



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) February 19, 2004

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**Aastrom Biosciences, Inc.**

(Exact name of registrant as specified in charter)

Michigan

(State or other jurisdiction  
of incorporation)

0-22025

(Commission  
File Number)

94-3096597

(IRS Employer  
Identification No.)

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

(Address of principal executive offices)

48106

(Zip Code)

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

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Not Applicable

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

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**Item 7. Financial Statements and Exhibits.**

<b>Exhibit No.</b>	<b>Description</b>
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 conference 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 Any information in this report supercedes inconsistent or outdated information contained in earlier Regulation FD disclosures.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: February 19, 2004

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EXHIBIT INDEX

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



Investor Presentation  
February 2004

The Cell Therapy Company  
(*Nasdaq: ASTM*)

## SAFE HARBOR

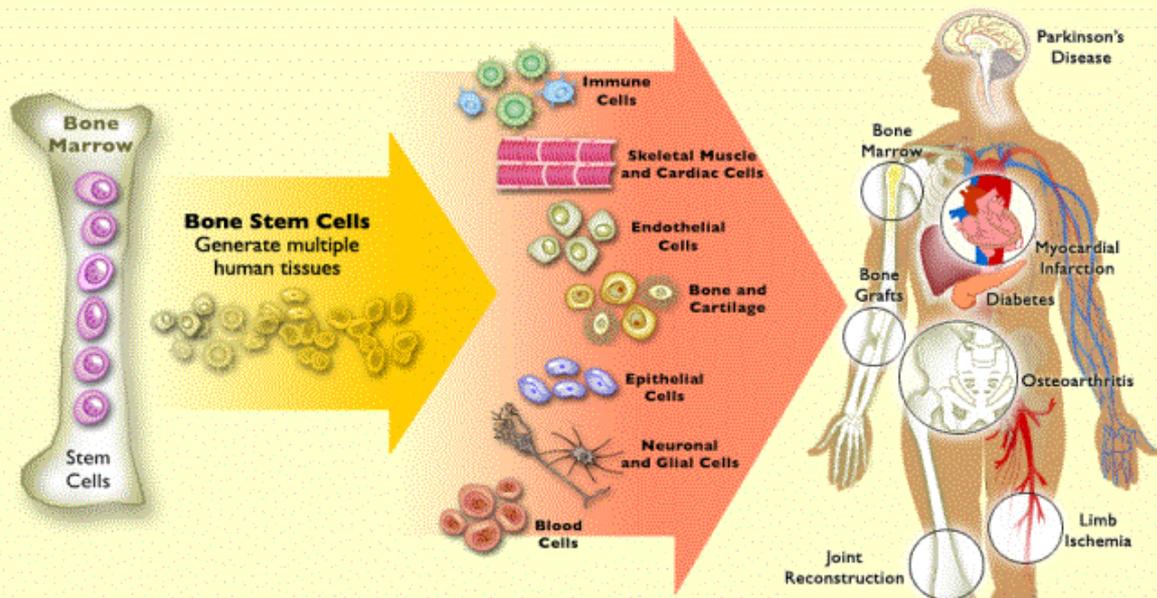
- This presentation contains forward-looking statements, including, without limitation, statements concerning product-development objectives and anticipated timing, clinical trial timing and results, potential market opportunities, market development plans, anticipated key milestones and potential advantages and applications of the AastromReplicell™ System and related products, 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, 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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## Highlights

- Proprietary stem cell products for regeneration or repair of human tissues developed from patient's own bone marrow
- Clinical validation for safety and efficacy of stem cell platform successfully completed for both the cell product and the manufacturing system
- Tissue Repair Cell (TRC) product in active clinical trials for bone graft indications
- Lead target markets include: fracture repair, spine fusion, dental implants, and peripheral vascular disease
- Strategic partnership with MTF -- the largest commercial provider of allograft tissue matrix in U.S.

# Capturing the Therapeutic Potential of Bone Marrow Stem Cells

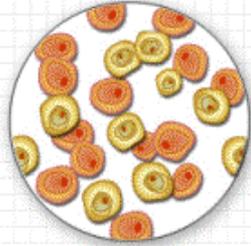
Regenerate tissues with stem cells grown from bone marrow collected from the patient...



# 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* with patented single-pass perfusion technology
- Proven patient safety
- Proven tissue generation function
- Cell production automation with GMP compliance
- 12-day fixed production
- Scalable
- Collaboration & alliance platform

**... enable *Prescription Cell Products***

# Prescription Cell Products: *How The Process Works*

Small cell sample  
collected from patient

Cells go to  
production lab

Cell product produced in  
AastromReplicell System

Cells used to generate  
healthy tissues



Prescription Cell Products  
should generate revenue  
just like pharmaceuticals

# Aastrom's Tissue Repair Cells (TRCs)

## Stem Cell-Based Product to Generate Human Tissue

- Mixture of multi-lineage stem and progenitor cells produced with the AastromReplicell™ System
- Contain large numbers of cells that can form bone, cartilage, adipose, vascular and hematopoietic tissues
- Multi-center clinical trials have been successfully completed showing TRCs are:
  - Clinically safe
  - Able to engraft to form healthy tissues (blood and immune cells)
- Shown to generate durable skeletal bone in hypophosphatasia patient

# Aastrom Tissue Repair Cells

## Active Lead Product Indications

Product	Applications	Annual Market Opportunity	Clinical Status
<b>Bone Grafting</b>			
• BG-Fracture	Non-union fractures	\$1.0B	Active
• BG-Dental	Implants	TBD	Active (2Q 04)
• BG-Spine	Vertebral fusion	\$2.4B	Preclinical
<b>Vascular Tissue</b>			
• VT-Ischemia	Diabetic limb ischemia	\$2.0B	Preclinical
• VT-Cardiac	Myocardial infarct	TBD	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*

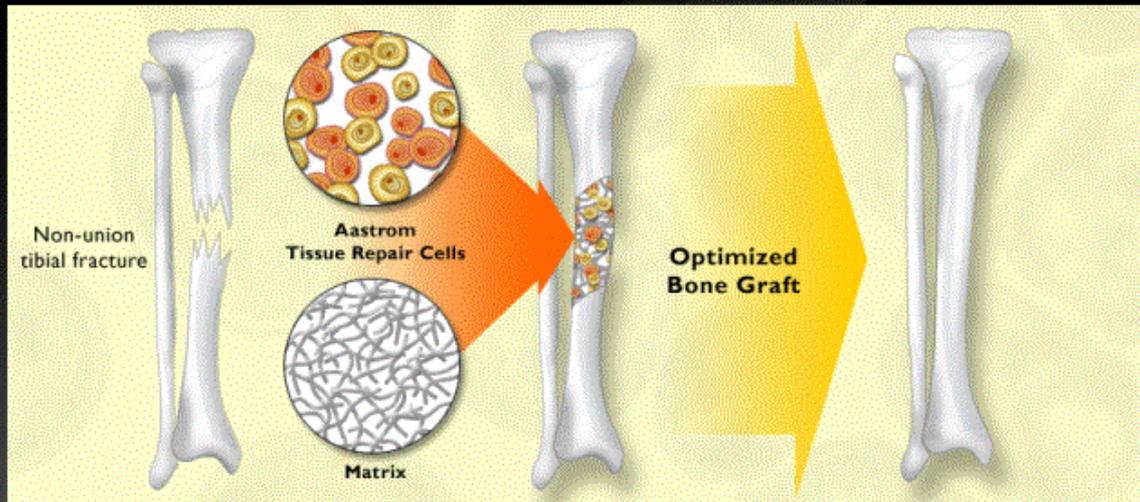
# Bone Graft Product Comparison

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

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



# The Optimized Bone Graft Solution



## Strategic Partner:

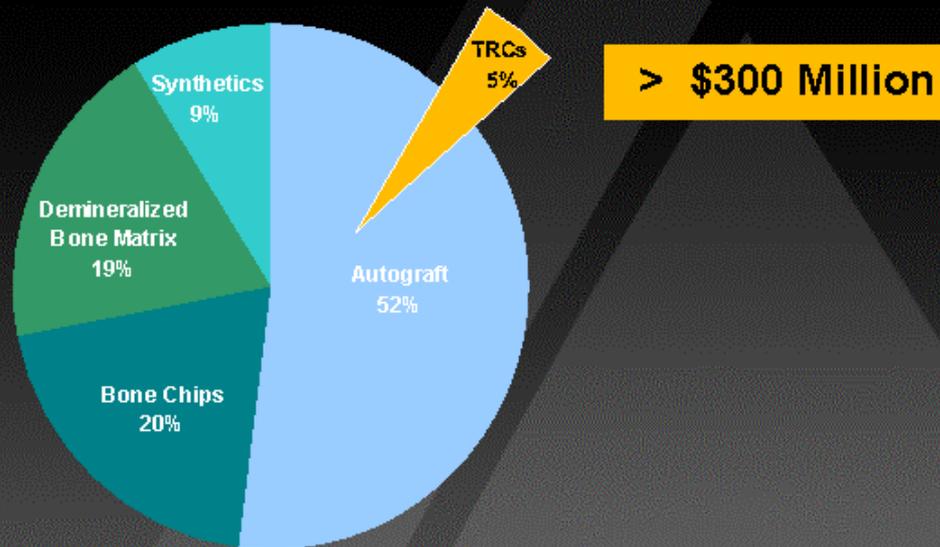


### 2003 Alliance Between Leaders in Stem Cells and Orthopedic Matrix

- 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

1.4 Million Bone Grafts in U.S. and Europe Annually



Source: Based on U.S. market data from CY 2000



# Bone Graft Market Strategy

## Market Entry Plan

- Target procedures currently using/requiring traditional Autograft instead of bone graft substitute products
- Focus on certain European countries for initial commercialization due to simpler regulatory pathway for autologous cells (manufacturing license only)
  - *First tier customers targeted during CY 2006*
- Implement U.S. randomized trials needed for FDA approval and for broader global use of product
- Involve strategic marketing partners for major fields

# Bone Graft Clinical Plan

## General Features

- Endpoints for all trials include:
  - Safety of TRCs in bone graft indication
  - Ability of TRCs to form localized bone
  - Assessment of tempo and quality of bone formation
- Comparison/randomization to traditional Autograft
  - Similar efficacy without the invasive collection
- Intent to fully replace use of traditional Autograft, rather than supplementing or improving it
- Phase II and EU Marketing trials are each <20 patients
- Randomized U.S. trials expected to be <200 patients

# Bone Graft Clinical Plan

## United States

- Fractures
  - Aug 2003: Phase I/II multi-center trial approved by FDA
  - Jan 2004: Initiated trial at lead site in Chicago
  - 20 patient target - 12 to 18 month expected duration
  - If results acceptable, plan to move to Phase III
- Spine Fusion
  - Preclinical work active
  - Lead protocol in development
  - Plan to submit IND in 3Q CY2004
- Dental
  - Delay until EU trial data available

# Bone Graft Clinical Plan

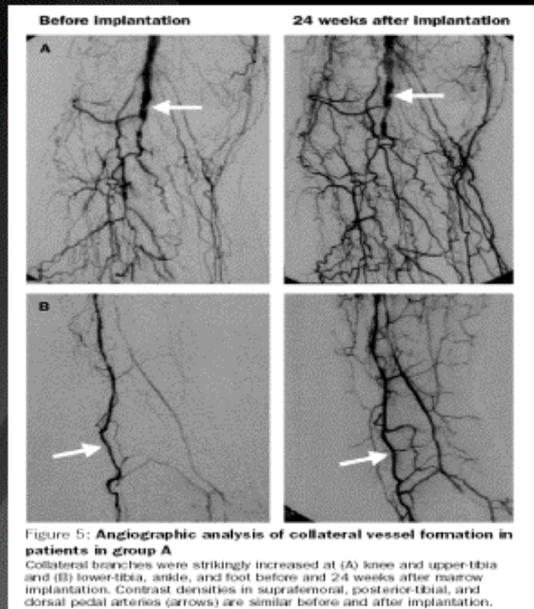
## European Union

- Fractures
  - Jan 2004: Lead trial underway in Bochum, GR
  - 10 patient target - approximately 12 month duration
  - Target 1 to 3 additional centers in CY2004
- Spine Fusion
  - Protocol in preparation
  - Plan to start patient accrual in CY2004
  - Target 1 to 3 additional centers in CY2005
- Dental (Implants, Sinus Lift)
  - Lead trial in Bonn delayed pending manufacturing site license
  - New sites in active protocol preparation
  - Target multiple centers active in CY2005 following initiation of lead site in CY2004

# Peripheral Vascular Disease

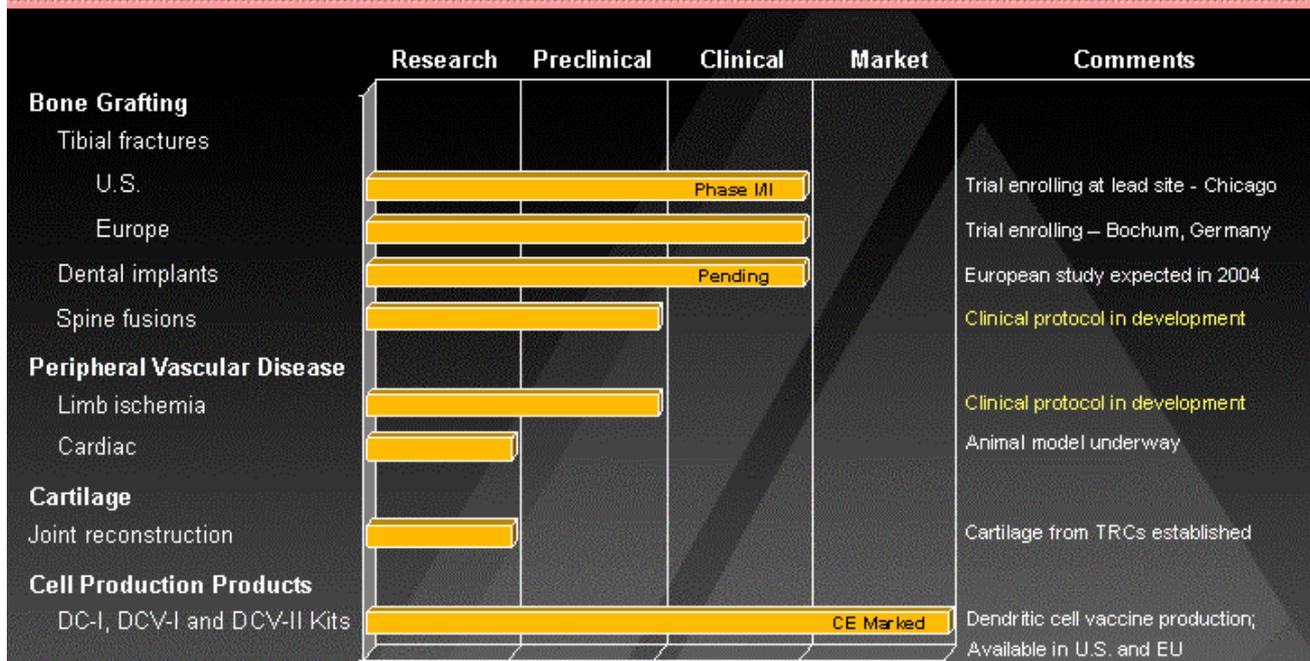
## Major Clinical Issue in Diabetes Patients

- Degenerated vascular tissue in limbs of 400,000+ patients in U.S. and Europe
- No real effective treatment available - Often results in amputation
- Recent clinical data suggests large volumes of bone marrow can regenerate vascular tissue in these patients
- TRCs have potential to substitute for large volume bone marrow and produce the same clinical result



Source: [Lancet](#) 360: 427-435, 2002

# Development Pipeline



# Cell Production Products

## Collaboration & Alliance Platform for Early and Long-Term Revenue

- Incorporate AastromReplicell™ System into as many cell therapy programs/collaborations as possible
- Recurring revenue from consumable kit sales following initial sale of instrumentation
- First dendritic cell vaccine collaborations moving into clinical trials (Duke; Stanford; Mannheim,GR)
- Modest revenue received



## Summary

- Strategic industry position with a proven proprietary stem cell product and means for commercialization
- Profitability targeted through non-U.S. markets, with future growth resulting from U.S. therapeutic markets
- Lead focus on bone graft products for large and diverse markets, with new marketing partner options
- Active preclinical pipeline for peripheral vascular and bone/cartilage indications
- Momentum driven by clinical results, strategic relationships, access to major markets and multiple paths to revenue



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