreement or becomes publicly available thereafter through no wrongful act of Receiving Party;

(ii) it was known to Receiving Party prior to the date of disclosure or becomes known to Receiving Party thereafter from a third party having an apparent bona tide right to disclose the information;

(iii) it is disclosed by Receiving Party in accordance with the terms of Disclosing Party's prior written approval;

(iv) it is disclosed by Disclosing Party without restriction on further disclosure;

(v) it is independently developed by Receiving Party; or,

(vi) Receiving Party is obligated to produce it pursuant to a requirement of applicable law or an order of a court of competent jurisdiction or a facially valid administrative, Congressional or other subpoena, provided that the Receiving Party, subject to the requirement or order or subpoena (A) promptly notifies Disclosing Party and (B) cooperates reasonably with Disclosing Party's efforts to contest or limit the scope of such disclosure.

8.8 Each party reserves the right, in its sole discretion and without prior notice to any other party, to disclose its own Proprietary Information to any third party for any purpose.

Section 9: Budget and Payments
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9.1 General. Company agrees to support this Study with a research grant of three hundred sixteen thousand seven hundred and fifty-five Dollars ($316,755.00), inclusive of indirect costs, 50% to be paid upon execution of this Agreement, 25% to be paid by month three of the study, and 25% to be paid by month six of the study, all subject to the internal-controls provisions of the Sarbanes-Oxley Act.

9.2 Checks. Checks shall be made payable to The General Hospital Corporation, Federal Tax ID No.: 04-2697983, shall reference the name of the Principal Investigator, the Protocol number, and the Research Management agreement number 2009A055353, and shall be

forwarded to:

Massachusetts General Hospital
Research Finance
PO Box 414876
Boston, MA 02241-4876

9.3 IRB Fee. Company shall pay a one-time, non-refundable, non-overhead-bearing fee of twenty five hundred dollars ($2,500.00) to Institution to cover its IRB's costs for reviewing the initial Protocol and any subsequent annual reviews that may be required. Institution shall invoice Company for this fee upon execution of this Agreement.

Section 10: Term and Termination
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10.1 Term. The term of this Agreement shall be from the Effective Date until completion of the Parties' substantive obligations under the Agreement in the performance of the Study, unless earlier terminated in accordance with Section

10.2 Termination.

(a) Either Party hereto shall have the right to terminate the Study and this Agreement at any time upon six (6) months prior written notice thereof to the other Party, except that either Party may terminate the Study and this Agreement at any time upon thirty (30) days prior written notice thereof to the other Party in the event of a material breach of the Agreement by the other Party, and except that either Party may terminate the Study and this Agreement immediately upon written notice to the other Party if necessary to protect the health, welfare or safety of any Study subject.

(b) If the Principal Investigator ceases to serve in such role during the term of the Agreement, Institution shall promptly notify Company. Institution may name a substitute principal investigator (who shall thereafter be referred to as Principal Investigator for purposes of this Agreement), subject to the approval of Company, which approval will not be unreasonably withheld by the Company. If the Parties fail to reach agreement with respect to continuation of the Study and the Agreement within ninety (90) days following the date on which Institution notifies Company that the original Principal Investigator became unavailable, Company shall have the right to terminate the Study and this Agreement immediately upon written notice to Institution.

10.3 Continuation of Enrolled Subjects. The Parties agree that if, at the time either Party receives notice of termination pursuant to this section, any subjects are enrolled in the Study, said subjects shall complete the Study, at Company's expense, if completion is in the best interest of said subjects.

10.4 Continuation of Grant/Payments. In the event of any termination other than a for-

cause termination by Company for Institution's material breach, the amount of the research grant by Company to support the Study shall be appropriately prorated to allow Institution to recover reasonable costs and noncancellable commitments incurred, including without limitation, termination salary costs of any Institution personnel released as a result of such termination, and other payments payable by Company for procedures or portions of procedures completed at the time of termination shall be made/fulfilled.

10.5 Survival. The obligations of the Parties under Sections 1.1 (Priority), 1.3, [1.4,] 2.1, 3.1, 3.2, 3.3, 4.1, 5.1-5.5, 6.1, 7.1, 8.1-8.8, 10.3, 10.4, 11.1, 11.2, 11.3, 12.1, 13.2, and 13A13.8 shall survive any

termination or expiration of this Agreement.

Section 11: Subject Injury; Insurance; Coordination with Other Agreements

11.1 Injury.

(a) Company agrees to reimburse Institution for (or otherwise pay for) the care and treatment of any illness or injury occurring to a person involved in the Study resulting from their participation in the Study.

(b) Company represents and warrants that it will not allow any Company representative or agent to insert or negotiate into the Study's informed consent form any language whatsoever.

(c) Company's commitment under (a) above shall not apply to any illness or injury to the extent it directly results from: (i) the negligence or reckless or intentional misconduct of, or violation of law by, Institution, Principal Investigator, or Institution's personnel; or (ii) failure of Institution, Principal Investigator, or Institution's personnel to adhere to the terms of the Protocol for the Study, provided, however, that emergency medical care shall not be deemed a violation of the Protocol.

11.2 Insurance.

(a) Company shall, at its sole cost and expense, procure and maintain policies of general liability insurance in amounts not less than Two Million Dollars ($2,000,000) per occurrence and Two Million Dollars ($2,000,000) annual aggregate covering its obligations under this Agreement, including contractual liability coverage for injury under this Section 11, if any.

(b) Company shall provide Institution at its request with written evidence of such insurance prior to the commencement of the Study. Company shall provide Institution with written notice at least thirty (30) days prior to the cancellation, non-renewal or material change, in such insurance; if Company docs not obtain replacement insurance providing comparable coverage within such thirty- (30-) day period, Institution shall have the right to terminate this Agreement effective at the end of such thirty- (30-) day period without notice of any additional waiting periods.

11.3 Coordination with Other Agreements. The Parties do not intend any provision in this Agreement concerning insurance commitments or indemnification commitments (if any) to affect or be affected by any additional insurance or indemnification commitments that may be provided for in any separate contract, purchase order, terms and conditions document, or other agreement between the Parties related to the Study (including agreements related to the purchase, lease, or use of any Study Equipment).

Section 12: Notices

12.1 Any written notices, reports, correspondences or other communications required under or pertaining to this Agreement shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed as follows:

Jason McLaren, J.D., Pharm.D.
Agreement Associate
Partners Clinical Research Office
101 Huntington Avenue, 4th Floor
Boston, MA 02199

Eric Rosenberg, M.D.
Massachusetts General Hospital
55 Fruit St.
Boston, MA 02114

Allen D. Allen
CytoDyn, Inc.
1511 Third Street
Santa Fe, New Mexico 87505

Section 13: Miscellaneous
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13.1 Amendment. The terms of this Agreement can be modified only by a writing, which is signed by authorized representatives of Institution and Company.

13.2 Choice of Law; Jurisdiction and Venue. This Agreement shall be governed by and construed and interpreted in accordance with the laws of the Commonwealth of Massachusetts. Each Party agrees to submit to the exclusive jurisdiction of the Superior Court for Suffolk County, Massachusetts, and the United States District Court for the District of Massachusetts with respect to any claim, suit, or action in law or equity arising in any way out of this Agreement or the subject matter hereof.

13.3 Assignment. Neither Party to this Agreement may assign its obligations hereunder without the prior written consent of the other Party.

13.4 Entire Agreement. This Agreement, including any exhibits, attachments, and other documents that are incorporated by reference herein, constitutes the entire understanding and agreement between the Parties, and supersedes and replaces all prior agreements, understandings, writings and discussions between the Parties with respect to the subject matter of this Agreement.

13.5 Waiver. The failure of a Party in any instance to insist upon the strict performance of the terms of this Agreement shall not be construed to be a waiver or relinquishment of any of the terms of the Agreement, whether at the time of the Party's failure to insist upon strict performance or at any time in the future, and such term(s) shall continue in full force and effect.

13.6 Severability. Each clause of this Agreement is a distinct and severable clause and if any clause is deemed illegal, void, or unenforceable, the validity, legality, or enforceability of any other clause of this Agreement will not be affected thereby.

13.7 Additional Partners HealthCare Hospital Site. In the event that an additional Partners HealthCare hospital becomes an enrolling site for this Study, then the Sponsor agrees that the substantive terms of the clinical trial agreement with the additional Partners HealthCare hospital will be the same as in this Agreement except with respect to budget and contracting party.

13.8. Titles. All the titles and headings contained in the Agreement are inserted only as a matter of convenience and reference and do not define, limit, extend, or describe the scope of this Agreement or the intent of any of its provisions.

13.9 Counterpart Signatures. This Agreement may be executed in one or more counterparts, each of which counterpart shall be deemed an original Agreement and all of which shall constitute but one Agreement.

13.10 No Agency. Joint Venture or Partnership. Each Party's relationship to the other Party under this Agreement will be that of an independent contractor and neither Party shall be considered to be an agent, joint venturer or partner of the other Party.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be duly executed as of the Effective Date above written.

Signature page to follow.

CytoDyn, Inc.	THE GENERAL HOSPITAL CORPORATION
By: /s/ Allen D. Allen	By:
Name: Allen D. Allen	Name: Jason McLaren
Title: President and CEO	Title: Agreement Assoc.
Date: September 28, 2009	Date:

Read and Acknowledged:

By: ERIC S. ROSENBERG, MD
Date:

EXHIBIT A

1. PROTOCOL Protocol Summary

1.1 Rationale
In vivo studies using Cytolin, a monoclonal antibody that binds LFA1, suggested that Cytolin increases CD4+ T cell counts and decreases HIV viral load in HIV infected individuals. This study is a laboratory based pilot study to determine the immunologic mechanisms of action of this compound.

1.2. Hypothesis
Cytolin preserves CD4+ T cell number and function in vitro by inhibiting CTL mediated killing of virus-specific CD4+ T helper cells.

1.3. Design
This is an observational study that will enroll 10 HIV- and 10 HIV+ individuals. Each subject will attend 3 study visits over a 6 month period. Laboratory studies testing the in vitro effects of Cytolin on T cell function and HIV replication will be done for each study visit.

2. Study Objectives
2.1. Primary objective - determine the in vitro effect of Cytolin on CD4+ and CD8+ T cell effector functions in HIV infected individuals.
2.2. Secondary objective - determine the in vitro effect of Cytolin on HIV replication.

3. Introduction
3.1. Background

One of the characteristic features of HI V infection is the progressive loss of CD4+ T cells. There arc likely several mechanisms by which CD4+ T cells are lost. One possibility is that these cells are killed by cytotoxic T lymphocytes 1. Since there are relatively few HIV infected CD4+ T cells, if CTL lysis is a major contributor to the loss of CD4+ T cells, then killing of both infected and uninfected CD4+ T cells would have to occur. It has been observed that CD8+ CTL from HIV infected individuals but not HIV seronegative controls lyse activated CD4+ T cells 1. The mechanism of lysis appears to be MHC restricted, as HLA mismatched targets were not lysed. This means that C08+ CTL from HIV+ subjects recognized an unknown antigen normally presented via MHC class I on activated CD4+ T cells.

Cytolin is a murine monoclonal antibody that binds to an epitope (also known as S6FI) on Lymphocyte Function-Associated Antigen I (LF Al)2. This epitope is preferentially expressed on cytolytic CD8+ T cells and appears to be induced following antigen specific activation. It is also present on null cells (such as NK cells) and infrequently on CD4+ T cells. CD8+ T cells expressing S6Fl have been shown to be elevated during the asymptomatic phase of HIV infection3. Furthemwre, the CD8+ T cells that kill HIV -infected cells are known to express the S6FI epitopc4-. Although some anti-LFAI antibodies have been shown to block cytolysis, anti-S6Fl antibodies do not appear to block this effector function 2.

LFAI is an adhesion molecule expressed on T cells. Binding of LFA1 to ICAM on antigen presenting cells stabilizes the interaction between the cells allowing signaling through the T cell receptor. ICAM is also expressed on lymphocytes. During budding, HIV incorporates ICAM into its envelope. Transmission of HIV into uninfected T cells is facilitated by the LFA1 - rCAM interaction. Anti-LFA1 antibodies have been shown to inhibit cell-to-cell transmission of HIV. It is currently unknown whether Cytolin has this affect.

Cytolin has been tested as a therapeutic in HIV infected individuals 5, 6. In pilot studies, Cytolin was shown to reduce HIV plasma viral load by 0.5-1 log and increase relative CD4+ T cell counts. Since viral load and CD4+ T cell counts arc predictive of clinical progression, these results suggest that the use of Cytolin may delay disease progression.

3.2. Rationale

This study is a laboratory based pilot study to test the hypothesis that Cytolin preserves CD4+ T cell number and function and decreases HIV replication in vitro. Cytolin has been administered on a compassionate use basis to HIV infected individuals. These studies suggested that Cytolin may increase CD4+ T cell counts and decrease HIV viral load in infected individuals. It is hypothesized that the increase in CD4+ T cell number is a result of

Cytolin inhibiting lysis of uninfected CD4+ T cells by CD8+ cytotoxic T Lymphocytes (CTL). It is currently unknown whether the increase in CD4+ T cell number also restores CD4+ T cell effector functions which are typically weak or absent in HIV infected individuals. The decline in viral load observed in subjects treated with Cytolin is thought to occur as a result of inhibiting transmission of the virus to uninfected cells by preventing the interaction of adhesion molecules that arc incorporated into the viral envelope with their ligands on target cells. However, this hypothesis is based on the use of other antibodies that bind LFA1. It is currently not known whether Cytolin has the same effect.

4. Selection and Enrollment of Subjects

4.1. Inclusion Criteria

- Men and women age 18-65 years
- HIV seropositive - subjects identified with HIV infection defined by a positive HIV 1/2 ELISA and HIV-l Western Blot who do not meet criteria for antiretroviral therapy (viral load<100,000 copies/ml, CD4+>350 cells/ul).
- HIV seronegative - subjects identified as HIV uninfected defined by a nonreactive HIV 1/2 ELISA.

- Ability and willingness to give written informed consent.

4.2. Exclusion Criteria

- Presentation with an opportunistic infection or AIDS-defining illness.
- Receipt of investigational research agent within 30 days prior to study entry.
- Prior receipt of experimental HIV vaccine. Individuals who received a saline placebo are not excluded, provided they did not receive a sham vector or adjuvant.
- Receipt of immunosuppressive medications or immune modulators within the past six months. Individuals taking corticosteroid nasal spray for allergic rhinitis, topical steroids or over the counter medications for acute, uncomplicated dermatitis for a period no longer than 14 days will not be excluded.
- Active drug or alcohol use, dependence, or psychiatric illness that in the opinion of the study investigator would interfere with adherence to study protocol.
- Serious illness requiring hospitalization.

4.3. Study Enrollment Procedures

This protocol and the informed consent will be reviewed and approved by the Massachusetts General Hospital/Partners Protection of Human Subjects Committee (MGH IRB) prior to implementation of the study. When an individual has been identified as a potential candidate for the study, study staff will explain the details of the study and obtain written informed consent.

5. Study Treatment

No treatment will be given to any subject enrolled in this study. If a subject becomes eligible for antiretroviral therapy, treatment can be initiated at the discretion of the subject and his/her health care provider. Subjects who initiate antiretroviral therapy may continue on the study.

6. Clinical Evaluations

6.1. Schedule of events

Three study visits are scheduled at 3 month intervals over the course of 6 months. There will be a window period of +/- 7 days around the specific study date in which the subject will be allowed to participate in thc scheduled encounter. The date of all study visits will be determined at study entry.

Evaluation	Entry	3 month	6 month
Medical History	X		
Physical Exam/medications	X		
HIV ELISA and Western Blot	X		
CMV, EBV, VZV serology	X		
HLA typing	X		
HIV RNA viral load	X	X	X
CD4+/CD8+ subsets	X	X	X

Immunology studies	X	X	X
Virology studies	X	X	X

6.2. Special Instructions and Definition of Evaluations

- A medical history must be present in source documents and completed

prior to enrollment. The medical history should include any previous non-HIV related diagnoses of major organ systems.

- o A medication history documenting any previous use of immune-based therapies, HIV -related vaccines, antiretroviral therapies must be obtained at study entry.

- o A physical exam will be performed at study entry which includes determination of vital signs (temperature, pulse, blood pressure) and weight. Signs and symptoms of HI V-related and AIDS defining events will be documented. All confirmed and probable diagnoses made since the last study visit will be recorded in source documents.

- o Enumeration of the absolute count and percentage of CD4+ and CD8+ lymphocytes must be done by MGH clinical laboratory which is a CLIA certified clinical laboratory.

- o Plasma HIV RNA will be performed using the Roche standard method by the MGH clinical laboratory which is CLIA and VQA certified.

- o Class I HLA typing will be done.

- o The plasma titer of antibodies to Cytomegalovirus, Epstein Bar virus, and Varicella Zoster virus will be determined.

- o Laboratory studies - see section 8.

7. Laboratory Studies

7.1. Primary Objective - determine the ill vitro effect of Cytolin on T cell number and effector functions in HIV infected individuals.

7.1.1. To determine the effect of Cytolin on T cell number, PBMC will be incubated in the presence and absence of Cytolin and the frequency of CD4+ and CD8+ lymphocytes will be assessed using flow cytometry. Since Cytolin is hypothesized to prevent the lysis of activated CD4+ T cells, the cells will additionally be stained with CD69, CD25, and CD38 to determine if these cellular subsets arc preferentially maintained in cultures which contain Cytolin. It has previously been shown that CTL from HIV+ but not HIV- subjects lyse activated CD4+ T cells. Therefore, thcsc experiments will be done using cells from seropositive and seronegative donors. We anticipate that Cytolin will have no significant effect on CD4+ T cell numbers from HIV- subjects.

7.1.2. Based on the currently available data it is unclear whether Cytolin will block lytic activity of CTL. Furthermore, we arc interested in whether Cytolin can block lysis of un infected but not infected CD4+ T cells. To determine whether Cytolin prevents lysis of target cells, infected CD4+ T cells will be used as targets and autologous CD8+ T cells will be used as effectors in a flow cytometry based cytotoxicity assay. In this assay, targets are labeled with Cell Tracker Orange then added to CD8+ effectors in the presence and absence of CylOlin. Following incubation, target cell death is measured by incorporation of 7AAD. Infected target cells will be identified using an antibody to the HIV protein, p24. This will allow us to determine the relative number of infected and uninfected CD4+ T cells that arc lysed. We will also label effector cells with antibodies against CDJ07a and granzymes to correlate these effector molecules with lytic activity.

7.1.3. Although S6F1 is preferentially expressed on cytolytic CD8+ T cells, it has also been shown to be expressed on a subpopulation of CD4+ T cells. The effect of Cytolin on CD4+ T cells is currently unknown. To determine whether Cytolin binds to CD4+ T cells, an aliquot of Cytolin will be conjugated to a fluorophore then used to label CD8+ depleted PBMC. Cells will also be stained with the activation markers CD25, CD69, CD38 and the cytolytic marker CDI07a. This will allow us to

determine whether activated, cytolytic CD4+ T cells bind

Cytolin. These experiments will be performed on HIV+ and HIV- subjects to determine whether the S6Fl epitope is differentially regulated on CD4+ cells in HIV+ individuals.

7.1.4. To determine the effect of Cytolin on CD4+ T cell functions proliferation, cytokine secretion (IL2, TNFa, IFNg), and expression of the co-stimulatory marker CD4+0L will be assess in the presence and absence of Cytolin by flow cytometry. PBMC or CD8+ depleted PBMC will be incubated with Cytolin then stimulated with antigen (CMV, EBV, VZV, or HIV) to determine the direct and indirect effects of Cytolin on CD4+ T cells. Since CD4+ T cell function is typically weak or absent in HIV infected individuals, these experiments will be performed on HIV+ and HIV- subjects. This will allow us to determine whether function can be restored in HIV+ subjects. Ifnot, experiments using cells from the HIV- subjects may provide insight into whether CD4+ T cell function is altered in any way. If so, Cytolin may benefit HIV+ subjects who maintain CD4+ T cell function as a result of being treated very early during the course of their infection.

7.2. Secondary objective - determine the in vitro effect of Cytolin on HIV replication.

7.2.1. Transmission of HI V from cell-to-cell is facilitated by interactions between LFA1 and ICAM. Given that Cytolin reduced viral loads in HIV infected individuals, we hypothesize that Cytolin blocks this interaction. To test this hypothesis HIV infected PHA blasts will be co-cultured with uninfected target cells in the presence and absence of Cytolin and viral replication will be determined using a p24 assay. These experiments will be performed using cells from HIV- subjects.

7.2.2. An alternative hypothesis is that infected cells are lysed even the presence of Cytolin. Although this hypothesis is being addressed as described in section 8.1.2, we will further test this hypothesis by measuring the ability of CTL to suppress HIV replication in the presence and absence of Cytolin. In this assay, HIV infected CD4+ T cells are co-cultured with autologous CD8+ T cells and viral replication is monitored using a p24 ELISA. These experiments take into account all CD8+ T cell effector functions, not just cell killing. This approach may provide additional insight into the mechanisms of action of Cytolin in vivo. These experiments will be performed using cells from HIV+ and HIV - subjects.

8. Statistical Considerations

8.1. General Design Issues

The design of this study reflects the need to obtain blood from HIV+ and HIV- individuals in order to determine the in vitro effect of Cytolin on T cell function and HIV replication.

8.2. Sample Size Considerations

Our experience with these type of experiments suggests that 10 HIV+ and JO HIV- subjects will be sufficient to extract meaningful results.

8.3. Enrollment and Accrual

Based on the history of recruitment of subjects with HIV infection at the study site, it is anticipated that one to four subjects per month may be recruited. Thus it is expected that it will take one year to enroll all subjects.

Experience at this site indicates that patients will likely show good adherence to the study visit schedule.

8.4. Monitoring

Data completeness and quality will be monitored monthly by the laboratory manager and the study manager. Because of the small size and single site nature of the study it will be easy to examine the data for inconsistencies and missing data. Data will also be assessed for completeness and accuracy and inconstancies will be addressed with each research subject at the final study visit.

9. Data Collection and Monitoring

9.1. Records to be kept
At enrollment written informed consent will be obtained by study staff and recorded in the research chart. At each study visit, all clinical data including demographic data, HIV viral load, and T cell counts will be collected

using standardized forms created in advance specifically for this study. Data from these forms will be entered into a database within two weeks of the study visit. At study entry, retrospective HIV viral load, CD4+ and C08+ counts will be obtained from the subjects primary care physician if it is available.

Subjects will not be identified by name on any forms, but rather by a patient identification number (PID) assigned by study staff at enrollment. The key to the identity of subjects will be maintained solely by the Study Coordinator.

Research charts will be kept on site in a locked cabinet or room during the entire study period, which will end two months after the final study visit of the last enrolled subject. The study database will be password protected and only available to study staff.

9.2. Role of Data Management
Eric S. Rosenberg, MD, principal investigator, is responsible for the Clinical Management Plan for this protocol at Massachusetts General Hospital.

Sue Bazner, MSN NP, Study Coordinator, has been designated by Dr. Rosenberg to be responsible for the implementation of the Clinical Quality Management Plan.

Jenna Rychert, PhD, Laboratory Coordinator, has been designated by Dr. Rosenberg to be responsible for the implementation of the Laboratory studies.

9.3. Clinical Site Monitoring and Record Availability
This is a single site study and all monitoring will be conducted at the Massachusetts General Hospital. All study records will be kept in a locked cabinet.

10. Human Subjects
10.1 Institutional Review Board (IRB) review and Informed Consent
This protocol and the informed consent document and any subsequent modifications will be reviewed and approved by the IRT or ethics committee responsible for oversight of the study. A signed consent form will be obtained from the subject. The consent fonn will describe the purpose of the study, the procedures to be followed, and the risks and benefits of participation. A copy of the signed consent will be given to the subject and documented in the research chart.

10.2. Subject Confidentiality
All laboratory specimens, evaluation forms, reports, and other records will be identified with the PID to maintain subject confidentiality. All records will be kept locked. All computer and networking programs will be done with coded numbers only. Clinical information will not be released without written permission of the subject, except when necessary for monitoring by IRB or the Office for Human Research Protections.

10.3. Study Discontinuation
The study may be discontinued at any time by the IRB or other government agencies as part of their duties to ensure the protection of research subjects.

11. Biohazard Containment
Appropriate precautions to prevent the transmission of HIV and other blood-borne pathogens will be undertaken in the drawing of blood, shipping and handling of

specimens, and all laboratory experiments.

12. References

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EXHIBIT B

BUDGET AND PAYMENT SCHEDULE