
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, 2004

Aastrom Biosciences, Inc.

(Exact name of registrant as specified in its charter)

Michigan
(State or other jurisdiction of
incorporation)

0-22025
(Commission File No.)

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

24 Frank Lloyd Wright Drive
P.O. Box 376
Ann Arbor, Michigan 48106
(Address of principal executive offices)

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

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

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

[Item 7.01 Regulation FD Disclosure.](#)

[Item 9.01 Financial Statements and Exhibits.](#)

[SIGNATURES](#)

[EXHIBIT 99.1](#)

[Table of Contents](#)

Item 7.01 Regulation FD Disclosure.

Attached hereto as Exhibit 99.1, 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 Any information in this report supercedes inconsistent or outdated information contained in earlier Regulation FD disclosures.

Item 9.01 Financial Statements and Exhibits.

(c) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Slides used in presentation

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.

Date: September 15, 2004

AASTROM BIOSCIENCES, INC.

By: /s/ Alan M. Wright
Alan M. Wright
Senior Vice President, Administrative and Financial
Operations, CFO



*Proprietary Cell Products for
Regenerative Medicine*

Investor Presentation
September, 2004

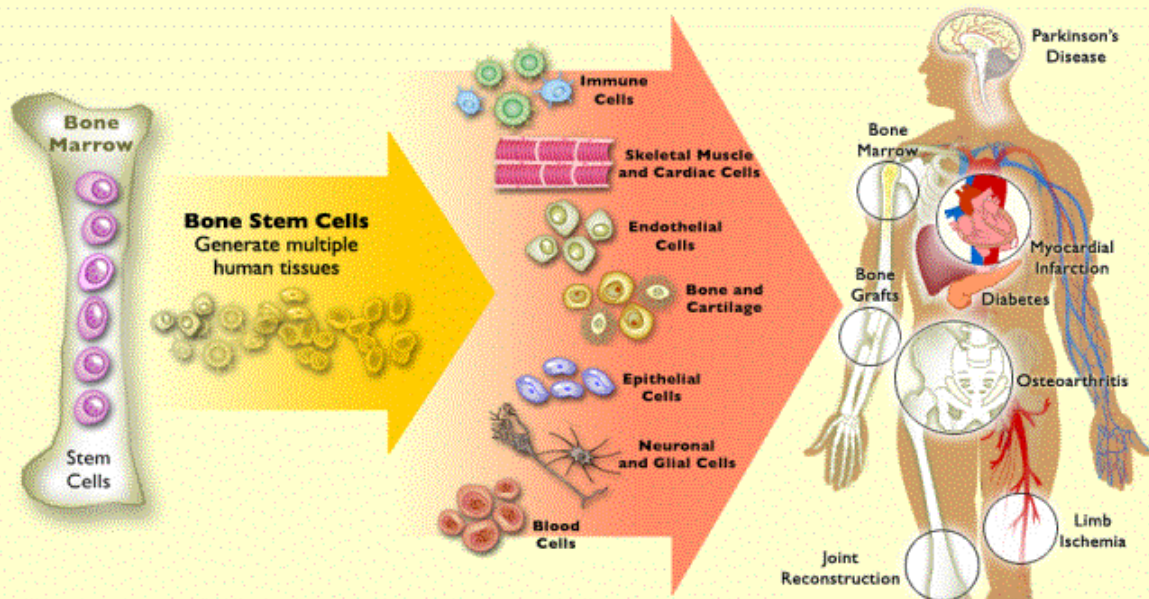
(Nasdaq:ASTM)

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 and revenue models, 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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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 adult stem cells and industry-unique manufacturing capability...

Proprietary Bone Marrow Stem and Progenitor Cell Product



- Tissue Repair Cells – bone, vascular, blood, cartilage and adipose forming capability
- Produced *ex vivo* with patented single-pass perfusion technology
- Proven patient safety
- Proven tissue generation function

AastromReplicell System



- Cell production automation with GMP compliance
- 12-day fixed production
- Scalable
- Point of Care or Centralized manufacturing capability

... enable Prescription Cell Products

Prescription Cell Products: *How The Process Works*

Small cell sample
collected from patient

Cells go to
production lab

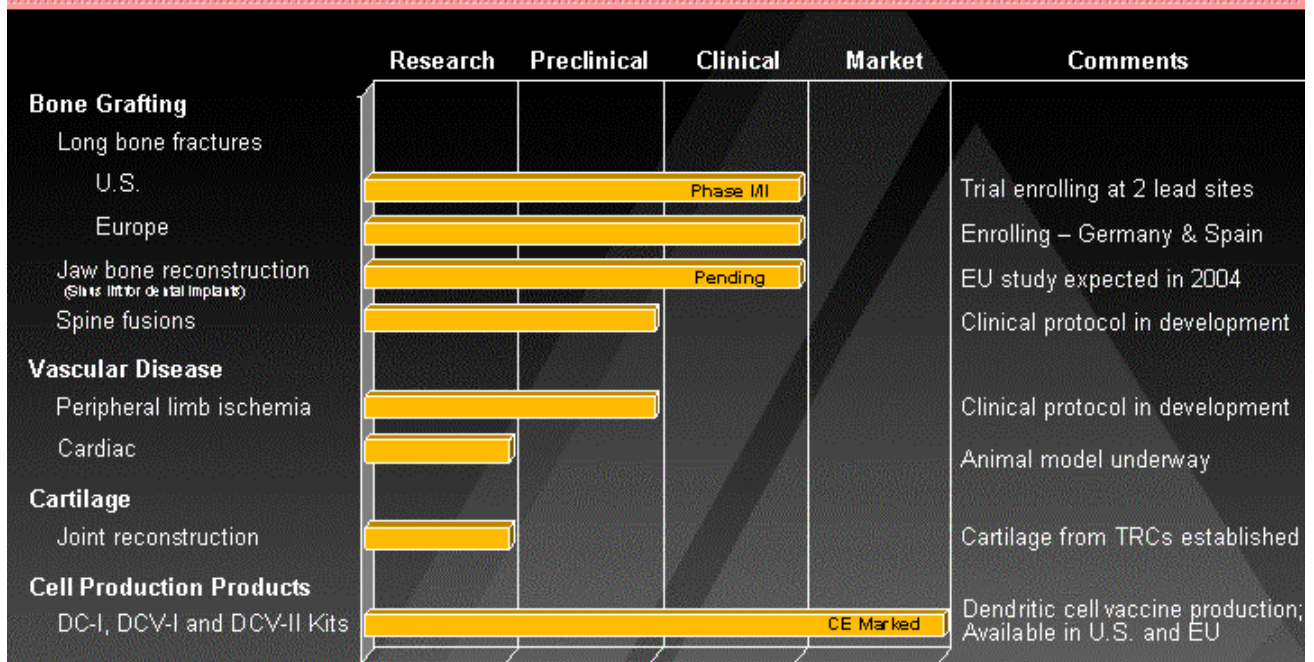
Cell product produced in
AastromReplicell System

Cells used to generate
healthy tissues



Prescription Cell Products
should generate revenue
just like pharmaceuticals

Development Pipeline



Aastrom Tissue Repair Cells

Active Lead Product Indications

Product	Applications	Applicable Market Size (Patients) *	Clinical Status
Bone Grafting			
• BG-Fracture	Long bone fractures	110,000	U.S./EU: Active
• BG-Spine	Spine fusions	420,000	Preclinical
• BG-Dental	Sinus lift	215,000	EU: 4Q/CY2004
Vascular Disease			
• VT-Ischemia	Diabetic limb ischemia	485,000	Preclinical

* Estimated U.S. and EU market data for CY2010



Bone Graft Market Issues

Clinical Issues

- Multiple clinical indications to either repair or build new localized bone tissue (fractures, reconstructions, fusions)
- Current solutions can be effective, but each has limitations
- Autograft procedure (surgically chiseled bone and marrow from the hip) works well, *but* very painful after-effects at the collection site, and limited quantities
- Recent bone graft substitute products are less effective than Autograft for tempo and quality of bone formation
- Optimal solution is to less invasively provide:
 - High number of bone forming cells
 - Vascular tissue forming cells

Bone Graft Product Comparison

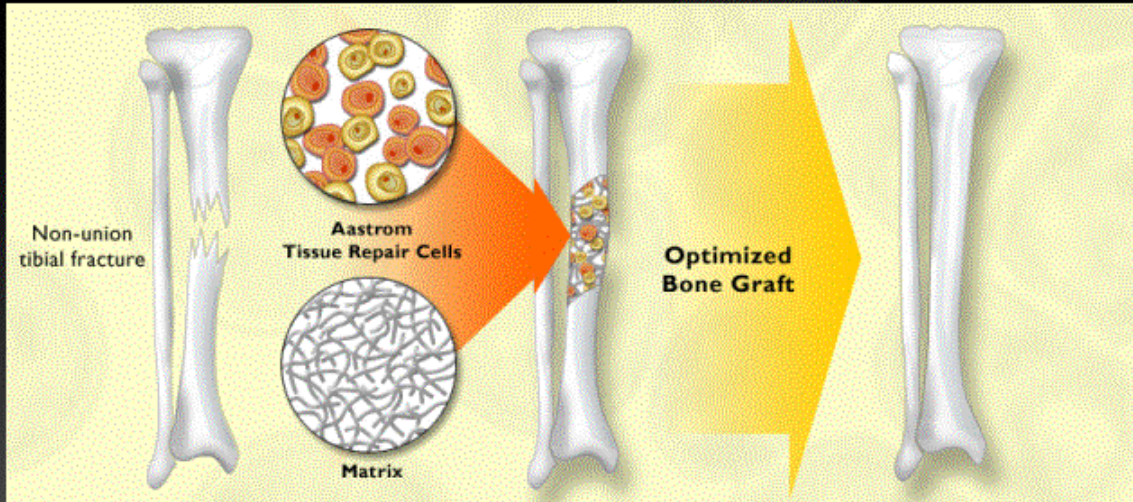
	Therapy	Cells	Stimulation	Lattice
Alternatives	Autograft (Gold Standard)	++	+++	+++
	Synthetic Matrix	no	no	++
	Allograft/DBM Matrix	no	++ (variable)	+++
	BMP	no	+++	no
	Aastrom TRCs	+++	++	no
	Aastrom TRCs + Matrix	+++	+++	+++

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



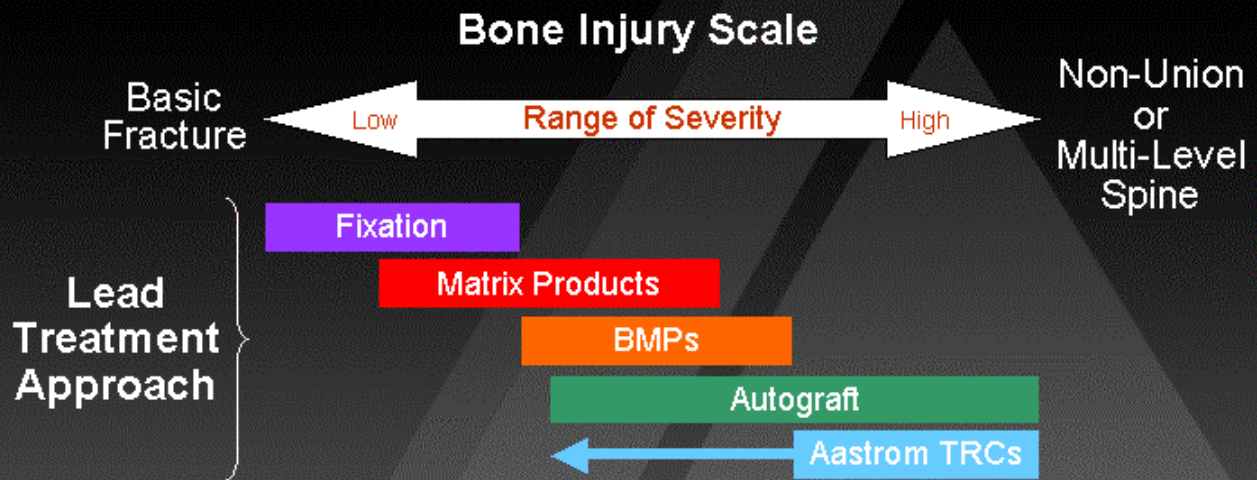
Aastrom's Optimized Bone Graft Solution

The first stem cell product for bone generation!



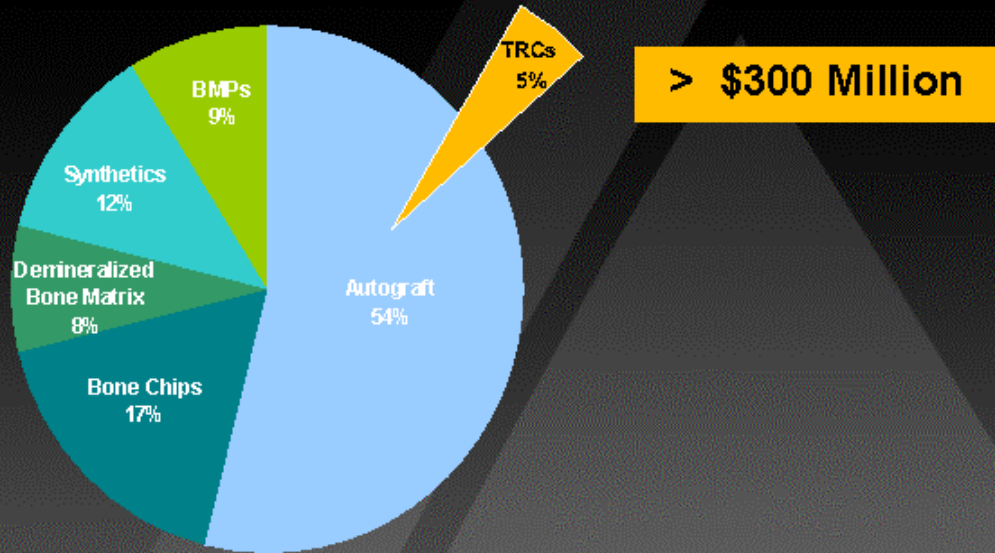
Bone Graft Market

Conceptual Product Use Model



Bone Graft Market Opportunity

Global Market: 1.5 Million Bone Grafts Annually



Source: Datamonitor – Estimated Global Market Data for CY2005



TRC Intended Advantages

Bone Graft Orthopedic Product Objectives

- Effectiveness of traditional Autograft for tempo and quality of bone formation
- Bone forming capability of *1+ liters* of autologous bone marrow cells
- Regeneration of vascular as well as bone tissue
- Tissue growth directed by natural processes, and *not* by a pharmaceutical
- Reliable, safe and logistically simple therapy process
- Potential savings in:
 - OR time
 - Patient recovery rate and support
 - Time to return to desired quality of life

Bone Graft Market Strategy

Aastrom 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
- Implement U.S. randomized trials needed for FDA approval and for broader global use of product
- Involve strategic marketing partners in each major field

Bone Graft Clinical Strategy

- Lead with indications in which results can be evaluated in short-term trials with relative ease:
 - Tibial non-union indication (long bone fracture) due to significant unmet medical need, and “requirement” for data here before spine allowed by FDA and surgeons; and
 - Dental/sinus lift indication due to relative ease of assessing bone formation tempo and quality, and large market potential
- Initiate spine fusion (largest market) study once good bone growth has been proven to occur in dental and/or long bone fracture
- Explore marketing trials for revision/other markets

Bone Graft Clinical Plan

European Union

- Fractures (Non-Union)
 - Lead studies underway in Bochum, GR and Barcelona, SP
 - 10 patient target
 - Process logistics working well
- Spine Fusion
 - Plans waiting for supportive data from fracture and sinus lift studies
- Dental (Sinus Lift)
 - Lead trials for sinus lift in preparation for 4Q/CY2004 start
 - Bone formation measured by biopsy/histology

Bone Graft Clinical Plan

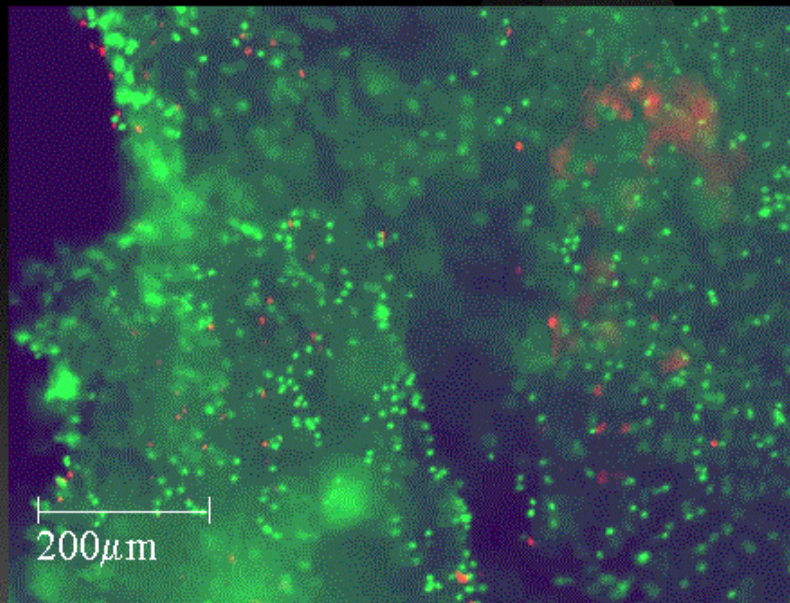
United States

- Fractures (Non-Union and Fresh)
 - Phase I/II multi-center trial approved by FDA
 - Two sites currently active; 1-2 more expected by 2Q/CY2005
 - 20 patient target
 - If results acceptable, plan to move to Phase III
- Spine Fusion
 - Lead protocol in development (gutter fusion model)
 - Plan to submit IND in 4Q CY2004
- Dental (Sinus Lift)
 - Delay until EU trial data available

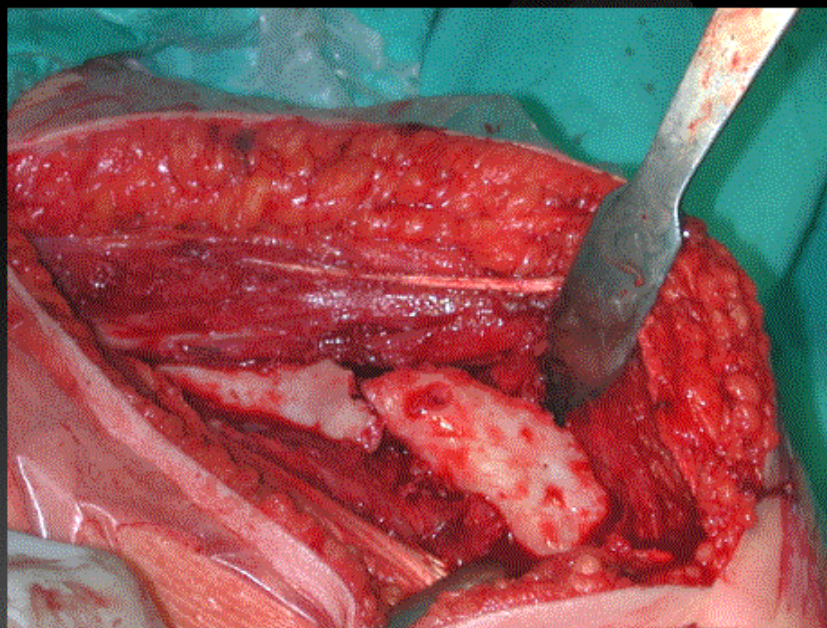
Combining TRCs and Matrix



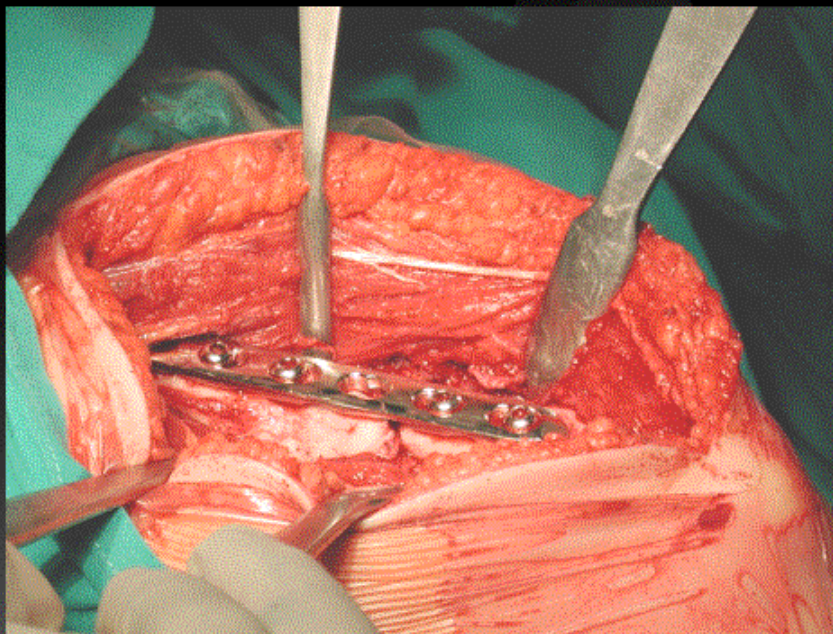
TRCs with Matrix



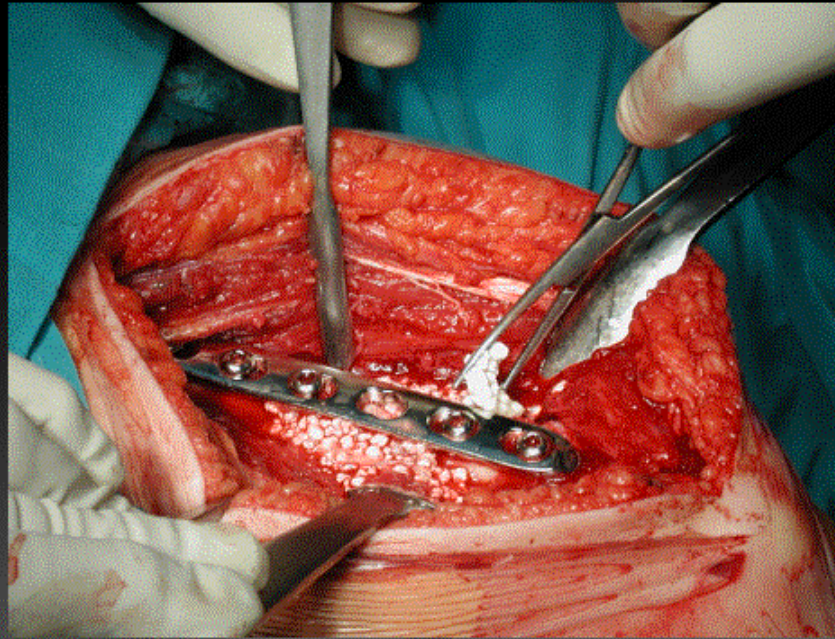
BG-Fracture Trial: Non-Union Fracture



BG-Fracture Trial: Fracture Fixation



BG-Fracture Trial: TRCs and Matrix



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
- Provides Aastrom with access to allograft matrix supply, the preferred matrix for the U.S. bone graft market
- Aastrom gains access to and input from the MTF orthopedic staff, industry expertise and network
- Companies both contribute to development and clinical expenses for products that combine cells and matrix

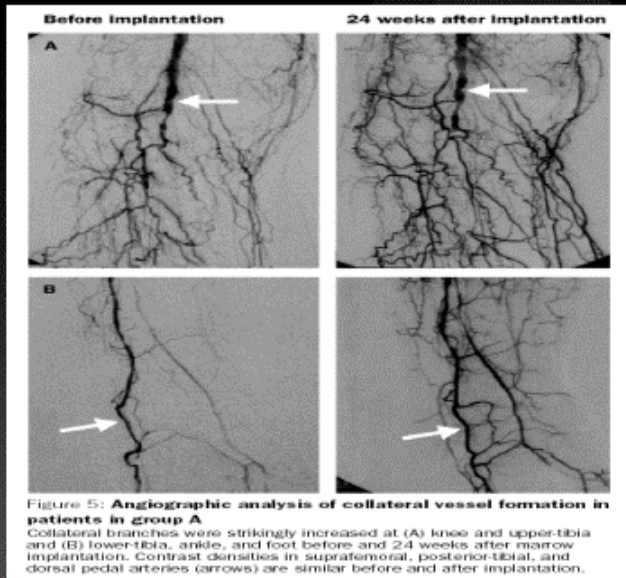
Peripheral Vascular Disease

Rational for TRC Development

- Published clinical results show effectiveness of large volume bone marrow for limb ischemia
 - Diabetic and Buerger's disease patients
 - Similar published reports for cardiac ischemia
- TRCs shown as effective substitute for large volume bone marrow in BMT indication
- TRC's vascular lineage capability demonstrated *in vitro*
- Market opportunity large, with limited therapeutic competition
 - U.S. market targeted at 400,000 to 700,000 per year
 - Reimbursement levels are high for current treatments
- TRCs ready to go to trial
 - Leverage existing infrastructure for bone grafting

Peripheral Vascular Disease

Effect of Bone Marrow Stem Cells



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

Peripheral Vascular Disease

Lead Development Strategy

- Research
 - Vascular forming capability for TRCs completed
 - Pursuing grants for further research development
- Clinical
 - Clinical study for demonstration of TRC effect on vascular regeneration in limb ischemia planned in CY2005
 - Compare with unexpanded bone marrow
- Market Development
 - Pursue strategic marketing partner for involvement in Phase III level trials

Aastrom Balance Sheet Data

(June 30, 2004 - Actual)

- Cash and Investments \$ 16,900,000
- Total Assets \$ 18,200,000
- Shareholders' Equity \$ 17,600,000
- Average Cash Usage Per Month \$ 900,000



Summary

- Strategic industry position with a proven proprietary adult stem cell product and means for commercial production
- Profitability targeted through non-U.S. markets, with future growth resulting from U.S. markets
- Active clinical trials for large and diverse bone graft markets
- Opportunities for new marketing partnerships
- Preclinical pipeline includes 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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