

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 8-K
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) September 15, 2003

Aastrom Biosciences, Inc.

(Exact name of registrant as specified in charter)

Michigan

0-22025

94-3096597

(State or other jurisdiction
of incorporation)

(Commission
File Number)

(IRS Employer
Identification No.)

24 Frank Lloyd Wright Drive, P.O. Box 376, Ann Arbor Michigan

48106

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code (734) 930-5555

Not Applicable

(Former name or former address, if changed since last report)

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Item 7. Financial Statements and Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99	Slides used in presentations

Item 9. Regulation FD Disclosure.

Attached hereto as Exhibit 99, which is incorporated herein by reference, is a copy of certain slides used by the Company in making a webcast presentation and that are expected to be used in subsequent presentations to interested parties, including analysts and shareholders. This information is not “filed” pursuant to the Securities Exchange Act and is not incorporated by reference into any Securities Act registration statements. Additionally, the submission of this report on Form 8-K is not an admission as to the materiality of any information in this report that is required to be disclosed solely by Regulation FD. Any information in this report supercedes inconsistent or outdated information contained in earlier Regulation FD disclosures.

SIGNATURES

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

Aastrom Biosciences, Inc.

By: /s/ Alan M. Wright

Senior Vice President,
Administration and Financial Operations

Date: September 15, 2003

EXHIBIT INDEX

Exhibit No.	Description
99	Slides used in presentations



Investor Presentation
September, 2003

The Cell Therapy Company
(Nasdaq: ASTM)

SAFE HARBOR

- This presentation contains forward-looking statements, including, without limitation, statements concerning product-development objectives and anticipated timing, clinical trial results, revenue projections, potential market opportunities, market development plans, anticipated key milestones and potential advantages and applications of the AastromReplicell™ System, which involve certain risks and uncertainties. Actual results may differ significantly from the expectations contained in the forward-looking statements.
 - Among the factors that may result in differences are the results obtained from clinical trials and development activities, regulatory approval requirements, sales, competitive conditions and availability of resources.
 - These and other significant factors are discussed in greater detail in Aastrom's Annual Report on Form 10-K and other filings with the Securities and Exchange Commission.
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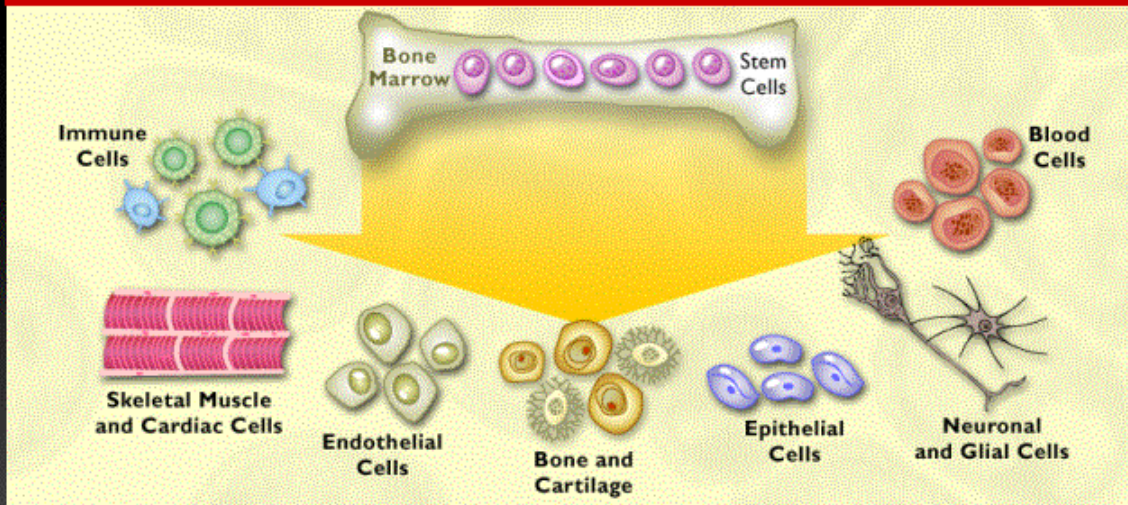


Develops proprietary bone marrow stem cell products for the regenerative repair of damaged human tissues

(Nasdaq: ASTM)

Capturing the Therapeutic Potential of Bone Marrow Stem Cells

Regenerate tissues with stem cells grown from bone marrow collected from the patient...

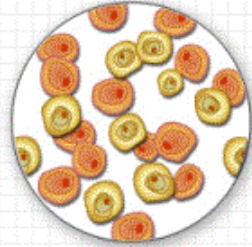


... for blood, vascular tissue, bone grafts, joint reconstruction, myocardial infarction, Parkinson's, diabetes, and osteoarthritis

What's Unique About Aastrom

Proprietary stem cells and industry-unique manufacturing capability...

Proprietary Bone Marrow
Stem Cell Product



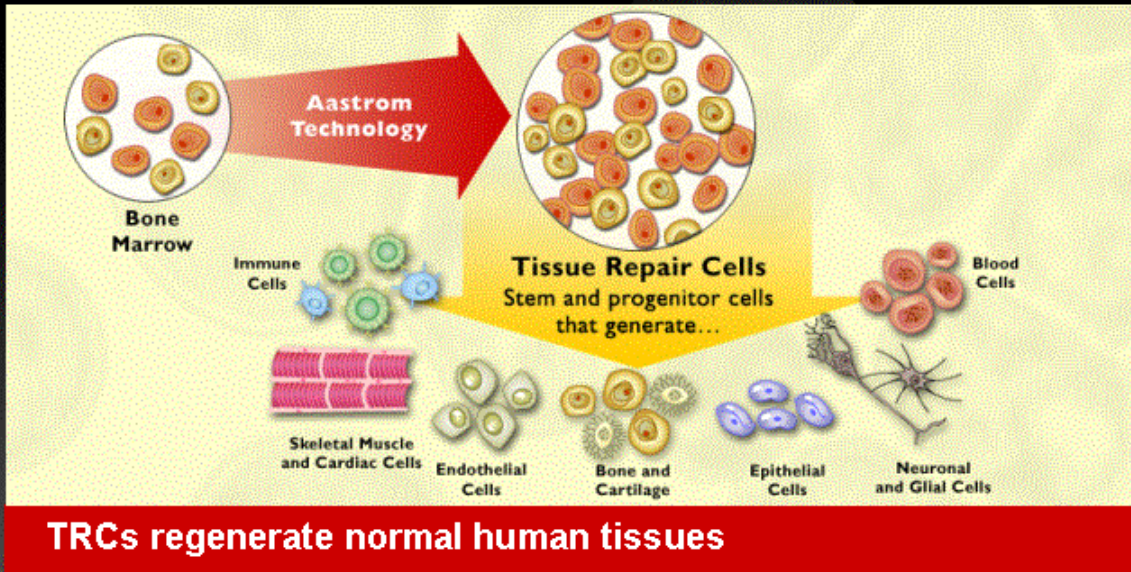
AastromReplicell™ System



- Unique mixture of stem and progenitor cells
- Produced *ex vivo*
- Proven patient safety
- Proven functionality
- Automation
- Single-pass perfusion
- 12-day production
- GMP-compliant
- Scalable

... enables *Prescription Cell Products*

Aastrom's Tissue Repair Cells (TRCs)



Prescription Cell Products: *How The Process Works*

Small cell sample
collected from patient

Cells go to
production lab

Cell product produced in
AastromReplicell System

TRCs used to generate
healthy tissues



Prescription Cell Products
generate revenue just like
pharmaceuticals



Prescription Cell Products Business

Tissue Repair Cell Program

Aastrom Tissue Repair Cells

Established Results

- Over 160 patients have safely received TRCs at major U.S. medical centers
 - Loyola, Duke, University of Pennsylvania, MD Anderson, Hackensack Medical Center, University of Michigan
- Cells have engrafted stably to form healthy tissues
 - Blood cells, immune system cells and bone
- TRCs shown to produce same clinical result as 1 liter bone marrow transplant
- TRCs shown to generate skeletal bone in hypophosphatasia patient
- TRCs shown in lab to generate bone, cartilage and adipose (80+ fold increase in bone forming cells)

Aastrom Tissue Repair Cells

Active Lead Products

Product	Applications	Annual Market Opportunity	Clinical Status
Bone Grafting			
• BG-Fracture	Non-union fractures	\$1.0B	Active (4Q 03)
• BG-Dental	Implants	(Private)	Active (4Q 03)
• BG-Spine	Vertebral fusion	\$2.4B	Preclinical
Peripheral Vascular Tissue			
• VT-Ischemia	Diabetic limb ischemia	\$2.0B	Preclinical
• VT-Cardiac	Myocardial infarct	ND	Preclinical

Bone Graft Market

Traditional Autograft is the “Gold Standard”

- Use of patient’s own bone chips and cells to build new bone tissue
- Autograft usually collected by chiseling material from the hip during a surgical procedure
- Works well for bone grafting (good efficacy)
- Very painful and undesired after-effects at the donation site (hip) are both short and long term
- High cost of recovery
- Strong desire for alternative to Autograft that has the *efficacy without the after-effects*

Bone Graft Product Comparison

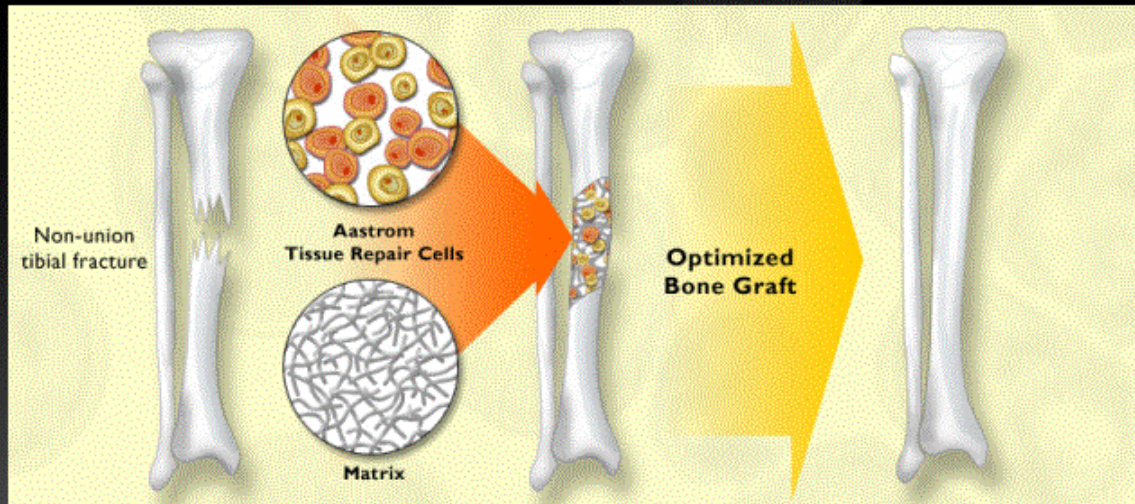
Alternatives

Therapy	Cells	Stimulation	Lattice
Autograft (Gold Standard)	+++	+++	+++
Synthetic Matrix	no	no	++
Allograft/DBM Matrix	no	++ (variable)	+++
BMP	no	+++	no
Aastrom TRCs	+++	++	no
Aastrom TRCs + Matrix	+++	+++	+++

Sources: J Bone Joint Surg Am 83 (Suppl. 2): 98-103, 2001
Aastrom in-house data



The Optimized Bone Graft Solution



TRCs in Bone Grafting

The efficacy of Autograft, without the after-effects!

**Aastrom
TRCs**

+



=

**Optimized
Bone Graft**

Strategic Alliance Opportunity

Strategic Partner:



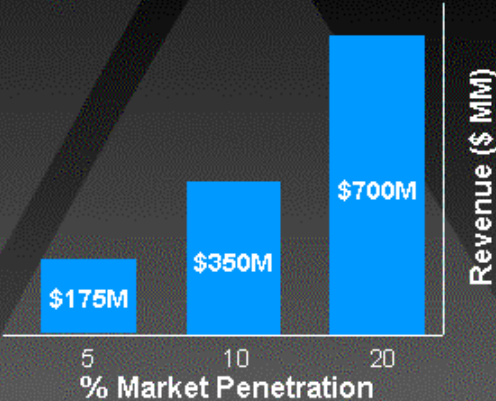
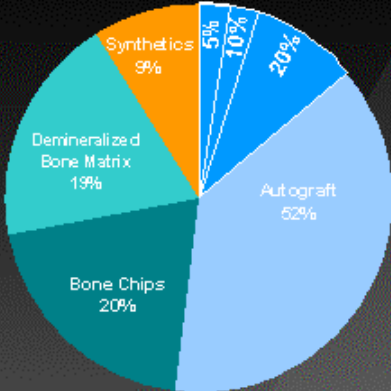
Alliance between leaders in stem cells and orthopedic tissue matrix

- Largest market provider of allograft tissue matrix (>\$220 million revenue)
- Direct sales force as well as active marketing relationships with Synthes Spine, Osteotech, and others
- Gives Aastrom access to allograft matrix supply, the preferred matrix for the U.S. bone graft market
- Gives Aastrom access to and input from the MTF orthopedic staff, industry expertise and network
- Companies work together, and share in development and clinical expenses for products that combine cells and matrix

Bone Graft Market Opportunity

United States - 2000

1.4 million bone grafts in U.S. and Europe each year; approximately half are Autograft



Bone Graft Market Strategy

Market Entry Plan

- Target the Autograft market
 - Provide efficacy of Autograft without the painful after-effects
 - No need to compete with bone graft substitutes
- Enter European market first
 - Enables commercialization 3 to 5 years before U.S.
 - Simpler regulatory pathway for autologous cells

Bone Graft Market Strategy

European Market Development Plan

- Target small marketing clinical trials at major European orthopedic centers
 - Centers become customers after successful use of TRCs
- In Europe, cells from the patient are not regulated as drugs, but the manufacturing process is controlled
 - Need license to manufacture cells
 - CE marked AastromReplicell System aids license process
- Target larger randomized trials in U.S.
 - Needed for FDA approval as IND/BLA biologic product
 - Will stimulate larger market share in Europe
- In Europe, seek separate marketing partner for each product
 - Spine; Trauma (fractures); Dental

Bone Graft Clinical Strategy

U.S. Clinical Trial Plan

- Initial multi-center trial for non-union tibial fracture
 - FDA approved IND for Phase I/II trial in August 2003
- Target start date = 4Q/03
 - Lead sites selected
 - Up to 20 patients at up to three centers
 - Approximately one year to complete accrual
 - Begin with three long term non-unions fractures for safety
 - If safety satisfactory, extend to acute non-union patients
- Planning spine fusion trial for next study
- Multi-center randomized trial needed for BLA approval

Bone Graft Clinical Strategy

European Clinical Trial Plan

- Two lead trials to start in Germany
 - Non-union tibial fracture
 - Dental implant bone grafting
- Trial designs
 - Up to 20 patients
 - Single center studies
 - Target start dates = 4Q/03
 - Approximately one year to complete accrual
 - Plan to file for CE Mark approval with successful data from 5-10 patients
 - Collaboration with Mathys Medical for matrix
- Planning spine fusion trial for next study

Peripheral Vascular Disease

Major clinical issue in diabetes patients

- Degenerated vascular tissue in limbs
- 400,000+ patients in U.S. and Europe
- No current effective treatment available
- Often results in amputation
- Recent clinical data suggests large volumes of bone marrow can regenerate effective vascular tissue in these patients

Peripheral Vascular Disease

Effect of Bone Marrow Stem Cells

Can TRCs substitute for large volume bone marrow and produce the same clinical result?

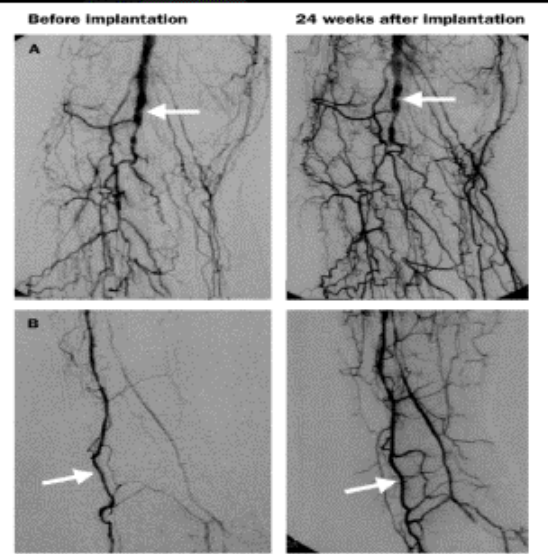


Figure 5: **Angiographic analysis of collateral vessel formation in patients in group A**

Collateral branches were strikingly increased at (A) knee and upper-tibia and (B) lower-tibia, ankle, and foot before and 24 weeks after marrow implantation. Contrast densities in suprafemoral, posterior-tibial, and dorsal pedal arteries (arrows) are similar before and after implantation.

Peripheral Vascular Product Strategy

- Further establish TRC capability to generate endothelial cells
- Develop external funding support
 - First NIH grant in process
- Initiate clinical trials to determine feasibility of VC-I cells
 - First trial targeted for 2-3Q/04
- In Europe, target small marketing trials at major diabetes centers; centers become customers
- In U.S., target randomized trials for FDA approval and to stimulate larger market share in Europe

Aastrom TRC Products

Development Summary

- Principal focus on bone graft products
 - Large, multi-application market in bone grafting
 - Most clinical endpoints are short-term
 - Completed preclinical studies provide strong rationale
 - Next step: complete phase I/II patient data and secure CE Mark for non-U.S. markets
- Determine capability of TRCs to generate vascular tissue
- Use grant funding and collaborations for new development areas including cartilage, cardiac and peripheral vasculature cell mixtures

Other Business Development Areas

Prescription Cell Products

Tissue Repair Cells

- Osteoporosis
 - Phase I/II trial collaboration
- Osteoarthritis (bone and cartilage)
 - Being explored with matrix combinations

Therapeutic Cells

- Dendritic cell vaccines - Dendricell™ - for cancer
 - Grant funded clinical trials planned with collaborators
- T-cell immunotherapy for cancer and viruses
 - Active preclinical research program



Cell Production Products Business

Business Strategy

AstromReplicell™ System Platform

- Patented human cell production from “single-pass perfusion”
 - Industry-unique automation and GMP compliance



Prescription Cell Products Business

- Tissue Repair Cells (TRCs)
 - Lead to construction of normal tissue such as bone
- Therapeutic Cells (TCs)
 - Intended to act like drugs (vaccines for cancer and viruses)

Cell Production Products Business

- Instruments and single-use kits
- Target Market
 - Clinical research market
 - Third-party therapeutic cell developers

Cell Production Products

Market Strategy

- Incorporate AastromReplicell™ System in as many cell therapy programs as possible
 - Near-term revenue from customers in early clinical trials
 - Large long-term revenue from customers with successful cell therapy
- Recurring revenue from consumable kit sales following initial sale of instrumentation
- *Business now generating revenue*



Zellera AG

Expanding Aastrom's Business in Europe

- Wholly owned subsidiary in Berlin, Germany
- Establishes relationships for clinical trials
- Directs product marketing
- Manages sub-distributor relationships in Italy, Switzerland and Turkey
- Coordinates installation and servicing with NovaMed GMBH
- Completes customer training and support

Aastrom's Key 12-Month Milestones

(September 2003)

- Initiate and complete Phase I / II trials for bone graft products
 - Tibial non-union fracture trial planned in Europe and U.S.
 - If results positive, complete CE Mark
 - Possible next indication trials (e.g., dental and spinal fusion)
- Determine capability of TRCs for vascular applications
- Bring Cell Production Products business towards profitability, and expand territories
- Initiate collaborative clinical trials for Dendricell™
- Increase level of grant support for development programs

Recent Announcements *

Feel the Momentum!

- April 2, 2003: Publication of clinical result showing new bone formation in patient
- April 16, 2003: Collaboration with Mathys for German bone graft trial
- May 12, 2003: Second consecutive quarter reporting product revenue
- May 21, 2003: Award of an NIH grant for development of Aastrom's patented cell production technologies
- May 30, 2003: Immunotherapy collaboration with Stanford University
- June 10, 2003: ASTM and MTF strategic alliance for bone graft and cartilage generation medical indications
- July 10, 2003: Completion of \$9.5 million financing to bring cash to approximately \$16 million
- August, 2003: CE Mark for dendritic cell vaccine production kit
- Sept 2, 2003: FDA Approves IND for first bone graft trial

* Sampling of recent Aastrom press releases





Investor Presentation
September, 2003

The Cell Therapy Company
(Nasdaq: ASTM)