## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## Form 10-K

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

for the fiscal year ended December 31, 2012

or

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

Commission File Number 0-22025

## Aastrom Biosciences, Inc.

(Exact name of registrant as specified in its charter)

Michigan

(State or other jurisdiction of incorporation or organization)

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

Name of Each Exchange on Which Registered

The NASDAQ Stock Market, Inc.

Accelerated filer - x

Smaller reporting company - o

24 Frank Lloyd Wright Drive, Lobby K Ann Arbor, MI 48106

(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: (800) 556-0311

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

Title of Class Common Stock (No par value)

Securities registered pursuant to Section 12(g) of the Act: **None** 

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer - o

Non-accelerated filer - o (Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

The aggregate market value of the registrant's Common Stock, no par value ("Common Stock"), held by non-affiliates of the registrant (based on the closing sales price of the Common Stock as reported on the NASDAQ Capital Market) on June 29, 2012 was approximately \$91,121,948. This computation excludes shares of Common Stock held by directors, officers and each person who holds 5% or more of the outstanding shares of Common Stock, since such persons may be deemed to be affiliates of the registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 5, 2013, 45,664,079 shares of Common Stock, no par value, were outstanding.

## DOCUMENTS INCORPORATED BY REFERENCE

DocumentForm 10-K ReferenceProxy Statement for the Annual Meeting of Shareholders scheduled for May 2, 2013Items 10, 11, 12, 13 and 14 of Part III

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## AASTROM BIOSCIENCES, INC.

#### **ANNUAL REPORT ON FORM 10-K**

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Except for the historical information presented, the matters discussed in this Report, including our product development and commercialization goals and expectations, our plans and anticipated timing and results of clinical development activities, potential market opportunities, revenue expectations and the potential advantages and applications of our products and product candidates under development, include forward-looking statements that involve risks and uncertainties. Our actual results may differ significantly from the results discussed in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed under the caption "Risk Factors." Unless the context requires otherwise, references to "we," "us," "our" and "Aastrom" refer to Aastrom Biosciences, Inc.

## PART I

#### Item 1. Business

## **Change in Fiscal Year End**

In 2010, our Board of Directors approved the change in our fiscal year end from June 30 to December 31. The change became effective at the end of the quarter ended December 31, 2010. All references to "years", unless otherwise noted, refer to the 12-month fiscal year, which prior to July 1, 2010, ended on June 30, and beginning with December 31, 2010, ends on December 31, of each year.

#### **General Information**

We were incorporated in 1989 and are a regenerative medicine company focused on the development of innovative cell therapies to repair or regenerate damaged or diseased tissues. We are developing patient-specific, expanded multicellular therapies for use in the treatment of severe, chronic ischemic cardiovascular diseases. We believe ixmyelocel-T (the generic name for our multicellular therapy) is a disease modifying therapy with multi-functional properties including: tissue remodeling, immuno-modulation and the promotion of angiogenesis. Our proprietary cell-manufacturing technology enables the manufacture of multicellular therapies, expanded from an adult patient's own bone marrow, to be delivered directly to damaged tissues. Preclinical and clinical data suggest that ixmyelocel-T may be safe and effective in treating patients with severe, chronic ischemic cardiovascular diseases such as critical limb ischemia (CLI), the most severe form of peripheral arterial disease (PAD), and dilated cardiomyopathy (DCM), the third leading cause of heart failure. Over 200 patients have been treated in recent clinical trials using ixmyelocel-T, and over 400 patients safely treated since our inception. In November 2011, we released positive Phase 2b data from our RESTORE-CLI clinical trial and launched our pivotal Phase 3 REVIVE trial in CLI in February 2012. During the fourth quarter of 2012, we launched a randomized, placebo-controlled, double-blinded Phase 2b ixCELL-DCM trial for patients with ischemic DCM.

#### **Our Therapy**

Ixmyelocel-T is a patient-specific, expanded multicellular therapy developed using our proprietary, fully-closed, automated processing system. Ixmyelocel-T is a product derived from an adult patient's own bone marrow but it is significantly enhanced compared with the original bone marrow. Our process enhances the patient's bone marrow mononuclear cells by expanding the mesenchymal stromal cells and M2 anti-inflammatory macrophages while retaining many of the hematopoietic cells. These cell types, known to regulate the immune response, are important in the resolution of pathologic inflammation and tissue repair. The manufacture of our patient-specific, expanded multicellular therapies is done under current Good Manufacturing Practices (cGMP) and current Good Tissue Practices (cGTP) guidelines required by the U.S. Food and Drug Administration (FDA).

Our therapy has several features that we believe are primarily responsible for success in treating adult patients with severe, chronic cardiovascular diseases:

*Patient-specific (autologous)* — we start with the patient's own cells, which are accepted by the patient's immune system allowing the cells to integrate into existing functional tissues. This characteristic of our therapy, we believe, eliminates both the risk of rejection and of having to use immunosuppressive therapy pre- or post-therapy. Our data also suggests that ixmyelocel-T provides the potential for long-term engraftment and tissue repair.

*Expanded* — we begin with a small amount of bone marrow from the patient (up to 60 ml) and significantly expand the number of certain cell types, primarily CD90+ (mesenchymal stromal cells or MSCs) and CD14+autofluorescent+ (M2 anti-inflammatory macrophages) to far more than are present in the patient's own bone marrow (up to 200 times the number of certain cell types compared with the starting bone marrow).

*Multicellular* — we believe the multiple cell types in ixmyelocel-T, which are normally found in bone marrow — but in smaller quantities — possess the key functions required for reducing chronic inflammation, immuno-modulation, and the promotion of

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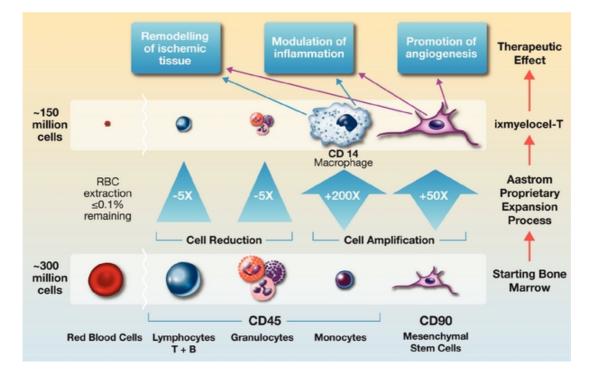
angiogenesis. By reducing inflammation, we believe ixmyelocel-T provides the ideal conditions to allow for the growth of new tissue and blood vessels.

*Minimally invasive* — our procedure for taking bone marrow (an "aspirate") can be performed in an out-patient setting and takes approximately 15 minutes. For diseases such as CLI, the administration of ixmyelocel-T is performed in an out-patient setting (e.g., a physician's office) in a one-time, approximately 20 minute procedure. For DCM, injection is performed in the cardiac catheterization laboratory. A catheter, similar to those used for balloon angioplasty and stenting is inserted and 12-20 direct injections to the heart muscle are performed. This is also a one-time procedure.

*Safe* — bone marrow and bone marrow-derived therapies have been used safely and efficaciously in medicine for over three decades. Our product, ixmyelocel-T, a bone marrow-derived, patient-specific, expanded multicellular therapy, leverages this body of scientific study and medical experience, and appears well tolerated in over 400 patients treated to date.

#### **Cell Composition**

The following graphic summarizes the key cell types that are expanded from the starting bone marrow to the final ixmyelocel-T product:



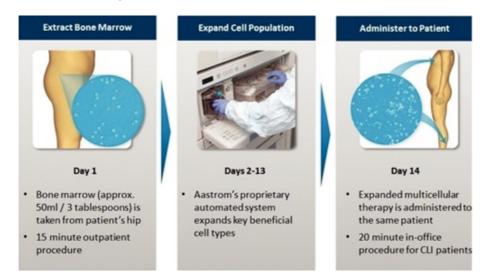
Ixmyelocel-T is the only product known to have expanded the anti-inflammatory M2 macrophages. We believe that our therapy is best suited for chronic, ischemic diseases with significant inflammation. Our multi-cellular therapy could be ideal to modulate the inflammation and allow for remodeling of ischemic tissue and angiogenesis.

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## **Manufacturing Process**

Our therapy is produced at our cell manufacturing facility in the United States, located at our headquarters in Ann Arbor, Michigan.

The following graphic summarizes the treatment process:



#### **Clinical Development Programs**

Our clinical development programs are focused on addressing areas of high unmet medical needs in severe, chronic ischemic cardiovascular diseases. We have completed a successful Phase 2b clinical trial in CLI. We have reached agreement with the FDA on Chemistry, Manufacturing and Control (CMC) which allowed us to launch our pivotal Phase 3 REVIVE clinical trial in the first quarter of 2012 with a protocol approved by the FDA through the Special Protocol Assessment (SPA) process. Our CLI development program has also received Fast Track Designation from the FDA. We have completed our Phase 1/2 clinical trials in DCM and launched a randomized, placebo-controlled, double-blinded Phase 2b ixCELL-DCM trial in the fourth quarter of 2012. Our DCM development program has received Orphan Disease Designation from the FDA.

The following summarizes the status of our active clinical programs:

| PERIPHERAL ARTERIAL DISEASE | PRECLINICAL  | PHASE 1 | PHASE 2 | PHASE 3 |  |  |  |  |
|-----------------------------|--|---------|---------|---------|--|--|--|--|
| Critical Limb Ischemia      | FDA FAST TRACK DESIGNATION & SPECIAL PROTOCOL ASSESSMENT |         |         |         |  |  |  |  |
| HEART FAILURE               | PRECLINICAL  | PHASE 1 | PHASE 2 | PHASE 3 |  |  |  |  |
|                             |  |         |         |         |  |  |  |  |

Results to date in our clinical trials may not be indicative of results obtained from subsequent patients enrolled in those trials or from future clinical trials. Further, our future clinical trials may not be successful or we may not be able to obtain the required Biologic License Application (BLA) approval to commercialize our products in the United States in a timely fashion, or at all. See "Risk Factors".

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## Critical Limb Ischemia

## Background

CLI is the most serious and advanced stage of peripheral arterial disease (PAD) resulting from chronic inflammation and lipid accumulation. PAD is a chronic atherosclerotic disease that progressively restricts blood flow in the limbs and can lead to serious medical complications. This disease is often associated with other serious clinical conditions including hypertension, cardiovascular disease, dyslipidemia, diabetes, obesity and stroke. CLI is used to describe patients with chronic ischemia-induced pain (even at rest) or tissue loss (ulcers or gangrene) in the limbs, often leading to amputation and death. Many CLI patients are considered "unsuitable for revascularization" (formerly "no option") patients as they have exhausted all other reasonable treatment options and will likely require amputation. The one-year and four-year mortality rates for CLI patients that are unsuitable for revascularization that progress to amputation are approximately 25% and 70%, respectively. Ixmyelocel-T, our disease modifying therapy with multiple functions, has shown significant promise in the treatment of CLI patients with existing tissue loss that are unsuitable for revascularization in the U.S.

## Phase 2b Clinical Program - RESTORE CLI

Our U.S. Phase 2b RESTORE-CLI program was a multi-center, randomized, double-blind, placebo-controlled clinical trial. This clinical trial was designed to evaluate the safety and efficacy of ixmyelocel-T in the treatment of patients with CLI that are unsuitable for revascularization. It was the largest multi-center, randomized, double-blind, placebo-controlled cellular therapy study ever conducted in CLI patients. We completed enrollment of this trial in February 2010 with a total of 86 patients at 18 sites across the United States, with the last patient treated in March 2010. These patients were followed for a period of 12 months after treatment. In addition to assessing the safety of our product, efficacy endpoints included time to first occurrence of treatment failure — the trial's primary efficacy end-point — (defined as major amputation, all-cause mortality, doubling in wound surface area and de novo gangrene), amputation-free survival (defined as major amputation and all-cause mortality), major amputation rates, level of amputation, wound healing, patient quality of life and pain scores. The primary purpose of the trial was to assess performance of our therapy and, if positive, prepare for a Phase 3 program.

Final results of the Phase 2b RESTORE-CLI clinical trial were presented at the American Heart Association Scientific Sessions in November 2011 and published in the peer-reviewed journal Molecular Therapy in April 2012. Patients in the treatment arm showed a 62% reduction in risk relative to placebo in the primary efficacy endpoint of time to first occurrence of treatment failure (p=0.0032). While the study was not powered to show statistical significance in the secondary endpoint of amputation free survival, results from a subgroup of 45 patients with wounds at baseline (the approximate profile of the Phase 3 patient population) showed a 61% reduction in risk (21% ixmyelocel-T treated versus 44% control event rate; p=0.0802). The study also met the primary safety endpoint with no meaningful differences between the treated and control groups.

#### Phase 3 Clinical Program — REVIVE

In February 2012, several principal investigators participating in the pivotal Phase 3 REVIVE clinical trial for patients with CLI that are unsuitable for revascularization began screening patients. The first patient was randomized and aspirated in May 2012. We had previously received Fast Track Designation from the FDA for use of ixmyelocel-T for CLI in October 2010 and reached agreement with the FDA on a Special Protocol Assessment (SPA) in July 2011. The Phase 3 REVIVE Trial that we agreed to with the FDA under the SPA process includes 594 CLI patients with tissue loss (ulcers and gangrene) at baseline that are unsuitable for revascularization. Patients will be randomized 1:1 and followed for 12 months for the primary efficacy endpoint of amputation-free survival. Patients will be followed for an additional 6 months for safety. We anticipate that enrollment will occur at approximately 100 sites across the U.S.

#### **Dilated Cardiomyopathy**

#### Background

DCM is a severe, chronic cardiovascular disease that leads to enlargement of the heart, reducing the pumping function of the heart to the point that blood circulation is impaired. Patients with DCM typically present with symptoms of congestive heart failure, including limitations in physical activity and shortness of breath. DCM is now the third leading cause of heart failure in the U.S. There are two types of DCM: ischemic and non-ischemic. Ischemic DCM, the most common form representing an estimated 60% of all DCM patients, is associated with atherosclerotic cardiovascular disease. We estimate that there are approximately 125,000 ischemic DCM patients in the U.S., our target patient population for further clinical development. Patient prognosis depends on the stage and cause of the disease but is typically characterized by a very poor quality of life and a high mortality rate.

Current treatments for DCM patients are limited to heart transplantation and placement of left ventricular assist devices (LVADs). There are less than 2,500 heart transplantations in the U.S. each year. Many DCM patients are not eligible and transplants are extremely expensive

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at an estimated cost of over \$1 million. LVADs are also expensive at an estimated cost of over \$175,000 and have a mortality rate of 50% at two years.

In February 2007, the FDA granted Orphan Drug Designation to ixmyelocel-T for the treatment of DCM. Our DCM development program is currently in Phase 2b. We recently completed follow up on two U.S. Phase 1/2 trials investigating surgical and catheter-based delivery for our product in the treatment of DCM. The final results from these Phase 1/2 clinical trials were presented at the Society for Cardiovascular Angiography and Interventions (SCAI) meeting on May 10, 2012.

#### Surgical Trial Program - DCM

We completed enrollment of 40 ischemic and non-ischemic DCM patients in the IMPACT-DCM clinical trial in January 2010 and the final patient was treated in March 2010. Participants in the IMPACT-DCM clinical trial were required to have New York Heart Association (NYHA) functional class III or IV heart failure, a left ventricular ejection fraction (LVEF) of less than or equal to 30% (60-75% is typical for a healthy person), and meet other eligibility criteria, including optimized medical therapy. Patients were randomized in an approximate 3:1 ratio of treatment to control group. Patients in the treatment group received our therapy through direct injection into the heart muscle during minimally invasive-surgery (involving a chest incision of approximately 2 inches). The primary objective of this study was to assess the safety of ixmyelocel-T in patients with DCM. Efficacy measures included cardiac dimensions and tissue mass, cardiac function (e.g. cardiac output, LVEF, cardiopulmonary exercise testing parameters), cardiac perfusion and viability, as well as other efficacy endpoints. NYHA functional class and quality of life were also assessed. Patients were followed for 12 months after treatment with an additional 2 year follow-up phone call recently completed in all patients.

#### Catheter Trial Program - DCM

The Catheter-DCM clinical trial was designed to explore catheter-based direct injection delivery of ixmyelocel-T to treat DCM patients. This multi-center, randomized, controlled, prospective, open-label, Phase 2 study enrolled DCM patients at clinical sites across the United States.

We reported final 12-month results from the Catheter-DCM Phase 2 trial at the SCAI 2012 Scientific Sessions on May 10, 2012. The trial included 22 ischemic DCM (IDCM) and non-ischemic DCM (NIDCM) patients with a NYHA heart failure class of III or IV, or moderate to severe heart failure, and a left ventricular ejection fraction of 30 percent or less, which is a measure of how much blood leaves the heart with each pump. Patients were randomized to receive an injection of the treatment into their heart muscles or to a control group, and were followed at three, six and 12 months. After 12 months, no procedural complications and no difference in adverse events were reported among patients who received the treatment and the control group. IDCM patients who received the cell treatment had a lower mean number of major adverse cardiac events (MACE) (0.22 compared to 1.67 in the control group). IDCM patients who received the treatment were more likely to see improvement in NYHA class, six-minute walking distance and ejection fraction, compared to those in the control group. No consistent trends were noted in NIDCM patients.

## Phase 2b Clinical Program — ixCELL-DCM

In February 2013, several sites began screening patients with ischemic DCM in the ixCELL-DCM trial, which is a randomized, double-blind, placebocontrolled clinical trial. The first patient is expected to be randomized in April 2013. The Phase 2b ixCell-DCM trial will enroll 108 ischemic DCM patients. Patients will be randomized 1:1 and followed for 12 months for the primary efficacy endpoint of major adverse cardiac events (MACE), plus hospitalizations and emergency department visits. Patients will be followed for an additional 12 months for safety. We anticipate that enrollment will occur at approximately 30 sites across the U.S.

#### Production

## Cell Manufacturing and Cell Production Components

We operate a centralized cell manufacturing facility in Ann Arbor, Michigan. The facility supports the current U.S. clinical trials and has sufficient capacity, with minor modifications, to supply our early commercialization requirements. We may establish and operate larger commercial-scale cell manufacturing facilities for the U.S. market in the future to accommodate potential market growth.

We have established relationships with manufacturers that are registered with the FDA as suppliers of medical products to produce various components of our patented cell manufacturing system.

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We have established relationships with various third parties who manufacture and/or supply certain components, equipment, disposable devices and other materials used in our cell manufacturing process to develop our cell products, as well as our final assemblies, component parts, subassemblies and associated spare parts used in the instrumentation platform of our cell production system.

There can be no assurance that we will be able to continue our present arrangements with our manufacturers and/or suppliers, supplement existing relationships or establish new relationships, or that we will be able to identify and obtain certain components, equipment, disposable devices, other materials, including ancillary materials that are necessary to develop our product candidates or that are used in our cell manufacturing and cell production components processes. Our dependence upon third parties for the supply and manufacture of such items could adversely affect our ability to develop and deliver commercially feasible cell products on a timely and competitive basis. See "Risk Factors."

#### **Our Arrangement with Vention Medical**

In October 2010, we entered into a contract manufacturing and supply agreement (Supply Agreement) with ATEK Medical, LLC (ATEK) for the manufacture of our proprietary cell cassette for use in our manufacturing process. In November 2011, ATEK was purchased by Vention Medical (Vention) and currently operates as a division of Vention. There have been no changes to the terms of the Supply Agreement as a result of this purchase.

Pursuant to the terms of the Supply Agreement, we have granted Vention the exclusive right to manufacture our proprietary cell cassette, which includes assembly, labeling, packaging and sterilization. Vention will be responsible for obtaining all of our approved components pertaining to the cassettes and we are obligated to order and purchase the cassettes from Vention on an agreed upon schedule and in agreed upon quantities. In addition, we will provide Vention with reasonable engineering support to initiate and ramp up manufacturing of the cassettes and will supply all manufacturing equipment.

The Supply Agreement has an initial term of four years and will terminate automatically without notice unless prior to that time the term is extended by mutual written consent delivered at least six months prior to the termination date. The minimum term extension is generally to be no less than two years.

The Supply Agreement provides that we may discontinue the manufacture of the cassettes at our sole discretion. In such event, we agree to use commercially best efforts to notify Vention at least 120 days prior to our intention to discontinue manufacture of the cassettes. Failure to provide such notice will not be a breach of the Supply Agreement, but without such notice, we agree to purchase from Vention (i) certain finished goods that are in usable condition and (ii) certain components or raw materials inventory or work in process in each case to the extent convertible into finished cassettes.

We or Vention may terminate the Supply Agreement if the other party materially defaults in the performance of any provision of the Supply Agreement and, should any such default occur, then the non-defaulting party may give written notice to the defaulting party that if the default is not cured within 45 days, the Supply Agreement will be terminated. If the non-defaulting party gives such notice and the default is not cured during the 45 day period, then the Supply Agreement shall automatically terminate at the end of such period unless an extension is mutually agreed to by Vention and us. In addition to other remedies, either party may terminate the Supply Agreement at any time if either of us breach our respective confidentiality obligations under the Supply Agreement, in which case termination shall be effective immediately upon receipt of notice from the non-breaching party of the breach and of termination. Either party may immediately terminate the Supply Agreement by written notice if the other party is or becomes insolvent, appoints or has appointed a receiver for all or substantially all of its assets, or makes an assignment for the benefit of its creditors. In addition, either party may terminate the Supply Agreement by written notice if the other party files a voluntary petition, or has filed against it an involuntary petition, for bankruptcy and such petition is not dismissed within 90 days.

Upon termination of the Supply Agreement, Vention agrees to provide reasonable technical support at Vention's published engineering rates for the transfer of manufacturing technology to an alternative manufacturer chosen by us to conduct final manufacture, package and test of the cassettes in the event that Vention, for a period of 150 days from the date of receipt of the associated purchase order, is unable to manufacture all of our orders for any reason, or if Vention fails or refuses to meet our orders for cassettes pursuant to the terms of the Supply Agreement.

There can be no assurance that we will be able to continue our present arrangement with Vention. Our dependence upon our arrangement with Vention for the supply and manufacture of our proprietary cell cassette could adversely affect our ability to develop and deliver commercially feasible cell products on a timely and competitive basis. See "Risk Factors."

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#### **Research & Development**

Our therapy is produced from the patient's bone marrow using Aastrom's proprietary manufacturing system. The product is composed of a mixture of cell types normally found in bone marrow but at different quantities. For example, the mesenchymal stromal cells, identified with the CD90+ cell surface marker, as well as monocytes and activated macrophages, identified with CD14 marker, are expanded approximately 50 and 200 fold, respectively, while other CD45+ mononuclear cells from the bone marrow remain during the manufacturing process. We have demonstrated in the laboratory that the cells in our

therapy are capable of multiple biological activities thought to play a critical role in repairing diseased and damaged tissues. These activities include aspects of tissue remodeling, promotion of angiogenesis and resolution of inflammation. In addition to these properties demonstrated *in vitro*, we have also shown that the therapy increases blood perfusion in both rat and mouse models of critical limb ischemia. In addition to these initial preclinical observations, we have on-going preclinical studies designed to further characterize the mechanism of action of our product in the treatment of cardiovascular diseases. This data supports our current clinical-stage research where we are exploring the use of our therapies to regenerate tissue in patients with CLI and DCM.

In addition, our proprietary cell manufacturing system has demonstrated the capability to produce other types of cells. In the future, we may continue to explore the application of our manufacturing technology for the production of other cell types where there are potential opportunities to collaborate in the development of new cell therapies.

#### **Patents and Proprietary Rights**

Our success depends in part on our ability, and the ability of our licensors, to obtain patent protection for our products and processes. We have exclusive rights to approximately 19 unexpired issued U.S. patents. Eleven of these patents are material patents that protect our cellular therapy. We own ten of these patents and one has been licensed exclusively from the University of Michigan. These patents present various claims relating to (i) the composition of our cellular therapy, (ii) methods to manufacture or administer the cellular therapy, and (iii) the bioreactor device (the Aastrom Replicell System) that is used to make our product. The number of U.S. patents of each type with expiration range is listed in the table below.

| Patent Type           | Number | Expiry (Years) |
|-----------------------|--------|----------------|
| Composition of Matter | 2      | 1 and 16       |
| Methods               | 1      | 14             |
| Bioreactor Device     | 7      | 1 - 2          |

Certain patent equivalents to the U.S. patents have also been issued in other jurisdictions including Australia, Japan, the Republic of Korea and Canada and under the European Patent Convention. In addition, we have filed applications for patents in the United States and equivalent applications in certain other countries claiming other aspects of our cell products and manufacturing processes. Our most significant patent that protects the composition of the cellular therapy directly, "Mixed cell populations for tissue repair and separation technique for cell processing" (US Patent 7,871,605), was issued in January 2011 and will expire in 2029. A divisional application of 7,871,605 for administration of this composition to patients was allowed by the USPTO in January 2012 and was issued in the April 2012 and will expire in 2027. A second divisional application of 7,871,605 directed to the methods of manufacture of our cell compositions was issued in March 2013 and will expire in 2027. Patents that protect our automated bioreactor device and culture system expire in 2015, but we will continue to rely on trade secrets and un-patentable know-how.

The validity and breadth of claims in medical technology patents involve complex legal and factual questions and, therefore, may be highly uncertain. No assurance can be given that any patents based on pending patent applications or any future patent applications by us, or our licensors, will be issued, that the scope of any patent protection will exclude competitors or provide competitive advantages to us, that any of the patents that have been or may be issued to us or our licensors will be held valid if subsequently challenged or that others will not claim rights in or ownership of the patents and other proprietary rights held or licensed by us. Furthermore, there can be no assurance that others have not developed or will not develop similar products, duplicate any of our products or design around any patents that have been or may be issued to us or our licensors. Since patent applications in the U.S. are maintained in secrecy until they are published 18 months after filing, we also cannot be certain that others did not first file applications for inventions covered by our and our licensors' pending patent applications, nor can we be certain that we will not infringe any patents that may be issued to others on such applications.

We rely on certain licenses granted by the University of Michigan for certain patent rights. If we breach such agreements or otherwise fail to comply with such agreements, or if such agreements expire or are otherwise terminated, we may lose our rights in such patents.

We also rely on trade secrets and un-patentable know-how that we seek to protect, in part, by confidentiality agreements. It is our policy to require our employees, consultants, contractors, manufacturers, outside scientific collaborators and sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's

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relationship with us is to be kept confidential and not disclosed to third parties except in specific limited circumstances. We also require signed confidentiality or material transfer agreements from any company that is to receive our confidential information. In the case of employees, consultants and contractors, the agreements generally provide that all inventions conceived by the individual while rendering services to us shall be assigned to us as the exclusive property of Aastrom. There can be no assurance, however, that these agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets or un-patentable know-how will not otherwise become known or be independently developed by competitors.

Our success will also depend in part on our ability to develop commercially viable products without infringing the proprietary rights of others. We do not believe any of our currently contemplated products or processes infringe any existing valid issued patent. However, the results of patent litigation are unpredictable, and no assurance can be given that patents do not exist or could not be filed which would have an adverse effect on our ability to market our products or maintain our competitive position with respect to our products. If our technology components, designs, products, processes or other subject matter are claimed under other existing U.S. or foreign patents, or are otherwise protected by third party proprietary rights, we may be subject to infringement actions. In such event, we may challenge the validity of such patents or other proprietary rights or we may be required to obtain licenses from such companies in order to develop, manufacture or market our products. There can be no assurances that we would be able to obtain such licenses or that such licenses, if available, could be obtained on commercially reasonable terms. Furthermore, the failure to either develop a commercially viable alternative or obtain such licenses could result in delays in marketing our proposed products or the inability to proceed with the development, manufacture or sale of products requiring such licenses, which could have a material adverse effect on our business, financial condition and results of operations. If we are required to defend ourselves against charges of patent infringement or to protect our proprietary rights against third parties, substantial costs will be incurred regardless of whether we are successful. Such proceedings are typically protracted with no certainty of success. An adverse outcome could subject us to significant liabilities to third parties and force us to curtail or cease our development and sale of our products and processes.

Certain of our and our licensors' research has been or is being funded in part by the Department of Commerce and by a Small Business Innovation Research Grant obtained from the Department of Health and Human Services. As a result of such funding, the U.S. Government has certain rights in the technology developed with such funding. These rights include a non-exclusive, fully paid-up, worldwide license under such inventions for any governmental purpose. In addition, the U.S. Government has the right to require us to grant an exclusive license under any of such inventions to a third party if the U.S. Government determines that: (i) adequate steps have not been taken to commercialize such inventions; (ii) such action is necessary to meet public health or safety needs; or (iii) such action is necessary to meet requirements for public use under federal regulations. Additionally, under the federal Bayh Dole Act, a party which acquires an exclusive license for an invention that was partially funded by a federal research grant is subject to the following government rights: (i) products using the invention which are sold in the United States are to be manufactured substantially in the United States, unless a waiver is obtained; (ii) the government may force the granting of a license to a third party who will make and sell the needed product if the licensee does not pursue reasonable commercialization of a needed product using the invention; and (iii) the U.S. Government may use the invention for its own needs.

#### Sales and Marketing

We currently do not have the sales or marketing resources required to fully commercialize our therapeutic products. We intend to advance our programs to a point where we can evaluate the options to seek a development and/or commercialization partnership, or to make the investment to complete development and commercialize a product alone. We may also choose to undertake some pilot level of sales and marketing activity while seeking a commercial partnership.

#### **Government Regulation**

Our research and development activities and the manufacturing and marketing of our products are subject to the laws and regulations of governmental authorities in the United States and other countries in which our products will be marketed. Specifically, in the United States, the FDA, among other activities, regulates new product approvals to establish safety and efficacy of these products. Governments in other countries have similar requirements for testing and marketing. In the United States, in addition to meeting FDA regulations, we are also subject to other federal laws, such as the Occupational Safety and Health Act and the Environmental Protection Act, as well as certain state laws.

Our cell products will be regulated as somatic cell therapies/biologics/pharmaceuticals. With this classification, commercial production of our products will need to occur in registered/licensed facilities in compliance with Good Manufacturing Practice (GMP) for biologics (cellular products) or drugs.

## **Regulatory Process**

Our products are subject to regulation as biological products under the Public Health Service Act and the Food, Drug and Cosmetic Act. Different regulatory requirements may apply to our products depending on how they are categorized by the FDA under these laws. The FDA

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has indicated that it intends to regulate products based on our technology as licensed biologics through the Center for Biologics Evaluation and Research. As current regulations exist, the FDA will require regulatory approval for certain human cellular- or tissue-based products, including our cell products, through a BLA submission.

Approval of new biological products is a lengthy procedure leading from development of a new product through preclinical and clinical testing. This process takes a number of years and the expenditure of significant resources. There can be no assurance that our product candidates will ultimately receive regulatory approval.

Regardless of how our product candidates are regulated, the Federal Food, Drug, and Cosmetic Act and other Federal and State statutes and regulations govern or influence the research, testing, manufacture, safety, labeling, storage, record-keeping, approval, distribution, use, product reporting, advertising and promotion of such products. Noncompliance with applicable requirements can result in civil penalties, recall, injunction or seizure of products, refusal of the government to approve or clear product approval applications or to allow us to enter into government supply contracts, withdrawal of previously approved applications and criminal prosecution.

#### **Product Approval**

In order to obtain FDA approval of a new medical product, sponsors must submit proof of safety and efficacy. In most cases, such proof entails extensive preclinical studies and clinical trials. The testing, preparation of necessary applications and processing of those applications by the FDA is expensive and may take several years to complete. There can be no assurance that the FDA will act favorably or in a timely manner in reviewing submitted applications, and we may encounter significant difficulties or costs in our efforts to obtain FDA approvals, in turn, which could delay or preclude us from marketing any products we may develop. The FDA may also require post-marketing testing and surveillance of approved products, or place other conditions on the approvals. These requirements could cause it to be more difficult or expensive to sell the products, and could therefore restrict the commercial applications of such products. Product approvals may be withdrawn if compliance with applicable regulations is not maintained or if problems occur following commercialization. For patented technologies, delays imposed by the governmental approval process may materially reduce the period during which we will have the exclusive right to exploit such technologies.

If clinical trials of a proposed medical product are required, the manufacturer or distributor of a drug or biologic will have to submit an IND application with the FDA prior to commencing human clinical trials. The submission must be supported by data, typically including the results of preclinical and laboratory testing. Following submission of the IND, the FDA has 30 days to review the application and raise safety and other clinical trial issues. If we are not notified of objections within that period, clinical trials may be initiated, and human clinical trials may commence at a specified number of investigational sites with the number of patients approved by the FDA. We have submitted several INDs for our cell products, and we have conducted clinical trials under these INDs.

Our products will be regulated by the FDA as a licensed biologic, although there can be no assurance that the FDA will not choose to regulate this product in a different manner in the future. The FDA categorizes human cell- or tissue-based products as either minimally manipulated or more than minimally manipulated, and has determined that more than minimally manipulated products require clinical trials to demonstrate product safety and efficacy and the submission of a BLA for marketing authorization. For products that may be regulated as biologics, the FDA requires: (i) preclinical laboratory and animal testing; (ii) submission to the FDA of an IND application, which must be approved prior to the initiation of human clinical trials; (iii) adequate and wellcontrolled clinical trials to establish the safety and efficacy of the product for its intended use; (iv) submission to the FDA of a BLA; and (v) review and approval of the BLA as well as inspections of the manufacturing facility by the FDA prior to commercial marketing of the product.

We conduct preclinical testing for internal use and as support for submissions to the FDA. Preclinical testing generally includes various types of in-vitro laboratory evaluations of our products as well as animal studies to assess the safety and the functionality of the product. Clinical trials are identified by phases (i.e., Phase 1, Phase 2, Phase 3, etc.). Depending on the type of preclinical and/or clinical data available, the trial sponsor will submit a request to the FDA to initiate a specific phase study (e.g., a Phase 1 trial represents an initial study in a small group of patients to test for safety and other relevant factors; a Phase 2 trial represents a study in a larger number of patients to assess the safety and efficacy of a product; and, Phase 3 trials are initiated to establish safety and efficacy in an expanded patient population at multiple clinical trial sites).

The results of the preclinical tests and clinical trials are submitted to the FDA in the form of a BLA for marketing approval. The testing, clinical trials and approval process are likely to require substantial time and effort and there can be no assurance that any approval will be granted on a timely basis, if at all. Additional animal studies or clinical trials may be requested during the FDA review period that may delay marketing approval. After FDA approval for the initial indications, further clinical trials may be necessary to gain approval for the use of the product for additional indications. The FDA requires that adverse effects be reported to the FDA and may also require post-marketing testing to monitor for adverse events, which can involve significant expense.

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Under current requirements, facilities manufacturing biological products for commercial distribution must be licensed. To accomplish this, an establishment registration must be filed with the FDA. In addition to the preclinical studies and clinical trials, the BLA includes a description of the facilities, equipment and personnel involved in the manufacturing process. An establishment registration/license is granted on the basis of inspections of the applicant's facilities in which the primary focus is on compliance with GMPs and the ability to consistently manufacture the product in the facility in accordance with the BLA. If the FDA finds the results of the inspection unsatisfactory, it may decline to approve the BLA, resulting in a delay in production of products.

As part of the approval process for human biological products, each manufacturing facility must be registered and inspected by the FDA prior to marketing approval. In addition, state agency inspections and approvals may also be required for a biological product to be shipped out of state.

#### **Commercial Strategy**

We are currently focused on utilizing our technology to produce expanded, patient specific multicellular products for use in severe, chronic ischemic cardiovascular indications. At such time as we satisfy applicable regulatory approval requirements, we expect the sales of our cell-based products to constitute nearly all of our product sales revenues.

We do not expect to generate positive cash flows from our consolidated operations for at least the next several years and then only if we achieve significant product sales. Until that time, we expect that our revenue sources from our current activities will consist of only minor sales of our cell products and manufacturing supplies to our academic collaborators, grant revenue, research funding and potential licensing fees or other financial support from potential future corporate collaborators.

We expect that we will need to raise significant additional funds or pursue strategic transactions or other strategic alternatives in order to complete our product development programs, complete clinical trials needed to market our products, and commercialize our products. To date, we have financed our operations primarily through public and private sales of our equity securities, and we expect to continue to seek to obtain the required capital in a similar manner. As a development stage company, we have never been profitable and do not anticipate having net income unless and until significant product sales commence. With respect to our current activities, this is not likely to occur until we obtain significant additional funding, complete the required clinical trials for regulatory approvals, and receive the necessary approvals to market our products. If we cannot raise such funds, we will not be able to develop or enhance products, take advantage of future opportunities, or respond to competitive pressures or unanticipated requirements, which would have a material adverse impact on our business, financial condition and results of operations. As a result of the need to raise additional capital and a net capital deficiency, there is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively over at least the next twelve months, which raises substantial doubt as to our ability to continue as a going concern. Through December 31, 2012, we have accumulated a net loss attributable to common shareholders of approximately \$275,315,000. We cannot provide any assurance that we will be able to achieve profitability on a sustained basis, if at all, obtain the required funding, obtain the required regulatory approvals, or complete additional corporate partnering or acquisition transactions.

#### **Competitive Environment**

The biotechnology and medical device industries are characterized by rapidly evolving technology and intense competition. Our competitors include major multi-national medical device companies, pharmaceutical companies, biotechnology companies and stem cell companies operating in the fields of tissue engineering, regenerative medicine, cardiac, vascular, orthopedics and neural medicine. Many of these companies are well-established and possess technical, research and development, financial, and sales and marketing resources significantly greater than ours. In addition, many of our smaller potential competitors have formed strategic collaborations, partnerships and other types of joint ventures with larger, well established industry competitors that afford these companies potential research and development and commercialization advantages in the technology and therapeutic areas currently being pursued by us. Academic institutions, governmental agencies and other public and private research organizations are also conducting and financing research activities which may produce products directly competitive to those being commercialized by us. Moreover, many of these competitors may be able to obtain patent protection, obtain FDA and other regulatory approvals and begin commercial sales of their products before us.

Our potential commercial products address a broad range of existing and emerging therapeutic markets, in which cell-based therapy is a new and as of yet, unproven, commercial strategy. In a large part, we face primary competition from existing medical devices and drug products. Some of our competitors have longer operating histories and substantially greater resources. These include companies such as Baxter International, Inc. (Baxter), Biomet, Inc., Johnson & Johnson, Inc., Medtronic, Inc. (Medtronic), and others.

In the general area of cell-based therapies, we potentially compete with a variety of companies, most of whom are specialty medical products or biotechnology companies. Some of these, such as Baxter, Johnson & Johnson, Medtronic and Miltenyi Biotec are well-established and have substantial technical and financial resources compared to ours. However, as cell-based products are only just emerging as viable medical therapies, many of our most direct competitors are smaller biotechnology and specialty medical products companies. These include Advanced Cell Technology, Inc., Cytomedix, Inc. (formerly Aldagen, Inc.), Arteriocyte Medical Systems, Inc., Athersys, Inc., Bioheart, Inc., Cytori Therapeutics, Inc., International Stem Cell Corporation, Neostem, Inc., Terumo Medical

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Corporation (formerly Harvest Technologies Corporation), Mesoblast, Osiris Therapeutics, Inc., Pluristem, Inc. Stem Cells, Inc., Tengion, Inc. and others.

## Employees

As of December 31, 2012, we employed 77 individuals on a full-time equivalent basis. A significant number of our management and professional employees have had prior experience with pharmaceutical, biotechnology or medical product companies. None of our employees are covered by collective bargaining agreements, and management considers relations with our employees to be good.

#### **Executive Officers**

| Name                        | Position                              | Age | Officer Since |
|-----------------------------|---------------------------------------|-----|---------------|
| Dominick C. Colangelo       | President and Chief Executive Officer | 49  | 2013          |
| Daniel R. Orlando           | Chief Commercial Officer              | 47  | 2012          |
| Ronnda L. Bartel, Ph.D.     | Chief Scientific Officer              | 54  | 2010          |
| Sharon M. Watling, Pharm.D. | Vice President Clinical Development   | 49  | 2011          |
| Brian D. Gibson             | Vice President of Finance             | 34  | 2011          |

*Dominick C. Colangelo* — Mr. Colangelo joined Aastrom in 2013 with more than twenty years of executive management and corporate development experience in the biopharmaceutical industry, including nearly a decade with Eli Lilly and Company. Most recently, he was President and Chief Executive Officer of Promedior, Inc. During his career, he has held a variety of executive positions of increasing responsibility in product development, pharmaceutical operations, sales and marketing, and corporate development. He has extensive experience in the acquisition, development and commercialization of therapies to treat fibrovascular, metabolic and cardiovascular diseases. During his tenure at Eli Lilly and Company, he held positions as Director of Strategy and Business Development for Lilly's Diabetes Product Group and also served as a founding Managing Director of Lilly Ventures. Mr. Colangelo received his B.S.B.A. in Accounting, Magna Cum Laude, from the State University of New York at Buffalo and a J.D. degree, with Honors, from the Duke University School of Law.

*Daniel R. Orlando* — Mr. Orlando joined Aastrom as Chief Commercial Officer in August of 2012. On December 14, 2012, Mr. Orlando served as interim CEO of Aastrom from December 2012 to March 2013. He has more than 20 years of commercial product preparation and launch experience including leadership roles in sales, marketing and most recently as a vice president of business development for North and South America at Takeda Pharmaceuticals. As an early employee at Takeda North America, he served as the original brand director for Actos, which became the #1 branded anti-diabetic agent in the U.S. Mr. Orlando's initial pharmaceutical experience came in progressively expanding roles in sales and marketing at Abbott Laboratories. He holds an MBA from Florida Atlantic University and a BA in economics with Honors from the University of Florida.

*Ronnda L. Bartel, Ph.D.* — Dr. Bartel joined Aastrom in 2006 and is responsible for research, development, quality, IT, manufacturing and engineering operations. Dr. Bartel has more than 20 years of research and product development experience and most recently was Executive Director, Biological Research at MicroIslet and Vice president, Scientific Development at StemCells, Inc. Earlier in her career, she was Senior Principal Scientist, Cell Biology at Advanced Tissue Sciences and was involved in the development and approval of two of the first three cell based products approved by the FDA. She has also worked as Senior Director, Science and Technology at SRS Capital, LLC evaluating life science investments and has also held positions in clinical development, drug delivery, business development and manufacturing. Dr. Bartel holds a Ph.D. in Biochemistry from the University of Kansas, completed postdoctoral work at the University of Michigan and received a B.A. in Chemistry and Biology from Tabor College.

*Sharon M. Watling, Pharm.D* — Dr. Watling joined Aastrom in February 2010 and is responsible for clinical development and clinical operations. She has over 12 years of experience in clinical development, with an emphasis on translational science, clinical development, and clinical strategies. Her industry career started in late stage development within Warner-Lambert/Parke Davis and evolved while at Pfizer to include an early clinical leadership role in cardiovascular-metabolic diseases. Following Pfizer, she was site leader and senior director, clinical development at Metabasis, Inc. Most recently, she served as the research and development strategy leader at Cognigen Corporation, working with multiple companies to incorporate modeling and simulation practices into their development strategies. Prior to industry, she was an intensive care unit clinical specialist at various academic institutions. Dr. Watling holds a Pharm.D. from the University of Michigan College of Pharmacy.

*Brian D. Gibson* — Mr. Gibson joined Aastrom in July 2010 and is Vice President of Finance. He brings more than 11 years of finance and accounting experience to Aastrom. Prior to joining Aastrom, Mr. Gibson was a senior manager at PricewaterhouseCoopers, with broad experience in multiple industries, including life sciences and healthcare. Mr. Gibson holds a BA in accounting with high honor from the Eli Broad College of Business at Michigan State University and is a certified public accountant.

Our former President and Chief Executive Officer, Timothy M. Mayleben, resigned from these positions in December 2012.

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#### **Available Information**

Additional information about Aastrom is contained at our website, <u>www.aastrom.com</u>. Information on our website is not incorporated by reference into this report. We make available on our website free of charge our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K as soon as reasonably practicable after those reports are filed with the Securities and Exchange Commission. Our reports filed with the Securities and Exchange Commission are also made available to read and copy at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. You

may obtain information about the Public Reference Room by calling the SEC at 1-800-SEC-0330. Reports filed with the SEC are also made available on its website at www.sec.gov. The following Corporate Governance documents are also posted on our website: Code of Business Conduct and Ethics, Code of Ethics for Senior Financial Officers, Board Member Attendance at Annual Meetings Policy, Director Nominations Policy, Shareholder Communications with Directors Policy and the Charters for each of the Committees of the Board of Directors.

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## Item 1A. Risk Factors

Our operations and financial results are subject to various risks and uncertainties, including those described below, that could adversely affect our business, financial condition, results of operations, cash flows, and trading price of our common stock. The risks and uncertainties described below are not the only ones we face. There may be additional risks and uncertainties that are not known to us or that we do not consider to be material at this time. If the events described in these risks occur, our business, financial condition, and results of operations would likely suffer.

#### **Risks Related to our Business**

#### Our past losses and expected future losses cast doubt on our ability to continue as a going concern and operate profitably.

As of December 31, 2012, we have \$13,638,000 of cash and cash equivalents. This is not sufficient to sustain our operations for one year. In light of our financial position, we are evaluating strategic and financial opportunities in the short-term in order to maintain adequate liquidity through December 31, 2013 and beyond. Additionally, we could sell shares through an At the Market Sales Agreement (ATM) in order to raise additional capital, though there are certain factors, such as volume of trading in our stock, our stock price and the ability to terminate the agreement with notice, which could limit the amount we could raise in a short period of time. On a longer term basis, we will need to raise additional funds in order to complete product development programs and complete clinical trials needed to market and commercialize our products. We cannot be certain that such funding will be available on favorable terms, if at all. Some of the factors that will impact our ability to raise additional capital and our overall success include: the rate and degree of progress for our product development, the rate of regulatory approval to proceed with clinical trial programs, the level of success achieved in clinical trials, the requirements for marketing authorization from regulatory bodies in the United States and other countries, the liquidity and market volatility of our equity securities, regulatory and manufacturing requirements and uncertainties, technological developments by competitors, and other factors. If we cannot raise additional capital and a net capital deficiency, there is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively over at least the next twelve mooths, which raises substantial doubt as to our ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We were incorporated in 1989 and have experienced substantial operating losses since inception. As of December 31, 2012, we have incurred a cumulative net loss attributable to common shareholders totaling approximately \$275,315,000 and we have continued to incur losses since that date. These losses have resulted principally from costs incurred in the research and development (including clinical trials) of our cell culture technologies and our cell manufacturing system, general and administrative expenses, and the prosecution of patent applications. We expect to continue to incur significant operating losses over the next several years and at least until, and probably after, product sales increase, primarily owing to our research and development programs, including preclinical studies and clinical trials, and the establishment of marketing and distribution capabilities necessary to support commercialization efforts for our products. We cannot predict with any certainty the amount of future losses. Our ability to achieve profitability will depend, among other things, on successfully completing the development of our product candidates, timely initiation and completion of clinical trials, obtaining regulatory approvals, establishing manufacturing, sales and marketing arrangements with third parties, maintaining supplies of key manufacturing components, acquisition and development of complementary activities and raising sufficient cash to fund our operating activities. Therefore, we may not be able to achieve or sustain profitability.

## We may not be able to raise the required capital to conduct our operations and develop and commercialize our products.

We will require substantial additional capital resources in order to conduct our operations, complete our product development programs, complete our clinical trials needed to market our products (including a Phase 3 clinical trial for CLI and a Phase 2b clinical trial for DCM), and commercialize these products and cell manufacturing facilities. In order to grow and expand our business, to introduce our new product candidates into the marketplace and to acquire or develop complementary business activities, we will need to raise a significant amount of additional funds. We will also need significant additional funds or a collaborative partner, or both, to finance the research and development activities of our cell product candidates for additional indications. Accordingly, we are continuing to pursue additional sources of financing.

Our future capital requirements will depend upon many factors, including:

- · continued scientific progress in our research, clinical and development programs;
- · costs and timing of conducting clinical trials and seeking regulatory approvals;

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- competing technological and market developments;
- $\cdot$  avoiding infringement and misappropriation of third-party intellectual property;
- $\cdot$  obtaining valid and enforceable patents that give us a competitive advantage;
- our ability to establish additional collaborative relationships;

- our ability to effectively launch a commercial product;
- the effect of commercialization activities and facility expansions, if and as required; and
- · complementary business acquisition or development opportunities.

We entered into an At the Market Sales Agreement (ATM) on June 16, 2011, which allows us to raise approximately \$20,000,000 through sales of our common stock from time to time. However, there are certain factors, such as volume of trading in our stock, our stock price and the ability to terminate the agreement with notice, which limit the amount that can be raised in a short period of time through the ATM. Regardless of the usage of the ATM, we need to raise additional capital in order to fund the clinical trials of ixmyelocel-T for CLI and DCM, complete our product development programs, complete clinical trials needed to market our products and commercialize these products.

We will need to raise additional funds in order to complete our product development programs, complete clinical trials needed to market our products (including clinical trials for our CLI and DCM programs), and commercialize these products. Because of our long-term funding requirements, we may try to access the public or private equity markets if conditions are favorable to complete a financing, even if we do not have an immediate need for additional capital at that time, or whenever we require additional operating capital. In addition, we may seek collaborative relationships, incur debt and access other available funding sources. This additional funding may not be available to us on reasonable terms, or at all. Some of the factors that will impact our ability to raise additional capital and our overall success include:

- the rate and degree of progress for our product development;
- the rate of regulatory approval to proceed with clinical trial programs;
- the level of success achieved in clinical trials;
- the requirements for marketing authorization from regulatory bodies in the United States and other countries;
- the liquidity and market volatility of our equity securities; and
- regulatory and manufacturing requirements and uncertainties, technological developments by competitors.

If adequate funds are not available in the future, we may not be able to develop or enhance our products, take advantage of future opportunities, or respond to competitive pressures or unanticipated requirements and we may be required to delay or terminate research and development programs, curtail capital expenditures, and reduce business development and other operating activities. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could have a material adverse effect on our business, operating results, financial condition and prospects.

#### Failure to obtain and maintain required regulatory approvals would severely limit our ability to sell our products.

We must obtain the approval of the FDA before commercial sales of our cell product candidates may commence in the United States, which we believe will ultimately be the largest market for our products. We will also be required to obtain additional approvals from various foreign regulatory authorities to initiate sales activities of cell products in those jurisdictions. If we cannot demonstrate the safety, purity and potency of our product candidates, including our cell product candidates, produced in our production system, the FDA or other regulatory authorities could delay or withhold regulatory approval of our product candidates.

Finally, even if we obtain regulatory approval of a product, that approval may be subject to limitations on the indicated uses for which it may be marketed. Even after granting regulatory approval, the FDA and regulatory agencies in other countries continue to review and inspect marketed products, manufacturers and manufacturing facilities, which may create additional regulatory burdens. Later discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on the product or manufacturer, including a

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withdrawal of the product from the market. Further, regulatory agencies may establish additional regulations that could prevent or delay regulatory approval of our products.

## Our product development programs are based on novel technologies and are inherently risky.

We are subject to the risks of failure inherent in the development of products based on new technologies. The novel nature of our therapeutics creates significant challenges in regard to product development and optimization, manufacturing, government regulation, third party reimbursement and market acceptance. For example, if regulatory agencies have limited experience in approving cellular therapies for commercialization, the development and commercialization pathway for our therapies may be subject to increased uncertainty, as compared to the pathway for new conventional drugs.

## Any changes in the governmental regulatory classifications of our products could prevent, limit or delay our ability to market or develop our products.

The FDA establishes regulatory requirements based on the classification of a product. Because our product development programs are designed to satisfy the standards applicable to biological licensure for our cellular products, any change in the regulatory classification or designation would affect our ability to obtain FDA approval of our products. Each of these cell products is, under current regulations, regulated as a biologic, which requires a BLA.

## Our inability to complete our product development activities successfully would severely limit our ability to operate or finance operations.

In order to commercialize our cell product candidates in the United States, we must complete substantial clinical trials and obtain sufficient safety, purity and potency results to support required registration approval and market acceptance of our cell product candidates. We may not be able to successfully complete the development of our product candidates, or successfully market our technologies or product candidates. We, and any of our potential collaborators, may encounter problems and delays relating to research and development, regulatory approval and intellectual property rights of our technologies and product candidates. Our research and development programs may not be successful, and our cell culture technologies and product candidates may not facilitate the production of cells outside the human body with the expected results. Our technologies or product candidates and the cells produced in such products. If any of these events occur, we may not have adequate resources to continue operations for the period required to resolve any issues delaying commercialization and we may not be able to raise capital to finance our continued operation during the period required for resolution of any such issues.

#### We must successfully complete our clinical trials to be able to market certain of our products.

To be able to market therapeutic cell products in the United States, we must demonstrate, through extensive preclinical studies and clinical trials, the safety and efficacy of our processes and product candidates. If our clinical trials are not successful, our products may not be marketable. The results of early stage clinical trials do not ensure success in later clinical trials, and interim results are not necessarily predictive of final results.

Our ability to complete our clinical trials in a timely manner depends on many factors, including the rate of patient enrollment. Patient enrollment can vary with the size of the patient population, the proximity of suitable patients to clinical sites, perceptions of the utility of cell therapy for the treatment of certain diseases, and the eligibility criteria for the study. For example, patients enrolling in our studies need to provide an adequate amount of bone marrow to process and expand for injection and some patients may not be able to provide sufficient starting material despite our study inclusion and exclusion criteria designed to prevent this. Bone marrow is an inherently variable starting material. We have experienced delays in patient accrual in our previous clinical trials. If we experience future delays in patient enrollment, we could experience increased costs and delays associated with clinical trials, which would impair our product development programs and our ability to market our products.

Furthermore, the FDA monitors the progress of clinical trials and it may suspend or terminate clinical trials at any time due to patient safety or other considerations.

Our research programs are currently directed at improving product functionality for certain clinical indications, improving product shelf life, and decreasing the cost of manufacturing our products. These production process changes may alter the functionality of our cells and require various additional levels of experimental and clinical testing and evaluation. Any such testing could lengthen the time before these products would be commercially available.

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Even if successful clinical results are reported for a product from a completed clinical trial, this does not mean that the results will be sustained over time, or will be sufficient for a marketable or regulatory approvable product.

# We will rely on third parties to conduct some of our clinical trials, and their failure to perform their obligations in a timely or competent manner may delay development and commercialization of our product candidates.

We have engaged and we may use clinical research organizations (CRO) to assist in conduct of our clinical trials. There are numerous alternative sources to provide these services. However, we may face delays outside of our control if these parties do not perform their obligations in a timely or competent fashion or if we are forced to change service providers. Any third party that we hire to conduct clinical trials may also provide services to our competitors, which could compromise the performance of their obligations to us. If we experience significant delays in the progress of our clinical trials, the commercial prospects for product candidates could be harmed and our ability to generate product revenue would be delayed or prevented. In addition, we and any provider that we retain will be subject to Good Clinical Practice, or GCP requirements. If GCP and other regulatory requirements are not adhered to by us or our third-party providers, the development and commercialization of our product candidates could be delayed.

Any failure of such CRO to successfully accomplish clinical trial monitoring, data collection, safety monitoring and data management and the other services it provides for us in a timely manner and in compliance with regulatory requirements could have a material adverse effect on our ability to complete clinical development of our products and obtain regulatory approval. Problems with the timeliness or quality of the work of a CRO may lead us to seek to terminate the relationship and use an alternate service provider. However, making such changes may be costly and may delay our trials, and contractual restrictions may make such a change difficult or impossible. Additionally, it may be difficult to find a replacement organization that can conduct our trials in an acceptable manner and at an acceptable cost.

## Failure of third parties, including Vention Medical, to manufacture or supply certain components, equipment, disposable devices and other materials used in our cell manufacturing process would impair our cell product development.

We rely on third parties, including Vention Medical (Vention), to manufacture and/or supply certain of our devices/manufacturing equipment and to manufacture and/or supply certain components, equipment, disposable devices and other materials used in our cell manufacturing process to develop our cell products. Vention is our sole supplier of cell cassettes for which it would be difficult to obtain alternate sources of supply on a short-term basis. If any of our manufacturers or suppliers fails to perform their respective obligations, or if our supply of certain components, equipment, disposable devices and other materials is limited or interrupted, it could impair our ability to manufacture our products, which would delay our ability to conduct our clinical trials or market our product candidates on a timely and cost-competitive basis, if at all.

In addition, we may not be able to continue our present arrangements with our suppliers, supplement existing relationships, establish new relationships or be able to identify and obtain the ancillary materials that are necessary to develop our product candidates in the future. Our dependence upon third parties for the supply and manufacture of these items could adversely affect our ability to develop and deliver commercially feasible products on a timely and competitive basis.

# Manufacturing of our cell products in centralized facilities may increase the risk that we will not have adequate quantities of our cell products for clinical programs.

We are subject to regulatory compliance and quality assurance requirements at our production site in Ann Arbor, Michigan. This site could be subject to ongoing, periodic, unannounced inspection by regulatory agencies to ensure strict compliance with GMP regulations and other governmental regulations. We do not have redundant cell manufacturing sites. In the event our cell production facility is damaged or destroyed or is subject to regulatory restrictions, our clinical trial programs and other business prospects would be adversely affected.

#### Even if we obtain regulatory approvals to sell our products, lack of commercial acceptance could impair our business.

We will be seeking to obtain regulatory approvals to market our cell products for tissue repair treatments. Even if we obtain all required regulatory approvals, we cannot be certain that our products and processes will be accepted in the marketplace at a level that would allow us to operate profitably. Our products may be unable to achieve commercial acceptance for a number of reasons, such as the availability of alternatives that are less expensive, more effective, or easier to use; the perception of a low cost-benefit ratio for the product amongst physicians and hospitals; or an inadequate level of product support from ourselves or a commercial partner. Our technologies or product candidates may not be employed in all potential applications being investigated, and any reduction in applications would limit the market acceptance of our technologies and product candidates, and our potential revenues.

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#### The market for our products will be heavily dependent on third party reimbursement policies.

Our ability to successfully commercialize our product candidates will depend on the extent to which government healthcare programs, such as Medicare and Medicaid, as well as private health insurers, health maintenance organizations and other third party payers will pay for our products and related treatments.

Reimbursement by third party payers depends on a number of factors, including the payer's determination that use of the product is safe and effective, not experimental or investigational, medically necessary, appropriate for the specific patient and cost-effective. Reimbursement in the United States or foreign countries may not be available or maintained for any of our product candidates. If we do not obtain approvals for adequate third party reimbursements, we may not be able to establish or maintain price levels sufficient to realize an appropriate return on our investment in product development. Any limits on reimbursement from third party payers may reduce the demand for, or negatively affect the price of, our products. For example, in the past, published studies suggested that stem cell transplantation for breast cancer, which constituted a significant portion of the overall stem cell therapy market at the time, may have limited clinical benefit. The lack of reimbursement for these procedures by insurance payers has negatively affected the market for our products in this indication in the past.

Managing and reducing health care costs has been a general concern of federal and state governments in the United States and of foreign governments. In addition, third party payers are increasingly challenging the price and cost-effectiveness of medical products and services, and many limit reimbursement for newly approved health care products. In particular, third party payers may limit the indications for which they will reimburse patients who use any products that we may develop. Cost control initiatives could decrease the price for products that we may develop, which would result in lower product revenues to us.

#### Use of animal-derived materials could harm our product development and commercialization efforts.

Some of the manufacturing materials and/or components we use in, and are critical to, implementation of our technology involve the use of animalderived products, including fetal bovine serum. Suppliers or regulatory changes may limit or restrict the availability of such materials for clinical and commercial use. We currently purchase all of our fetal bovine sera from protected herds in Australia and New Zealand. These sources are considered to be the safest and raise the least amount of concern from the global regulatory agencies. If, for example, the so-called "mad cow disease" occurs in New Zealand or in Australia, it may lead to a restricted supply of the serum currently required for our product manufacturing processes. Any restrictions on these materials would impose a potential competitive disadvantage for our products or prevent our ability to manufacture our cell products. The FDA has issued draft regulations for controls over bovine materials. These proposed regulations do not appear to affect our ability to purchase the manufacturing materials we currently use. However, the FDA may issue final regulations that could affect our operations. Our inability to develop or obtain alternative compounds would harm our product development and commercialization efforts. There are certain limitations in the supply of certain animal-derived materials, which may lead to delays in our ability to complete clinical trials or eventually to meet the anticipated market demand for our cell products.

## Given our limited internal manufacturing, sales, marketing and distribution capabilities, we need to develop increased internal capability or collaborative relationships to manufacture, sell, market and distribute our products.

We have only limited internal manufacturing, sales, marketing and distribution capabilities. As market needs develop, we intend to establish and operate commercial-scale manufacturing facilities, which will need to comply with all applicable regulatory requirements. We will also need to develop new configurations of our cell manufacturing system for these facilities to enable processes and cost efficiencies associated with large-scale manufacturing. Establishing these facilities will require significant capital and expertise. We may need to make such expenditures when there are significant uncertainties as to the market opportunity. Any delay in establishing, or difficulties in operating, these facilities will limit our ability to meet the anticipated market demand for our cell products. We intend to get assistance to market some of our future cell products through collaborative relationships with companies with established sales, marketing and distribution capabilities. Our inability to develop and maintain those relationships would limit our ability to market, sell and distribute our products. Our inability to enter into successful, long-term relationships could require us to develop alternate arrangements at a time when we need sales, marketing or distribution capabilities to meet existing demand. We may market one or more of our products through our own sales force. Our inability to develop and retain a qualified sales force could limit our ability to market, sell and distribute our cell products.

## If we do not keep pace with our competitors and with technological and market changes, our products will become obsolete and our business may suffer.

The markets for our products are very competitive, subject to rapid technological changes, and vary for different candidates and processes that directly compete with our products. Our competitors may have developed, or could in the future develop, new technologies that compete with our products or even render our products obsolete. As an example, in the past, published studies have suggested that hematopoietic stem cell therapy use for bone marrow transplantation, following marrow ablation due to chemotherapy, may have limited clinical benefit in the treatment of breast cancer, which was a significant portion of the overall hematopoietic stem cell transplant market. This resulted in the practical elimination of this market for our cell-based product for this application.

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Our cell manufacturing system is designed to improve and automate the processes for producing cells used in therapeutic procedures. Even if we are able to demonstrate improved or equivalent results, the cost or process of treatment and other factors may cause researchers and practitioners to not use our products and we could suffer a competitive disadvantage. Finally, to the extent that others develop new technologies that address the targeted application for our products, our business will suffer.

#### The current credit and financial market conditions may exacerbate certain risks affecting our business.

We rely upon third parties for certain aspects of our business, including collaboration partners, wholesale distributors, contract clinical trial providers, contract manufacturers and third-party suppliers. Because of the recent tightening of global credit and the volatility in the financial markets, there may be a delay or disruption in the performance or satisfaction of commitments to us by these third parties, which could adversely affect our business.

#### If we cannot attract and retain key personnel, our business may suffer.

Our success depends in large part upon our ability to attract and retain highly qualified scientific and management personnel. We face competition for such personnel from other companies, research and academic institutions and other entities. Further, in an effort to conserve financial resources, we have implemented reductions in our work force on three previous occasions, most recently in fiscal 2008. As a result of these and other factors, we may not be successful in hiring or retaining key personnel. Our inability to replace any key employee could harm our operations.

#### **Risks Related to Intellectual Property**

#### If our patents and proprietary rights do not provide substantial protection, then our business and competitive position will suffer.

Our success depends in large part on our ability to develop or license intellectual property rights to protect our proprietary products and technologies. This involves complex legal, scientific, and factual questions and uncertainties. We rely upon patent, trade secret, copyright and contract laws to protect proprietary technology and trademark law to protect brand identities. However, we cannot assure you that any patent applications filed by, assigned to, or licensed to us will be granted, and that the scope of any of our issued or licensed patents will be sufficiently broad to offer meaningful protection. In addition, our issued patents or patents licensed to us could be successfully challenged, invalidated, held to be unenforceable, or circumvented so that our patent rights would not create an effective competitive barrier. We also cannot assure you that the inventors of the patents and applications that we own or license were the first to invent or the first to file on the inventions, or that a third party will not claim ownership in one of our patent applications. We cannot assure you that a third party does not have or will not obtain patents that dominate the patents we own or license now or in the future. Furthermore, we rely on exclusive, world-wide licenses relating to the production of human cells granted to us by the University of Michigan. If we materially breach such agreements or otherwise fail to materially comply with such agreements, or if such agreements expire or are otherwise terminated by us, we may lose our rights under the patents held by the University of Michigan. At the latest, each of these licenses will terminate when the patent underlying the license expires, with the last to expire during the third quarter of 2013. Once the patents expire, third parties may be able to practice the inventions covered by those patents and thus compete with us.

Patent law relating to the scope of claims in the biotechnology field is evolving and our patent rights in this country and abroad are subject to this uncertainty.

We also rely on trade secrets and un-patentable know-how that we seek to protect, in part, by confidentiality agreements with our employees, consultants, suppliers and licensees. These agreements may be breached, and we might not have adequate remedies for any breach. Our competitors may also independently develop technologies substantially equivalent or superior to ours. If this were to occur, our business and competitive position would suffer.

#### Intellectual property litigation could harm our business.

Our success will also depend in part on our ability to develop commercially viable products without infringing the proprietary rights of others. Our cell processing system and cell compositions utilize a wide variety of technologies and we can give no assurance that we have identified or can identify all inventions and patents that may be infringed by development and manufacture of our cell compositions. Although we have not been subject to any filed infringement claims, patents could exist or could be filed which would prohibit or limit our ability to market our products or maintain our competitive position. In the event of an intellectual property dispute, we may be forced to litigate. Such litigation is typically protracted and the results are unpredictable. Intellectual property litigation would divert management's attention from developing our products and would force us to incur substantial costs regardless of whether we are successful. An adverse outcome could subject us to significant liabilities to third parties including treble damages and the opposing party's attorney fees, and force us to pay significant license fees and royalties or cease the development and sale of our products and processes.

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We have hired and will continue to hire individuals who have experience in cell culture and cell based therapeutics and may have confidential trade secret or proprietary information of third parties. We caution these individuals not to use or reveal this third-party information, but we cannot assure you that these individuals will not use or reveal this third-party information. Thus, we could be sued for misappropriation of proprietary information and trade secrets. Such claims are expensive to defend and could divert our attention and could result in substantial damage awards and injunctions that could have a material adverse effect on our business, financial condition or results of operations.

# We may need to initiate lawsuits to protect or enforce our patents or other proprietary rights, which would be expensive and, if unsuccessful, may cause us to lose some of our intellectual property rights.

To protect or enforce our patent rights, it may be necessary for us to initiate patent litigation proceedings against third parties, such as infringement suits or interference proceedings. These lawsuits would be expensive, take significant time and would divert management's attention from other business concerns. These lawsuits could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly, and our patent applications at risk of not being

issued. Further, these lawsuits may provoke the defendants to assert claims against us. The patent position of biotechnology firms is highly uncertain, involves complex legal and factual questions and recently has been the subject of much litigation. We cannot assure you that we will prevail in any of such suits or proceedings or that the damages or other remedies awarded to us, if any, will be commercially valuable.

## The government maintains certain rights in technology that we develop using government grant money and we may lose the revenues from such technology if we do not commercialize and utilize the technology pursuant to established government guidelines.

Certain of our and our licensors' research have been or are being funded in part by government grants. As a result of such funding, the U.S. Government has established guidelines and has certain rights in the technology developed with the grant. These rights include a non-exclusive, fully paid-up, worldwide license under such inventions for any governmental purpose. In addition, the U.S. Government has the right to require us to grant an exclusive license under any of such inventions to a third party if the U.S. Government determines that: (i) adequate steps have not been taken to commercialize such inventions; (ii) such action is necessary to meet public health or safety needs; or (iii) such action is necessary to meet requirements for public use under federal regulations. Additionally, under the federal Bayh Dole Act, a party which acquires an exclusive license for an invention that was partially funded by a federal research grant is subject to the following government rights: (i) products using the invention which are sold in the United States are to be manufactured substantially in the United States, unless a waiver is obtained; (ii) the government may force the granting of a license to a third party who will make and sell the needed product if the licensee does not pursue reasonable commercialization of a needed product using the invention; and (iii) the U.S. Government may use the invention for its own needs. If we fail to meet these guidelines, we would lose our exclusive rights to these products, and we would lose potential revenue derived from the sale of these products.

#### Potential product liability claims could affect our earnings and financial condition.

We face an inherent business risk of exposure to product liability claims in the event that the manufacture and/or use of our products during clinical trials, or after commercialization, results in adverse events. As a result, we may incur significant product liability exposure, which could exceed existing insurance coverage. We may not be able to maintain adequate levels of insurance at reasonable cost and/or reasonable terms. Excessive insurance costs or uninsured claims would increase our operating loss and adversely affect our financial condition.

#### **Risks Related to an Investment in our Common Stock**

#### We may be unable to continue as a going concern in which case our securities will have little or no value.

We need to raise additional capital and have a net capital deficiency. This raises substantial doubt about our ability to continue as a going concern. In the event we are not able to continue operations you will likely suffer a complete loss of your investment in our securities.

# Our stock price has been volatile and future sales of substantial numbers of our shares could have an adverse effect on the market price of our shares.

The market price of shares of our common stock has been volatile, ranging in closing price between \$1.15 and \$2.64 during the period ended December 31, 2012. The price of our common stock may continue to fluctuate in response to a number of events and factors, such as:

- clinical trial results;
- the amount of our cash resources and our ability to obtain additional funding;
- announcements of research activities, business developments, technological innovations or new products by us or our competitors;
- entering into or terminating strategic relationships;

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- · regulatory developments in both the United States and abroad;
- · disputes concerning patents or proprietary rights;
- changes in our revenues or expense levels;
- public concern regarding the safety, efficacy or other aspects of the products or methodologies we are developing;
- $\cdot$  ~ news or reports from other stem cell, cell therapy or regenerative medicine companies;
- reports by securities analysts;
- · status of the investment markets;
- concerns related to management transitions; and
- delisting from the NASDAQ Capital Market.

Any of these events may cause the price of our shares to fall, which may adversely affect our business and financing opportunities. In addition, the stock market in general and the market prices for biotechnology companies in particular have experienced significant volatility recently that often has been unrelated to the operating performance or financial conditions of such companies. These broad market and industry fluctuations may adversely affect the trading price of our stock, regardless of our operating performance or prospects.

## The sale of our common stock through future equity offerings may cause dilution and could cause the price of our common stock to decline.

We have registered \$100,000,000 of securities for public sale pursuant to our registration statement on Form S-3 declared effective in July 2011. In addition, we registered \$75,000,000 of securities for public sale pursuant to our registration statement on Form S-3 filed in November 2010. In December 2010, we offered 10,000,000 shares of common stock and warrants to purchase up to 10,000,000 shares of common stock under such registration statement and pursuant to a prospectus supplement first made available on December 10, 2010. Additionally, we entered into an At the Market Sales Agreement (ATM) on June 16, 2011, which allows us to raise approximately \$20,000,000 through sales of our common stock from time to time under such registration statement. However, there are certain factors, such as volume of trading in our stock, our stock price and the ability to terminate the agreement with notice, which limit the amount that can be raised in a short period of time through the ATM.

Sales of our common stock offered through future equity offerings may result in substantial dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock to investors, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

# Eastern Capital Limited, holds a large percentage of our outstanding capital stock and has significant influence over the outcome of corporate actions requiring shareholder approval; and such shareholder's priorities for our business may be different from other shareholders.

All of the accumulated dividends in B-1 non-voting preferred stock and outstanding Series B-2 voting preferred stock, representing a significant amount of our outstanding capital stock on a fully-converted basis, are held by Eastern Capital Limited. The accumulated dividends in our B-1 non-voting preferred stock are exchangeable for shares of Series B-2 voting preferred stock and, in March 2017, are convertible into shares of our common stock. Based solely on the number of shares of Series B-2 Preferred Stock that Eastern Capital holds as of the date of this report, Eastern Capital has beneficial ownership of approximately twenty-two percent (22%) (calculated on an as converted to common stock basis and excluding any shares that will accrue as a dividend on the shares of Series B-2 Preferred) of our voting securities based on the approximately fifty-six million shares of common stock and Series B-2 Preferred Stock outstanding as of the date of this report. Furthermore, in connection with the March 2012 financing, we amended our Shareholder Rights Plan to allow Eastern Capital to acquire beneficial ownership of up to 49.9% of the Company's outstanding securities without being deemed an "Acquiring Person" for purposes of our Shareholder Rights Plan. As a result of their current ownership and their ability to acquire more of our securities, they will be able to significantly influence the outcome of any financing transaction or other matter submitted to our shareholders for approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transaction. The interests of Eastern Capital may differ from the interests of our other shareholders. For example, Eastern Capital could delay

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or prevent a change of control of Aastrom even if such a change of control would benefit Aastrom's other shareholders. The significant concentration of stock ownership may adversely affect the trading price of Aastrom's common stock due to our investors' perception that conflicts of interest may exist or arise.

In addition, the shares of Series B-1 Preferred Stock and the shares of Series B-2 Preferred Stock which may be issued upon exchange of the shares of Series B-1 Preferred Stock have certain rights, preferences and privileges that rank senior to the shares of our common stock. For example, the shares of Series B-1 Preferred Stock and Series B-2 Preferred Stock are entitled to receive a liquidation preference prior to any payment being made to holders of common stock upon a voluntary or involuntary liquidation, dissolution or winding up of the Company, or we experience a change of control. Furthermore, if the shares of Series B-1 Preferred Stock are never exchanged for shares of Series B-2 Preferred Stock and any dividend shares accrued thereon at a price equal to the greater of (A) \$3,250 (subject to adjustments for stock splits and similar events) plus all accrued dividends and (B) the then fair market value of a share of common stock multiplied by the number of shares of common stock into which such share of Series B-1 Preferred Stock is then convertible. Such redemption would be completed in three annual installments beginning not more than 120 days after we receive a request for redemption. The requirement for us to redeem Eastern Capital's shares of Series B-1 Preferred Stock in cash could diminish our working capital, the consequences of which could have a material adverse effect on our business, operating results, financial condition and prospects.

#### Our corporate documents and Michigan law contain provisions that may make it more difficult for us to be acquired.

Our Board of Directors has the authority, without shareholder approval, to issue additional shares of preferred stock and to fix the rights, preferences, privileges and restrictions of these shares without any further vote or action by our shareholders. Michigan law contains a provision that makes it more difficult for a 10% shareholder, or its officers, to acquire a company. This authority, together with certain provisions of our charter documents, may have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, control of our company. This effect could occur even if our shareholders consider the change in control to be in their best interest. We have adopted a shareholder rights plan, the purpose of which is, among other things, to enhance our Board's ability to protect shareholder interests and to ensure that shareholders receive fair treatment in the event any coercive takeover attempt of our company is made in the future. The shareholder rights plan could make it more difficult for a third party to acquire, or could discourage a third party from acquiring, our company or a large block of our company's common stock.

#### **Forward-looking statements**

This report, including the documents that we incorporate by reference, contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but are not always, made through the use of words or phrases such as "anticipates," "estimates," "plans," "projects," "trends," "opportunity," "comfortable," "current," "intention," "position," "assume," "potential," "outlook," "remain," "continue," "maintain," "sustain," "seek," "achieve," "continuing," "ongoing," "expects," "management believes," "we believe," "we intend" and similar words or phrases, or future or conditional verbs such as "will," "would," "could," "may," or similar expressions. Accordingly, these statements involve estimates, assumptions and uncertainties which could cause actual results to differ materially from those expressed in them. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this report, and in particular those factors listed under the section "Risk Factors."

Because the factors referred to in the preceding paragraph could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements we make, you should not place undue reliance on any such forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement or statements to reflect events or

circumstances after the date on which such statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. These forwardlooking statements regarding:

- · potential strategic collaborations with others;
- future capital needs;
- · adequacy of existing capital to support operations for a specified time;
- · product development and marketing plans;
- · features and successes of our cellular therapies;

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- manufacturing and facility capabilities;
- · clinical trial plans and anticipated results, including the publication thereof;
- anticipation of future losses;
- · replacement of manufacturing sources;
- · commercialization plans; or
- · revenue expectations and operating results.

#### Item 1B. Unresolved Staff Comments

Not applicable.

## **Item 2.** Properties

We lease approximately 30,000 square feet of office, manufacturing and research and development space in Ann Arbor, Michigan under a lease agreement. This lease was entered into in January 2007 and covers a period of six years, beginning on the date we occupied the new space in May 2007. This lease also includes two five-year options to extend the term to 2018 and 2023, respectively. We believe that our facilities are adequate for our current needs. Additional facilities may be required to support expansion for research and development activities or to assume manufacturing operations that are currently fulfilled through contract manufacturing relationships.

#### Item 3. Legal Proceedings

We are currently not party to any material legal proceedings, although from time to time we may become involved in disputes in connection with the operation of our business.

#### Item 4. Mine Safety Disclosures

Not applicable.

## PART II

#### Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchase of Equity Securities

Our common stock is currently quoted on the NASDAQ Capital Market under the symbol "ASTM". The following table sets forth the high and low closing prices per share of common stock as reported on the NASDAQ Stock Market.

## **Price Range of Common Stock**

|                              | High       | Low        |
|------------------------------|------------|------------|
| Year ended December 31, 2011 |            | <br>       |
| First Quarter                | \$<br>3.25 | \$<br>2.06 |
| Second Quarter               | 3.27       | 2.48       |
| Third Quarter                | 2.89       | 2.01       |
| Fourth Quarter               | 2.75       | 1.79       |
|                              |            |            |
| Year ended December 31, 2012 |            |            |
| First Quarter                | \$<br>2.20 | \$<br>1.78 |
| Second Quarter               | 2.64       | 1.94       |
| Third Quarter                | 2.18       | 1.57       |
| Fourth Quarter               | 1.63       | 1.15       |
|                              |            |            |

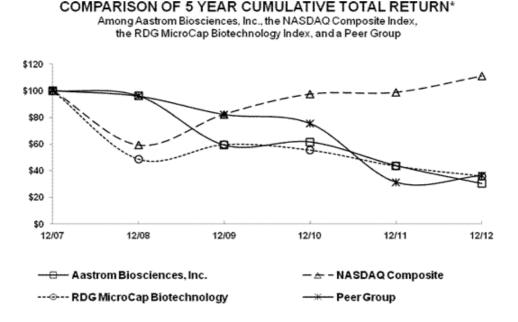
As of March 5, 2013 there were approximately 518 holders of record of the common stock. We have never paid any cash dividends on our common stock and we do not anticipate paying such cash dividends in the foreseeable future. We currently anticipate that we will retain all future earnings, if any, for use in the development of our business.

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#### **Comparison of Shareholder Return**

Set forth below is a line graph comparing changes in the cumulative total return on Aastrom's common stock, a broad market index (the NASDAQ Composite Index), an index of biotechnology companies with under \$300 million of market capitalization (the RDG MicroCap Biotechnology Index) and a peer group consisting of the following regenerative medicine companies: Advanced Cell Technology, Inc., Athersys, Inc., Cytori Therapeutics, International Stem Cell Corporation, Neostem, Inc., Osiris Therapeutics, Inc., Pluristem Therapeutics Inc., StemCells, Inc. and Tengion, Inc., for the period commencing on December 31, 2007 and ending on December 31, 2012 (1).



\*\$100 invested on 12/31/07 in stock or index, including reinvestment of dividends Fiscal year ending December 31.

| Aastrom/Index             | 12/31/2007 | 12/31/08 | 12/31/09     | 12/31/10 | 12/31/11 | 12/31/12 |
|---------------------------|------------|----------|--------------|----------|----------|----------|
| Aastrom Biosciences, Inc. | 100.00     | 96.15    | 59.13        | 61.54    | 43.75    | 30.29    |
| NASDAQ Composite          | 100.00     | 59.03    | 82.25        | 97.32    | 98.63    | 110.78   |
| RDG MicroCap              |            |          |              |          |          |          |
| Biotechnology             | 100.00     | 48.62    | <b>59.56</b> | 55.44    | 43.40    | 35.89    |
| Peer Group                | 100.00     | 95.95    | 82.15        | 75.34    | 31.29    | 36.30    |

(1) Assumes that \$100 was invested on December 31, 2007 in Aastrom's common stock and each index, and that all dividends were reinvested. No cash dividends have been declared on Aastrom's common stock. Shareholder returns over the indicated period should not be considered indicative of future shareholder returns.

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## Equity Compensation Plan Information as of December 31, 2012

The following table sets forth information as of December 31, 2012 with respect to compensation plans (including individual compensation arrangements) under which equity securities are authorized for issuances:

|  | Number of Securities<br>to be Issued upon Exercise<br>of Outstanding Options,<br>Warrants and Rights | Weighted Average<br>Exercise Price of<br>Outstanding<br>Options, Warrants<br>and Rights |      | Number of Securities<br>Remaining Available<br>for Future Issuance<br>Under Equity<br>Compensation Plans |
|--|--|---|------|--|
| Equity compensation plans approved by security |  |   |      |  |
| holders (employees and directors)(1)           | 9,987,468  | \$  | 2.38 | 3,356,559(2)   |

- (1) The material features of these securities are described in Note 3 of the Consolidated Financial Statements.
- (2) Shares issuable under the 2009 Omnibus Incentive Plan.

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## Item 6. Selected Financial Data

The following selected financial data should be read in conjunction with our financial statements and the notes thereto, and with Item 7, "Managements' Discussion and Analysis of Financial Condition and Results of Operations." The statement of operations data has been derived from and should be read in conjunction with our audited financial statements and notes thereto included elsewhere in this Annual Report on Form 10-K. As previously announced, in 2010, we changed our fiscal year end to December 31 from June 30. The change became effective at the end of the quarter ended December 31, 2010. All references to "years", unless otherwise noted, refer to the 12-month fiscal year, which prior to July 1, 2010, ended on June 30, and beginning with December 31, 2010, ends on December 31 of each year.

The following tables include selected consolidated summary financial data for the year ended December 31, 2012 and each of the last five years.

|   | Year Ended June 30,<br>2008 2009 2010 |          |          |          | Six Months<br>Ended Year Ended<br>December 31, December 31,<br>2010 2011 |          |    |          | Year Ended<br>December 31,<br>2012 | March 24, 1989<br>(Inception) to<br>December 31,<br>2012 |          |          |          |           |
|---|---------------------------------------|----------|----------|----------|--|----------|----|----------|------------------------------------|--|----------|----------|----------|-----------|
| Statement of Operations<br>Data (in thousands,<br>except per share<br>amounts): |                                       |          |          |          |  |          |    |          |                                    |  |          |          |          |           |
| Revenues:   |                                       |          |          |          |  |          |    |          |                                    |  |          |          |          |           |
| Product sales and   |                                       |          |          |          |  |          |    |          |                                    |  |          |          |          |           |
| rentals   | \$                                    | 208      | \$       | 182      | \$   | 89       | \$ | 9        | \$                                 | 18   | \$       | 21       | \$       | 1,898     |
| Research and  |                                       |          |          |          |  |          |    |          |                                    |  |          |          |          |           |
| development   |                                       |          |          |          |  |          |    |          |                                    |  |          |          |          |           |
| agreements  |                                       | —        |          | _        |  | —        |    | —        |                                    | —  |          | —        |          | 2,105     |
| Grants  |                                       | 314      |          | _        |  |          |    | 244      |                                    |  |          |          |          | 9,901     |
| Total revenues  |                                       | 522      |          | 182      |  | 89       |    | 253      |                                    | 18   |          | 21       |          | 13,904    |
| Costs and expenses:   |                                       |          |          |          |  |          |    |          |                                    |  |          |          |          |           |
| Cost of product sales   |                                       |          |          |          |  |          |    |          |                                    |  |          |          |          |           |
| and rentals (1)   |                                       | 56       |          | 112      |  | 34       |    | 2        |                                    | 4  |          | 6        |          | 3,047     |
| Research and  |                                       |          |          |          |  |          |    |          |                                    |  |          |          |          |           |
| development   |                                       | 15,249   |          | 11,289   |  | 12,658   |    | 8,609    |                                    | 21,330   |          | 26,025   |          | 216,730   |
| Selling, general and  |                                       |          |          |          |  |          |    |          |                                    |  |          |          |          |           |
| administrative  |                                       | 6,436    |          | 4,950    |  | 5,201    |    | 3,265    |                                    | 7,724  |          | 7,750    |          | 92,598    |
| Total costs and   |                                       |          |          |          |  |          |    |          |                                    |  |          |          |          |           |
| expenses  |                                       | 21,741   |          | 16,351   |  | 17,893   |    | 11,876   |                                    | 29,058   |          | 33,781   |          | 312,375   |
| Loss from operations  |                                       | (21,219) |          | (16,169) |  | (17,804) |    | (11,623) |                                    | (29,040)   |          | (33,760) |          | (298,471) |
| Other income (expense):   |                                       |          |          |          |  |          |    |          |                                    |  |          |          |          |           |
| (Increase) decrease in  |                                       |          |          |          |  |          |    |          |                                    |  |          |          |          |           |
| fair value of   |                                       |          |          |          |  |          |    |          |                                    |  |          |          |          |           |
| warrants  |                                       | 4,632    |          | (115)    |  | 3,171    |    | (7,500)  |                                    | 9,329  |          | 4,248    |          | 16,537    |
| Other income  |                                       |          |          | —        |  | —        |    | —        |                                    | —  |          | —        |          | 1,249     |
| Interest income   |                                       | 1,170    |          | 296      |  | 115      |    | 40       |                                    | 53   |          | 50       |          | 10,822    |
| Interest expense  |                                       | (84)     |          | (73)     |  | (40)     |    | (5)      |                                    | (10)   |          | (12)     |          | (491)     |
| Net loss  | \$                                    | (15,501) | \$       | (16,061) | \$   | (14,558) | \$ | (19,088) | \$                                 | (19,668)   | \$       | (29,474) | \$       | (270,354) |
| Accretion of convertible  |                                       |          |          |          |  |          |    |          |                                    |  |          |          |          |           |
| preferred stock   |                                       |          |          |          |  |          |    |          |                                    |  |          | 3,993    |          | 4,961     |
| Net loss attributable to  | <u>_</u>                              |          | <u>_</u> |          | <u>_</u>   | <i></i>  | ÷  | (10.000) | <i>_</i>                           | (10.000)   | <u>_</u> |          | <u>_</u> |           |
| common shareholders   | \$                                    | (15,501) | \$       | (16,061) | \$   | (14,558) | \$ | (19,088) | \$                                 | (19,668)   | \$       | (33,467) | \$       | (275,315) |
| Net loss per share<br>attributable to common<br>shareholders (basic and         |                                       |          |          |          |  |          |    |          |                                    |  |          |          |          |           |
| diluted)  | \$                                    | (.96)    | \$       | (0.90)   | \$   | (0.59)   | \$ | (0.65)   | \$                                 | (0.51)   | \$       | (0.81)   |          |           |
| Weighted average number<br>of common shares<br>outstanding (basic and           |                                       |          |          |          |  |          |    |          |                                    |  |          |          |          |           |
| diluted)  |                                       | 16,140   |          | 17,877   |  | 24,729   |    | 29,186   |                                    | 38,627   |          | 41,199   |          |           |
|   |                                       | <u>`</u> |          |          |  |          |    |          |                                    |  |          |          |          |           |
|   |                                       |          |          |          |  |          | 26 | 5        |                                    |  |          |          |          |           |
|   |                                       |          |          |          |  |          |    |          |                                    |  |          |          |          |           |

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|                                       | _  |        | Year | Ended June 30, |    |        |    | Six Months<br>Ended<br>ecember 31, |    | /ear Ended<br>ecember 31, |    | ear Ended<br>cember 31, |  |
|---------------------------------------|----|--------|------|----------------|----|--------|----|------------------------------------|----|---------------------------|----|-------------------------|--|
|                                       | 20 | 2008   |      | 2009           |    | 2010   |    | 2010                               |    | 2011                      |    | 2012                    |  |
| Balance Sheet Data (in thousands):    |    |        |      |                |    |        |    |                                    |    |                           |    |                         |  |
| Cash, cash equivalents and short-term | \$ | 22,462 | \$   | 17,000         | \$ | 19,119 | \$ | 31,248                             | \$ | 5,530                     | \$ | 13,638                  |  |

| investments                              |           |           |           |           |           |           |
|--|-----------|-----------|-----------|-----------|-----------|-----------|
| Working capital                          | 21,545    | 15,572    | 13,847    | 1,835     | (14,495)  | 8,331     |
| Total assets                             | 26,217    | 19,276    | 20,531    | 32,827    | 7,739     | 15,178    |
| Long-term debt                           | 1,229     | 784       | 305       | 255       | 80        | 40        |
| Series B -1 non-voting convertible       |           |           |           |           |           |           |
| preferred stock                          | —         |           | —         |           | —         | 3,923     |
| Series B -2 voting convertible preferred |           |           |           |           |           |           |
| stock                                    | —         |           | —         |           | —         | 37,690    |
| Deficit accumulated during the           |           |           |           |           |           |           |
| development stage                        | (172,473) | (188,534) | (203,092) | (222,180) | (241,848) | (275,315) |
| Total shareholders' equity               | 22,916    | 17,284    | 14,781    | 2,922     | (12,971)  | (32,100)  |
|  |           |           |           |           |           |           |

(1) Cost of product sales and rentals for the period from Inception to December 31, 2012 include a charge of \$2,239,000 for excess inventories.

#### Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

### **Change in Fiscal Year End**

In 2010, our Board of Directors approved the change in our fiscal year end from June 30 to December 31. The change became effective at the end of the quarter ended December 31, 2010. All references to "years", unless otherwise noted, refer to the 12-month fiscal year, which prior to July 1, 2010, ended on June 30, and beginning with December 31, 2010, ends on December 31, of each year. All amounts presented for the six months ended December 31, 2009, the twelve months ended December 31, 2010 and the six months ended December 31, 2011 are unaudited.

## Overview

We were incorporated in 1989 and are a regenerative medicine company focused on the development of innovative cell therapies to repair or regenerate damaged or diseased tissues. We are developing patient-specific, expanded multicellular therapies for use in the treatment of severe, chronic ischemic cardiovascular diseases. We believe ixmyelocel-T (the generic name for our multicellular therapy) is a disease modifying therapy with multi-functional properties including: tissue remodeling, immuno-modulation and the promotion of angiogenesis. Our proprietary cell-manufacturing technology enables the manufacture of multicellular therapies, expanded from an adult patient's own bone marrow, to be delivered directly to damaged tissues. Preclinical and clinical data suggest that ixmyelocel-T may be safe and effective in treating patients with severe, chronic ischemic cardiovascular diseases such as critical limb ischemia (CLI), the most severe form of peripheral arterial disease (PAD), and dilated cardiomyopathy (DCM), the third leading cause of heart failure. Over 200 patients have been treated in recent clinical trials using ixmyelocel-T, and over 400 patients safely treated since our inception. In November 2011, we released positive Phase 2b data from our RESTORE-CLI clinical trial and launched our pivotal Phase 3 REVIVE trial in CLI in February 2012. During the fourth quarter of 2012, we launched a randomized, placebo-controlled, double-blinded Phase 2b ixCELL-DCM trial for patients with ischemic DCM.

## **Our Therapy**

Ixmyelocel-T is a patient-specific, expanded multicellular therapy developed using our proprietary, fully-closed, automated processing system. Ixmyelocel-T is a product derived from an adult patient's own bone marrow but it is significantly enhanced compared with the original bone marrow. Our process enhances the patient's bone marrow mononuclear cells by expanding the mesenchymal stromal cells and M2 anti-inflammatory macrophages while retaining many of the hematopoietic cells. These cell types, known to regulate the immune response, are important in the resolution of pathologic inflammation and tissue repair. The manufacture of our patient-specific, expanded multicellular therapies is done under current Good Manufacturing Practices (cGMP) and current Good Tissue Practices (cGTP) guidelines required by the U.S. Food and Drug Administration (FDA).

Our therapy has several features that we believe are primarily responsible for success in treating adult patients with severe, chronic cardiovascular diseases:

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|---|---|
| 2 | / |

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*Patient-specific (autologous)* — we start with the patient's own cells, which are accepted by the patient's immune system allowing the cells to integrate into existing functional tissues. This characteristic of our therapy, we believe, eliminates both the risk of rejection and of having to use immunosuppressive therapy pre- or post-therapy. Our data also suggests that ixmyelocel-T provides the potential for long-term engraftment and tissue repair.

*Expanded* — we begin with a small amount of bone marrow from the patient (up to 60 ml) and significantly expand the number of certain cell types, primarily CD90+ (mesenchymal stromal cells or MSCs) and CD14+autofluorescent+ (M2 anti-inflammatory macrophages) to far more than are present in the patient's own bone marrow (up to 200 times the number of certain cell types compared with the starting bone marrow).

*Multicellular* — we believe the multiple cell types in ixmyelocel-T, which are normally found in bone marrow — but in smaller quantities — possess the key functions required for reducing chronic inflammation, immuno-modulation, and the promotion of angiogenesis. By reducing inflammation, we believe ixmyelocel-T provides the ideal conditions to allow for the growth of new tissue and blood vessels.

*Minimally invasive* — our procedure for taking bone marrow (an "aspirate") can be performed in an out-patient setting and takes approximately 15 minutes. For diseases such as CLI, the administration of ixmyelocel-T is performed in an out-patient setting (e.g., a physician's office) in a one-time, approximately 20 minute procedure. For DCM, injection is performed in the cardiac catheterization laboratory. A catheter, similar to those used for balloon angioplasty and stenting is inserted and 12-20 direct injections to the heart muscle are performed. This is also a one-time procedure.

*Safe* — bone marrow and bone marrow-derived therapies have been used safely and efficaciously in medicine for over three decades. Our product, ixmyelocel-T, a bone marrow-derived, patient-specific, expanded multicellular therapy, leverages this body of scientific study and medical experience, and appears well tolerated in over 400 patients treated to date.

#### **Cell Composition**

Ixmyelocel-T is the only product known to have expanded the anti-inflammatory M2 macrophages. We believe that our therapy is best suited for chronic, ischemic diseases with significant inflammation. Our multi-cellular therapy could be ideal to modulate the inflammation and allow for remodeling of ischemic tissue and angiogenesis

#### **Manufacturing Process**

Our therapy is produced at our cell manufacturing facility in the United States, located at our headquarters in Ann Arbor, Michigan.

#### **Clinical Development Programs**

Our clinical development programs are focused on addressing areas of high unmet medical needs in severe, chronic ischemic cardiovascular diseases. We have completed a successful Phase 2b clinical trial in CLI. We have reached agreement with the FDA on Chemistry, Manufacturing and Control (CMC) which allowed us to launch our pivotal Phase 3 REVIVE clinical trial in the first quarter of 2012 with a protocol approved by the FDA through the Special Protocol Assessment (SPA) process. Our CLI development program has also received Fast Track Designation from the FDA. We have completed our Phase 1/2 clinical trials in DCM and launched a randomized, placebo-controlled, double-blinded Phase 2b ixCELL-DCM trial in the fourth quarter of 2012. Our DCM development program has received Orphan Disease Designation from the FDA.

Results to date in our clinical trials may not be indicative of results obtained from subsequent patients enrolled in those trials or from future clinical trials. Further, our future clinical trials may not be successful or we may not be able to obtain the required Biologic License Application (BLA) approval to commercialize our products in the United States in a timely fashion, or at all. See "Risk Factors".

#### Critical Limb Ischemia

## Background

CLI is the most serious and advanced stage of peripheral arterial disease (PAD) resulting from chronic inflammation and lipid accumulation. PAD is a chronic atherosclerotic disease that progressively restricts blood flow in the limbs and can lead to serious medical complications. This disease is often associated with other serious clinical conditions including hypertension, cardiovascular disease, dyslipidemia, diabetes, obesity and stroke. CLI is used to describe patients with chronic ischemia-induced pain (even at rest) or tissue loss (ulcers or gangrene) in the limbs, often leading to amputation and death. Many CLI patients are considered "unsuitable for

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revascularization" (formerly "no option") patients as they have exhausted all other reasonable treatment options and will likely require amputation. The oneyear and four-year mortality rates for CLI patients that are unsuitable for revascularization that progress to amputation are approximately 25% and 70%, respectively. Ixmyelocel-T, our disease modifying therapy with multiple functions, has shown significant promise in the treatment of CLI patients with existing tissue loss that are unsuitable for revascularization. Currently, there are an estimated 250,000 CLI patients that are unsuitable for revascularization in the U.S.

#### Phase 2b Clinical Program - RESTORE CLI

Our U.S. Phase 2b RESTORE-CLI program was a multi-center, randomized, double-blind, placebo-controlled clinical trial. This clinical trial was designed to evaluate the safety and efficacy of ixmyelocel-T in the treatment of patients with CLI that are unsuitable for revascularization. It was the largest multi-center, randomized, double-blind, placebo-controlled cellular therapy study ever conducted in CLI patients. We completed enrollment of this trial in February 2010 with a total of 86 patients at 18 sites across the United States, with the last patient treated in March 2010. These patients were followed for a period of 12 months after treatment. In addition to assessing the safety of our product, efficacy endpoints included time to first occurrence of treatment failure — the trial's primary efficacy end-point — (defined as major amputation, all-cause mortality, doubling in wound surface area and de novo gangrene), amputation-free survival (defined as major amputation and all-cause mortality), major amputation rates, level of amputation, wound healing, patient quality of life and pain scores. The primary purpose of the trial was to assess performance of our therapy and, if positive, prepare for a Phase 3 program.

Final results of the Phase 2b RESTORE-CLI clinical trial were presented at the American Heart Association Scientific Sessions in November 2011 and published in the peer-reviewed journal Molecular Therapy in April 2012. Patients in the treatment arm showed a 62% reduction in risk relative to placebo in the primary efficacy endpoint of time to first occurrence of treatment failure (p=0.0032). While the study was not powered to show statistical significance in the secondary endpoint of amputation free survival, results from a subgroup of 45 patients with wounds at baseline (the approximate profile of the Phase 3 patient population) showed a 61% reduction in risk (21% ixmyelocel-T treated versus 44% control event rate; p=0.0802). The study also met the primary safety endpoint with no meaningful differences between the treated and control groups.

## Phase 3 Clinical Program — REVIVE

In February 2012, several principal investigators participating in the pivotal Phase 3 REVIVE clinical trial for patients with CLI that are unsuitable for revascularization began screening patients. The first patient was randomized and aspirated in May 2012. We had previously received Fast Track Designation from the FDA for use of ixmyelocel-T for CLI in October 2010 and reached agreement with the FDA on a Special Protocol Assessment (SPA) in July 2011. The Phase 3 REVIVE Trial that we agreed to with the FDA under the SPA process includes 594 CLI patients with tissue loss (ulcers and gangrene) at baseline that are unsuitable for revascularization. Patients will be randomized 1:1 and followed for 12 months for the primary efficacy endpoint of amputation-free survival. Patients will be followed for an additional 6 months for safety. We anticipate that enrollment will occur at approximately 100 sites across the U.S.

## **Dilated Cardiomyopathy**

DCM is a severe, chronic cardiovascular disease that leads to enlargement of the heart, reducing the pumping function of the heart to the point that blood circulation is impaired. Patients with DCM typically present with symptoms of congestive heart failure, including limitations in physical activity and shortness of breath. DCM is now the third leading cause of heart failure in the U.S. There are two types of DCM: ischemic and non-ischemic. Ischemic DCM, the most common form representing an estimated 60% of all DCM patients, is associated with atherosclerotic cardiovascular disease. We estimate that there are approximately 125,000 ischemic DCM patients in the U.S., our target patient population for further clinical development. Patient prognosis depends on the stage and cause of the disease but is typically characterized by a very poor quality of life and a high mortality rate.

Current treatments for DCM patients are limited to heart transplantation and placement of left ventricular assist devices (LVADs). There are less than 2,500 heart transplantations in the U.S. each year. Many DCM patients are not eligible and transplants are extremely expensive at an estimated cost of over \$1 million. LVADs are also expensive at an estimated cost of over \$175,000 and have a mortality rate of 50% at two years.

In February 2007, the FDA granted Orphan Drug Designation to ixmyelocel-T for the treatment of DCM. Our DCM development program is currently in Phase 2b. We recently completed follow up on two U.S. Phase 1/2 trials investigating surgical and catheter-based delivery for our product in the treatment of DCM. The final results from these Phase 1/2 clinical trials were presented at the Society for Cardiovascular Angiography and Interventions (SCAI) meeting on May 10, 2012.

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#### Surgical Trial Program - DCM

We completed enrollment of 40 ischemic and non-ischemic DCM patients in the IMPACT-DCM clinical trial in January 2010 and the final patient was treated in March 2010. Participants in the IMPACT-DCM clinical trial were required to have New York Heart Association (NYHA) functional class III or IV heart failure, a left ventricular ejection fraction (LVEF) of less than or equal to 30% (60-75% is typical for a healthy person), and meet other eligibility criteria, including optimized medical therapy. Patients were randomized in an approximate 3:1 ratio of treatment to control group. Patients in the treatment group received our therapy through direct injection into the heart muscle during minimally invasive-surgery (involving a chest incision of approximately 2 inches). The primary objective of this study was to assess the safety of ixmyelocel-T in patients with DCM. Efficacy measures included cardiac dimensions and tissue mass, cardiac function (e.g. cardiac output, LVEF, cardiopulmonary exercise testing parameters), cardiac perfusion and viability, as well as other efficacy endpoints. NYHA functional class and quality of life were also assessed. Patients were followed for 12 months after treatment with an additional 2 year follow-up phone call recently completed in all patients.

#### Catheter Trial Program - DCM

The Catheter-DCM clinical trial was designed to explore catheter-based direct injection delivery of ixmyelocel-T to treat DCM patients. This multicenter, randomized, controlled, prospective, open-label, Phase 2 study enrolled DCM patients at clinical sites across the United States.

We reported final 12-month results from the Catheter-DCM Phase 2 trial at the SCAI 2012 Scientific Sessions on May 10, 2012. The trial included 22 ischemic DCM (IDCM) and non-ischemic DCM (NIDCM) patients with a NYHA heart failure class of III or IV, or moderate to severe heart failure, and a left ventricular ejection fraction of 30 percent or less, which is a measure of how much blood leaves the heart with each pump. Patients were randomized to receive an injection of the treatment into their heart muscles or to a control group, and were followed at three, six and 12 months. After 12 months, no procedural complications and no difference in adverse events were reported among patients who received the treatment and the control group. IDCM patients who received the cell treatment had a lower mean number of major adverse cardiac events (MACE) (0.22 compared to 1.67 in the control group). IDCM patients who received the treatment were more likely to see improvement in NYHA class, six-minute walking distance and ejection fraction, compared to those in the control group. No consistent trends were noted in NIDCM patients.

#### Phase 2b Clinical Program — ixCELL-DCM

In February 2013, several sites began screening patients with ischemic DCM in the ixCELL-DCM trial, which is a randomized, double-blind, placebocontrolled clinical trial. The first patient is expected to be randomized in April 2013. The Phase 2b ixCell-DCM trial will enroll 108 ischemic DCM patients. Patients will be randomized 1:1 and followed for 12 months for the primary efficacy endpoint of major adverse cardiac events (MACE), plus hospitalizations and emergency department visits. Patients will be followed for an additional 12 months for safety. We anticipate that enrollment will occur at approximately 30 sites across the U.S.

#### **Critical Accounting Estimates**

The preparation of our consolidated financial statements in accordance with U.S. generally accepted accounting principles (GAAP) requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, net revenues and expenses, and related disclosures. We believe our estimates and assumptions are reasonable; however, actual results and the timing of the recognition of such amounts could differ from these estimates.

*Stock-Based Compensation* — Calculating stock-based compensation expense requires the input of highly subjective assumptions. We apply the Black-Scholes option-pricing model to determine the fair value of our stock options. Inherent in this model are assumptions related to expected stock-price volatility, option life, risk-free interest rate and dividend yield. We estimate the volatility of our common stock at the date of grant based on historical volatility. We estimate the expected life of options that vest solely on service using the "simplified method" provided for in the Securities and Exchange Commission Staff Accounting Bulletin No. 110. The "simplified method" is permitted for estimating the expected term of "plain-vanilla" stock options for which the historical stock option exercise experience is likely not indicative of future exercise patterns. The risk-free interest rate is based on our historical rate, which we anticipate to remain at zero. The assumptions used in calculating the fair value of stock options represent our best estimates, however; these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and different assumptions are used, the stock-based compensation expense could be materially different in the future. In addition, we are required to estimate the expected forfeiture rate and only recognize expense for those stock options and restricted stock awards and units expected to vest over the service period. We estimate the forfeiture rate considering the historical experience of our stock-based awards. If the actual forfeiture rate is different from the estimate, we adjust the expense accordingly.

*Warrants* — Warrants that could require cash settlement or have anti-dilution price protection provisions are recorded as liabilities at their estimated fair value at the date of issuance, with subsequent changes in estimated fair value recorded in other income (expense) in our statement of operations in each subsequent period. In general, warrants with anti-dilution provisions are measured using the Monte Carlo valuation model, while the others are measured using the Black-Scholes valuation model. Both of the methodologies are based, in part, upon inputs for which there is little or no observable market data, requiring the Company to develop its own assumptions. Inherent in both of these models are assumptions related to expected stock-price volatility, expected life, risk-free interest rate and dividend yield. We estimate the volatility of our common stock at the date of issuance, and at each subsequent reporting period, based on historical volatility that matches the expected remaining life of the warrants. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected remaining life of the warrants. The expected life of the warrants is assumed to be equivalent to their remaining contractual term. The dividend rate is based on our historical rate, which we anticipate to remain at zero. For those warrants valued using a Monte Carlo model, we estimate the probability and timing of potential future financings and fundamental transactions, as applicable. The assumptions used in calculating the estimated fair value of the warrants represent our best estimates; however, these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and different assumptions are used, the warrant liability and the change in estimated fair value could be materially different.

The summary of significant accounting policies should be read in conjunction with our consolidated financial statements and related notes and this discussion of our results of operations.

#### **Results of Operations**

Total revenues were \$21,000 for the year ended December 31, 2012 compared to \$18,000 for the year ended December 31, 2011. Total revenues decreased to \$18,000 for the year ended December 31, 2011 from \$253,000 for the twelve months ended December 31, 2010. Total revenues decreased to \$9,000 for the six months ended December 31, 2011 from \$253,000 for the six months ended December 31, 2010. The decreases for the six months and year ended December 31, 2011 are due to the non-recurring proceeds from the Qualifying Therapeutic Discovery Project in November 2010. Total revenues increased to \$253,000 for the six months ended December 31, 2010 from \$89,000 for the six months ended December 31, 2009. The increase is due to proceeds from the Qualifying Therapeutic Discovery Project in November 2010. At such time as we satisfy applicable regulatory approval requirements, we expect the sales of our cell-based products will constitute nearly all of our product sales revenues.

Total costs and expenses increased to \$33,781,000 for the year ended December 31, 2012 from \$29,058,000 for the year ended December 31, 2011 due to increased CRO and consulting costs related to the Phase 3 REVIVE clinical trial, as well as increased cash compensation associated with an increase in headcount. Total costs and expenses increased to \$29,058,000 for the year ended December 31, 2011 from \$21,279,000 for the twelve months ended December 31, 2010. Total costs and expenses increased to \$15,282,000 for the six months ended December 31, 2011 from \$11,876,000 for the six months ended December 31, 2010. The increases in both periods are due to increased cash compensation and non-cash stock based compensation associated with an increase in headcount, as well as increased CRO costs and increased consulting costs due to preparations for the Phase 3 CLI program. Total costs and expenses increased consulting and non-cash stock-based compensation expense.

Research and development expenses increased to \$26,025,000 for the year ended December 31, 2012 from \$21,330,000 for the year ended December 31, 2011 due to increased CRO and consulting costs related to the Phase 3 REVIVE clinical trial, as well as increased cash compensation and non-cash stock based compensation associated with an increase in headcount. Research and development expenses increased to \$21,330,000 for the year ended December 31, 2011 from \$15,073,000 for the twelve months ended December 31, 2010 due to increased cash compensation and non-cash stock based compensation associated with an increase in headcount, as well as increased CRO costs and increased cash compensation and non-cash stock based compensation associated with an increase in headcount, as well as increased CRO costs and increased consulting costs due to preparations for the Phase 3 CLI program. Research and development expenses increased to \$11,654,000 for the six months ended December 31, 2011 from \$8,609,000 for the six months ended December 31, 2010 due to increased headcount and clinical activity related to DCM and CLI programs. Research and development expenses increased to \$8,609,000 for the six months ended December 31, 2009 due to preparation for our Phase 3 CLI program.

Our major ongoing research and development programs are focused on the clinical development of our technology platform for the treatment of severe, chronic cardiovascular diseases. The following table summarizes the allocation of cost for our research and development projects (*in thousands*):

|   |    | 12 Months Ended December 31, |    |        |    |        |  |  |  |  |  |
|---|----|------------------------------|----|--------|----|--------|--|--|--|--|--|
|   |    | 2010                         |    |        |    | 2012   |  |  |  |  |  |
| Critical Limb Ischemia                  | \$ | 6,799                        | \$ | 15,842 | \$ | 21,650 |  |  |  |  |  |
| Dilated Cardiomyopathy                  | -  | 8,191                        | -  | 5,452  | -  | 4,366  |  |  |  |  |  |
| Other                                   |    | 83                           |    | 36     |    | 9      |  |  |  |  |  |
| Total research and development expenses | \$ | 15,073                       | \$ | 21,330 | \$ | 26,025 |  |  |  |  |  |
|   | 31 |                              |    |        |    |        |  |  |  |  |  |

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|   | Six Months Ended December 31, |    |       |    |        |  |  |  |  |  |
|---|-------------------------------|----|-------|----|--------|--|--|--|--|--|
|   | <br>2009                      |    | 2010  |    | 2011   |  |  |  |  |  |
|   |                               |    |       |    |        |  |  |  |  |  |
| Critical Limb Ischemia                  | \$<br>2,456                   | \$ | 4,092 | \$ | 9,337  |  |  |  |  |  |
| Dilated Cardiomyopathy                  | 3,673                         |    | 4,494 |    | 2,307  |  |  |  |  |  |
| Other                                   | 65                            |    | 23    |    | 10     |  |  |  |  |  |
| Total research and development expenses | \$<br>6,194                   | \$ | 8,609 | \$ | 11,654 |  |  |  |  |  |

Selling, general and administrative expenses increased slightly to \$7,750,000 for the year ended December 31, 2012 from \$7,724,000 for the year ended December 31, 2011 due to an increase in legal and consulting expenses, offset by a decrease in non-cash stock-based compensation. Selling, general and administrative expenses increased to \$7,724,000 for the year ended December 31, 2011 from \$6,204,000 for the twelve months ended December 31, 2010 due

to an increase in non-cash stock-based compensation, and legal and consulting expenses. Selling, general and administrative expenses increased to \$3,626,000 for the six months ended December 31, 2011 from \$3,265,000 for the six months ended December 31, 2010. Selling, general and administrative expenses increased to \$3,265,000 for the six months ended December 31, 2010 from \$2,262,000 for the six months ended December 31, 2009 due to an increase in non-cash stock-based compensation and consulting costs.

Non-cash income (expense) from the change in fair value of warrants was \$4,248,000 for the year ended December 31, 2012 compared to \$9,329,000 for the year ended December 31, 2011 due to changes in the fair value of our stock price as well as the exchange of the December 2010 warrants for common stock which reduced the total warrants outstanding. Non-cash income (expense) from the change in fair value of warrants was \$9,329,000 for the year ended December 31, 2011 compared to (\$4,593,000) for the twelve months ended December 31, 2010. Non-cash income (expense) from the change in fair value of warrants was \$10,540,000 for the six months ended December 31, 2011 compared to (\$7,500,000) for the six months ended December 31, 2011 compared to (\$7,500,000) for the six months ended December 31, 2010 compared to (\$7,500,000) for the six months ended December 31, 2010 compared to \$264,000 for the six months ended December 31, 2009. The fluctuations are due to the issuance of warrants in the January 2010 and December 2010 financings, as well as changes in the fair value of our warrant liability resulting from changes in the fair value of our common stock. Fluctuations in the fair value of warrants in future periods could result in significant non-cash adjustments to the consolidated financial statements, however any income or expense recorded will not impact our cash and cash equivalents, operating expenses or cash flows.

Interest income was \$50,000 in the year ended December 31, 2012 compared to \$53,000 for the year ended December 31, 2011. Interest income was \$53,000 in the year ended December 31, 2011 compared to \$106,000 for the twelve months ended December 31, 2010. Interest income was \$16,000 in the six months ended December 31, 2010 compared to \$40,000 for the six months ended December 31, 2010. Interest income was \$40,000 in the six months ended December 31, 2010 compared to \$49,000 for the six months ended December 31, 2010 compared to \$49,000 for the six months ended December 31, 2009. The fluctuations in interest income are due primarily to corresponding changes in the levels of cash, cash equivalents and short-term investments combined with interest rate changes during the periods.

The non-cash accretion of convertible preferred stock for the year ended December 31, 2012 was \$3,993,000, compared to zero for all other periods. The Series B-1 Preferred Stock was issued in March 2012 and is accreted to its redemption value through charges to shareholders' deficit using the effective interest method.

Our net loss attributable to common shareholders was \$33,467,000, or \$0.81 per share for the year ended December 31, 2012 compared to \$19,668,000, or \$0.51 per share for the year ended December 31, 2011. Our net loss attributable to common shareholders was \$19,668,000, or \$0.51 per share for the year ended December 31, 2011 compared to \$25,534,000, or \$0.90 per share for the twelve months ended December 31, 2010. Our net loss attributable to common shareholders for the six months ended December 31, 2011 was \$4,723,000 or \$0.12 per share, compared to \$19,088,000 or \$0.65 per share for the six months ended December 31, 2010. Our net loss attributable to common shareholders was \$19,088,000, or \$0.65 per share for the six months ended December 31, 2010 compared to \$8,112,000, or \$0.38 per share for the six months ended December 31, 2009. The changes in net loss attributable to common shareholders are primarily due to the non-cash fluctuations in the fair value of warrants, in addition to the changes in research and development expenses and selling, general and administrative expense as described in more detail above. The loss per share comparisons were also impacted by the issuance of 10,000,000 shares of common stock in December 2010 and 6,510,000 shares of common stock in January 2010.

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Non-cash stock-based compensation expense included in research and development expenses and general, selling and administrative expenses is summarized in the following table (*in thousands*):

|   | 12 Months Ended December 31, |       |            |               |          |       |  |  |  |
|---|------------------------------|-------|------------|---------------|----------|-------|--|--|--|
|   |                              | 2010  |            | 2011          |          | 2012  |  |  |  |
|   |                              |       |            |               |          |       |  |  |  |
| Research and development                        | \$                           | 672   | \$         | 2,126         | \$       | 2,508 |  |  |  |
| General, selling and administrative             |                              | 730   |            | 1,617         |          | 1,102 |  |  |  |
| Total non-cash stock-based compensation expense | \$                           | 1,402 | \$         | 3,743         | \$       | 3,610 |  |  |  |
|   |                              |       |            |               |          |       |  |  |  |
|   |                              | Siz   | x Months E | nded December | 31,      |       |  |  |  |
|   |                              | 2009  |            | 2010          |          | 2011  |  |  |  |
| Research and development                        | \$                           | 361   | \$         | 549           | \$       | 1,091 |  |  |  |
| General, selling and administrative             |                              | (11)  |            | 494           |          | 804   |  |  |  |
| Total non-cash stock-based compensation expense | <u>ф</u>                     | 350   | <u>ф</u>   | 1.043         | <u>ф</u> | 1,895 |  |  |  |

Non-cash stock-based compensation expense was \$3,610,000 for the year ended December 31, 2012 compared to \$3,743,000 for the year ended December 31, 2011. Non-cash stock-based compensation for the year ended December 31, 2012 decreased by the reversal of previously recognized expense for options that were forfeited in excess of our estimated rate of forfeiture. Approximately \$977,000 of this reversal was for certain options held by Timothy Mayleben that were forfeited when he stepped down as Chief Executive Officer and President in December 2012. Non-cash stock-based compensation expense was \$3,743,000 for the year ended December 31, 2011 compared to \$1,402,000 for the twelve months ended December 31, 2010. Non-cash stock-based compensation expense was \$1,895,000 for the six months ended December 31, 2011 compared to \$1,043,000 for the six months ended December 31, 2010. The increases in both periods are primarily due to increased headcount and higher fair value of options granted. Non-cash stock-based compensation expense for the six months ended December 31, 2010 compared to \$350,000 for the six months ended December 31, 2009. Stock-based compensation expense for the six months ended December 31, 2009 and for the twelve months ended December 31, 2010 was impacted by the reversal of previously recognized expense for options that were forfeited in excess of our estimated rate of forfeiture. Approximately \$279,000 of the reversal was for certain options held by George W. Dunbar that were forfeited when he stepped down as Chief Executive Officer, President and Chief Financial Officer in December 2009.

Because of the uncertainties of clinical trials and the evolving regulatory requirements applicable to our products, estimating the completion dates or cost to complete our major research and development programs would be highly speculative and subjective. The risks and uncertainties associated with developing our products, including significant and changing governmental regulation and the uncertainty of future clinical study results, are discussed in greater detail in the "Any changes in the governmental regulatory classifications of our products could prevent, limit or delay our ability to market and

develop our products," "Our inability to complete our product development activities successfully would severely limit our ability to operate or finance operations," and "We must successfully complete our clinical trials to be able to market certain of our products," sections under the heading "Risk Factors" in Item 1A of this report. The lengthy process of seeking regulatory approvals for our product candidates, and the subsequent compliance with applicable regulations, will require the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could cause our research and development expenditures to increase and, in turn, have a material adverse effect on our results of operations. We cannot be certain when any net cash inflow from products validated under our major research and development project, if any, will commence.

We have not generated any net taxable income since our inception and therefore have not paid any federal income taxes since inception. We issued shares of common stock in prior years, which resulted in multiple ownership changes under relevant taxation rules (Section 382 of the Internal Revenue Code). Consequently, pursuant to these taxation rules, the utilization of net operating loss and tax credit loss and tax carryforwards may be significantly limited in future periods, even if we generate taxable income. Such limitations may result in our carryforwards expiring before we can utilize them. At December 31, 2012, we had generated cumulative U.S. federal and state tax net operating loss and tax credit carryforwards of \$176,001,000, \$22,229,000 and \$1,600,000, respectively, which will expire in various periods through 2032 if not utilized. Our ability to utilize our net operating loss and tax credit carryforwards may become subject to further annual limitation in the event of future changes in ownership under the taxation rules.

## Liquidity and Capital Resources

We are currently focused on utilizing our technology to produce patient specific cell-based products for use in regenerative medicine applications. At such time as we satisfy applicable regulatory approval requirements, we expect the sales of our cell-based products to constitute nearly all of our product sales revenues.

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We do not expect to generate positive cash flows from our consolidated operations for at least the next several years and then only if we achieve significant product sales. Until that time, we expect that our revenue sources from our current activities will consist of only minor sales of our cell products and manufacturing supplies to our academic collaborators, grant revenue, research funding and potential licensing fees or other financial support from potential future corporate collaborators.

We expect that we will need to raise significant additional funds or pursue strategic transactions or other strategic alternatives in order to complete our product development programs, complete clinical trials needed to market our products, and commercialize our products. To date, we have financed our operations primarily through public and private sales of our equity securities, and we expect to continue to seek to obtain the required capital in a similar manner. As a development stage company, we have never been profitable and do not anticipate having net income unless and until significant product sales commence. With respect to our current activities, this is not likely to occur until we obtain significant additional funding, complete the required clinical trials for regulatory approvals, and receive the necessary approvals to market our products. Through December 31, 2012, we had accumulated a net loss attributable to common shareholders of approximately \$275,315,000. As a result of the need to raise additional capital and a net capital deficiency, there is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively over at least the next twelve months, which raises substantial doubt as to our ability to continue as a going concern. We cannot provide any assurance that we will be able to achieve profitability on a sustained basis, if at all, obtain the required funding, obtain the required regulatory approvals, or complete additional corporate partnering or acquisition transactions.

We have financed our operations since inception primarily through public and private sales of our equity securities, which, from inception through December 31, 2012, have totaled approximately \$243,215,000 and, to a lesser degree, through grant funding, payments received under research agreements and collaborations, interest earned on cash, cash equivalents, and short-term investments, and funding under equipment leasing agreements. These financing sources have generally allowed us to maintain adequate levels of cash and other liquid investments.

Our combined cash and cash equivalents totaled \$13,638,000 at December 31, 2012, an increase of \$8,108,000 from December 31, 2011. The primary source of cash and cash equivalents was due to the issuance of Series B Preferred Stock with net proceeds of \$37,620,000. The primary uses of cash during the year ended December 31, 2012 were for employee related expenses and expenses related to our Phase 3 CLI program. As of December 31, 2012 we had \$13,349,000 of cash deposited into an Insured Cash Sweep (ICS) program which is administered by Bank of New York Mellon. This program maximizes our Federal Deposit Insurance Company (FDIC) coverage by dividing our ICS funds into amounts under the standard FDIC maximum and places these amounts with other ICS Network member banks (each an FDIC-insured institute). These funds are placed in savings accounts at the member banks earning interest while still maintaining insurance coverage.

Our combined cash and cash equivalents totaled \$5,530,000 at December 31, 2011, a decrease of \$25,718,000 from December 31, 2010. The primary uses of cash during the year ended December 31, 2011 were for employee related expenses and preparations for the Phase 3 CLI program.

Our combined cash, cash equivalents and short-term investments totaled \$31,248,000 at December 31, 2010, an increase of \$12,129,000 from June 30, 2010. During the six months ended December 31, 2010, the primary source of cash, and cash equivalents and short-term investments was from the sale of our equity securities in December 2010 with net proceeds of \$20,600,000, in addition to \$1,074,000 from the exercise of stock purchase warrants and stock options. The primary uses of cash, cash equivalents and short-term investments during the six months ended December 31, 2010 included \$9,252,000 for our operations and working capital requirements, and \$305,000 in capital expenditures.

Our future cash requirements will depend on many factors, including continued scientific progress in our research and development programs, the scope and results of clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting and enforcing patents, competing technological and market developments, costs of possible acquisition or development of complementary business activities and the cost of product commercialization. We do not expect to generate positive cash flows from operations for at least the next several years due to the expected spending for research and development programs and the cost of commercializing our product candidates. We intend to seek additional funding through research and development agreements or grants, distribution and marketing agreements and through public or private debt or equity financing transactions. Successful future operations are subject to several technical and risk factors, including our continued ability to obtain future funding, satisfactory product development, obtaining regulatory approval and market acceptance for our products.

In order to complete our Phase 3 CLI trial, grow and expand our business, introduce our product candidates into the marketplace and possibly acquire or develop complementary business activities, we will need to raise additional funds. We will also need additional funds or a collaborative partner, or both, to finance the research and development activities of our product candidates for the expansion of additional cell types. We expect that our primary sources of

capital for the foreseeable future will be through collaborative arrangements and through the public or private sale of our equity or debt securities. There can be no assurance that such collaborative arrangements, or any public or private financing, will be available on acceptable terms, if at all, or can be sustained. Several factors will affect our ability to raise additional funding, including, but not limited to, market volatility of our common stock, continued stock market listing and economic conditions affecting the public markets generally or some portion or the entire technology sector.

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In October 2008, we entered into a common stock purchase agreement with Fusion Capital Fund II, LLC (Fusion Capital) pursuant to which we were entitled to sell up to \$15,000,000 of our common stock to Fusion Capital. In April 2009, we concluded the sales of the registered shares under this common stock purchase agreement. Under this purchase agreement we issued 2,836,583 shares of common stock for net proceeds of approximately \$8,600,000. In connection with entering into this common stock purchase agreement, we issued to Fusion Capital 242,040 shares of our common stock as a commitment fee. We also issued to Fusion Capital an additional 139,229 shares as a pro rata commitment fee.

In June 2009, we entered into a \$30,000,000 common stock purchase agreement with Fusion Capital. Pursuant to the purchase agreement with Fusion Capital, we had the right to sell to Fusion Capital up to \$30,000,000 of our common stock over a 25-month period, which began on July 1, 2009. Such sales were to be made from time to time in amounts between \$100,000 and \$4,000,000, depending on certain conditions as set forth in the agreement. In consideration for entering into the purchase agreement, we issued 181,530 shares of our common stock to Fusion Capital as an initial commitment fee. During fiscal 2010, 1,718,538 shares of our common stock (including 51,432 shares related to its commitment fee) were issued to Fusion Capital for net proceeds of approximately \$5,100,000. No additional shares were issued to Fusion Capital subsequent to October 2009, and we terminated the agreement with Fusion Capital in November 2010.

On January 21, 2010, we completed the sale of 6,509,637 units (including 740,387 units sold to the underwriter pursuant to the exercise of its overallotment option) at a public offering price of \$2.08 per unit. Each unit consisted of (i) one share of our common stock, (ii) a Class A warrant to purchase 0.75 of a share of our common stock at an exercise price of \$2.48 per share (as adjusted for the anti-dilution provision triggered by various financing's) and (iii) a Class B warrant to purchase 0.50 of a share of our common stock at an exercise price of \$2.08 per share. We received approximately \$12,400,000 in net proceeds from the sale of the units (including the partially exercised option of the over-allotment), after underwriting discounts and commissions and other offering expenses.

The 6,509,637 units consist of an aggregate of 6,509,637 shares of our common stock, Class A warrants to purchase an aggregate of 4,882,228 shares of our common stock and Class B warrants to purchase an aggregate of 3,254,818 shares of our common stock. The Class A warrants are exercisable for a five year period commencing on July 21, 2010. The Class B warrants were exercisable at any time from January 21, 2010 through July 21, 2010 and expired unexercised.

On December 15, 2010, we completed the sale of 10,000,000 units at a public offering price of \$2.25 per unit. Each unit consisted of one share of our common stock and a warrant to purchase one share of our common stock at an exercise price of \$1.75 per share (as adjusted from \$3.22 per share for the antidilution provision triggered by usage of the Company's ATM during the third quarter). We received approximately \$20,600,000 in net proceeds from the sale of the units, after underwriting discounts and commissions and other offering expenses. The warrants to purchase 10,000,000 shares of our common stock are exercisable for a five year period commencing on December 15, 2010. On June 27, 2012, the Company announced the closing of a common stock exchange program for the remaining December 2010 warrants, which was completed on July 27, 2012, resulting in the issuance of 4,845,949 shares of common stock in exchange for 9,691,900 warrants. As of December 31, 2012, 308,100 December 2010 warrants remained outstanding.

On March 9, 2012, we completed the sale of 12,308 shares of Series B-1 Non-Voting Convertible Preferred Stock (Series B-1 Preferred Stock) at an offering price of \$3,250 per share. We received approximately \$37,620,000 in net proceeds from the sale of the shares, after offering expenses. In addition to the Series B-1 Preferred Stock, which was issued at the closing, we also authorized Series B-2 Voting Convertible Preferred Stock (Series B-2 Preferred Stock). The Series B-1 Preferred Stock and Series B-2 Preferred Stock collectively are referred to as the Series B Preferred Stock. The Series B-1 Preferred Stock is not entitled to vote on matters on which the common shareholders are generally entitled to vote. The Series B-2 Preferred Stock are entitled to vote with the holders of the common stock as a single class, with each share of Series B-2 Preferred Stock having the number of votes equal to the number of shares of common stock issuable upon conversion of such Series B-2 Preferred Stock. On May 3, 2012, shareholder approval was obtained in accordance with Nasdaq Marketplace Rule 5635(b), which allowed the holder of Series B-1 Preferred Stock to exchange all of the then outstanding shares for shares of Series B-2 Preferred Stock on a one-for-one basis. The Series B Preferred Stock will, with respect to dividend rights and rights on liquidation, winding-up and dissolution, rank on parity with any other class or series of Aastrom capital stock that we may issue in the future which is designated as being on parity with the Series B Preferred Stock, and rank senior to our common stock and Series A Preferred Stock. The Series B Preferred Stock is convertible, at the option of the holder thereof at any time after the five year anniversary of the closing of the offering, into shares of our common stock at a conversion price of \$3.25 per share of common stock. At any time after the five year anniversary of issuance, Aastrom may elect to convert any or all outstanding shares of Series B Preferred Stock into shares of our common stock, subject to certain limitations. Dividends on the Series B Preferred Stock will be cumulative and compound daily, at a rate of 11.5% per annum, payable upon conversion, liquidation, redemption or other similar events, and payable in cash or Series B Preferred Stock until the five year anniversary of issuance. Following the five year anniversary of issuance and until the earlier of the tenth anniversary of the issuance and the date no Series B Preferred Stock remain outstanding, dividends will accrue at a rate of 8% per annum and will be payable in cash or Series B-1 Preferred Stock, at our option. Unless prohibited by Michigan law governing distributions to shareholders, the Series B-1 Preferred Stock shall be redeemable at the option of holder of the Series B-1 Preferred Stock commencing at any time after the five year anniversary of issuance, liquidation, winding up, dissolution or other similar events, subject to certain terms and limitations.

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#### Going Concern

As of December 31, 2012, we have \$13,638,000 of cash and cash equivalents. This is not sufficient to sustain our operations for one year. In light of our financial position, we are evaluating strategic and financial opportunities in the short-term in order to maintain adequate liquidity through December 31, 2013 and beyond. Additionally, we could sell shares through an At the Market Sales Agreement (ATM) in order to raise additional capital, though there are certain factors, such as volume of trading in our stock, our stock price and the ability to terminate the agreement with notice, which could limit the amount we could

raise in a short period of time. On a longer term basis, we will need to raise additional funds in order to complete product development programs and complete clinical trials needed to market and commercialize our products. We cannot be certain that such funding will be available on favorable terms, if at all. Some of the factors that will impact our ability to raise additional capital and our overall success include: the rate and degree of progress for our product development, the rate of regulatory approval to proceed with clinical trial programs, the level of success achieved in clinical trials, the requirements for marketing authorization from regulatory bodies in the United States and other countries, the liquidity and market volatility of our equity securities, regulatory and manufacturing requirements and uncertainties, technological developments by competitors, and other factors. If we cannot raise such funds, we will not be able to develop or enhance products, take advantage of future opportunities, or respond to competitive pressures or unanticipated requirements, which would have a material adverse impact on our business, financial condition and results of operations. As a result of the need to raise additional capital and a net capital deficiency, there is uncertainty regarding our ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. These estimates are based on certain assumptions which could be negatively impacted by the matters discussed under this heading and under the caption "Risk Factors," in Item 1A of this report.

If we cannot raise necessary funding in the future, we may not be able to continue as a going concern or develop or enhance products, take advantage of future opportunities, or respond to competitive pressures or unanticipated requirements, which would have a material adverse impact on our business, financial condition and results of operations. See "Risk Factors" and "Notes to Consolidated Financial Statements" included herein.

#### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements or relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities.

#### Long-Term Contractual Obligations and Commitments

The following table summarizes future estimated cash payments to be made under existing contractual obligations (in thousands):

|                         |             | <br>Payments Due by Period |    |      |    |      |    |      |    |                      |
|-------------------------|-------------|----------------------------|----|------|----|------|----|------|----|----------------------|
| Contractual Obligations | Total       | 2013                       |    | 2014 |    | 2015 |    | 2016 | N  | fore than<br>5 Years |
| Operating leases        | \$<br>3,450 | \$<br>1,055                | \$ | 992  | \$ | 992  | \$ | 359  | \$ | 52                   |
| Capital leases          | 40          | 34                         |    | 6    |    |      |    | _    |    | —                    |
| Total                   | \$<br>3,490 | \$<br>1,089                | \$ | 998  | \$ | 992  | \$ | 359  | \$ | 52                   |

## **New Accounting Standards**

Not applicable.

#### Item 7A. Quantitative and Qualitative Disclosures About Market Risk

As of December 31, 2012, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates or credit conditions on our securities portfolio.

Our vendors in countries outside the U.S. are typically paid in Euros. However, such expenditures have not been significant to date. Accordingly, we are not directly exposed to significant market risks from currency exchange rate fluctuations. We believe that the interest rate risk related to our accounts receivable is not significant. We manage the risk associated with these accounts through periodic reviews of the carrying value for non-collectability and establishment of appropriate allowances. We do not enter into hedging transactions and do not purchase derivative instruments.

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## Item 8. Financial Statements and Supplementary Data

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Aastrom Biosciences, Inc.:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of shareholders' equity (deficit) and of cash flows present fairly, in all material respects, the financial position of Aastrom Biosciences, Inc. and its subsidiaries (a development stage company) at

December 31, 2012 and December 31, 2011, and the results of their operations and their cash flows for the years ended December 31, 2012 and December 31, 2011, for the six month period ended December 31, 2010, for the year ended June 30, 2010, and, cumulatively, for the period from March 24, 1989 (Inception) to December 31, 2012 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our audits, which were integrated audits as of December 31, 2012, December 31, 2011 and June 30, 2010. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations, has a net capital deficiency and has insufficient liquidity to fund its future operations which raises substantial doubt about their ability to continue as a going concern. Management's plan in regard to this matter is also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP Detroit, Michigan March 18, 2013

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#### AASTROM BIOSCIENCES, INC. (a development stage company)

#### CONSOLIDATED BALANCE SHEETS (in thousands)

|  |    | Decem  | ber 31, |        |
|--|----|--------|---------|--------|
| ASSETS   |    | 2011   |         | 2012   |
| CURRENT ASSETS   |    |        |         |        |
|  | \$ | 5,530  | \$      | 13,638 |
| Cash and cash equivalents<br>Receivables   | Э  | 5,530  | Ф       | 28     |
| Other current assets   |    | -      |         |        |
|  |    | 636    |         | 324    |
| Total current assets   |    | 6,175  |         | 13,990 |
| PROPERTY AND EQUIPMENT, NET  |    | 1,564  |         | 1,188  |
| Total assets   | \$ | 7,739  | \$      | 15,178 |
|  |    |        |         |        |
| LIABILITIES, CONVERTIBLE PREFERRED STOCK AND SHAREHOLDERS' DEFICIT   |    |        |         |        |
| CURRENT LIABILITIES:   |    |        |         |        |
| Accounts payable and accrued expenses  | \$ | 2,963  | \$      | 3,247  |
| Accrued employee benefits  |    | 1,042  |         | 383    |
| Current portion of long-term debt  |    | 40     |         | 34     |
| Warrant liabilities  |    | 16,625 |         | 1,995  |
| Total current liabilities  |    | 20,670 |         | 5,659  |
| LONG-TERM DEBT   |    | 40     |         | 6      |
| Total liabilities  |    | 20,710 |         | 5,665  |
| COMMITMENTS AND CONTINGENCIES (Notes 7 and 8)  |    |        |         |        |
| Series B-1 non-voting convertible preferred stock, no par value; shares authorized and reserved — zero and |    |        |         |        |
| 39, respectively; shares issued and outstanding - zero   |    | _      |         | 3,923  |
| Series B-2 voting convertible preferred stock, no par value; shares authorized and reserved — zero and 39, |    |        |         | - ,    |
| respectively; shares issued and outstanding — zero and 12, respectively                                    |    | _      |         | 37,690 |
|  |    |        |         | .,     |

| Total convertible preferred stock  | _         | 41,613    |
|--|-----------|-----------|
| SHAREHOLDERS' DEFICIT:   |           |           |
| Common Stock, no par value; shares authorized —150,000; shares issued and outstanding — 38,635 and |           |           |
| 43,784, respectively   | 228,877   | 243,215   |
| Deficit accumulated during the development stage   | (241,848) | (275,315) |
| Total shareholders' deficit  | (12,971)  | (32,100)  |
| Total liabilities, convertible preferred stock and shareholders' deficit                           | \$ 7,739  | \$ 15,178 |

The accompanying Notes to Consolidated Financial Statements are an integral part of these statements.

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## AASTROM BIOSCIENCES, INC. (a development stage company)

## CONSOLIDATED STATEMENTS OF OPERATIONS (In thousands, except per share amounts)

|  | Y  | /ear Ended<br>June 30,<br>2010 |    | Six Month Period<br>Ended<br>December 31,<br>2010 |    | Year Ended<br>ecember 31,<br>2011     |    | ear Ended<br>cember 31,<br>2012 | March 24, 1989<br>(Inception) to<br>December 31,<br>2012 |
|--|----|--------------------------------|----|---|----|---------------------------------------|----|---------------------------------|--|
| REVENUES:  |    |                                |    |   |    |                                       |    |                                 |  |
| Product sales and rentals  | \$ | 89                             | \$ | 9   | \$ | 18                                    | \$ | 21                              | \$<br>1,898  |
| Research and development agreements  |    |                                |    | —   |    |                                       |    | —                               | 2,105  |
| Grants   |    |                                |    | 244   |    |                                       |    |                                 | <br>9,901  |
| Total revenues   |    | 89                             |    | 253   |    | 18                                    |    | 21                              | 13,904   |
| COSTS AND EXPENSES:  |    |                                |    |   |    |                                       |    |                                 | <br>   |
| Cost of product sales and rentals  |    | 34                             |    | 2   |    | 4                                     |    | 6                               | 3,047  |
| Research and development   |    | 12,658                         |    | 8,609   |    | 21,330                                |    | 26,025                          | 216,730  |
| Selling, general and administrative  |    | 5,201                          |    | 3,265   |    | 7,724                                 |    | 7,750                           | 92,598   |
| Total costs and expenses   |    | 17,893                         |    | 11,876  |    | 29,058                                |    | 33,781                          | 312,375  |
| LOSS FROM OPERATIONS   |    | (17,804)                       |    | (11,623)  |    | (29,040)                              |    | (33,760)                        | (298,471)  |
| OTHER INCOME (EXPENSE):  |    |                                |    | iii   |    | · · · · · · · · · · · · · · · · · · · |    | · · · · ·                       | <br>· · · · ·  |
| (Increase) decrease in fair value of warrants                                    |    | 3,171                          |    | (7,500)   |    | 9,329                                 |    | 4,248                           | 16,537   |
| Other income   |    |                                |    | _   |    | _                                     |    | _                               | 1,249  |
| Interest income  |    | 115                            |    | 40  |    | 53                                    |    | 50                              | 10,822   |
| Interest expense   |    | (40)                           |    | (5)   |    | (10)                                  |    | (12)                            | (491)  |
| Total other income (expense)   |    | 3,246                          |    | (7,465)   |    | 9,372                                 |    | 4,286                           | <br>28,117   |
| NET LOSS   | \$ | (14,558)                       | \$ | (19,088)  | \$ | (19,668)                              | \$ | (29,474)                        | \$<br>(270,354)  |
| Accretion of convertible preferred stock   |    | _                              |    | _   |    | _                                     |    | 3,993                           | 4,961  |
| NET LOSS ATTRIBUTABLE TO COMMON  |    |                                |    |   |    |                                       |    |                                 | <br>   |
| SHAREHOLDERS   | \$ | (14,558)                       | \$ | (19,088)  | \$ | (19,668)                              | \$ | (33,467)                        | \$<br>(275,315)  |
| NET LOSS PER SHARE ATTRIBUTABLE TO<br>COMMON SHAREHOLDERS (Basic and<br>Diluted) | \$ | (0.59)                         | \$ | (0.65)  | \$ | (0.51)                                | \$ | (0.81)                          |  |
| Weighted average number of common shares   | φ  | (0.35)                         | Ψ  | (0.03)  | Ψ  | (0.51)                                | Ψ  | (0.01)                          |  |
| outstanding (Basic and Diluted)  |    | 24,729                         |    | 29,186  |    | 38,627                                |    | 41,199                          |  |

The accompanying Notes to Consolidated Financial Statements are an integral part of these statements.

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## AASTROM BIOSCIENCES, INC. (a development stage company)

## CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT) (In thousands, except per share data)

|   | Preferre<br>Shares | ed Stock<br>Amount | Commo | on Stock<br>Amount | Deficit<br>Accumulated<br>During the<br>Development<br>Stage | Total<br>Shareholders'<br>Equity (Deficit) |
|---|--------------------|--------------------|-------|--------------------|--|--|
| BALANCE, MARCH 24, 1989 (Inception)                       |                    | <u>\$</u>          |       | <u>\$</u>          | <u>\$</u>  | \$ —                                       |
| Net loss  |                    |                    |       |                    | (202,124)  | (202,124)                                  |
| Issuance of common stock for cash, services and license   |                    |                    |       |                    |  |  |
| rights  |                    |                    | 149   | 2,336              |  | 2,336                                      |
| Issuance of Series A through Series E Preferred Stock for |                    |                    |       |                    |  |  |
| cash, net of issuance costs of \$342                      | 9,452              | 34,218             |       |                    |  | 34,218                                     |
| Issuance of Series E Preferred Stock at \$17.00 per Share | 206                | 3,500              |       | (3,500)            |  |  |
| Exercise of stock options and stock purchase warrants,    |                    |                    | 1,088 | 7,293              |  | 7,293                                      |

| and issuance of stock under Employee Stock Purchase<br>Plan   |                  |   |        |            |              |             |
|---|------------------|---|--------|------------|--------------|-------------|
| Issuance of Stock Purchase Rights for cash in                 |                  |   |        |            |              |             |
| September 1995 and March 1996                                 |                  |   |        | 3,500      |              | 3,500       |
| Principal payment received under shareholder note             |                  |   |        | 5,500      |              | 5,500       |
| Receivable  |                  |   |        | 31         |              | 31          |
| Initial public offering of common stock at \$56.00 per share, |                  |   |        | 51         |              | 51          |
| net of issuance costs of \$2,865                              |                  |   | 406    | 19,885     |              | 19,885      |
| Conversion of preferred stock                                 | (11,866)         | (55,374)                                      | 2,720  | 55,374     |              |             |
| Compensation expense related to stock options and             | (11,000)         | (00,07 1)                                     | 2,720  | 00,071     |              |             |
| warrants granted  |                  |   |        | 9,089      |              | 9,089       |
| Issuance of 5.5% Convertible Preferred Stock at \$5.00 per    |                  |   |        | 5,000      |              | 5,000       |
| share, net of issuance costs of \$1,070                       | 2,200            | 9,930   |        |            |              | 9,930       |
| Issuance of 1998 Series I Convertible Preferred Stock at      | ,                | ,   |        |            |              | ,           |
| \$1,000 per share, net of issuance costs of \$460             | 5                | 4,540   | 5      | 149        |              | 4,689       |
| Issuance of 1999 Series III Convertible Preferred Stock at    |                  |   |        |            |              |             |
| \$1,000 per share, net of issuance costs of \$280             | 3                | 2,720   | 6      | 90         |              | 2,810       |
| Issuance of common stock, net of issuance costs of \$11,480   |                  |   | 23,719 | 122,254    |              | 122,254     |
| Issuance of restricted stock, net of cancellations            |                  |   | 54     | _          |              | _           |
| Issuance of stock under Direct Stock Purchase Plan            |                  |   | 94     | 943        |              | 943         |
| Dividends and yields on preferred stock                       |                  | 466   | 19     | 502        | (968)        | _           |
| Repurchase and retirement of common shares outstanding        |                  |   | (4)    | (73)       |              | (73)        |
| BALANCE, JUNE 30, 2010  |                  |   | 28,256 | 217,873    | (203,092)    | 14,781      |
| Net loss  |                  |   |        |            | (19,088)     | (19,088)    |
| Exercise of stock options and stock purchase warrants         |                  |   | 360    | 1,498      |              | 1,498       |
| Compensation expense related to stock options and             |                  |   |        |            |              |             |
| restricted stock awards and units granted                     |                  |   |        | 1,043      |              | 1,043       |
| Issuance of common stock, net of issuance costs of \$1,944    |                  |   | 10,000 | 4,688      |              | 4,688       |
| BALANCE, DECEMBER 31, 2010                                    |                  | —   | 38,616 | 225,102    | (222,180)    | 2,922       |
| Net loss  |                  |   |        |            | (19,668)     | (19,668)    |
| Exercise of stock options                                     |                  |   | 19     | 32         |              | 32          |
| Compensation expense related to stock options granted         | · <u>·····</u> · |   |        | 3,743      |              | 3,743       |
| BALANCE, DECEMBER 31, 2011                                    |                  | —   | 38,635 | 228,877    | (241,848)    | (12,971)    |
| Net loss  |                  |   |        |            | (33,467)     | (33,467)    |
| Exercise of stock options                                     |                  |   | 144    | 214        |              | 214         |
| Compensation expense related to stock options granted         |                  |   |        | 3,610      |              | 3,610       |
| Issuance of common stock, net of issuance costs of \$147      |                  |   | 5,005  | 10,514     |              | 10,514      |
| BALANCE, DECEMBER 31, 2012                                    |                  | <u>\$                                    </u> | 43,784 | \$ 243,215 | \$ (275,315) | \$ (32,100) |

The accompanying Notes to Consolidated Financial Statements are an integral part of these statements.

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## AASTROM BIOSCIENCES, INC. (a development stage company)

## CONSOLIDATED STATEMENTS OF CASH FLOWS (In thousands)

|  | <br>ar Ended<br>June 30,<br>2010 | Per | x Month<br>iod Ended<br>cember 31,<br>2010 | <br>ear Ended<br>cember 31,<br>2011 | <br>ear Ended<br>cember 31,<br>2012 | (Iı | rch 24, 1989<br>nception) to<br>ecember 31,<br>2012 |
|--|----------------------------------|-----|--|-------------------------------------|-------------------------------------|-----|---|
| OPERATING ACTIVITIES:                                    |                                  |     |  |                                     |                                     |     |   |
| Net loss   | \$<br>(14,558)                   | \$  | (19,088)                                   | \$<br>(19,668)                      | \$<br>(29,474)                      | \$  | (270,354)   |
| Adjustments to reconcile net loss to net cash used for   |                                  |     |  |                                     |                                     |     |   |
| operating activities:                                    |                                  |     |  |                                     |                                     |     |   |
| Depreciation and amortization                            | 592                              |     | 259  | 647                                 | 649                                 |     | 8,147   |
| Loss on property held for resale                         | _                                |     |  | _                                   | _                                   |     | 110   |
| Amortization of discounts and premiums on                |                                  |     |  |                                     |                                     |     |   |
| investments  | _                                |     | _  | _                                   | _                                   |     | (1,704)   |
| Stock compensation expense                               | 710                              |     | 1,043                                      | 3,743                               | 3,610                               |     | 17,495  |
| Increase (decrease) in fair value of warrant liabilities | (3,171)                          |     | 7,500                                      | (9,329)                             | (4,248)                             |     | (16,537)  |
| Inventory write downs                                    | _                                |     |  | _                                   | _                                   |     | 2,240   |
| Stock issued pursuant to license agreement               | _                                |     |  |                                     | _                                   |     | 3,300   |
| Provision for losses on accounts receivable              | _                                |     | _  | _                                   | _                                   |     | 204   |
| Changes in operating assets and liabilities:             |                                  |     |  |                                     |                                     |     |   |
| Receivables  | 42                               |     | (9)  | 16                                  | (19)                                |     | (277)   |
| Inventories  | 1                                |     | _  | _                                   |                                     |     | (2,335)   |
| Other current assets                                     | 72                               |     | (43)                                       | (210)                               | 312                                 |     | (304)   |
| Accounts payable and accrued expenses                    | 896                              |     | 976  | 63                                  | 284                                 |     | 3,015   |
| Accrued employee benefits                                | 331                              |     | 110  | 246                                 | (659)                               |     | 383   |
| Net cash used for operating activities                   | <br>(15,085)                     |     | (9,252)                                    | <br>(24,492)                        | <br>(29,545)                        |     | (256,617)   |

| INVESTING ACTIVITIES:                              |              |              |             |    |        |              |
|--|--------------|--------------|-------------|----|--------|--------------|
| Organizational costs                               | _            | _            |             |    |        | (73)         |
| Purchase of short-term investments                 | (5,000)      |              |             |    |        | (217,041)    |
| Maturities of short-term investments               |              | 5,000        |             |    |        | 218,745      |
| Property and equipment purchases                   | (120)        | (305)        | (1,031)     |    | (273)  | (7,490)      |
| Proceeds from sale of property held for resale     |              |              | —           |    |        | 400          |
| Net cash provided by (used for) investing          |              |              |             |    |        |              |
| activities   | (5,120)      | 4,695        | (1,031)     |    | (273)  | (5,459)      |
|  |              |              |             |    |        | <br>         |
| FINANCING ACTIVITIES:                              |              |              |             |    |        |              |
| Net proceeds from issuance of preferred stock      | —            |              | —           |    | 37,620 | 89,267       |
| Net proceeds from issuance of common stock and     |              |              |             |    |        |              |
| warrants   | 17,526       | 21,805       | 32          |    | 346    | 185,054      |
| Payments received for stock purchase rights        | —            | —            | —           |    |        | 3,500        |
| Restricted cash used as compensating balance       | 277          | —            | —           |    | —      |              |
| Proceeds from long-term debt                       | —            | —            | —           |    | —      | 751          |
| Payments on long-term debt                         | (479)        | (119)        | (227)       |    | (40)   | (2,840)      |
| Other, net   | <br>         | <br>         | <br>        | _  |        | <br>(18)     |
| Net cash provided by (used for) financing          |              |              |             |    |        |              |
| activities   | <br>17,324   | <br>21,686   | <br>(195)   |    | 37,926 | <br>275,714  |
|  |              |              |             |    |        |              |
| NET INCREASE (DECREASE) IN CASH AND CASH           |              |              |             |    |        |              |
| EQUIVALENTS  | (2,881)      | 17,129       | (25,718)    |    | 8,108  | 13,638       |
| CASH AND CASH EQUIVALENTS AT BEGINNING             |              |              |             |    |        |              |
| OF PERIOD  | <br>17,000   | <br>14,119   | <br>31,248  |    | 5,530  | <br>         |
| CASH AND CASH EQUIVALENTS AT END OF                |              |              |             |    |        |              |
| PERIOD   | \$<br>14,119 | \$<br>31,248 | \$<br>5,530 | \$ | 13,638 | \$<br>13,638 |
|  |              |              |             |    |        |              |
| SUPPLEMENTAL CASH FLOW INFORMATION:                |              |              |             |    |        |              |
| Interest paid                                      | \$<br>40     | \$<br>11     | \$<br>16    | \$ | 13     | \$<br>504    |
| Equipment acquired under capital lease obligations | \$<br>—      | \$<br>69     | \$<br>52    | \$ |        | \$<br>1,295  |
| Accretion of convertible preferred stock           | \$<br>       | \$<br>       | \$<br>—     | \$ | 3,993  | \$<br>4,961  |
| Warrants exchanged for common stock                | \$<br>_      | \$<br>—      | \$<br>_     | \$ | 10,382 | \$<br>10,382 |

The accompanying Notes to Consolidated Financial Statements are an integral part of these statements.

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## AASTROM BIOSCIENCES, INC. (a development stage company)

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 1. Organization and Summary of Significant Accounting Policies

Aastrom Biosciences, Inc. was incorporated in March 1989 (Inception), began employee-based operations in 1991, and is in the development stage. The Company operates its business in one reportable segment — research and product development involving the development of patient-specific cell products for use in regenerative medicine.

Successful future operations are subject to several technical hurdles and risk factors, including satisfactory product development, timely initiation and completion of clinical trials, regulatory approval and market acceptance of the Company's products and the Company's continued ability to obtain future funding.

The Company is subject to certain risks related to the operation of its business and development of its products and product candidates. As of December 31, 2012 the Company had \$13,638,000 of cash and cash equivalents. This is not sufficient to sustain operations for one year. In light of our financial position, we are evaluating strategic and financial opportunities in the short-term in order to maintain adequate liquidity through December 31, 2013 and beyond. Additionally, the Company could sell shares through an At the Market Sales Agreement (ATM) in order to raise additional capital, though there are certain factors, such as volume of trading in the stock, the stock price and the ability to terminate the agreement with notice, which could limit the amount the Company could raise in a short period of time. On a longer-term basis, the Company will need to raise additional funds in order to complete product development programs and complete clinical trials needed to market and commercialize its products. The Company cannot be certain that such funding will be available on favorable terms, if at all. Some of the factors that will impact the Company's ability to raise additional capital and our overall success include: the rate and degree of progress for product development, the rate of regulatory approval to proceed with clinical trial programs, the level of success achieved in clinical trials, the requirements for marketing authorization from regulatory bodies in the United States and other countries, the liquidity and market volatility of the Company's equity securities, regulatory and manufacturing requirements and uncertainties, technological developments by competitors, and other factors. If the Company cannot raise such funds, the Company will not be able to develop or enhance products, take advantage of future opportunities, or respond to competitive pressures or unanticipated requirements, which would have a material adverse impact on the business, financial condition and results of operations. As a result of the need to raise additional capital and a net capital deficiency, there is uncertainty regarding the Company's ability to maintain liquidity sufficient to operate our business effectively over at least the next twelve months, which raises substantial doubt as to our ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

*Principles of Consolidation* — The consolidated financial statements include the accounts of Aastrom and its wholly-owned subsidiary, Aastrom Biosciences GmbH, located in Berlin, Germany and Aastrom Biosciences, SL, located in Barcelona, Spain (collectively, the Company). All inter-company transactions and accounts have been eliminated in consolidation.

*Fiscal Year Change* — On November 11, 2010, the Board of Directors approved the change in the Company's fiscal year end from June 30 to December 31. The change became effective at the end of the quarter ended December 31, 2010. All references to "years", unless otherwise noted, refer to the 12-month fiscal year, which prior to July 1, 2010, ended on June 30, and beginning with January 1, 2011, ends on December 31, of each year. In addition, the Company presents the Consolidated Statement of Operations and Consolidated Statement of Cash Flows for the six month transition period ended December 31, 2010.

*Cash and Cash Equivalents* — Cash and cash equivalents include cash and highly liquid short-term investments with original maturities of three months or less.

*Fair Value Measurements* — Fair value is the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is determined based upon assumptions that market participants would use in pricing an asset or liability. Fair value measurements are rated on a three-tier hierarchy as follows:

- · Level 1 inputs: Quoted prices (unadjusted) for identical assets or liabilities in active markets;
- · Level 2 inputs: Inputs, other than quoted prices included in Level 1, that are observable either directly or indirectly; and
- · Level 3 inputs: Unobservable inputs for which there is little or no market data, which require the reporting entity to develop its own assumptions.

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In many cases, a valuation technique used to measure fair value includes inputs from multiple levels of the fair value hierarchy described above. The lowest level of significant input determines the placement of the entire fair value measurement in the hierarchy.

See Note 5 for disclosures related to the fair value of the Company's warrants. The Company does not have any other assets or liabilities on the balance sheet as of December 31, 2012 that are measured at fair value.

*Diversity of Credit Risk* — The Company has established guidelines relative to diversification and maturities of its investments in an effort to limit risk. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates. The Company has not experienced any losses on its cash equivalents.

*Property and Equipment* — Property and equipment is recorded at cost and depreciated or amortized using the straight-line method over the estimated useful life of the asset (primarily three to five years) or the underlying lease term for leasehold improvements, whichever is shorter. When assets are disposed of, the cost and accumulated depreciation are removed from the accounts. Repairs and maintenance are charged to expense as incurred.

*Revenue Recognition* — The Company's revenue can be generated from grants and research agreements, collaborative agreements, licensing fees and product sales. Revenue from grants and research agreements is recognized on a cost reimbursement basis consistent with the performance requirements of the related agreement. Revenue from collaborative agreements is recognized when the scientific or clinical results stipulated in the agreement have been met and there are no ongoing obligations on the Company's part. Revenue from product sales is recognized when title to the product transfers and there are no remaining obligations that will affect the customer's final acceptance of the sale. Revenue from licensing fees under licensing agreements is recognized when there are no future performance obligations remaining with respect to such revenues. Payments received before all obligations are fulfilled are classified as deferred revenue.

*Research and Development Costs* — Research and development costs are expensed as incurred. These costs include direct research and development costs such as salaries, clinical trial expenses, consulting fees and other expenses that are specific to the Company's research and development programs, as well as an allocation of indirect costs such as facility expenses, human resources and information technology expenses.

*Stock-Based Compensation* — Calculating stock-based compensation expense requires the input of highly subjective assumptions. We apply the Black-Scholes option-pricing model to determine the fair value of our stock options. Inherent in this model are assumptions related to expected stock-price volatility, option life, risk-free interest rate and dividend yield. We estimate the volatility of our common stock at the date of grant based on historical volatility. We estimate the expected life of options that vest solely on service using the "simplified method" provided for in the Securities and Exchange Commission Staff Accounting Bulletin No. 110. The "simplified method" is permitted for estimating the expected term of "plain-vanilla" stock options for which the historical stock option exercise experience is likely not indicative of future exercise patterns. The risk-free interest rate is based on our historical rate, which we anticipate to remain at zero. The assumptions used in calculating the fair value of stock options represent our best estimates; however, these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and different assumptions are used, the stock-based compensation expense could be materially different in the future. In addition, we are required to estimate the expected forfeiture rate and only recognize expense for those stock options expected to vest over the service period. We estimate the forfeiture rate considering the historical experience of our stock-based awards. If the actual forfeiture rate is different from the estimate, we adjust the expense accordingly.

*Income Taxes* — Deferred tax assets are recognized for deductible temporary differences and tax credit carryforwards and deferred tax liabilities are recognized for taxable temporary differences. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized.

*Net Loss Per Share Attributable to Common Shareholders*'— Basic earnings (loss) per share is calculated using the two-class method, which is an earnings allocation formula that determines earnings (loss) per share for the holders of the Company's common shares and holders of the Series B Preferred Stock. The Series B Preferred Stock shares contain participation rights in undistributed earnings, but do not share in the losses of the Company. Therefore, in the event of a loss from continuing operations, the Series B Preferred Stock is not considered in the calculation of basic loss per share.

Net loss per common share attributable to common shareholders' is computed using the weighted-average number of common shares outstanding during the period. Common equivalent shares are not included in the diluted per share calculation where the effect of their inclusion would be anti-dilutive. The aggregate number of common equivalent shares (related to options, warrants and preferred stock) that have been excluded from the computations of diluted

net loss per common share was 12,200,500 for the year ended June 30, 2010, 19,599,700 for the six month transition period ended December 31, 2010, 23,382,190 for the year ended December 31, 2011 and 29,076,811 for the year ended December 31, 2012.

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*Use of Estimates* — The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reported period. Actual results could differ from those estimates.

*Financial Instruments* — The Company's financial instruments include cash equivalents and receivables for which the current carrying amounts approximate market value based upon their short-term nature.

*Warrants* — Warrants that could be cash settled or have anti-dilution price protection provisions are recorded as liabilities at their estimated fair value at the date of issuance, with subsequent changes in estimated fair value recorded in other income (expense) in our statement of operations in each subsequent period. In general, warrants with anti-dilution provisions are measured using the Monte Carlo valuation model, while the others are measured using the Black-Scholes valuation model. Both of the methodologies are based, in part, upon inputs for which there is little or no observable market data, requiring the Company to develop its own assumptions. The assumptions used in calculating the estimated fair value of the warrants represent our best estimates; however, these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and different assumptions are used, the warrant liability and the change in estimated fair value could be materially different.

Long-Lived Assets — The Company reviews its long-lived assets for impairment whenever an event or change in circumstances indicates that the carrying values of an asset may not be recoverable. If such an event or change in circumstances occurs and potential impairment is indicated because the carrying values exceed the estimated future undiscounted cash flows of the asset, the Company would measure the impairment loss as the amount by which the carrying value of the asset exceeds its fair value. No significant events or changes in circumstances were identified by the Company that would indicate that the carrying value of an asset was not recoverable for any of the periods presented in the accompanying consolidated financial statements.

#### 2. Selected Balance Sheet Information

Property and Equipment (in thousands):

|                               | De | ecember 31,<br>2011 | December 31,<br>2012 |         |  |
|-------------------------------|----|---------------------|----------------------|---------|--|
| Machinery and equipment       | \$ | 3,041               | \$                   | 2,507   |  |
| Furniture and fixtures        |    | 678                 |                      | 706     |  |
| Computer software             |    | 410                 |                      | 193     |  |
| Computer equipment            |    | 467                 |                      | 307     |  |
| Office equipment              |    | 105                 |                      | 55      |  |
| Leasehold improvements        |    | 998                 |                      | 1,018   |  |
|                               |    | 5,699               |                      | 4,786   |  |
| Less accumulated depreciation |    | (4,135)             |                      | (3,598) |  |
|                               | \$ | 1,564               | \$                   | 1,188   |  |

Accounts Payable and Accrued Expenses (in thousands):

|                  | December 31,<br>2011 | December 31,<br>2012 |
|------------------|----------------------|----------------------|
| Accounts payable | \$<br>2,239          | \$<br>2,843          |
| Accrued expenses | 724                  | 404                  |
|                  | \$<br>2,963          | \$<br>3,247          |

#### Accrued Employee Benefits (in thousands):

|                        | December 31,<br>2011 | December 31,<br>2012 |     |  |
|------------------------|----------------------|----------------------|-----|--|
| Vacation pay and other | \$<br>398            | \$                   | 383 |  |
| Bonus                  | 644                  |                      | —   |  |
|                        | \$<br>1,042          | \$                   | 383 |  |
|                        | <br>                 |                      |     |  |

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## 3. Stock-Based Compensation

## Stock Option and Equity Incentive Plans

The Company has historically had various stock incentive plans and agreements that provide for the issuance of nonqualified and incentive stock options as well as other equity awards. Such awards may be granted by the Company's Board of Directors to certain of the Company's employees, directors and consultants. Options granted under these plans expire no later than ten years from the date of grant, and other than those granted to non-employee directors, generally become exercisable over a four-year period, under a graded-vesting methodology, following the date of grant. The Company generally issues new shares upon the exercise of stock options.

In December 2009, the shareholders approved the 2009 Omnibus Incentive Plan (the 2009 Plan). The 2009 Plan provides incentives through the grant of stock options, stock appreciation rights, restricted stock awards and restricted stock units. The exercise price of stock options granted under the 2009 Plan shall not be less than the fair market value of the Company's common stock on the date of grant. The 2009 Plan replaced the 1992 Stock Option Plan, the 2001 Stock Option Plan and the Amended and Restated 2004 Equity Incentive Plan (the Prior Plans), and no new awards will be granted under the Prior Plans. However, the expiration or forfeiture of options previously granted under the Prior Plans will increase the awards available for issuance under the 2009 Plan.

As of December 31, 2012, there were 3,356,559 shares available for future grant under the 2009 Plan.

#### Service-Based Stock Options

During the period ended December 31, 2012, the Company granted 5,467,445 service-based options to purchase common stock. These were granted with exercise prices equal to the fair value of the Company's stock at the grant date, generally vest over four years (other than 370,000 non-employee options which generally vest over one year) and have a term of ten years. The weighted average grant-date fair value of service-based options granted during the year ended June 30, 2010 was \$1.33, \$0.99 for the six month transition period ended December 31, 2010, \$1.54 for the year ended December 31, 2011 and \$1.20 for the year ended December 31, 2012.

The net compensation costs recorded for the service-based stock options related to employees, consultants and directors (including the impact of the forfeitures) were \$698,000 for the year ended June 30, 2010, \$1,043,000 for the six month transition period ended December 31, 2010, \$3,743,000 for the year ended December 31, 2011 and \$3,610,000 for the year ended December 31, 2012.

The fair value of each service-based stock option grant for the reported periods is estimated on the date of the grant using the Black-Scholes optionpricing model using the weighted average assumptions noted in the following table.

| Service-Based Stock Options     | Year Ended<br>June 30,<br>2010 | Six Month Period<br>December 31,<br>2010 | Year Ended<br>December 31,<br>2011 | Year Ended<br>December 31<br>2012 |
|---------------------------------|--------------------------------|--|------------------------------------|-----------------------------------|
| Expected dividend rate          | 0%                             | 0%                                       | 0%                                 | 0%                                |
| Expected stock price volatility | 70.2% - 72.8%                  | 70.6% - 77.4%                            | 72.1% - 78.9%                      | 73.9% - 79.1%                     |
| Risk-free interest rate         | 2.4% - 3.1%                    | 1.5% - 2.1%                              | 1.4% - 2.7%                        | 0.9% - 1.5%                       |
| Expected life (years)           | 5.5 - 6.3                      | 6.1 - 6.3                                | 6.0 - 6.3                          | 5.5 - 6.3                         |
|                                 |                                |  |                                    |                                   |
|                                 |                                | 46                                       |                                    |                                   |

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The following table summarizes the activity for service-based stock options for the indicated periods:

| Service-Based Stock Options      | Options     | ,  | Weighted Average<br>Exercise Price | Weighted Average<br>Remaining<br>Contractual Term |    | Aggregate<br>Intrinsic<br>Value |
|----------------------------------|-------------|----|------------------------------------|---|----|---------------------------------|
| Outstanding at June 30, 2009     | 1,365,382   | \$ | 7.76                               | 7.9   | \$ | 114,000                         |
| Granted                          | 2,508,525   | \$ | 2.02                               |   |    |                                 |
| Forfeited or expired             | (590,727)   | \$ | 7.63                               |   |    |                                 |
| Outstanding at June 30, 2010     | 3,283,180   | \$ | 3.40                               | 8.6   | \$ | 2,750                           |
| Granted                          | 1,700,000   | \$ | 1.54                               |   |    |                                 |
| Exercised                        | (7,500)     | \$ | 1.80                               |   | \$ | 3,000                           |
| Forfeited or expired             | (678,471)   | \$ | 4.85                               |   |    |                                 |
| Outstanding at December 31, 2010 | 4,297,209   | \$ | 2.43                               | 8.9   | \$ | 3,159,000                       |
| Granted                          | 4,310,550   | \$ | 2.31                               |   |    |                                 |
| Exercised                        | (19,688)    | \$ | 1.64                               |   | \$ | 21,000                          |
| Forfeited or expired             | (508,404)   | \$ | 2.33                               |   |    |                                 |
| Outstanding at December 31, 2011 | 8,079,667   | \$ | 2.38                               | 8.4   | \$ | 674,000                         |
| Granted                          | 5,467,445   | \$ | 2.21                               |   |    |                                 |
| Exercised                        | (144,167)   | \$ | 1.48                               |   | \$ | 52,000                          |
| Cancelled                        | (1,057,700) | \$ | 2.03                               |   |    |                                 |
| Forfeited or expired             | (2,357,777) | \$ | 2.18                               |   |    |                                 |
| Outstanding at December 31, 2012 | 9,987,468   | \$ | 2.38                               | 7.5   | \$ |                                 |
| Exercisable at December 31, 2012 | 4,209,163   | \$ | 2.67                               | 5.8   | \$ | _                               |

As of December 31, 2012, there was approximately \$5,138,000, of total unrecognized compensation cost related to non-vested service-based stock options granted under the 2009 Plan and the Prior Plans. That cost is expected to be recognized over a weighted-average period of 2.9 years.

The total fair value of stock options vested during the year ended June 30, 2010 was \$1,084,000, \$622,000 for the six month transition period ended December 31, 2010, \$2,182,000 for the year ended December 31, 2011 and \$2,987,000 for the year ended December 31, 2012.

## 4. Shareholders' Equity

In October 2008, the Company entered into a common stock purchase agreement with Fusion Capital Fund II, LLC (Fusion Capital) pursuant to which the Company was entitled to sell up to \$15,000,000 of its common stock to Fusion Capital. In April 2009, the Company concluded the sales of the registered shares under this common stock purchase agreement. Under this purchase agreement the Company issued 2,836,583 shares of common stock for net proceeds of approximately \$8,600,000. In connection with entering into this common stock purchase agreement, the Company issued to Fusion Capital 242,040 shares of its common stock as a commitment fee. The Company also issued to Fusion Capital an additional 139,229 shares as a pro rata commitment fee.

In June 2009, the Company entered into a \$30,000,000 common stock purchase agreement with Fusion Capital. Pursuant to the purchase agreement with Fusion Capital, the Company had the right to sell to Fusion Capital up to \$30,000,000 of its common stock over a 25-month period, which began on July 1, 2009. Such sales were to be made from time to time in amounts between \$100,000 and \$4,000,000, depending on certain conditions as set forth in the agreement. In consideration for entering into the purchase agreement, the Company issued 181,530 shares of its common stock to Fusion Capital as an initial commitment fee. During fiscal 2010, 1,718,538 shares of the Company's common stock (including 51,432 shares related to its commitment fee) were issued to Fusion Capital for net proceeds of approximately \$5,100,000. The Company terminated the agreement with Fusion Capital in November 2010.

On January 21, 2010, the Company completed the sale of 6,509,637 units (including 740,387 units sold to the underwriter pursuant to the exercise of its over-allotment option) at a public offering price of \$2.08 per unit. Each unit consisted of (i) one share of the Company's common stock, (ii) a Class A warrant to purchase 0.75 of a share of the Company's common stock at an exercise price of \$2.48 per share (as adjusted from \$2.97 per share for the anti-dilution provision triggered through various financings) and (iii) a Class B warrant to purchase 0.50 of a share of the Company's common stock at an exercise price of \$2.08 per share. The Company received approximately \$12,400,000 in net proceeds from the sale of the units (including the partially exercised option of the over-allotment), after underwriting discounts and commissions and other offering expenses.

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On December 15, 2010, the Company completed the sale of 10,000,000 units at a public offering price of \$2.25 per unit. Each unit consisted of one share of the Company's common stock and a warrant to purchase one share of the Company's common stock at an exercise price of \$1.75 per share (as adjusted from \$3.22 per share for the anti-dilution provision triggered by usage of the Company's ATM). The Company received approximately \$20,600,000 in net proceeds from the sale of the units, after underwriting discounts and commissions and other offering expenses. The warrants to purchase 10,000,000 shares of the Company's common stock are exercisable for a five year period commencing on December 15, 2010.

On June 16, 2011, the Company entered into an At the Market Sales Agreement (ATM) with McNicoll, Lewis & Vlak LLC (MLV), pursuant to which the Company may sell shares of its common stock through MLV, as sales agent, in registered transactions from its shelf registration statement filed in November 2010, for aggregate proceeds of up to \$20,300,000. Shares of common stock sold under the ATM are to be sold at market prices. The Company will pay up to 3% of the gross proceeds to MLV as a commission. As of December 31, 2012, the Company raised gross proceeds of \$279,000. Subsequent to December 31, 2012, the Company has raised gross proceeds of \$2,451,000 utilizing the ATM.

#### Dividends

No cash dividends have been declared or paid by the Company since its Inception.

#### 5. Stock Purchase Warrants

The Company has historically issued warrants to purchase shares of the Company's common stock in connection with certain of its common stock offerings. The following warrants were outstanding during the year ended June 30, 2010, the six month transition period ended December 31, 2010, the years ended December 31, 2011 and 2012, and include provisions that could require cash settlement of the warrants or have anti-dilution price protection provisions requiring each to be recorded as liabilities of the Company at the estimated fair value at the date of issuance, with changes in estimated fair value recorded as non-cash income or expense in the Company's statement of operations in each subsequent period:

- warrants to purchase an aggregate of 740,131 shares of the Company's common stock, issued on October 17, 2007 in connection with the Company's registered direct offering, exercisable from April 18, 2008 through April 17, 2013 at an exercise price of \$12.72 per share, all of which remained outstanding as of December 31, 2012;
- (ii) Class A warrants to purchase an aggregate of 4,882,228 shares of the Company's common stock, issued on January 21, 2010 in connection with the Company's registered public offering, exercisable for a five year period commencing on July 21, 2010 at an exercise price of \$2.48 per share (as adjusted for the anti-dilution provision triggered by the close of the Company's exchange program for the December 2010 warrants, as described below, and usage of the ATM during the third quarter), 4,525,978 of which remained outstanding as of December 31, 2012; and
- (iii) warrants to purchase an aggregate of 10,000,000 shares of the Company's common stock, issued on December 15, 2010 in connection with the Company's registered public offering (December 2010 warrants), exercisable for a five year period commencing on December 15, 2010 at an exercise price of \$1.75 per share (as adjusted from \$3.22 per share for the anti-dilution provision triggered by usage of the Company's ATM during the third quarter). On June 27, 2012, the Company announced the closing of a common stock exchange program for the remaining December 2010 warrants, which was completed on July 27, 2012, resulting in the issuance of 4,845,949 shares of common stock in exchange for 9,691,900 warrants. As of December 31, 2012, 308,100 December 2010 warrants remained outstanding.

All of the warrants listed above could require net cash settlement in the event that registered shares are not available at the time of exercise of such warrant. The Class A warrants and the December 2010 warrants also contain anti-dilution provisions that adjust the exercise price of the warrant if the Company issues or sells, or is deemed to have issued or sold, any shares of its common stock or securities exercisable or convertible into shares of common stock for no consideration or for a consideration per share less than the applicable exercise price in effect immediately prior to the time of such issue or sale. In the event of such a subsequent issuance of common stock of the Company, (i) the exercise price of the Class A warrants would be adjusted to a point between the current exercise price per share of such Class A warrant and the price per share at which the new shares of common stock of the Company are being issued based on a weighted average calculation as outlined in the Class A warrant agreement, and (ii) the exercise price of the December 2010 warrants would be adjusted to the price per share at which the new shares of common stock of the Company are being issued. Notwithstanding the foregoing, there are certain issuances of the Company that would not trigger the anti-dilution provisions of the Class A warrants or the December 2010 warrants, including but not limited to, issuances under any duly authorized Company stock option, restricted stock plan or stock purchase plan whether now existing or hereafter approved by the Company and its stockholders in the future, or as an inducement grant to employees, consultants, directors or officers. The December 2010 warrants also contain a feature that allows the warrant holder to put the warrants back to the Company and receive cash in the event of a fundamental transaction, such as a change in control of the Company or a sale of all or substantially all of its assets. The value received by the warrant holder upon exercise of the put right is based on a B

The Class A warrants and the December 2010 warrants are measured using the Monte Carlo valuation model, while the other warrants listed above are measured using the Black-Scholes valuation model. Both of the methodologies are based, in part, upon inputs for which there is little or no observable market data, requiring the Company to develop its own assumptions. The assumptions used in calculating the estimated fair value of the warrants represent the Company's best estimates; however, these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and different assumptions are used, the warrant liabilities and the change in estimated fair value of the warrants could be materially different.

Inherent in both the Monte Carlo and Black-Scholes valuation models are assumptions related to expected stock-price volatility, expected life, risk-free interest rate and dividend yield. The Company estimates the volatility of its common stock based on historical volatility that matches the expected remaining life of the warrants. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected remaining life of the warrants. The expected life of the warrants is assumed to be equivalent to their remaining contractual term. The dividend rate is based on the historical rate, which the Company anticipates to remain at zero.

The Monte Carlo model is used for the Class A warrants and the December 2010 warrants to appropriately value the potential future exercise price adjustments triggered by the anti-dilution provisions as well as the value of the put feature of the December 2010 warrants. These both require Level 3 inputs which are based on the Company's estimates of the probability and timing of potential future financings and fundamental transactions. The other assumptions used by the Company are summarized in the following tables for warrants that were outstanding as of any of the balance sheet dates presented on our consolidated balance sheets:

| October 2007 Warrants           | December 31, 2011 | December 31, 2012 |      |
|---------------------------------|-------------------|-------------------|------|
| Closing stock price             | \$ 1.8            | 2 \$ 1.2          | 26   |
| Expected dividend rate          |                   | 0%                | 0%   |
| Expected stock price volatility | 93.               | 5% 44             | 4.0% |
| Risk-free interest rate         | 0.1               | 1% 0              | ).1% |
| Expected life (years)           | 1.2               | 5 0.2             | 25   |
| January 2010 Class A Warrants   | December 31, 2011 | December 31, 2012 |      |
| Closing stock price             | \$ 1.8            | 2 \$ 1.2          | 26   |
| Expected dividend rate          |                   | 0%                | 0%   |
| Expected stock price volatility | 86.               | 1% 74             | 4.0% |
| Risk-free interest rate         | 0.                | 5% 0              | ).4% |
| Expected life (years)           | 3.5               | 0 2.5             | 50   |
| December 2010 Warrants          | December 31, 2011 | December 31, 2012 |      |
| Closing stock price             | \$ 1.8            | 2 \$ 1.2          | 26   |
| Expected dividend rate          |                   | 0%                | 0%   |
| Expected stock price volatility | 83.               | 6% 70             | ).1% |
| Risk-free interest rate         | 0.                | 6% 0              | ).4% |
| Expected life (years)           | 3.9               | 6 2.9             | 96   |

The following table summarizes the change in the estimated fair value of the Company's warrant liabilities (in thousands):

| Warrant Liabilities                 |              |
|-------------------------------------|--------------|
| Balance at December 31, 2010        | \$<br>25,954 |
| Decrease in fair value              | (9,329)      |
| Balance at December 31, 2011        | 16,625       |
| Warrants exchanged for common stock | (10,382)     |
| Decrease in fair value              | (4,248)      |
| Balance at December 31, 2012        | \$<br>1,995  |
|                                     | <br>         |

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#### 6. Income Taxes

A reconciliation of income taxes computed using the federal statutory rate to the taxes reported in our consolidated statements of operations is as follows *(in thousands)*:

|  | Year E | nded June 30,<br>2010 | Six Months<br>Ended<br>December 31,<br>2010 | ]  | Year Ended<br>December 31,<br>2011 | Year Ended<br>ecember 31,<br>2012 |
|--|--------|-----------------------|---|----|------------------------------------|-----------------------------------|
| Loss before income taxes                 | \$     | 14,558                | \$<br>19,088                                | \$ | 19,668                             | \$<br>29,474                      |
| Federal statutory rate                   |        | 34%                   | 34%   |    | 34%                                | 34%                               |
| Taxes computed at federal statutory rate |        | (4,950)               | (6,490)                                     |    | (6,687)                            | (10,021)                          |
| Loss attributable to foreign operations  |        | 116                   | _   |    | _                                  | —                                 |
| Warrants                                 |        | (1,076)               | 2,550                                       |    | (3,172)                            | 1,445                             |
| Nondeductible stock compensation         |        | —                     | —   |    | 1,559                              | 872                               |
| Michigan business tax repeal             |        | —                     |   |    | 1,214                              | —                                 |
| Michigan NOL benefit                     |        | —                     | _   |    |                                    | (1,334)                           |
| Net operating loss expirations           |        | —                     |   |    |                                    | 612                               |
| Other                                    |        | 136                   | 397   |    | 336                                | 300                               |
| Change in valuation allowance            |        | 5,776                 | 3,543                                       |    | 6,750                              | 8,126                             |
| Reported income taxes                    | \$     |                       | \$<br>                                      | \$ |                                    | \$<br>                            |

Deferred tax assets consist of the following (in thousands):

|   | <br>ear Ended<br>cember 31,<br>2011 | Year Ended<br>December 31,<br>2012 |
|---|-------------------------------------|------------------------------------|
| Net operating loss carryforwards              | \$<br>53,224                        | \$<br>61,174                       |
| Research and development credit carryforwards | 1,600                               | 1,600                              |
| Employee benefits and stock compensation      | 1,167                               | 1,314                              |
| Other, net                                    | 364                                 | 393                                |
| Total deferred tax assets                     | <br>56,355                          | <br>64,481                         |
| Valuation allowance                           | (56,355)                            | (64,481)                           |
| Net deferred tax assets                       | \$<br>_                             | \$<br>                             |

As of December 31, 2012, the Company's U.S. federal and state tax net operating loss and tax credit carryforwards are \$176,001,000, \$22,229,000 and \$1,600,000, respectively. These net operating loss carryforwards will expire between 2013 and 2032. The tax credit carryforwards will expire between 2022 and 2030. Effective January 1, 2012, the Michigan Business Tax (MBT) has been repealed. As a result of this repeal, the MBT net operating loss of \$65,520,000 will not carry forward and has been derecognized in 2011.

The Company's net operating losses are subject to the limitations imposed under section 382 of the Internal Revenue Code. These limits are triggered when a change in control occurs, and are computed based upon several variable factors including the share price of the Company's common stock on the date of the change in control. A change in control is generally defined as a cumulative change of 50% or more in the ownership positions of certain stockholders during a rolling three year period. Based on common stock issuances over the Company's history and the likelihood of additional issuances, it is possible that the use of the Company's existing net operating losses will be limited. If a limitation occurs, it is likely that a significant portion of our net operating losses will expire unutilized regardless of the amount of future profitability.

Due to the historical losses incurred by the Company, a full valuation allowance for deferred tax assets, including the deferred tax assets for the aforementioned net operating losses and credits, has been provided since they are not more likely than not to be realized. If the Company achieves profitability, these deferred tax assets may be available to offset future income taxes. The increase in the valuation allowance was \$6,750,000 and \$8,126,000 for the years ended December 31, 2011 and 2012, respectively.

The Company assesses uncertain tax positions in accordance with the provisions of Financial Accounting Standards Board Accounting Standards Codification (ASC) 740-10-5, "Accounting for Uncertain Tax Positions." This pronouncement prescribes a recognition threshold and measurement methodology for recording within the financial statements uncertain tax positions taken, or expected to be taken, in the Company's income tax returns. As of December 31, 2011 and 2012, the Company had an unrecognized tax benefit of \$2,100,000. There were no increases, decreases, or settlements related to uncertain tax positions in 2011 or 2012. Income tax expense would be reduced by zero if the gross unrecognized tax benefits were recognized due to the valuation allowance. It is not anticipated that the unrecognized tax benefits will significantly increase or decrease within the next twelve months.

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The Company files U.S. federal and Michigan income tax returns. Due to the Company's net operating loss carryforwards, Federal income tax returns from incorporation are still subject to examination. Michigan tax returns for the year ended December 31, 2011 and forward are subject to examination.

#### 7. Licenses, Royalties and Collaborative Agreements and Commitments

*University of Michigan* — In August 1989, the Company entered into a research agreement with the University of Michigan (the University). In March 1992, and as provided for under the research agreement, the Company also entered into a license agreement for the technology developed under the research agreement. The license agreement, as amended, provides for a royalty to be paid to the University equal to 2% of net sales of products containing the licensed technology sold by the Company. Such royalties have been nominal since Inception. This license agreement will expire in 2014.

*Corning Incorporated* — In December 2002, the Company entered into an agreement with Corning Incorporated (Corning) that granted Corning an exclusive sublicense relating to the Company's cell transfection technology. Under the terms of the agreement, the Company retains exclusive rights to the applications of the technologies involving cells for therapeutic applications. In addition, the agreement provides for future royalty payments on net sales of licensed products sold under the sublicense amounting to 5% of such sales up to \$50,000,000. However, the Company does not expect to receive material revenue from this source for several years, if ever.

*RealBio Technologies* — In May 2009, the Company entered into an agreement with RealBio Technologies, Inc. (RealBio) that granted RealBio an exclusive license to utilize our technology outside of the Company's core area of focus - human regenerative medicine. In return for this license, the Company received a minority equity interest in RealBio, which was not material as of December 31, 2012.

*Manufacture, Supply and Other Agreements* — The Company has entered into various agreements relating to the manufacture of its products and the supply of certain components. If the manufacturing or supply agreements expire or are otherwise terminated, the Company may not be able to identify and obtain ancillary materials that are necessary to develop its product and such expiration and termination could have a material effect on the Company's business.

#### 8. Commitments, Contingencies and Debt

During 2007, the Company entered into an operating lease with Domino's Farms Office Park, LLC, for approximately 30,000 square feet of office and lab space. This lease has a noncancelable term of six years, which began on May 14, 2007, and has two five-year market value renewals. The Company has elected to renew the lease at a reduced rate with a 5 year term commencing on May 14, 2013. The Company now has a right to terminate on the third anniversary of the renewal, and has two five-year market value renewal options. The Company's leased facility includes a Class 100,000 modular manufacturing clean room, laboratories and office space. The lease also provides the Company the right of first refusal on certain additional space.

As of December 31, 2012, future minimum payments related to our operating and capital leases and long-term debt are as follows (in thousands):

Payments Due by Period

| Contractual Obligations | Total       | 2013        | 2014      | 2015      | 2016      | ore then<br>5 Years |
|-------------------------|-------------|-------------|-----------|-----------|-----------|---------------------|
| Operating leases        | \$<br>3,450 | \$<br>1,055 | \$<br>992 | \$<br>992 | \$<br>359 | \$<br>52            |
| Capital leases          | 40          | 34          | 6         | —         | _         | —                   |
| Total                   | \$<br>3,490 | \$<br>1,089 | \$<br>998 | \$<br>992 | \$<br>359 | \$<br>52            |

Rent expense for the year ended June 30, 2010, six month transition period ended December 31, 2010, years ended December 31, 2011 and 2012, and for the period from March 24, 1989 (Inception) to December 31, 2012, was \$1,175,000, \$548,000, \$1,099,000, \$1,127,000 and \$13,219,000 respectively.

#### 9. Employee Savings Plan

The Company has a 401(k) savings plan that allows participating employees to contribute a portion of their salary, subject to annual limits and minimum qualifications. The Board may, at its sole discretion, approve Company matching contributions to the plan. The Company made contributions of \$200,000 for the year ended June 30, 2010, \$88,000 for the six month transition period ended December 31, 2010, \$159,000 and \$202,000 for the years ended December 31, 2011 and 2012, respectively, and \$1,906,000 for the period from March 24, 1989 (Inception) to December 31, 2012.

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#### **10. Preferred Stock**

#### Shareholder Rights Plan - Series A Junior Participating Cumulative Preferred Stock

On August 11, 2011, the Board of Directors of the Company adopted a Shareholder Rights Plan, as set forth in the Shareholder Rights Agreement between the Company and the rights agent, the purpose of which is, among other things, to enhance the Board's ability to protect shareholder interests and to ensure that shareholders receive fair treatment in the event any coercive takeover attempt of the Company is made in the future. The Shareholder Rights Plan could make it more difficult for a third party to acquire, or could discourage a third party from acquiring, the Company or a large block of the Company's common stock. The following summary description of the Shareholder Rights Plan should be read in conjunction with the Company's Shareholder Rights Plan, which was filed with the Securities and Exchange Commission as an exhibit to a Registration Statement on Form 8-A on August 12, 2011.

In connection with the adoption of the Shareholder Rights Plan, the Board of Directors of the Company declared a dividend distribution of one preferred stock purchase right (a "Right") for each outstanding share of common stock to stockholders of record as of the close of business on August 15, 2011. In addition, one Right will automatically attach to each share of common stock issued between August 15, 2011 and the distribution date. The Rights currently are not exercisable and are attached to and trade with the outstanding shares of common stock. Each Right entitles the registered holder of common stock to purchase from the Company a unit consisting of one ten-thousandth of a share (a "Unit") of Series A Junior Participating Preferred Stock, no par value per share, at a cash exercise prices of \$30.00 per Unit. There are currently 45,000 shares authorized and zero issued and outstanding. Under the Shareholder Rights Plan, the Rights become exercisable if a person or group becomes an "acquiring person" by acquiring 15% or more of the outstanding shares of common stock or if a person or group commences a tender offer that would result in that person owning 15% or more of the common stock. If a person or group becomes an "acquiring person and its affiliates, associates and transferees) would be entitled to purchase, at the then-current exercise price, such number of shares of the Company's preferred stock which are equivalent to shares of common stock having a value of twice the exercise price of the Right. If the Company is acquired in a merger or other business combination transaction after any such event, each holder of a Right would then be entitled to purchase, at the then-current exercise price of the Right.

The Rights may be redeemed in whole, but not in part, at a price of \$0.001 per Right (payable in cash, common stock or other consideration deemed appropriate by the Board of Directors) by the Board of Directors only until the earlier of (i) the time at which any person becomes an "acquiring person" or (ii) the expiration date of the Rights Agreement. Immediately upon the action of the Board of Directors ordering redemption of the Rights, the Right will terminate and thereafter the only right of the holders of Rights will be to receive the redemption price. The Rights will expire at the close of business on August 15, 2021, unless previously redeemed or exchanged by the Company as described above.

#### Series B Convertible Preferred Stock

On March 9, 2012, the Company completed the sale of 12,308 shares of Series B-1 Non-Voting Convertible Preferred Stock (Series B-1 Preferred Stock) at an offering price of \$3,250 per share. The Company received \$37,620,000 in net proceeds from the sale of the shares of Series B-1 Preferred Stock, after offering expenses. In addition to the Series B-1 Preferred Stock, which was issued at the closing, the Company also authorized Series B-2 Voting Convertible Preferred Stock (Series B-2 Preferred Stock). The Series B-1 Preferred Stock and Series B-2 Preferred Stock collectively are referred to as the Series B Preferred Stock. The Series B-1 Preferred Stock is not entitled to vote on matters on which the common shareholders are generally entitled to vote. The Series B-2 Preferred Stock are entitled to vote with the holders of the common stock as a single class, with each share of Series B-2 Preferred Stock having the number of votes equal to the number of shares of common stock issuable upon conversion of such Series B-2 Preferred Stock. On May 3, 2012, shareholder approval was obtained in accordance with Nasdaq Marketplace Rule 5635(b), which allowed the holder of Series B-1 Preferred Stock to exchange all of the then outstanding shares for shares of Series B-2 Preferred Stock on a one-for-one basis. The Series B Preferred Stock will, with respect to dividend rights and rights on liquidation, winding-up and dissolution, rank on parity with any other class or series of the Company capital stock that the Company may issue in the future which is designated as being on parity with the Series B Preferred Stock, and rank senior to our common stock and Series A preferred stock. The Series B Preferred Stock is convertible, at the option of the holder thereof at any time after the five year anniversary of the closing of the offering, into shares of common stock at a conversion price of \$3.25 per share of common stock. At any time after the five year anniversary of issuance, the Company may elect to convert any or all outstanding shares of Series B Preferred Stock into shares of our common stock, subject to certain limitations. Dividends on the Series B Preferred Stock will be cumulative and compound daily, at a rate of 11.5% per annum, payable upon conversion, liquidation, redemption or other similar events, and payable in cash or Series B-1 Preferred Stock until the five year anniversary of issuance. Following the five year anniversary of issuance and until the earlier of the tenth anniversary of the issuance and the date no Series B Preferred Stock remain outstanding, dividends will accrue at a rate of 8% per annum and will be payable in cash or Series B-1 Preferred Stock, at our option. Unless prohibited by Michigan law governing distributions to shareholders, the Series B-1 Preferred Stock shall be redeemable at the option of holder of the Series B-1 Preferred Stock commencing at any time after the five year anniversary of issuance, liquidation, winding up, dissolution or other similar events, subject to certain terms and limitations.

The Series B Preferred Stock does not, in its entirety, require liability classification and has been evaluated for embedded features to determine if those features require bifurcation and separate classification as derivative liabilities. The Series B Preferred Stock host contract was evaluated for equity or mezzanine classification based upon the nature of the redemption and conversion features. Generally, any feature that could require cash redemption for matters not within the Company's control, irrespective of probability of the event occurring, requires classification outside of shareholders' equity. The Series B Preferred Stock has been recorded as mezzanine of the Condensed Consolidated Balance Sheets and will be accreted to its redemption value through charges to shareholders' deficit using the effective interest method.

The carrying value of the Series B-1 Preferred Stock presented as mezzanine in the consolidated financial statements is \$3,923,000, as of December 31, 2012. As of December 31, 2012, there are no outstanding shares of Series B-1 Preferred Stock; however, as the Series B-1 Preferred Stock dividends can be redeemed for cash, the Company is required to accrete the carrying value of the Series B-1 Preferred Stock to its redemption value of \$31,102,000 by charges to accumulated deficit using the effective interest method. Such accretion for the year ended December 31, 2012 amounted to \$3,923,000. The redemption value is determined by the greater of the conversion price of the Series B-1 Preferred Stock or the common stock price, multiplied by the total accumulated dividends at the five year anniversary of issuance.

#### 11. Quarterly Financial Data (Unaudited)

The following is a summary of the Company's quarterly consolidated results of operations (unaudited) for the year ended December 31, 2012 and 2011. The sum of quarterly net loss per share, basic and diluted, may not equal total net loss per share, basic and diluted, due to variation in shares outstanding *(in thousands, except for per share data)*.

| Year Ended December 31, 2012                     | First<br>Quarter | Second<br>Quarter | Third<br>Quarter | Fourth<br>Quarter | ]  | Fiscal Year |
|--|------------------|-------------------|------------------|-------------------|----|-------------|
| Revenues   | \$<br>2          | \$<br>_           | \$<br>_          | \$<br>19          | \$ | 21          |
| Loss from operations                             | (8,558)          | (9,300)           | (8,285)          | (7,617)           |    | (33,760)    |
| Net loss attributable to common shareholders     | (9,744)          | (8,566)           | (7,252)          | (7,905)           |    | (33,467)    |
| Net loss per common share attributable to common |                  |                   |                  |                   |    |             |
| shareholders                                     | \$<br>(0.25)     | \$<br>(0.22)      | \$<br>(0.17)     | \$<br>(0.18)      | \$ | (0.81)      |

Net loss includes the (increase) / decrease in fair value of warrants of \$(900,000), \$1,948,000, \$2,241,000, \$959,000 and \$4,248,000 for the first quarter, second quarter, third quarter, fourth quarter and fiscal year, respectively.

| Year Ended December 31, 2011                                  | First<br>Quarter | Second<br>Quarter | Third<br>Quarter | Fourth<br>Quarter | 1  | Fiscal Year |
|---|------------------|-------------------|------------------|-------------------|----|-------------|
| Revenues  | \$<br>9          | \$<br>_           | \$<br>9          | \$<br>            | \$ | 18          |
| Loss from operations  | (6,260)          | (7,507)           | (7,439)          | (7,834)           |    | (29,040)    |
| Net loss attributable to common shareholders                  | (4,988)          | (9,957)           | (1,934)          | (2,789)           |    | (19,668)    |
| Net loss per common share attributable to common shareholders | \$<br>(0.13)     | \$<br>(0.26)      | \$<br>(0.05)     | \$<br>(0.07)      | \$ | (0.51)      |

Net loss includes the (increase) / decrease in fair value of warrants of \$1,254,000, (\$2,465,000), \$5,496,000, \$5,044,000 and \$9,329,000 for the first quarter, second quarter, third quarter, fourth quarter and fiscal year, respectively.

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## Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

There are none to report.

## Item 9A. Controls and Procedures

## **Evaluation of Disclosure Controls and Procedures**

The Company conducted an evaluation, under the supervision and with the participation of management, including the Company's Chief Executive Officer and Chief Accounting Officer ("CEO and CAO") of the effectiveness of the design and operation of the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"). Based on that evaluation, the CEO and CAO have concluded that the Company's disclosure controls and procedures were effective as of December 31, 2012, in ensuring that information related to the Company required to be disclosed in reports the Company files or submits under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (ii) accumulated and communicated to the Company's management, including the CEO and CAO, to allow timely decisions regarding required disclosure.

## Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Our internal control over financial reporting is a process designed under the supervision of our CEO and CAO to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external purposes in accordance with generally accepted accounting principles. Management evaluated the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control — Integrated Framework*. Management, under the supervision and with the participation of the CEO and CAO, assessed the effectiveness of our internal control over financial reporting as of December 31, 2012 and concluded that it was effective. Our independent registered public accounting firm, PricewaterhouseCoopers LLP, has audited the effectiveness of our internal control over financial reporting as of December 31, 2012, and has expressed an unqualified opinion thereon in their report which appears under Item 8.

#### Changes in Internal Control over Financial Reporting

During our fourth quarter of fiscal 2012, there were no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

#### Item 9B. Other Information

Not applicable.

#### PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K, and is incorporated by reference to our definitive Proxy Statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A in connection with our 2013 Annual Meeting of Shareholders scheduled for May 2, 2013.

#### Item 10. Directors, Executive Officers and Corporate Governance

The information relating to our directors is incorporated by reference to the Proxy Statement as set forth under the caption "Election of Directors." Information relating to our executive officers is set forth in Part I of this Report under the caption "Executive Officers."

Information with respect to delinquent filings pursuant to Item 405 of Regulation S-K is incorporated by reference to the Proxy Statement as set forth under the caption "Section 16(a) Beneficial Ownership Reporting Compliance."

#### Item 11. Executive Compensation

The information relating to executive compensation is incorporated by reference to the Proxy Statement under the caption "Executive Compensation and Related Information."

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#### Item 12. Security Ownership of Certain Beneficial Owners and Management, and Related Shareholder Matters

The information relating to ownership of our equity securities by certain beneficial owners and management is incorporated by reference to the Proxy Statement as set forth under the caption "Stock Ownership of Certain Beneficial Owners and Management."

#### Item 13. Certain Relationships and Related Transactions, and Director Independence

The information relating to certain relationships and related person transactions is incorporated by reference to the Proxy Statement under the caption "Certain Relationships and Related Party Transactions."

#### Item 14. Principal Accountant Fees and Services

The information relating to principal accountant fees and services is incorporated by reference to the Proxy Statement under the caption "Ratification of Appointment of Independent Registered Public Accounting Firm."

#### PART IV

#### Item 15. Exhibits and Financial Statement Schedules

(a) The following documents are filed as part of this Annual Report on Form 10-K:

- 1. Financial Statements (see Item 8).
- 2. All information is included in the Financial Statements or Notes thereto.
- 3. Exhibits:

See Exhibit Index.

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#### SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

# AASTROM BIOSCIENCES, INC.

/s/ DOMINICK C. COLANGELO Dominick C. Colangelo President and Chief Executive Officer (Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed on behalf of the registrant on March 18, 2013 by the following persons in the capacities indicated.

| Signature  | Title  |  |  |  |  |
|--|--|--|--|--|--|
| /s/ DOMINICK C. COLANGELO<br>Dominick C. Colangelo           | President and Chief Executive Officer, Director<br>(Principal Executive Officer)                                   |  |  |  |  |
| /s/ BRIAN D. GIBSON<br>Brian D. Gibson                       | Vice President of Finance, Chief Accounting Officer a<br>Treasurer<br>(Principal Financial and Accounting Officer) |  |  |  |  |
| /s/ ROBERT L. ZERBE, M.D.<br>Robert L. Zerbe, M.D.           | Chairman of the Board of Directors   |  |  |  |  |
| /s/ NELSON M. SIMS<br>Nelson M. Sims                         | Director   |  |  |  |  |
| /s/ RONALD M. CRESSWELL, PH.D.<br>Ronald M. Cresswell, Ph.D. | Director   |  |  |  |  |
| /s/ ALAN L. RUBINO<br>Alan L. Rubino                         | Director   |  |  |  |  |
| /s/ TIM M. MAYLEBEN<br>Tim M. Mayleben                       | Director   |  |  |  |  |
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## EXHIBIT INDEX

| Exhibit No. | Description  |
|-------------|--|
| 3.1         | Restated Articles of Incorporation of Aastrom, filed as Exhibit 4.1 to Aastrom's Current Report on Form 8-K filed on December 17, 2009, incorporated herein by reference.  |
| 3.2         | Certificate of Amendment to Restated Articles of Incorporation of Aastrom dated February 9, 2010, filed as Exhibit 3.2 to Aastrom's Post Effective Amendment No. 1 to Form S-1 filed on March 31, 2010, incorporated herein by reference.  |
| 3.3         | Certificate of Amendment to Restated Articles of Incorporation of Aastrom dated March 22, 2011, attached as Exhibit 3.1 to Aastrom's Current Report on Form 8-K filed on March 25, 2011, incorporated herein by reference.   |
| 3.4         | Certificate of Designation, Preferences and Rights, of Aastrom Biosciences, Inc. classifying and designating the Series A Junior<br>Participating Cumulative Preferred Stock, attached as Exhibit 3.1 to the Company's Current Report on Form 8-A filed on August 12,<br>2011, incorporated herein by reference.   |
| 3.5         | Certificate of Designations, Preferences and Rights, of Aastrom Biosciences, Inc. classifying and designating the Series B Non-Voting<br>Convertible Preferred Stock and the Series B-2 Voting Convertible Preferred Stock, attached as Exhibit 3.1 to the Company's Current<br>Report on Form 8-K filed on March 9, 2012, incorporated herein by reference. |
| 3.6         | Bylaws, as amended, attached as Exhibit 3.1 to Aastrom's Current Report on Form 8-K filed on November 12, 2010, incorporated herein by reference.  |
| 4.1         | Form of Senior Indenture for Senior Debt Securities, filed as Exhibit 4.1 to the Company's Registration Statement on Form S-3 filed on June 16, 2011 and incorporated herein by reference.   |
| 4.2         | Form of Indenture for Subordinated Debt Securities, filed as Exhibit 4.3 to the Company's Registration Statement on Form S-3 filed on June 16, 2011 and incorporated herein by reference.  |

| 4.3    | Shareholder Rights Agreement, dated as of August 11, 2011, between Aastrom Biosciences, Inc. and Continental Stock Transfer & Trust Company, as Rights Agent, attached as Exhibit 4.3 to the Company's Current Report on Form 8-A filed on August 12, 2011, incorporated herein by reference.                                   |
|--------|---|
| 4.4    | Amendment to Shareholder Rights Agreement, dated as of March 9, 2012, between Aastrom Biosciences, Inc. and Continental Stock<br>Transfer & Trust Company, as Rights Agent, attached as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on March 9,<br>2012, incorporated herein by reference.                    |
| 10.1 # | Form of Indemnification Agreement, attached as Exhibit 10.1 to Aastrom's Registration Statement on Form S-1 (No. 333-15415), filed on November 1, 1996, incorporated herein by reference.   |
| 10.2 # | Amended and Restated 1992 Incentive and Non-Qualified Stock Option Plan and forms of agreements thereunder, attached as Exhibit 10.5 to Aastrom's Registration Statement on Form S-1 (No. 333-15415), filed on November 1, 1996, incorporated herein by reference.  |
| 10.3 # | Form of Employment Agreement, attached as Exhibit 10.8 to Aastrom's Registration Statement on Form S-1 (No. 333-15415), filed on November 1, 1996, incorporated herein by reference.  |
| 10.4   | License Agreement, dated March 13, 1992, between Aastrom and the University of Michigan and amendments thereto dated March 13, 1992, October 8, 1993 and June 21, 1995, attached as Exhibit 10.17 to Aastrom's Registration Statement on Form S-1 (No. 333-15415), filed on November 1, 1996, incorporated herein by reference. |
| 10.5 # | Aastrom Biosciences 2001 Stock Option Plan, attached as Exhibit 10.72 to Aastrom's Annual Report on Form 10-K for the year ended June 30, 2002, incorporated herein by reference.   |
| 10.6 # | 2004 Equity Incentive Plan, attached as Exhibit 10.82 to Amendment No. 1 to Aastrom's Quarterly Report on Form 10-Q/A for the quarter ended September 30, 2004, incorporated herein by reference.   |
| 10.7 # | Form of Option and Restricted Stock Award Agreements for Grants under 2004 Equity Incentive Plan, attached as Exhibit 10.84 to Aastrom's Annual Report on Form 10-K for the year ended June 30, 2005, incorporated herein by reference.   |

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| 10.8    | Amendment dated December 5, 2002 to License Agreement with the University of Michigan, attached as Exhibit 10.87 to Aastrom's Annual Report on Form 10-K for the year ended June 30, 2005, incorporated herein by reference.  |
|---------|---|
| 10.9 #  | 2004 Equity Incentive Plan, as amended, attached as Exhibit 99.1 to Aastrom's Current Report on Form 8-K filed on November 8, 2006, incorporated herein by reference.   |
| 10.10 # | Forms of Grant Notice and Stock Option Agreement for Grants under 2004 Equity Incentive Plan, as amended, attached as Exhibit 99.2 to Aastrom's Current Report on Form 8-K filed on November 8, 2006, incorporated herein by reference.   |
| 10.11   | Form of Purchase Agreement, attached as Exhibit 10.3 to Aastrom's Current Report on Form 8-K filed on October 16, 2007, incorporated herein by reference.   |
| 10.12   | Form of Warrant, attached as Exhibit 10.4 to Aastrom's Current Report on Form 8-K filed on October 16, 2007, incorporated herein by reference.  |
| 10.13   | Standard Lease between Aastrom and Domino's Farms Office Park, L.L.C. dated January 31, 2007., attached as Exhibit 10.96 to Amendment No. 1 to Aastrom's Annual Report on Form 10-K for the year ended June 30, 2007, incorporated herein by reference.                           |
| 10.14 # | 2009 Omnibus Incentive Plan, attached as Appendix II to Aastrom's Proxy Statement filed on October 9, 2009, incorporated herein by reference.   |
| 10.15   | Class A Warrant Agreement, dated as of January 21, 2010, by and between the Registrant and Continental Stock Transfer & Trust<br>Company (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on<br>January 27, 2010). |
| 10.16   | Class B Warrant Agreement, dated as of January 21, 2010, by and between the Registrant and Continental Stock Transfer & Trust<br>Company (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on<br>January 27, 2010). |
| 10.17   | Underwriting Agreement, dated as of January 15, 2010, and between the Registrant and Oppenheimer & Co. Inc. (incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed with the SEC on January 15, 2010).                                 |
| 10.18 # | Form of indemnification agreement entered into between the Company and each of its directors, attached as Exhibit 10.1 to Aastrom's Current Report on Form 8-K filed on August 31, 2010, incorporated herein by reference.  |
| 10.19   | Amended Code of Business Conduct and Ethics, attached as Exhibit 14.1 to Aastrom's Current Report on Form 8-K filed on August 31, 2010, incorporated herein by reference.   |
| 10.20*  | Contract Manufacturing and Supply Agreement, dated as of November 1, 2010, by and between Vention Medical (formerly ATEK Medical, LLC) and the Company.   |

| 10.21  | Warrant agreement, dated as of December 15, 2010, by and between the Registrant and Continental Stock Transfer & Trust Company (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on December 16, 2010).   |
|--------|---|
| 10.22  | Underwriting Agreement, dated as of December 10, 2010, and between the Registrant and Stifel, Nicolaus & Company, Incorporated, Needham & Company, LLC and Roth Capital Partners (incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed with the SEC on December 10, 2010). |
| 10.23# | Amendment to the 2009 Omnibus Incentive Plan, dated March 21, 2011 (incorporated herein by reference to Exhibit 10.4 to the Company's current Report on Form 8-K, filed on March 25, 2011).   |
| 10.24# | Employment Agreement with Ronnda L. Bartel, PhD, dated March 22, 2011 (incorporated herein by reference to Exhibit 10.1 to the Company's current Report on Form 8-K, filed on March 25, 2011).  |

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### Employment Agreement with Sharon Watling, PharmD, dated March 22, 2011 (incorporated herein by reference to Exhibit 10.2 to the 10.25# Company's current Report on Form 8-K, filed on March 25, 2011). 10.26# Senior Executive Incentive Bonus Plan (incorporated herein by reference to Exhibit 10.3 to the Company's current Report on Form 8-K, filed on March 25, 2011). 10.27 At Market Issuance Sales Agreement, dated June 16, 2011, by and among Aastrom Biosciences, Inc. and McNicoll, Lewis & Vlak LLC (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on June 16, 2011). 10.28 Master Services Agreement by and between the Company and CRO, made and entered into as of September 23, 2011 (the "Master Services Agreement"). 10.29 Project Addendum to the Master Services Agreement, dated as of November 16, 2011 (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC November 22, 2011). 10.30 Registration Rights Agreement, dated March 9, 2012, between Aastrom Biosciences, Inc. and Eastern Capital Limited, attached as Exhibit 10.2 to Aastrom's Current Report on Form 8-K filed on March 9, 2012, incorporated herein by reference. 10.31 Securities Purchase Agreement, dated as of March 9, 2012, by and between Aastrom Biosciences, Inc. and Eastern Capital Limited (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on March 9, 2012). 10.32# Employment Offer Letter, dated as of August 20, 2012, by and between Aastrom Biosciences, Inc. and Daniel R. Orlando (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on December 12, 2012). 10.33# Employment Agreement, dated as of October 26, 2012, by and between Aastrom Biosciences, Inc. and Brian Gibson (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on October 26, 2012). 10.34# Amendment to the 2009 Omnibus Incentive Plan, dated May 3, 2012 (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed on August 7, 2012). 10.35 Form of Warrant Exchange Agreement, dated June 27, 2012 (incorporated herein by reference to Exhibit 10.1 to the Company's Report on Form 8-K, filed on June 27, 2012). 10.36# Executive Resignation Agreement, executed on December 12, 2012 and effective December 14, 2012, by and between Aastrom Biosciences, Inc. and Tim M. Mayleben. 10.37# Executive Employment Agreement, executed March 4, 2013 and effective March 1, 2013, by and between Aastrom Biosciences, Inc. and Dominick C. Colangelo (incorporated herein by reference to Exhibit 10.1 to the Company's Report on Form 8-K, filed on March 9, 2013). 21 Subsidiaries of Registrant. 23.1 Consent of Independent Registered Public Accounting Firm. 31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. 31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

- 32.1 Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 101.INS XBRL Instance Document

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- 101.SCH XBRL Taxonomy Extension Schema Document
- 101.CAL XBRL Taxonomy Extension Calculation Linkbase Document

101.LAB XBRL Taxonomy Extension Label Linkbase Document

101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

101.DEF XBRL Taxonomy Extension Definition Linkbase Document

# Management contract or compensatory plan or arrangement covering executive officers or directors of Aastrom.

\* Confidential treatment status has been requested as to certain portions thereto, which portions are omitted and filed with Securities and Exchange Commission.

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| GLOSSARY                                    |   |  |  |
|---|---|--|--|
| TERM  | DEFINITION  |  |  |
| Adverse Event                               | Any adverse change in health or "side-effect" that occurs in a person participating in a clinical trial, from the time they consent to joining the trial until a pre-specified period of time after their treatment has been completed.   |  |  |
| Autologous (Patient Specific)               | Originating from the patient receiving treatment. (Aastrom uses only autologous cells)  |  |  |
| BLA — Biologics License Application         | An application containing product safety, efficacy and manufacturing information required by the FDA to market biologics products in the U.S.   |  |  |
| CLI — Critical Limb Ischemia                | A vascular disease characterized by insufficient blood flow in the lower extremities that causes severe pain, tissue loss or both.  |  |  |
| CMC — Chemistry, Manufacturing, and Control | The composition, manufacture, and control of the drug substance and the drug product. It is information on the identification, quality, purity, and strength of the investigational product.  |  |  |
| Controlled Clinical Trial                   | A clinical study that compares patients receiving a specific treatment to patients receiving an alternate treatment for the condition of interest. The alternate treatment may be another active treatment, standard of care for the condition and/or a placebo (inactive) treatment.   |  |  |
| DCM — Dilated Cardiomyopathy                | A chronic cardiac disease where expansion of the patient's heart reduces the pumping function to a point that the normal circulation of blood cannot be maintained.   |  |  |
| Double-Blind Clinical Trial                 | Clinical trials in which neither the patient nor the physician know if the patient received the experimental treatment or a control/placebo.  |  |  |
| FDA — Food & Drug Administration            | The U.S. FDA ensures that medicines, medical devices, and radiation-emitting consumer products are safe and effective. Authorized by Congress to enforce the Federal Food, Drug, and Cosmetic Act and several other public health laws, the agency monitors the manufacture, import, transport, storage, and sale of \$1 trillion worth of goods annually.        |  |  |
| GMP — Good Manufacturing Practice           | GMP regulations require that manufacturers, processors, and packagers of drugs, medical devices, some food, and blood take proactive steps to ensure that their products are safe, pure, and effective. GMP regulations require a quality approach to manufacturing, enabling companies to minimize or eliminate instances of contamination, mix-ups, and errors. |  |  |
| Hematopoietic Stem Cells                    | Stem cells that give rise to all the blood cell types including myeloid (monocytes and macrophages, neutrophils, basophils, eosinophils, erythrocytes, megakaryocytes/platelets, dendritic cells), and lymphoid lineages (T-cells, B-cells, NK-cells).  |  |  |
| IMPACT-DCM                                  | Aastrom's U.S. Phase 2 dilated cardiomyopathy clinical trial.   |  |  |
| IND — Investigational New Drug              | An application submitted to the FDA for a new drug or biologic that, if allowed, will be used in a clinical trial.  |  |  |
| Ischemia                                    | A shortage or inadequate flow of blood to a body part (commonly an organ or tissue) caused<br>by a constriction or obstruction of the blood vessels supplying it.   |  |  |
| LVEF — Left Ventricular Ejection Fraction   | The fraction of blood pumped out of the left ventricle with each heart beat.  |  |  |
| Mesenchymal stromal cells                   | Connective tissue cells that, in the case of bone marrow derived MSC, function to support blood forming cells and secrete anti-inflammatory factors.  |  |  |
| M2 anti-inflammatory macrophages            | Specialized blood cells that remove damaged tissue and bacteria and secrete anti-inflammatory factors.  |  |  |
| Open-label Clinical Trial                   | A trial in which both the treating physician and the patient know whether they are receiving the experimental treatment or control/placebo treatment.   |  |  |

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| TERM                    | DEFINITION  |
|-------------------------|---|
| Orphan Drug Designation | "Orphan drug" refers to a drug or biologic that is intended for use in the treatment of a rare  |
|                         | disease or condition. Orphan drug designation from the U.S. Food and Drug Association           |
|                         | (FDA) qualifies the sponsor to receive certain benefits from the Government in exchange for     |
|                         | developing the drug for a rare disease or condition. The drug must then go through the FDA      |
|                         | marketing approval process like any other drug or biologic which evaluates for safety and       |
|                         | efficacy. Usually a sponsor receives a quicker review time and lower application fees for an    |
|                         | orphan product.   |
| Phase 1 Clinical Trial  | A Phase 1 trial represents an initial study in a small group of patients to test for safety and |
|                         | other relevant factors.   |
| Phase 2 Clinical Trial  | A Phase 2 trial represents a study in a moderate number of patients to assess the safety and    |

|                            | efficacy of a product.   |
|----------------------------|--|
| Phase 2b Clinical Trial    | A Phase 2b trial is a moderately-sized Phase 2 trial that is more specifically designed assess the     |
|                            | efficacy of a product than a Phase 2a trial.   |
| Phase 3 Clinical Trial     | Phase 3 studies are initiated to establish safety and efficacy in an expanded patient population       |
|                            | at multiple clinical trial sites and are generally larger than trials in earlier phases of             |
|                            | development.   |
| Prospective Clinical Trial | A clinical trial in which participants are identified and then followed throughout the study           |
|                            | going forward in time.   |
| Randomized Clinical Trial  | A clinical trial in which the participants are assigned randomly to different treatment groups.        |
| Somatic Cell               | Any of the cells responsible for forming the body of an organism such as internal organs,              |
|                            | bones, skin, connective tissues and blood.   |
| Stem Cell                  | Unspecialized (undifferentiated) cells that retain the ability to divide throughout a lifetime and     |
|                            | give rise to more specialized (differentiated) cells which take the place of cells that die or are     |
|                            | lost. In culture, these undifferentiated cells possess the ability to divide for indefinite periods in |
|                            | culture and may give rise to highly specialized cells.   |
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### MASTER SERVICES AGREEMENT

**THIS MASTER SERVICES AGREEMENT** (the "*Agreement*") is made and entered into as of September 23<sup>rd</sup>, 2011 (the "*Effective Date*") by and between **PPD DEVELOPMENT**, **LP**, a Texas limited partnership, with its principal executive offices located at 929 North Front Street, Wilmington, North Carolina 28401 ("*PPD*") 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, PPD 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 PPD 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 Addendum"*); and

WHEREAS, PPD 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. <u>SERVICES</u>.

1.1 <u>Services to be Provided by PPD</u>. PPD 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"*). PPD 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) PPD's standard operating procedures (*"SOPs"*), which have been approved by Sponsor, and (v) all applicable laws, rules and regulations. Sponsor agrees that PPD 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, PPD and Sponsor shall execute a Project Addendum evidencing such Services. Sponsor agrees that the Project Addendum shall be executed by both parties before PPD 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 <u>Out of Scope</u>. In the event that PPD 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 PPD's provision of such Out of Scope Services. The Out of Scope Agreement shall constitute an amendment to the applicable Project

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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.

1.4 <u>Sponsor Cooperation</u>. Sponsor will cooperate with PPD in providing information to PPD, 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 PPD's performance under this Agreement is dependant on Sponsor's timely and effective cooperation with PPD and performance of its obligations in accordance with the applicable Project Addendum. Accordingly, Sponsor acknowledges that any delay by Sponsor may result in PPD being released from an obligation or schedule deadline or in Sponsor having to pay extra fees in order for PPD 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 PPD 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. <u>PERSONNEL RETENTION.</u>

In the event of delays in the performance of the Study, i.e., after PPD is authorized to commence work, which are beyond the control of PPD, and where Sponsor desires for PPD to keep PPD 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 PPD 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 PPD on a monthly basis, and shall be due and payable by Sponsor within 30 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 PPD perform services which require PPD 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 PPD shall exercise all reasonable diligence to meet such enrollment estimates.

## 5. <u>FINAL PROTOCOL</u>.

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

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

Charges for Services. Sponsor shall pay PPD for all Services performed under this Agreement and any Project Addendum ("Direct Fees") 6.1 in accordance with the rates for such Services set forth in such Project Addendum. Sponsor shall also reimburse PPD for all out-of-pocket expenses 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, PPD 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 PPD. Sponsor shall pay each monthly invoice within thirty (30) days of receipt of said invoice to the extent consistent with the applicable budget and/or payment schedule. PPD 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 PPD has received payment of such Pass Through Costs from Sponsor. In connection with any contract between PPD 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 PPD 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. PPD 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, PPD may require investigator grants to be advanced by Sponsor at the timeframes mutually agreed upon by the parties.

6.2 <u>Payment after Termination</u>. Upon termination of any Project Addendum or this Agreement pursuant to Section 7 below, Sponsor shall pay PPD all Direct Fees and Pass Through Costs for all Services performed through the termination date. In addition, Sponsor shall reimburse PPD 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 PPD 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 PPD require greater utilization of resources at the outset such that compensation for such services based on a percentage of milestones completed prior to PPD fully completing the milestone would work to the detriment of PPD. 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 PPD 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 PPD shall be compensated on a time and materials basis for Services performed in accordance with the PPD Proposal for Services which formed the basis of the award of the Project to PPD.

6.4 <u>Payments</u>. Unless otherwise set forth in a Project Addendum, all payments to PPD under this Agreement or any Project Addendum shall be made as follows:

If made by check, payment mailed to:

PPD Development, LP 12937 Collections Center Drive Chicago, Illinois 60693

Tax ID# 74-2325267

Bank of America Acct: 000696217456 ABA: 026009593

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

7.1 Term. 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) PPD's receipt of all Direct Fees, Pass Through Costs, and any other payments due to PPD 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. PPD 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.

7.3 <u>Insolvency</u>. 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 law or seeking the appointment of a trustee, receiver, liquidator, custodian or other similar law or seeking the appointment of a trustee, receiver, liquidator, custodian 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, PPD shall cooperate with Sponsor to provide for an orderly wind-down of the Services provided by PPD 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. <u>PERSONNEL</u>.

8.1 <u>Project Management</u>. The Services with respect to each Project shall be performed by PPD under the direction of the person identified as the Project Manager in the applicable Project Addendum or such other person acceptable to Sponsor as PPD 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.

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>. PPD shall treat all information obtained from Sponsor or developed by PPD for Sponsor in connection with the performance of the Services (*"Sponsor Confidential Information"*) as the confidential and exclusive property of Sponsor.

9.2 <u>PPD Confidential Information</u>. Sponsor shall treat all information obtained from PPD including, without limitation, any PPD bids or proposals, standard operating procedures, personnel information, all PPD Property (as defined below) and any revisions, improvements or enhancements thereto (**"PPD Confidential Information"**) as the confidential and exclusive property of PPD.

9.3 <u>Use of Sponsor Confidential Information and PPD 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 Disclosure Required by Law. 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 <u>Return of Information</u>. 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 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, PPD hereby assigns to Sponsor all rights PPD 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 PPD's provision of the Services or (ii) specifically sets forth as a deliverable under a Project Addendum, and PPD shall assist Sponsor, at Sponsor's sole cost and expense, in obtaining or extending protection therefor. PPD warrants that it has and will continue to have agreements with its Agents to effect the terms of this Section 10.2.

10.3 <u>PPD Property</u>. PPD 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, *"PPD Property"*). For avoidance of doubt, methods of conducting and administering preclinical and clinical research that are proprietary to PPD are intended to be and shall be included within the PPD Property. Sponsor and PPD agree that any PPD Property or revisions, improvements or enhancements thereto shall be the sole and exclusive property of PPD, and Sponsor shall have no rights, title and interest to such PPD Property.

#### 11. INDEMNIFICATION.

11.1 <u>Sponsor Indemnity</u>. Sponsor shall indemnify, defend, and hold harmless PPD 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 PPD 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 PPD hereunder, including but not limited to, Project related services provided by PPD 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 PPD or its Agents or a breach of this Agreement by PPD or its Agents.

11.2 <u>PPD Indemnity</u>. PPD 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

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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 PPD or its Agents.

11.3 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 <u>Record Maintenance during Project</u>. During the term of this Agreement, PPD shall maintain all materials and all other data obtained or generated by PPD in the course of providing the Services hereunder, including all computerized records and files. PPD 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.

13.2 <u>Record Maintenance after Expiration or Termination</u>. 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 PPD 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 PPD, (ii) retained by PPD 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 PPD under applicable law. If PPD 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 PPD for its maintenance and storage costs. In no event shall PPD dispose of Records without first giving Sponsor sixty (60) days prior written notice of its intent to dispose of the Records. PPD 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. <u>DEBARMENT</u>.

PPD 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 PPD 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, PPD shall immediately notify Sponsor of same. The debarment of PPD or any of its Agents (which are providing services to Sponsor on a Project under this Agreement) that remains in place for a

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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, PPD is able to 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 PPD 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 PPD incurs Pass Through Costs in a currency other than the Contract Currency, PPD 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.

15.3 <u>Investigator Fees</u>. PPD shall pay investigator fees in the currency specified in the investigator agreements. For Sponsor invoicing and payment purposes, PPD 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. <u>MISCELLANEOUS</u>.

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>. PPD 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 PPD 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

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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 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.

16.6 <u>Notices</u>. 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 if 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 PPD:     | PPD Development, LP<br>3151 South 17th Street<br>Wilmington, North Carolina 28412<br>Attention: CEO<br>Tel: (910) 251-0081<br>Fax: (910) 762-5820                                      |
|----------------|--|
| If to Sponsor: | Aastrom Biosciences, Inc.<br>24 Frank Lloyd Wright Drive<br>Lobby K<br>Ann Arbor, MI 48105<br>Attention: Tim Mayleben, CEO and President<br>Tel: (734) 418-4410<br>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 State of North Carolina without reference to its conflicts of laws provisions.

16.8 <u>Severability</u>. 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

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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.

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.

16.11 <u>Assignment and Subcontracting</u>. 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) PPD may assign this Agreement or a Project Addendum or subcontract all or part of the Services to be performed hereunder to an Affiliate of PPD. **"Affiliate of PPD"** shall mean an entity which can provide the Services and which controls, is controlled by or is under common control with PPD or PPD's parent company Pharmaceutical Product Development, Inc. In the event the Services shall be performed by an Affiliate of PPD, such Affiliate of PPD 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 PPD employee or other PPD 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 PPD 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 PPD 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.

| PPD DEVELOPMENT, LP |                                    |         |                           |  |
|---------------------|------------------------------------|---------|---------------------------|--|
| By:<br>Its:         | PPD GP, LLC<br>General Partner     | Aastrom | Aastrom Biosciences, Inc. |  |
| By:                 | /s/ Brent Conway                   | By:     | /s/ Tim M. Mayleben       |  |
| Name:               | Brent Conway                       | Name:   | Tim M. Mayleben           |  |
| Title:              | VP, Business Development PPD, Inc. | Title:  | President & CEO           |  |
|                     |                                    | 10      |                           |  |

### **RESIGNATION AGREEMENT**

This Resignation Agreement ("<u>Resignation Agreement</u>") is made between Timothy M. Mayleben ("<u>Executive</u>") and Aastrom Biosciences, Inc. ("Aastrom" or the "<u>Company</u>," together with Executive, the "<u>Parties</u>").

WHEREAS, Executive is resigning from his employment with the Company effective, December 14, 2012 (the "Resignation Date");

**WHEREAS**, this Resignation Agreement fully supersedes any prior agreements and understandings related to Executive's employment at Aastrom, including, without limitation, the Executive Employment Agreement dated October 23, 2009 (the "<u>Employment Agreement</u>"), provided, Section 7 of the Employment Agreement, including each of its subparts (the "<u>Preserved Provisions</u>"), shall remain in full force and effect;

**WHEREAS**, in exchange for, among other things, Executive entering into, not revoking and complying with this Resignation Agreement, the Company shall provide Executive with the benefits as described below; and

WHEREAS, the payments set forth in this Resignation Agreement are the exclusive payments, benefits and rights to Executive in connection with the ending of Executive's employment, and by entering into this Resignation Agreement, Executive acknowledges and agrees that he is not entitled to any other severance pay, benefits, equity rights or any other form of compensation or payment including without limitation pursuant to the Employment Agreement or any other agreement, severance plan, program, policy or arrangement, except as otherwise specifically set forth herein.

**NOW, THEREFORE**, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

1. **Resignation from Employment, Officer Positions of the Company and its Subsidiaries and Affiliates.** As of the Resignation Date, Executive hereby resigns from his employment with the Company and as an officer of the Company as well as from any other officer positions he holds with any of the Company's subsidiaries or entities affiliated with the Company. Executive agrees to execute and deliver any documents reasonably necessary to effectuate such resignations. Executive acknowledges and agrees that he is not entitled to any severance pay or benefits in connection with such resignation, including pursuant to the Employment Agreement.

2. **Board Service**. Subject to the Company's bylaws, the Executive shall continue to serve as a member of the Company's Board of Directors for the duration of Executive's current term, to expire at the Company's 2013 Annual Meeting of Shareholders unless the Board of Directors chooses to renominate Executive for another term.

3. **Final Pay; Expense Reimbursement.** On the Company's next regular payroll date following the Resignation Date, the Company shall pay Executive his accrued but unpaid

base salary based on Executive's employment through the Resignation Date (at the rate of \$425,000 per year, prorated based on the Resignation Date). Executive acknowledges and agrees that he is not entitled to any other salary, bonus or in connection with his services to the Company nor is he entitled to payment for any accrued vacation other than the \$32,692.31 for accrued vacation that will be paid by the Company on the next regular payroll date following the Resignation Date. The Executive shall be entitled to be reimbursed for his reasonable business expenses incurred prior to the Separation Date in connection with his service on the Board of Directors and the Consulting Services (as defined below), subject to the Company's policies and procedures with respect to expense reimbursement.

Equity Interests. Executive holds the equity rights set forth in this Section 4 (the "Interests") and such Interests constitute all of the Δ ownership or other equity interests of the Company Executive owns, beneficially or of record. Notwithstanding anything to the contrary in the Notice of Grant of 2004 Stock Option, dated June 20, 2005, granting Executive an option to purchase 12,000 shares of common stock pursuant to the Company's 2004 Stock Option Plan, Notice of Grant of 2004 Stock Option, dated November 1, 2005, granting Executive an option to purchase 30,000 shares of common stock pursuant to the Company's 2004 Stock Option Plan, Notice of Grant of 2004 Stock Option, dated November 2, 2006, granting Executive an option to purchase 55,000 shares of common stock pursuant to the Company's 2004 Equity Incentive Plan, Notice of Grant of 2004 Stock Option, dated November 7, 2007, granting Executive an option to purchase 55,000 shares of common stock pursuant to the Company's 2004 Stock Option Plan, Notice of Grant of 2004 Stock Option, dated October 17, 2008, granting Executive an option to purchase 55,000 shares of common stock pursuant to the Company's 2004 Equity Incentive Plan, Notice of Grant of 2004 Stock Option, dated December 8, 2008, granting Executive an option to purchase 150,000 shares of common stock pursuant to the Company's 2004 Equity Incentive Plan, Incentive Stock Option Award Agreement, dated December 14, 2009, granting Executive an option to purchase 3,000,000 shares of common stock pursuant to the Company's 2009 Omnibus Incentive Plan, Incentive Stock Option Award Agreement, dated March 11, 2010, granting Executive an option to purchase 234,500 shares of common stock pursuant to the Company's 2009 Omnibus Incentive Plan, Incentive Stock Option Award Agreement, dated September 22, 2010, granting Executive an option to purchase 395,000 shares of common stock pursuant to the Company's 2009 Omnibus Incentive Plan, Incentive Stock Option Award Agreement, dated March 21, 2011, granting Executive an option to purchase 699,875 shares of common stock pursuant to the Company's 2009 Omnibus Incentive Plan, Incentive Stock Option Award Agreement, dated May 3, 2012, granting Executive an option to purchase 520,000 shares of common stock pursuant to the Company's 2009 Omnibus Incentive Plan, Incentive Stock Option Cancellation and Award Agreement, dated June 25, 2012, cancelling Executive's right to purchase 481,164 shares of common stock granted on March 21, 2011 and granting Executive an option to purchase 481,164 shares of common stock pursuant to the Company's 2009 Omnibus Incentive Plan, and Incentive Stock Option Cancellation and Award Agreement, dated August 29, 2012, cancelling Executive's right to purchase 317,000 shares of common stock granted on September 22, 2010 and granting Executive an option to purchase 283,000 shares of common stock, pursuant to the Aastrom Biosciences, Inc. 2009 Omnibus Incentive Plan (the "Equity Documents"), the Executive's Interests will be treated as set forth in this Section 4 and Executive shall forfeit any rights to any unissued ownership or other interests in the Company, including to any restricted stock units, other than as set forth herein.

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Vested

|            | Adjusted | As Adjusted | Balance as of 12/14/2012 | Shares<br>as of<br>12/14/2012 |
|------------|----------|-------------|--------------------------|-------------------------------|
| 6/20/2005  | 1,500    | \$<br>23.60 | 1,500                    |                               |
| 11/01/2005 | 3,750    | \$<br>17.84 | 3,750                    | —                             |
| 11/02/2006 | 6,875    | \$<br>12.24 | 6,875                    | —                             |
| 11/07/2007 | 6,875    | \$<br>7.60  | 6,875                    | —                             |
| 10/17/2008 | 6,875    | \$<br>2.32  | 6,875                    | —                             |
| 12/08/2008 | 18,750   | \$<br>2.96  | 18,750                   | —                             |
| 12/14/2009 | 375,000  | \$<br>2.40  | 281,250                  | 82,032                        |
| 03/11/2010 | 234,500  | \$<br>1.52  | 161,218                  | 65,954                        |
| 09/22/2010 | 78,000   | \$<br>1.49  | 78,000                   | —                             |
| 03/21/2011 | 218,711  | \$<br>2.26  | 218,711                  | —                             |
| 05/03/2012 | 520,000  | \$<br>2.49  | 65,000                   | 422,500                       |
| 06/25/2012 | 481,164  | \$<br>2.26  | 43,742                   | 393,680                       |
| 08/29/2012 | 283,000  | \$<br>1.67  | 31,444                   | 220,112                       |

All options that are vested as of December 14, 2012 shall remain vested and shall be exercisable by Executive until May 31, 2013. Fifty percent (50%) of all options that are unvested shall continue to vest per their terms until the earlier of May 31, 2013 or the date Executive leaves the Board of Directors (the earlier of the foregoing two dates, the "<u>Termination Date</u>"), at which point all vesting shall cease and no additional shares shall vest. Any special exercise provisions provided for pursuant to the applicable option agreements or the Employment Agreement, including any exercise period extending past May 31, 2013, shall terminate. All options that are unvested as of the Termination Date shall be cancelled per their terms and be subject to grant pursuant to the Company's equity incentive plans.

5. <u>Consulting Services</u>. After the Resignation Date, the Executive shall provide consulting services to the Company (the "<u>Consulting</u> <u>Services</u>") as requested by the Board in writing, including though electronic communications. Executive shall perform the Consulting Services between the Resignation Date and March 31, 2013, subject to earlier termination by Consultant or termination by the Company for cause, as determined by the Board in its reasonable and good faith discretion (the "<u>Consulting Period</u>"). In exchange for the Consulting Services, the Executive will be eligible to earn the payment(s) set forth on Exhibit A, but only if

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the respective milestone listed on Exhibit A occurs during the Consulting Period (each a "<u>Milestone Payment</u>"). If earned, each Milestone Payment will be paid within 10 days of the achievement of the applicable milestone.

Assignment of Developments. If at any time or times during Executive's employment or while performing the Consulting Services, 6. Executive (either alone or with others) makes, conceives, creates, discovers, invents or reduces to practice (or made, conceived, created, discovered, invented or reduced to practice) any Development that (i) relates to the business of the Company or any partner or sponsor of the Company or any of the products or services being developed, manufactured, licensed or sold by the Company or which may be used in relation therewith; or (ii) results from tasks assigned to Executive by the Company; or (iii) results from the use of premises or personal property (whether tangible or intangible) owned, leased or contracted for by the Company, then all such Developments and the benefits thereof are and shall immediately become the sole and absolute property of the Company and its assigns, as works made for hire or otherwise. The term "Development" shall mean any invention, modification, discovery, design, development, improvement, process, software program, work of authorship, documentation, content, formula, data, technique, know-how, trade secret or intellectual property right whatsoever or any interest therein (whether or not patentable or registrable under copyright, trademark or similar statutes or subject to analogous protection). Executive hereby assigns all rights (including, but not limited to, rights to inventions, patentable subject matter, copyrights and trademarks) Executive may have or may acquire in the Developments and all benefits and/or rights resulting therefrom to the Company and its assigns without further compensation and shall communicate, without cost or delay, and without disclosing to others the same, all available information relating thereto (with all necessary plans and models) to the Company. Executive will cooperate fully with the Company, both during and after Executive's employment and the Consulting Period, with respect to the procurement, maintenance and enforcement of the Company's intellectual property rights. Executive agrees to sign all papers which the Company may deem necessary or desirable in order to protect rights and interests in any Company-related development. If the Company is unable, after reasonable effort, to secure its signature on any such papers, Executive hereby irrevocably designates and appoints each officer of the Company as its agent and attorney-in-fact to execute any such papers on its behalf, and to take any and all actions as the Company may deem necessary or desirable in order to protect its rights and interests in any Company-related development.

7. **Releases.** Executive irrevocably and unconditionally releases and forever discharges the Company, all of its affiliated and related entities, its and their respective predecessors, successors and assigns, its and their respective employee benefit plans and the fiduciaries of such plans, and the current and former officers, directors, stockholders, executives, attorneys, accountants, and agents of each of the foregoing in their official and personal capacities (collectively referred to as the "<u>Releasees</u>") generally from all claims, demands, debts, damages and liabilities of every name and nature, known or unknown ("<u>Claims</u>") that, as of the date when Executive signs this Resignation Agreement, he has, ever had, now claims to have or ever claimed to have had against any or all of the Releasees. This release includes, without implication of limitation, the complete waiver and release of all Claims of or arising in connection with or for: the Employment Agreement including Claims for breach of express or implied contract; wrongful termination of employment whether in contract or tort; intentional, reckless, or negligent infliction of emotional distress; breach of any express or implied covenant

of employment, including the covenant of good faith and fair dealing; interference with contractual or advantageous relations, whether prospective or existing; deceit or misrepresentation; discrimination or retaliation under state, federal, or municipal law, including, without implication of limitation, Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e et seq., as amended, the Americans with Disabilities Act, 42 U.S.C. § 12101 et seq., the Age Discrimination in Employment Act, 29 U.S.C. § 621 et seq.; any other federal, state or local law or regulation prohibiting employment discrimination defamation or damage to reputation; reinstatement; punitive or emotional distress damages; wages, severance pay, vacation pay, back or front pay or other forms of compensation; and attorney's fees and costs. Executive understands that this general release of Claims extends to any and all Claims related to Executive's employment by the Company (including without limitation, any claims against the Company in respect of any stock-based awards of any kind or

alleged promises or assurances of such awards) and the termination of his employment, and all Claims in his capacity as a Company stockholder arising up to and through the date that Executive enters into this Resignation Agreement. Executive understands that this general release does not extend to any rights or claims that may arise out of acts or events that occur after the date on which Executive signs this Resignation Agreement. Executive represents that he has not assigned to any third party and has not filed with any agency or court any Claim released by this Resignation Agreement. This release does not affect Executive's rights or obligations under this Resignation Agreement, the Preserved Provisions or the Equity Documents nor shall it affect the Executive's rights to indemnification as an officer and/or director of the Company for Executive's service prior to the Resignation Date.

The Company voluntarily releases and forever discharges Executive from all claims, demands, debts, damages and liabilities of every name and nature, known or unknown that, as of the date when the Company signs this Resignation Agreement, it has, ever had, now claims to have or ever claimed to have had against Executive arising out of acts or omissions by Executive in connection with Executive's employment taken in the reasonable good faith belief that such acts or omissions were in the best interest of the Company *provided*, the Company's release of Executive shall not apply to any claims based on fraud or material willful misconduct by Executive.

8. **Return of Property**. Executive commits to returning to the Company all Company property, including, without limitation, computer equipment, software, keys and access cards, credit cards, files and any documents (including computerized data and any copies made of any computerized data or software) containing information concerning the Company, its business or its business relationships, provided Executive may retain (i) the laptop issued to him by the Company so long as he promptly returns it to Company so that a mirror image of the hard drive may be taken; (ii) his mobile telephone; and (iii) his desk chair. After returning all other Company property, Executive commits to deleting and finally purging any duplicates of files or documents that may contain Company or customer information from any non-Company computer or other device that remains Executive's property after the Resignation Date.

9. **Executive's Continuing Obligations and Nondisparagement**. Executive hereby reaffirms his obligations pursuant to the Preserved Provisions, which are incorporated by reference as material terms of this Resignation Agreement. Executive further agrees not to make any disparaging statements concerning the Company, any of its affiliates, or any of its or their

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current or former officers, directors, shareholders, employees, agents, products or services. The Company agrees to instruct its current Board members and senior executives not to make disparaging statements about the Executive *provided* that nothing in this Section 9 shall affect any person's obligation to testify truthfully in any legal proceeding or provide truthful information in response to a request from a governmental agency.

10. <u>Communications Concerning Executive's Resignation</u>. The Board will issue a press release about Executive's separation from employment with the Company (the "<u>Announcement</u>") on a date to be determined by the Board (the "<u>Announcement Date</u>"). On and after the Announcement Date, (i) Executive agrees not to make any statement inconsistent with the Announcement; and (ii) the Company will instruct its current Board members and senior executives not to make statements that are inconsistent with the Announcement *provided* that nothing in this Section 10 shall affect any person's obligation to testify truthfully in any legal proceeding or provide truthful information in response to a request from a governmental agency.

11. **Advice of Counsel**. This Resignation Agreement is a legally binding document and the Company's and Executive's signatures will commit each to its terms. Executive acknowledges that he has been advised to discuss all aspects of this Resignation Agreement with his attorney, that he has carefully read and fully understands all of the provisions of this Resignation Agreement and that Executive is voluntarily entering into this Resignation Agreement.

12. **Time for Consideration; Effective Date.** Executive acknowledges that he has been provided with the opportunity to consider this Resignation Agreement for twenty-one (21) days before signing it. To accept this Resignation Agreement, Executive must return a signed original of this Resignation Agreement so that it is received by the Company's Chairman, Board of Directors (the "<u>Chairman</u>"), on or before the expiration of this twenty-one (21) day period. Executive and the Company agree that any changes or modifications to this Resignation Agreement shall not restart the twenty-one (21) day period. For a period of seven (7) days from the day of the execution of this Resignation Agreement, Executive shall retain the right to revoke this Resignation Agreement by written notice that must be received by the Chairman before the end of such revocation period. This Resignation Agreement shall become effective on the business day immediately following the expiration of the revocation period (the "<u>Effective Date</u>"), provided that Executive does not revoke this Resignation Agreement during the revocation period.

13. **Enforceability.** Executive acknowledges that, if any portion or provision of this Resignation Agreement, including any part of the Preserved Provisions, shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision shall be valid and enforceable to the fullest extent permitted by law.

14. **Entire Agreement.** This Resignation Agreement constitutes the entire agreement between Executive and the Company concerning Executive's relationship with the Company, and supersedes and replaces any and all prior agreements and understandings between the Parties concerning the Executive's relationship with the Company including, without limitation, the Employment Agreement, provided, the Preserved Provisions and the Equity Documents, as

modified by Section 4 of this Resignation Agreement, shall continue to be in full force and effect.

15. **Waiver**. No waiver of any provision of this Resignation Agreement, including the Preserved Provisions, which are incorporated by reference into this Resignation Agreement, shall be effective unless made in writing and signed by the waiving party. The failure of either Party to require the performance of any term or obligation of this Resignation Agreement or the Preserved Provisions, or the waiver by either Party of any breach of this Resignation Agreement, including any part of the Preserved Provisions, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

16. <u>Taxes</u>. The Company shall undertake to make deductions, withholdings and tax reports with respect to payments and benefits under this Resignation Agreement and in connection with other compensation matters to the extent that it reasonably and in good faith determines that it is required to make such deductions, withholdings and tax reports. Nothing in this Resignation Agreement shall be construed to require the Company to make any payments to compensate Executive for any adverse tax effect associated with any payments or benefits made to Executive pursuant to this Resignation Agreement.

17. **Governing Law; Interpretation.** This Resignation Agreement shall be interpreted and enforced under the laws of the State of Michigan without regard to conflict of law principles. In the event of any dispute, this Resignation Agreement is intended by the parties to be construed as a whole, to be interpreted in accordance with its fair meaning, and not to be construed strictly for or against either Party or the "drafter" of all or any portion of this Resignation Agreement.

18. **Counterparts.** This Resignation Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be taken to be an original, but all of which together shall constitute one and the same document. Facsimile and PDF signatures shall be deemed to be of equal force and effect as originals.

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IN WITNESS WHEREOF, the Parties, intending to be legally bound, have executed this Resignation Agreement on the date(s) indicated below.

### AASTROM BIOSCIENCES INC.

/s/ Robert L. Zerbe, MD Chairman, Board of Directors December 12, 2012 Date

## I HAVE READ THIS RESIGNATION AGREEMENT THOROUGHLY, UNDERSTAND ITS TERMS AND HAVE SIGNED IT KNOWINGLY AND VOLUNTARILY. I UNDERSTAND THAT THIS RESIGNATION AGREEMENT IS A LEGAL DOCUMENT.

/s/ Tim M. Mayleben Timothy M. Mayleben December 12, 2012 Date

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## Exhibit A

| Payment   | Milestone  |
|-----------|--|
| \$ 75,000 | Board approval of a strategic license or similar collaboration agreement with a third party on terms acceptable to the Board |
| \$ 75,000 | Closing of an equity financing of the Company from which the Company receives gross proceeds of at least \$15,000,000        |

# SUBSIDIARIES OF REGISTRANT

Aastrom Biosciences GmbH, Germany Aastrom Biosciences, SL, Spain

## CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-180222, 333-155739, 333-108989, 333-107579, 333-170581 and 333-174945) and Form S-8 (Nos. 333-163832, 333-140624, 333-121006, 333-115505, 333-81340, 333-51556, 333-38886, 333-140624, 333-25021 and 333-174758) of Aastrom Biosciences, Inc. (a development stage company) of our report dated March 18, 2013 relating to the consolidated financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/PricewaterhouseCoopers LLP Detroit, Michigan March 18, 2013

### CERTIFICATION

I, Dominick C. Colangelo, certify that:

1. I have reviewed this Annual Report on Form 10-K of Aastrom Biosciences, Inc. for the year ended December 31, 2012;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ DOMINICK C. COLANGELO

Dominick C. Colangelo President and Chief Executive Officer (Principal Executive Officer)

Date: March 18, 2013

### CERTIFICATION

I, Brian D. Gibson, certify that:

1. I have reviewed this Annual Report on Form 10-K of Aastrom Biosciences, Inc. for the year ended December 31, 2012;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ BRIAN D. GIBSON

Brian D. Gibson Vice President of Finance, Chief Accounting Officer and Treasurer (Principal Financial and Accounting Officer)

Date: March 18, 2013

#### 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Aastrom Biosciences, Inc. (Company) on Form 10-K for the year ended December 31, 2012, as filed with the Securities and Exchange Commission on the date hereof (Report), each of the undersigned officers of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Section 906), the following:

(1) The Report fully complies with the requirements of section 13(a) and 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ DOMINICK C. COLANGELO

Dominick C. Colangelo President and Chief Executive Officer (Principal Executive Officer)

/s/ BRIAN D. GIBSON

Brian D. Gibson Vice President of Finance, Chief Accounting Officer and Treasurer (Principal Financial and Accounting Officer)

Date: March 18, 2013

A signed original of this written statement required by Section 906 has been provided to Aastrom Biosciences, Inc. and will be retained by Aastrom Biosciences, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.