UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 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): November 16, 2011

Aastrom Biosciences, Inc.

(Exact name of registrant as specified in its charter)

Michigan
(State or other jurisdiction of incorporation)

000-22025 (Commission File Number)

94-3096597 (I.R.S. Employer Identification No.)

24 Frank Lloyd Wright Drive, P.O. Box 376, Ann Arbor, Michigan (Address of principal executive offices)

48106 (Zip Code)

Registrant's telephone number, including area code: (734) 418-4400

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:

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01. Entry into a Material Definitive Agreement.

On November 16, 2011, Aastrom Biosciences, Inc. (the "Company") entered into a project addendum (the "November Addendum") to the Company's master services agreement (the "Agreement"), made and entered into as of September 23, 2011 (the "Effective Date"), by and between the Company and a contract research organization ("CRO"), for the performance of clinical development services in connection with certain clinical research programs the Company may conduct. Pursuant to the November Addendum, CRO will provide clinical development services related to a multicenter, randomized, double-blind, placebo-controlled, parallel group study to evaluate the efficacy, safety and tolerability of autologous tissue repair cells in patients with critical limb ischemia.

Pursuant to the Agreement, CRO agrees to provide to the Company the services identified and described in each project addendum, including the November Addendum, in compliance with the respective project protocol, the terms and conditions of the Agreement, the terms and conditions of the applicable project addendum, CRO's standard operating procedures and all applicable laws, rules and regulations. The Company agrees to pay CRO for all services performed under the Agreement and any project addendum, including the November Addendum, in accordance with the rates for such services set forth in the applicable project addendum. The Company also agrees to reimburse CRO for certain out-of-pocket expenses incurred in connection with the performance of services.

The Agreement has a term of three years from the Effective Date, unless extended by mutual written agreement by the parties. Each project addendum shall be effective upon the date signed by the last signatory thereto and shall terminate upon (a) the completion of the services to be provided thereunder and (b) CRO's receipt of all fees and payments due to CRO related to the services provided thereunder (unless earlier terminated in accordance the termination provisions of the Agreement). The Agreement and any project addendum, including the November Addendum, may be terminated with or without cause by the Company upon thirty days prior written notice. CRO may terminate the Agreement with or without cause upon thirty days prior written notice at any time during which no project addenda are then in effect. Either party may terminate the Agreement upon the uncurred material breach of a material provision of the Agreement (including any project addendum) that is not curred within thirty days after notice of breach sent by the non-breaching

party to the breaching party. In addition, either the Company or CRO may terminate the Agreement upon the occurrence of an insolvency event with respect to the other party, including any voluntary or involuntary proceeding seeking liquidation, reorganization or other relief under any bankruptcy, insolvency or other similar law. The termination of the Agreement by either party would automatically terminate all project addenda, including the November Addendum, unless otherwise agreed in writing. Upon termination, CRO agrees to cooperate with the Company to provide for an orderly wind-down of the services.

The Agreement provides that the Company will indemnify CRO and its agents from and against any and all damages, losses and other liabilities and expenses incurred by CRO under indemnity obligations imposed upon it by a third party, as approved by the Company, relating to the Agreement or any services provided by CRO thereunder, except for claims arising from the negligence or intentional misconduct on the part of CRO or its agents, or a breach of the Agreement by CRO or its agents. CRO shall indemnify, defend and hold harmless the Company and its agents from and against any and all damages, losses and other liabilities and expenses incurred in connection with any claim to the extent arising from the negligence or intentional misconduct of CRO or its agents.

The November Addendum may be assigned by either party without the prior written consent of the other party except to a successor-in-interest to the party's business; however, CRO may assign the November Addendum, or subcontract all or part of the services, to an affiliate of CRO.

In addition to the foregoing, the Agreement and the November Addendum contain customary terms and conditions, including, but not limited to provisions related to confidentiality, record storage, and intellectual property. The foregoing summary is qualified in its entirety by the text of the Agreement and the November Addendum, which are attached hereto as Exhibits 10.1 and 10.2, respectively, each with portions omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment. Exhibits 10.1 and 10.2 are redacted copies of the Agreement and the November Addendum and are incorporated herein by reference. There are no material relationships between the Company and CRO other than in respect of the Agreement (including the November Addendum thereunder).

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Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number

10.1* Master Services Agreement by and between the Company and CRO, made and entered into as of September 23, 2011 (the "Master Services Agreement")

10.2* Project Addendum to the Master Services Agreement, dated as of November 16, 2011

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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.

Aastrom Biosciences, Inc.

Date: November 22, 2011 By: /s/ Tim M. Mayleben

Name: Tim M. Mayleben

Title: Chief Executive Officer and President

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Index to Exhibits

Exhibit Number	Description
10.1*	Master Services Agreement by and between the Company and CRO, made and entered into as of September 23, 2011 (the "Master Services
	Agreement")
10.2*	Project Addendum to the Master Services Agreement, dated as of November 16, 2011

^{*} Application has been made with the Securities and Exchange Commission to seek confidential treatment of certain provisions. Omitted material for which confidential treatment has been requested has been filed separately with the Securities and Exchange Commission.

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MASTER SERVICES AGREEMENT

THIS MASTER SERVICES AGREEMENT (the "*Agreement*") is made and entered into as of September 23rd, 2011 (the "*Effective Date*") by and between [***] and **Aastrom Biosciences, Inc.**, a Michigan Corporation, with its principal executive offices located at 24 Frank Lloyd Wright Drive, Lobby K, Ann Arbor Michigan 48105 ("*Sponsor*").

WHEREAS, Sponsor is engaged in the development, manufacture, distribution and sale of pharmaceutical products; and

WHEREAS, [***] is a clinical research organization engaged in the business of managing clinical research programs and providing clinical development and other related services; and

WHEREAS, Sponsor may wish to retain the services of [* * *] from time to time to perform clinical development services in connection with certain clinical research programs Sponsor is conducting (individually, a "Project"), in which case the terms and conditions for each such Project shall be set forth in a project addendum to be attached to this Agreement and incorporated herein by reference (individually, a "Project Addendum" and collectively, the "Project Addenda"); and

WHEREAS, [* * *] is willing to provide such services to Sponsor in accordance with the terms and conditions of this Agreement and the attached Project Addenda.

NOW, THEREFORE, for good and valuable consideration contained herein, the exchange, receipt and sufficiency of which are acknowledged, the parties agree as follows:

1. SERVICES.

- 1.1 <u>Services to be Provided by [***]</u>. [***] hereby agrees to provide to Sponsor the services identified and described in the Services section of each Project Addendum attached to this Agreement (the "Services"). [***] shall perform the Services for each Project set forth in the applicable Project Addendum in compliance with (i) the protocol for the Project ("Protocol"), which shall be attached to and made a part of the applicable Project Addendum, (ii) the terms and conditions of this Agreement, (iii) the terms and conditions of the applicable Project Addendum, (iv) [***]'s standard operating procedures ("SOPs"), which have been approved by Sponsor, and (v) all applicable laws, rules and regulations. Sponsor agrees that [***] is responsible only for those Services set forth on a properly executed Project Addendum.
- 1.2 <u>Project Addendum.</u> In the event that the parties hereto shall reach agreement with respect to the provision of Services for a Project, [***] and Sponsor shall execute a Project Addendum evidencing such Services. Sponsor agrees that the Project Addendum shall be executed by both parties before [***] commences work under the Project Addendum, unless the parties otherwise agree in writing. Each Project Addendum shall be attached to this Agreement and incorporated into and made a part of this Agreement by reference, and each such Project Addendum and this Agreement shall constitute the entire agreement for the applicable Project. To the extent any terms set forth in a Project Addendum conflict with the terms set forth in this Agreement, the terms of this Agreement shall control unless otherwise specifically set forth in the Project Addendum.
- 1.3 Out of Scope. In the event that [***] is requested or required to perform services for a Project that are not specifically provided for in the applicable Project Addendum (the "Out of Scope Services"), such Out of Scope Services and a compensation schedule therefor (the "Out of Scope Agreement") must be mutually agreed upon by the parties in writing prior to [***]'s provision of such Out of Scope Services. The Out of Scope Agreement shall constitute an amendment to the applicable Project Addendum and the Out of Scope Services set forth therein shall be deemed to be Services as that term is used in this Agreement and the applicable Project Addendum.

[* * *] Universal MSA 14July06

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[* * *] Master Services Agreement

- 1.4 <u>Sponsor Cooperation.</u> Sponsor will cooperate with [***] in providing information to [***], taking action and executing documents, as set forth in the applicable Project Addendum, to achieve the objectives of this Agreement. Sponsor acknowledges and agrees that [***]'s performance under this Agreement is dependant on Sponsor's timely and effective cooperation with [***] and performance of its obligations in accordance with the applicable Project Addendum. Accordingly, Sponsor acknowledges that any delay by Sponsor may result in [***] being released from an obligation or schedule deadline or in Sponsor having to pay extra fees in order for [***] to meet a specific obligation or deadline despite the delay. Sponsor shall comply with all applicable laws, rules and regulations governing the performance of its obligations hereunder and the subject matter of this Agreement, including without limitation, Sponsor's Property (as defined below).
- 1.5 <u>Serious Adverse Event and Medical Management Plan.</u> Notwithstanding anything to the contrary herein, in the event [***] and Sponsor agree upon a serious adverse event and medical management plan relating to a specific Project ("SMMP"), the parties shall comply with the terms and conditions of any such SMMP. In the event of any conflict between the terms and conditions of the SMMP and the relevant Project Addendum, the terms and conditions of the SMMP shall control. Sponsor shall be responsible for any additional costs associated with compliance with the SMMP as set forth therein or as set forth in the applicable Out of Scope Agreement pursuant to Section 1.3 herein.

2. PERSONNEL RETENTION.

In the event of delays in the performance of the Study, i.e., after [* * *] is authorized to commence work, which are beyond the control of [* * *], and where Sponsor desires for [* * *] to keep [* * *] Study personnel assigned to the Study, the parties shall execute an Out of Scope Agreement pursuant to Section 1.3 herein providing for such personnel retention, and, in addition to any other sums payable to [* * *] hereunder, Sponsor agrees that Sponsor

shall pay a personnel fee calculated on an FTE-day basis as set forth in the applicable Out of Scope Agreement. Said personnel fees shall be invoiced by [* * *] on a monthly basis, and shall be due and payable by Sponsor within [* * *] days of receipt of invoice.

3. MEDDRA AND WHODRUG DICTIONARY LICENSE.

The parties acknowledge that MedDRA and Uppsala Monitoring Centre product licenses are required by all parties who wish to distribute or receive MedDRA or WHODrug dictionary terminology. Each party represents and warrants that it possesses a current MedDRA and/or Uppsala Monitoring Centre product license. In the event Sponsor requests that [***] perform services which require [***] to distribute MedDRA terminology or WHODrug dictionary to third parties, Sponsor shall be responsible for ensuring that all such third parties possess the necessary MedDRA and/or Uppsala Monitoring Centre product licenses.

4. ENROLLMENT DISCLAIMER.

Except as may otherwise be provided in a Project Addendum, enrollment numbers are good faith estimates and [* * *] shall exercise all reasonable diligence to meet such enrollment estimates.

5. FINAL PROTOCOL.

The parties agree that Sponsor shall be solely responsible for the final review, approval and adoption of the Protocol and [***] shall not be liable for such Protocol.

6. <u>COMPENSATION AND PAYMENT</u>.

6.1 <u>Charges for Services</u>. Sponsor shall pay [* * *] for all Services performed under this Agreement and any Project Addendum ("*Direct Fees*") in accordance with the rates for such Services set forth in such Project Addendum. Sponsor shall also reimburse [* * *] for all out-of-pocket expenses

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incurred in connection with the performance of the Services with respect to a Project, including, without limitation, investigator grants and fees, travel expenses, shipping and postage costs, copying and printing fees, copyright fees, third party drug storage and distribution fees, required Institutional Review Board or similar board or committee fees, and other "pass through" expenses incurred in accordance with the budget for the Services and included in the applicable Project Addendum (collectively, the "Pass Through Costs"). Except as otherwise expressly provided in a Project Addendum, [***] shall submit to Sponsor for each Project a monthly invoice describing the Services performed on such Project, the Direct Fees due for such Services, and all Pass Through Costs paid by [* * *]. Sponsor shall pay each monthly invoice within [* * *] days of receipt of said invoice to the extent consistent with the applicable budget and/or payment schedule. [* * *] shall have no obligation to pay subcontractor costs or investigator grant payments to any subcontractor or investigator site (the "Site") for conduct of services related to a Project until [* * *] has received payment of such Pass Through Costs from Sponsor. In connection with any contract between [* * *] and a third party that will perform Services as contemplated herein, provided that Sponsor has reviewed and approved the execution and delivery of such contract, then, it is the parties' express intent that such third party shall be a third party beneficiary to this Agreement to the extent necessary to enforce payment by Sponsor of any monies owed by [* * *] to the Site or Subcontractor for Services under such reviewed and approved contract. Notwithstanding anything to the contrary contained herein, Sponsor acknowledges and agrees that certain vendor and subcontractor contracts, including without limitation, contracts for investigator meetings and patient recruitment services, must be advanced and paid up front by Sponsor as provided in the applicable budget. [* * *] shall be under no obligation to incur any such vendor or subcontractor fees until such fees are received by Sponsor. In addition, in certain circumstances, [* * *] may require investigator grants to be advanced by Sponsor at the timeframes mutually agreed upon by the parties.

- Payment after Termination. Upon termination of any Project Addendum or this Agreement pursuant to Section 7 below, Sponsor shall pay [***] all Direct Fees and Pass Through Costs for all Services performed through the termination date. In addition, Sponsor shall reimburse [***] for all reasonable, non-cancelable obligations to third parties (where such obligations were created as a result of a Project being authorized by the Sponsor) that were incurred or to be incurred as provided in the applicable Project Addendum, otherwise as approved by Sponsor, or as reasonably required to ensure access to persons or assets required to perform the Services as described in the applicable Project Addendum; provided that the total amount payable under this Section 6.2 upon such a termination shall in no event exceed the amounts that would have been payable if the termination has not occurred and the Services had been performed in full. Any funds held by [***] which shall be shown by Sponsor to be unearned at the date of termination shall be returned to Sponsor within forty-five (45) days of after the termination date of the Project Addendum or this Agreement, whichever is applicable. Certain Services of [***] require greater utilization of resources at the outset such that compensation for such services based on a percentage of milestones completed prior to [***] fully completing the milestone would work to the detriment of [***]. Accordingly, the parties agree that in the event of early termination, compensation for partially completed milestones shall be made on a time and materials basis.
- 6.3 <u>Pre-Execution Services</u>. In the event Sponsor requests [***] to begin providing the Services for a Project prior to the execution by Sponsor of a Project Addendum or other mutually agreed upon writing, Sponsor agrees that [***] shall be compensated on a time and materials basis for Services performed in accordance with the [***] Proposal for Services which formed the basis of the award of the Project to [***].
- 6.4 <u>Payments</u>. Unless otherwise set forth in a Project Addendum, all payments to [* * *] under this Agreement or any Project Addendum shall be made as follows:

If made by check, payment mailed to: [***]

If made by wire transfer, payment wired to: [***]

[* * *] Master Services Agreement

7. <u>TERM AND TERMINATION</u>.

- 7.1 <u>Term.</u> The term of this Agreement shall commence on the Effective Date and shall continue for a period of three (3) years unless extended by mutual written agreement by the parties. Each Project Addendum shall be effective upon the date signed by the last signatory thereto and shall terminate upon (i) the completion of the Services to be provided thereunder, and (ii) [* * *]'s receipt of all Direct Fees, Pass Through Costs, and any other payments due to [* * *] related to the Services provided thereunder, unless earlier terminated in accordance with this Section 7.
- 7.2 <u>Early Termination.</u> This Agreement and any Project Addendum may be terminated with or without cause by Sponsor upon thirty (30) days prior written notice. [***] may terminate this Agreement with or without cause upon thirty (30) days prior written notice at any time during which no Project Addendums are then in effect. Either Party may terminate this Agreement upon the uncured material breach of a material provision of this Agreement (including any Project Addendum) that is not cured within thirty (30) days after notice of breach sent by the non-breaching Party to the breaching Party.
- Insolvency. Either party hereto may terminate this Agreement immediately upon the occurrence of an "Insolvency Event" with respect to the other party. For purposes of this Agreement, "Insolvency Event" shall mean (1) a party or any of its subsidiaries shall commence a voluntary proceeding seeking liquidation, reorganization or other relief with respect to itself or its debts under any bankruptcy, insolvency or other similar law or seeking the appointment of a trustee, receiver, liquidator, custodian or other similar official of it or any substantial part of its property, or shall consent to any such relief or to the appointment of or taking possession by any such official in an involuntary case or other proceeding commenced against it, or shall make a general assignment for the benefit of creditors, or shall fail generally to pay its debts as they become due, or shall take any action to authorize any of the foregoing; (2) an involuntary case or other proceeding shall be commenced against a party or any of its subsidiaries seeking liquidation, reorganization or other relief with respect to it or its debts under bankruptcy, insolvency or other similar law or seeking the appointment of a trustee, receiver, liquidator, custodian or other similar official of it or any substantial part of its property, and such involuntary case or other proceeding shall remain undismissed and unstayed for a period of sixty (60) days; or (3) an order for relief shall be entered against a party or any of its subsidiaries under the federal bankruptcy laws now or hereafter in effect.
- 7.4 <u>Effect of Termination</u>. The termination of this Agreement by either party shall automatically terminate all Project Addenda, unless otherwise agreed in writing.
- 7.5 <u>Wind Down.</u> Upon the termination of this Agreement or a Project Addendum, [***] shall cooperate with Sponsor to provide for an orderly wind-down of the Services provided by [***] hereunder.
- 7.6 <u>Provisions Surviving Termination</u>. The obligations of the parties contained in Sections 6, 7.4, 7.5, 7.6, 9, 10, 11, 12, 13.2, 16.2, 16.3, 16.6, 16.7, 16.8, 16.11, 16.12 and 16.13 hereof and herein shall survive termination of this Agreement.

8. PERSONNEL.

8.1 <u>Project Management.</u> The Services with respect to each Project shall be performed by [***] under the direction of the person identified as the Project Manager in the applicable Project Addendum or such other person acceptable to Sponsor as [***] may from time to time designate as the Project Manager, such Sponsor acceptance of the designated Project Manager not to be unreasonably withheld or delayed in all instances.

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8.2 <u>Covenant Not to Interfere</u>. During the period in which a particular Project is being conducted, neither party shall recruit, hire or employ any personnel of the other party who is material to the performance of such Project without the prior written consent of such other party.

9. <u>CONFIDENTIALITY</u>.

- 9.1 <u>Sponsor Confidential Information</u>. [***] shall treat all information obtained from Sponsor or developed by [***] for Sponsor in connection with the performance of the Services (*"Sponsor Confidential Information"*) as the confidential and exclusive property of Sponsor.
- 9.2 [***] Confidential Information. Sponsor shall treat all information obtained from [***] including, without limitation, any [***] bids or proposals, standard operating procedures, personnel information, all [***] Property (as defined below) and any revisions, improvements or enhancements thereto ("[***] Confidential Information") as the confidential and exclusive property of [***].
- 9.3 <u>Use of Sponsor Confidential Information and [***] Confidential Information.</u> Each party shall use the other's Confidential Information solely for the purposes contemplated by this Agreement and for no other purpose without the prior written consent of the other party. Neither party shall publish, disseminate or otherwise disclose Confidential Information of the other to any third party without first obtaining the written consent of such other party. Each party shall restrict the dissemination of the other's Confidential Information with its organization to only those persons who have a need to know, and shall ensure that all of its directors, officers, employees, agents, representatives and advisors (collectively, "Agents") are aware of this Agreement and bound by the terms of confidentiality stated herein.

- 9.4 Exceptions to Confidential Information. The above provisions of confidentiality shall not apply to that part of disclosing party's Confidential Information which the receiving party is able to demonstrate by documentary evidence: (i) was in the receiving party's possession prior to receipt from the disclosing party or is independently developed by the receiving party by persons who have not had access to the disclosing party's Confidential Information; (ii) was in the public domain at the time of receipt from disclosing party; (iii) subsequently becomes a part of the public domain through no fault of the receiving party or its Agents; and (iv) is lawfully received by the receiving party from a third party having a right of further disclosure.
- 9.5 <u>Disclosure Required by Law.</u> The non-disclosure obligations pursuant to this Agreement shall not apply to Confidential Information that a receiving party is required to disclose pursuant to any judicial action, order of the court or other governmental agency; provided, however, that the receiving party shall make all reasonable efforts to notify the disclosing party prior to the disclosure of Confidential Information and allow the disclosing party the opportunity to contest and avoid such disclosure, and further provided that the receiving party shall disclose only that portion of such Confidential Information that it is legally required to disclose.
- 9.6 Return of Information. Upon termination or expiration of this Agreement or at the disclosing party's earlier written request, the receiving party shall return, and shall cause its Agents to return, all documentary, electronic or other tangible forms of Confidential Information provided by the disclosing party including, without limitation, any and all copies thereof, or, at the disclosing party's request, destroy all or such parts of the disclosing party's Confidential Information as the disclosing party shall direct. Notwithstanding the foregoing, the receiving party may retain copies of such of the disclosing party's Confidential Information as is reasonably necessary for regulatory and business archival purposes, subject to the ongoing obligation to maintain the confidentiality of such information.
- 9.7 <u>Remedy</u>. Each party agrees that its obligations hereunder are necessary and reasonable in order to protect the other party and the other party's business, and expressly agrees that monetary damages would be inadequate to compensate the other party for any breach of the terms of this Agreement. Accordingly, each party agrees and acknowledges that any such violation or threatened violation will cause irreparable injury to the other party, and that, in addition to any other remedies that may be available, in law, in equity or otherwise, the other party shall be entitled to obtain injunctive relief

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against the threatened breach of this Agreement or a Project Addendum or the continuation of any such breach, without the necessity of proving actual damages.

9.8 <u>Privacy Laws</u>. All information containing personal data shall be handled in accordance with all applicable privacy laws, rules and regulations, including, without limitation, the European Data Protection Directive [EC/95/46] and Health Insurance Portability Accountability Act (HIPAA).

10. <u>INTELLECTUAL PROPERTY</u>.

- 10.1 <u>No License</u>. Neither anything contained herein, nor shall the delivery of any information to a party hereto, be deemed to grant the receiving party any right or license under any patent or patent application or to any know-how, technology or invention of the disclosing party.
- 10.2 <u>Sponsor Property.</u> Subject to Section 10.3 below, [***] hereby assigns to Sponsor all rights [***] or its Agents may have in any invention, technology, know-how or other intellectual property directly relating to the use or composition of a Project drug or Protocol and which (i) results from [***]'s provision of the Services or (ii) specifically sets forth as a deliverable under a Project Addendum, and [***] shall assist Sponsor, at Sponsor's sole cost and expense, in obtaining or extending protection therefor. [***] warrants that it has and will continue to have agreements with its Agents to effect the terms of this Section 10.2.
- 10.3 [***] Property. [***] possesses certain inventions, processes, technology, know-how, trade secrets, improvements, other intellectual property and assets, including, without limitation, those related to business or product plans or proposals, marketing strategies, standard operating procedures, data, composition of matter, research, experimental results, personnel data, financial information and conditions, pricing information, customer information, supplier/vendor information, raw materials, data collection and data management processes, laboratory analyses, analytical, biotechnology and clinical methods, procedures and techniques, computer technical expertise and software (including code) which have been independently developed without the benefit of any information provided by Sponsor (collectively, "[***] Property"). For avoidance of doubt, methods of conducting and administering preclinical and clinical research that are proprietary to [***] are intended to be and shall be included within the [***] Property. Sponsor and [***] agree that any [***] Property or revisions, improvements or enhancements thereto shall be the sole and exclusive property of [***], and Sponsor shall have no rights, title and interest to such [***] Property.

11. <u>INDEMNIFICATION</u>.

- 11.1 <u>Sponsor Indemnity</u>. Sponsor shall indemnify, defend, and hold harmless [***] and its Agents from and against any and all damages, liabilities, losses, fines, penalties, settlement amounts, costs and expenses of any kind or nature whatsoever, including, without limitation, reasonable attorneys' fees, expert witness fees, court costs, and amounts incurred by [***] under indemnity obligations imposed upon it by a third party provided to a Project where such third party provider has been approved by Sponsor and such obligations arise under an agreement that was reviewed and approved by Sponsor, incurred in connection with any claim, demand, action, proceeding, investigation or hearing (collectively, a "*Claim*") directly or indirectly relating to or arising from this Agreement or any Services provided by [***] hereunder, including but not limited to, Project related services provided by [***] at the request of Sponsor yet prior to finalization of the relevant Project Addendum; provided however, that Sponsor shall have no obligation of indemnity hereunder with respect to any Claim arising from the negligence or intentional misconduct on the part of [***] or its Agents or a breach of this Agreement by [***] or its Agents.
- 11.2 [***] <u>Indemnity</u>. [***] shall indemnify, defend and hold harmless Sponsor and its Agents from and against any and all damages, liabilities, losses, fines, penalties, settlement amounts, cost and expenses of any kind or nature whatsoever, including, without limitation, reasonable attorney's

fees, expert witnesses and court costs, incurred in connection with any Claim to the extent arising from the negligence or intentional misconduct of [* * *] or its Agents.

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Indemnification Procedure. Each indemnified party shall give the indemnifying party prompt notice of any Claim for which indemnification is sought hereunder. The indemnifying party shall have the right to control the defense and settlement of a Claim, provided the indemnifying party shall act reasonably and in good faith with respect to all matters relating to the settlement or disposition of the Claim, and the indemnified party shall reasonably cooperate in the investigation, defense and settlement of such Claim. Any indemnified party shall have the right to participate in, but not control, the defense and settlement of a Claim and to employ separate legal counsel of its own choice; provided, however, that such employment shall be at the indemnified party's own expense, unless (i) the employment thereof has been specifically authorized by the indemnifying party, or (ii) the indemnifying party has failed to assume the defense and employ counsel (in which case the indemnified party shall control the defense and settlement of such Claim). The costs and expenses, including reasonable fees and disbursements of counsel, incurred by any indemnified party in connection with any Claim shall be reimbursed on a monthly basis by the indemnifying party subject to refund in the event the indemnifying party is ultimately held not to be obligated to indemnify the indemnified party.

12. LIMITATION OF LIABILITY.

WITH THE EXCEPTION OF A PARTY'S INDEMNIFICATION OBLIGATIONS, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL LOSSES OR DAMAGES, WHETHER IN CONTRACT OR TORT.

13. <u>RECORD STORAGE</u>.

- 13.1 Record Maintenance during Project. During the term of this Agreement, [***] shall maintain all materials and all other data obtained or generated by [***] in the course of providing the Services hereunder, including all computerized records and files. [***] shall cooperate with any reasonable internal review or audit by Sponsor and make available to Sponsor for examination and duplication, during normal business hours and at mutually agreeable times, all documentation, data and information relating to a Project.
- Record Maintenance after Expiration or Termination. Upon the expiration or termination of this Agreement other than for Sponsor's breach of required payment hereunder, all materials and all other data and information obtained or generated by [***] in the course of providing the Services hereunder (collectively, the "Records") shall, at Sponsor's option, be (i) delivered to Sponsor at its expense and risk to its offices identified herein in such form as is then currently in the possession of [***], (ii) retained by [***] for Sponsor for a period of three (3) years, or (iii) disposed of at Sponsor's expense, as directed by written request of Sponsor, unless the Records are otherwise required to be stored or maintained by [***] under applicable law. If [***] is required or requested to maintain and/or store the Records for a period beyond three (3) years after the termination or expiration of this Agreement, Sponsor shall reimburse [***] for its maintenance and storage costs. In no event shall [***] dispose of Records without first giving Sponsor sixty (60) days prior written notice of its intent to dispose of the Records. [***] shall be entitled at its expense to retain copies of the Records reasonably necessary for regulatory purposes or to demonstrate the satisfaction of its obligations hereunder, all subject to the confidentiality obligations set forth in Section 9 above.

14. DEBARMENT.

[***] hereby certifies that it has not been debarred, and has not been convicted of a crime which could lead to debarment, under the Generic Drug Enforcement Act of 1992. If [***] or any of its Agents who perform Services for a Project is debarred or receives notice of an action or threat of action of debarment, [***] shall immediately notify Sponsor of same. The debarment of [***] or any of its Agents (which are providing services to Sponsor on a Project under this Agreement) that remains in place for a period of at least thirty (30) days shall be deemed to be a material breach of this Agreement, unless, with respect to the debarment of an Agent which is providing services to Sponsor hereunder, [***] is able to

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[* * *] Master Services Agreement

replace the Agent within such 30-day period, in which case the debarment of the replaced Agent shall not be a material breach of this Agreement.

15. <u>CURRENCY MANAGEMENT</u>.

- 15.1 <u>Direct Fees</u>. All Direct Fees owed to [***] for Services performed under this Agreement or any Project Addendum shall generally be invoiced to and paid by Sponsor in the "Contract Currency", which shall be defined as the currency or currencies designated in any budget or payment schedule set forth in a Project Addendum. However, any Services performed outside the United States shall be invoiced to and paid by Sponsor in the local currency where such Services are performed with any Services performed in Europe being invoiced to and paid by Sponsor in British pounds or Euros.
- 15.2 <u>Pass Through Costs</u>. Where [***] incurs Pass Through Costs in a currency other than the Contract Currency, [***] shall, for Sponsor invoicing and payment purposes, convert such costs to the Contract Currency based on the average of the daily exchange rates as published in the Wall Street Journal between the local currency and the Contract Currency for the month in which such costs were incurred.

Investigator Fees. [***] shall pay investigator fees in the currency specified in the investigator agreements. For Sponsor invoicing and payment purposes, [***] shall convert all investigator fees that are to be paid in a currency other than the Contract Currency to the Contract Currency. The conversion to the Contract Currency shall be based on the monthly average of the daily exchange rates as published in the Wall Street Journal between the currency specified in an investigator agreement and the Contract Currency for the month prior to the month the Sponsor invoice is raised. All amounts invoiced to Sponsor will be based upon an accrual of costs owed to investigators. At the end of the project a 'true up' will be completed between the estimated exchange rate used for the purposes of billing on the basis of the accrued costs versus the exchange rate when the actual payment is made to the sites and any variation billed or credited to the Sponsor as applicable.

16. MISCELLANEOUS.

- 16.1 <u>Independent Contractor Relationship</u>. The parties hereto are independent contractors, and nothing contained in this Agreement is intended, and shall not be construed, to place the parties in the relationship of partners, principal and agent, employer/employee or joint venturer. Neither party shall have any right, power or authority to bind or obligate the other, nor shall either hold itself out as having such right, power or authority.
- 16.2 <u>Publicity.</u> Neither party shall mention or otherwise use the name, insignia, symbol, trademark, trade name or logotype of the other party (or any abbreviation or adaptation thereof) in any publication, press release, promotional material or other form of publicity without the prior written approval of the other party in each instance. The restrictions imposed by this Section shall not prohibit a party from making any disclosure identifying the other party that is required by any applicable law, rule or regulation.
- 16.3 <u>Publication</u>. [***] may not publish any articles or make any presentations relating to the Services provided to Sponsor hereunder with respect to a Project or referring to data, information or materials generated as part of the Services without the prior written consent of Sponsor.
- 16.4 <u>Insurance</u>. Sponsor and [***] each will maintain insurance in types and amounts reasonably adequate to cover any liabilities arising out of its obligations hereunder, and, upon request, each party will provide to the other party a certificate of insurance showing that such insurance is in place, which certificate shall demonstrate the amounts, exclusions and deductibles of such insurance coverage.
- 16.5 <u>Force Majeure</u>. If either party shall be delayed, hindered, or prevented from the performance of any act required hereunder by reason of strike, lockouts, labor troubles, restrictive governmental or judicial orders or decrees, riots, insurrection, war, acts of God, inclement weather, or other cause beyond such party's reasonable control (each, a "*Disability*"), then performance of such act

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[* * *] Master Services Agreement

shall be excused for the length of time necessary to cure such Disability and resume performance. A party shall not be liable for any delays resulting from a Disability, and any affected timelines shall be extended for a period at least equal to that of the Disability and each Project budget shall be adjusted to reflect any cost increases resulting from such Disability. The party incurring the Disability shall provide notice to the other of the commencement and termination of the Disability.

Notices. Any notice required or permitted to be given hereunder by either party hereto shall be in writing and shall be deemed given on the date delivered (i) personally, (ii) on the first business day after the date sent if sent by recognized overnight courier, (iii) on the date transmitted if sent via facsimile (with confirmation of receipt generated by the transmitting machine), or (iv) on the second business day after the date deposited if mailed by certified mail, return receipt requested, postage prepaid. All notices to each party shall be sent to the address for said party set forth in the applicable Project Addendum. If no address is provided in the Project Addendum, then notices shall be sent to the following address:

If to [* * *]

If to Sponsor: Aastrom Biosciences, Inc.

24 Frank Lloyd Wright Drive

Lobby K

Ann Arbor, MI 48105

Attention: Tim Mayleben, CEO and President

Tel: (734) 418-4410 Fax: (734) 665-0485

Either party may change its notice address by notice to the other party hereto in the form and manner provided in this Section 16.6.

- 16.7 <u>Governing Law.</u> This Agreement and the rights and obligations of the parties hereunder shall be governed by and construed in accordance with the laws of the [***] without reference to its conflicts of laws provisions.
- Severability. If any provision of this Agreement or any Project Addendum is held to be illegal, invalid or unenforceable under any present or future law, and if the rights or obligations of any party hereto under this Agreement or such Project Addendum will not be materially or adversely affected thereby, (a) such provision will be fully severable, (b) this Agreement or such Project Addendum will be construed and enforced as if such illegal, invalid or unenforceable provision had never compromised a part hereof, (c) the remaining provisions of this Agreement or such Project Addendum will remain in full force and effect and will not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid or unenforceable provision, there will be added automatically as a party of this Agreement or such Project Addendum, a legal, valid and enforceable provision as similar in terms as to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the parties herein.
- 16.9 <u>Waiver</u>. Any term or condition of this Agreement or a Project Addendum may be waived at any time by the party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the party waiving such term or

condition. No waiver by any party hereto of any term or condition of this Agreement or a Project Addendum, in any one or more instances, shall be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement or such Project Addendum on any future occasion.

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[* * *] Master Services Agreement

- 16.10 <u>Amendments</u>. No amendment, change or modification to this Agreement or any Project Addendum shall be effective unless in writing and executed by the parties hereto.
- Assignment and Subcontracting. This Agreement and any Project Addendum may not be assigned by either party without the prior written consent of the other party; provided, however, that (i) a party hereto may assign this Agreement or a Project Addendum hereunder to a successor-in-interest to the party's business and (ii) [* * *] may assign this Agreement or a Project Addendum or subcontract all or part of the Services to be performed hereunder to an Affiliate of [* * *]. "Affiliate of [* * *]" shall mean an entity which can provide the Services and which controls, is controlled by or is under common control with [* * *] or [* * *]. In the event the Services shall be performed by an Affiliate of [* * *], such Affiliate of [* * *] may be the contracting party to any Project Addendum for the Services.
- 16.12 <u>Construction</u>. Except where the context otherwise requires, wherever used the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The language of this Agreement shall be deemed to be the language mutually chosen by the parties and no rule of strict construction shall be applied against either party hereto.
- 16.13 <u>Counterparts and Facsimile Signatures</u>. This Agreement, and any subsequent amendment(s), may be executed in counterparts and the counterparts, together, shall constitute a single agreement. A facsimile transmission of this signed Agreement bearing a signature on behalf of a party shall be legal and binding on such party.
- 16.14 <u>Representative</u> Sponsor represents and warrants that it shall not name any [***] employee or other [***] representative on Line 15 of Form FDA 1571 or as the Senior Medical Officer in Canada on Line 87 of Form HC/SC 3011 or in any similar capacity for clinical trials conducted in other countries. Sponsor acknowledges and understands that if Sponsor desires [***] to be responsible for review and evaluation of information relevant to the safety of the drug, Sponsor will have to enter into a separate contract with [***] for the provision of these services.
- 16.15 <u>Entire Agreement</u>. This Agreement constitutes the entire agreement between the parties and supersedes all prior negotiations, representations or agreements, either written or oral, with respect to the subject matter hereof.

IN WITNESS WHEREOF, this Agreement has been executed and delivered by the parties hereto by their duly authorized officers as of the date first above written.

[***]

Aastrom Biosciences, Inc.

By: /s/ Tim M. Mayleben

Name: Tim M. Mayleben

Title: President & CEO

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PROJECT ADDENDUM

THIS PROJECT ADDENDUM (the "*Project Addendum*") is made and entered into as of November 16, 2011 (the "*Effective Date*") by and between [***] and **AASTROM BIOSCIENCES, INC.**, with its principal executive offices located at 24 Frank Lloyd Wright Drive, Lobby K, Ann Arbor Michigan 48105 ("*Sponsor*").

WHEREAS, [***] and Sponsor entered into a certain Master Services Agreement ("Agreement") dated September 23, 2011; and

WHEREAS, pursuant to Section 1.2 of the Agreement, the parties now wish to enter into this Project Addendum for the purposes of setting forth the responsibilities and obligations of the parties in regards to conducting a certain clinical research program entitled "A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy, Safety and Tolerability of Autologous Tissue Repair Cells in Patients with Critical Limb Ischemia" ("Study") under Sponsor's protocol # 55-1009-1 ("Protocol"), which Protocol is incorporated herein by reference.

NOW, THEREFORE, for good and valuable consideration contained herein, the exchange, receipt and sufficiency of which are acknowledged, the parties agree as follows:

1. Services.

[***] shall perform those certain services set forth in the proposal submitted to Sponsor by [***], which proposal is attached hereto as Exhibit A and incorporated herein by reference ("*Services*").

2. <u>Compensation and Payment.</u>

2.1 - Compensation - For its performance of Services under this Project Addendum, [***] shall receive a total sum anticipated not to exceed \$[***] of which \$[***] shall be direct costs, and of which \$[***] shall be handled as indirect reimbursable costs. Should a change in any of the key Study parameters, e.g., countries included, number or country distribution of sites, number of patients, number of CRF pages, number of statistical tables or listings, study timeline or protocol design result in an increase or decrease in the Study budget (attached hereto as Exhibit B), such financial implications will be summarized in writing and approved by Sponsor.

The indirect reimbursable costs are estimated and may vary as circumstances require.

2.2 - Payment - Payment for the direct costs and indirect reimbursable costs will be made according to the Unitized Budget set forth in Exhibit B attached hereto and incorporated herein by reference. Upon execution of this Project Addendum Sponsor will pay \$[***] as an advance payment towards the direct fees. This payment is in addition to the \$[***] already invoiced under the previously executed Letter of Authorization ("LOA") for preliminary/start-up Services. The \$[***] advance payment will be held in reserve and used to pay for units associated with the final data cleaning activities. Sponsor will be invoiced monthly for units achieved pursuant to the Budget (Exhibit B) and indirect reimbursable costs as incurred. All payments made under the LOA will be applied to the monthly unit invoices until depleted.

In addition to the above referenced advance payment for direct fees, Sponsor shall pay upon execution of this Project Addendum \$[***] as an advance for investigator grants, and [***] will invoice Sponsor monthly as needed for additional investigator grants. [***] will not release payment for any 3rd party vendor cost including investigator meeting costs until Sponsor has remitted the applicable amount.

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2.3 — Payments to [* * *] shall be made to:

[***]

Or. if wired to: [***]

3. Standard Operating Procedure

[***] shall conduct the Study according to [***]'s Standard Operating Procedures ("SOPs"). These SOPs are subject to revision by [***] in which case [***] shall notify Sponsor of revision. If any such SOP revision can be reasonably expected to affect the budget or timelines for the Study, [***] shall submit to Sponsor revised cost estimates or timelines for the relevant Services which will become a part of this Project Addendum upon written approval by Sponsor. The current SOPs for conducting and monitoring clinical trials are available for review upon request by Sponsor.

Upon mutual agreement in writing, the parties may conduct the Study under Sponsor's standard operating procedures. In such case, Sponsor shall provide prompt and reasonable training to any [***] personnel subject to such SOPs at Sponsor's expense.

4. <u>Term and Termination.</u>

The term of this Project Addendum shall commence on the Effective Date and end upon the completion of Services unless otherwise terminated in accordance with the Agreement.

5. <u>Incorporation by Reference/Conflict of Terms.</u>

The terms and conditions of this Project Addendum and Exhibits hereto are hereby incorporated into and made a part of the Agreement. To the extent any terms contained in an Exhibit hereto conflict with this Project Addendum, the terms of this Project Addendum shall govern and control. In the event of any inconsistency between the Agreement, the Project Addendum, and the Protocol, the terms of the Protocol shall govern first, followed by the Project Addendum, and then by the Agreement unless otherwise specified.

6. Modifications.

Any changes to this Project Addendum or its Exhibits shall be documented by written Amendments executed by both parties and shall be attached hereto.

7. <u>Notices</u>.

Each Party represents that its respective contact person set forth below shall have the authority to make all executive decisions regarding this Project Addendum. Any notice required or permitted to be given hereunder by either party hereunder shall be in writing and shall be deemed given on the date received if delivered personally or by fax or five (5) days after the date postmarked if sent by registered or certified U.S. mail, return receipt requested, postage prepaid to the following address:

If to [* * *]

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If to Sponsor: Aastrom Biosciences, Inc.

24 Lloyd Wright Drive

Lobby K

Ann Arbor, MI 48105

Attn: Tim Mayleben, CEO and President

Tel: (734) 418-4410 Fax: (734) 665-0485

8. <u>Counterparts and Facsimiles.</u>

This Project Addendum may be executed in counterparts and the counterparts, together, shall constitute a single agreement. A facsimile transmission of this signed Project Addendum bearing a signature on behalf of a party shall be legal and binding on such party.

IN WITNESS WHEREOF, this Project Addendum has been executed and delivered by the parties hereto by their duly authorized officers as of the Effective Date.

[***] AASTROM BIOSCIENCES, INC.

By: /s/ Tim M. Mayleben

Name: Tim M. Mayleben

Title: President & CEO

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Exhibit A

Proposal

[See attached pages]

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APPENDIX 1: SPECIFICATIONS AND ASSUMPTIONS

[***]

Number of Randomized Patients 594

[***]

Participating Countries (Sites)

United States (80)

Estimated Enrollment Rate (Patents/Site/Month) 0.35

[***]

Maximum Duration of Patient Participation in Months 18.50

[***]

Number of Active Sites 80

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[***]

Pages 3 through 22 of Exhibit A have been redacted in their entirety and have been filed separately with the Secretary of the Commission.

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[***]

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Exhibit B

Budget

[***]

The remainder of the text on the two pages of Exhibit B have been redacted entirely and have been filed separately with the Secretary of the Commission.

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