
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of Earliest Event Reported): November 18, 2010

Aastrom Biosciences, Inc.

(Exact name of registrant as specified in its charter)

Michigan

(State or other jurisdiction
of incorporation)

000-22025

(Commission
File Number)

94-3096597

(I.R.S. Employer
Identification No.)

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

(Address of principal executive offices)

48106

(Zip Code)

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

Not Applicable

Former name or former address, if changed since last report

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

- 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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Item 7.01. Regulation FD Disclosure.

On November 18, 2010, Aastrom Biosciences, Inc. (the “Company”) hosted a webcast that included a slide presentation, a copy of which is furnished herewith as Exhibit 99.1.

Item 8.01. Other Events.

On November 18, 2010, the Company issued a press release, a copy of which is filed herewith as Exhibit 99.2 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

Exhibit 99.1. Webcast slide presentation dated November 18, 2010 furnished with this Report

Exhibit 99.2. Press release dated November 18, 2010 filed with this Report

SIGNATURES

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

Aastrom Biosciences, Inc.

Date: November 19, 2010

By: /s/ Timothy Mayleben

Name: Timothy Mayleben

Title: Chief Executive Officer and President

Exhibit Index

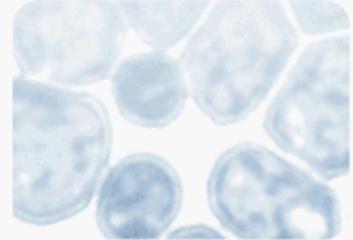
<u>Exhibit No.</u>	<u>Description</u>
99.1	Webcast slide presentation dated November 18, 2010 furnished with this Report
99.2	Press Release dated November 18, 2010 filed with this Report



Interim Analysis Results

RESTORE-CLI November 18, 2010

Richard J. Powell MD, on behalf of the RESTORE-CLI Investigators



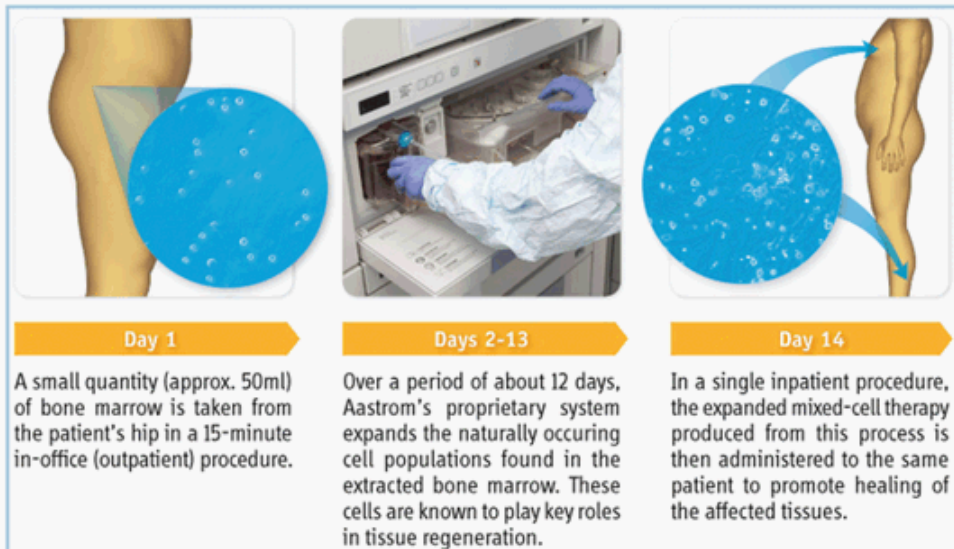
"This presentation includes the individual comments and opinions of Richard Powell MD, chief of vascular surgery at Dartmouth-Hitchcock Medical Center in Lebanon, NH. None of Dr. Powell's comments should be considered to be an endorsement of any product or service by Dartmouth-Hitchcock Medical Center."

Outline

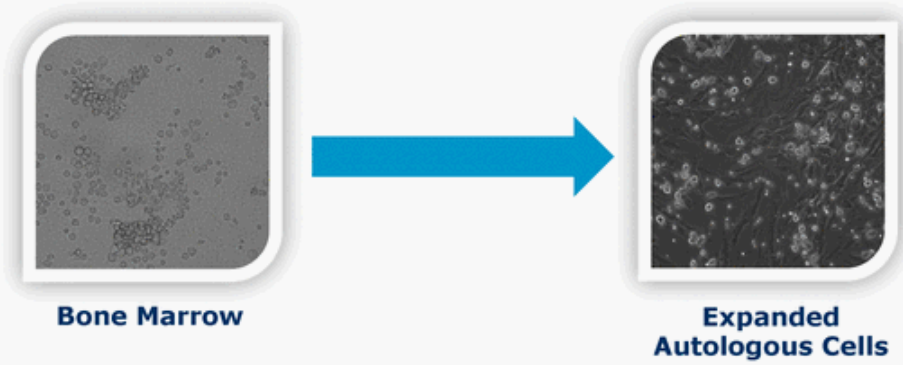
- ❖ Overview: Aastrom's Expanded Autologous Cellular Therapy
- ❖ Description: Critical Limb Ischemia
- ❖ Brief Overview: Study Design & Efficacy/Safety Data of Interest
- ❖ 2nd Interim Analysis Population Description:
 - Patients enrolled, randomized, and treated in time for 6 month follow-up
- ❖ 2nd Interim Analysis Results
 - Patient Demographics
 - Patient Disposition
 - Efficacy Results
 - Safety Overview
- ❖ Next Steps for the CLI Program



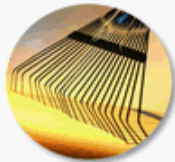
■ ■ Aastrom's Approach



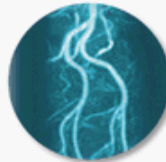
Aastrom's Therapy



Leveraging the body's regenerative systems and pathways



**Removes
damaged
tissue**



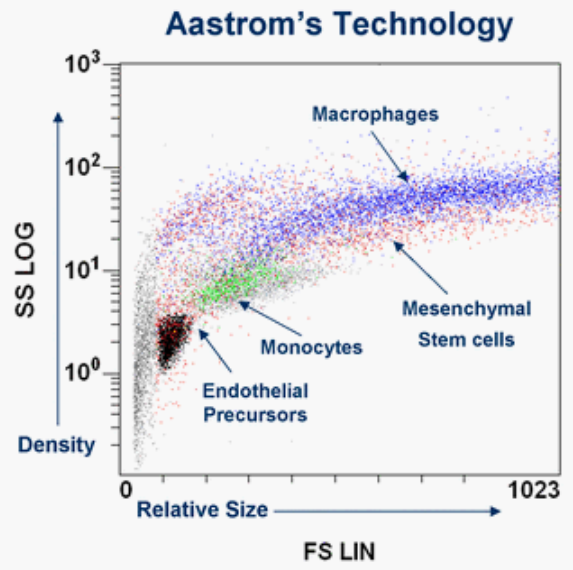
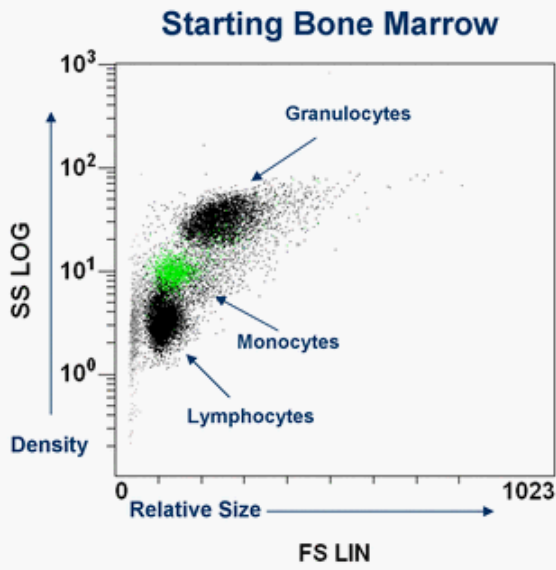
**Grows new
blood vessels
(Angiogenesis)**



**Reduces
Inflammation**



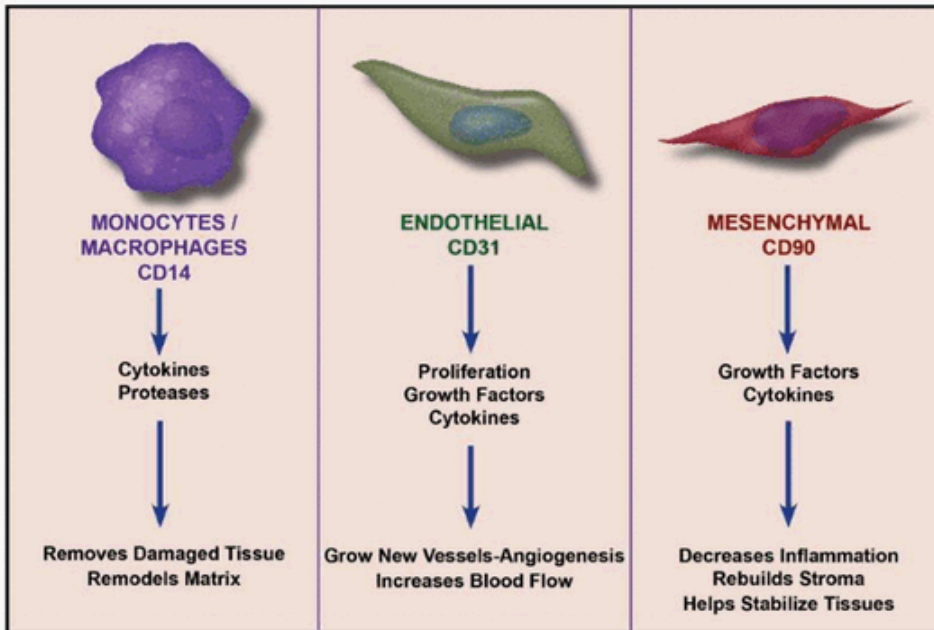
Aastrom's Technology



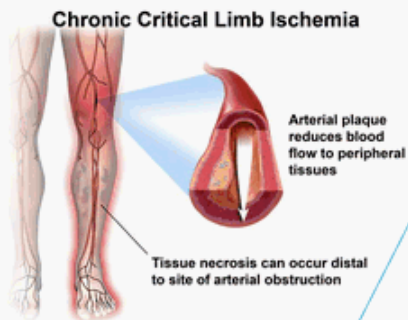
Aastrom's technology dramatically expands the tissue regenerative cell populations



■ ■ Key Cellular Components:

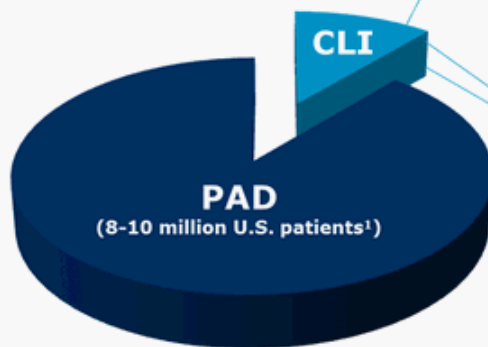


Critical Limb Ischemia (CLI)

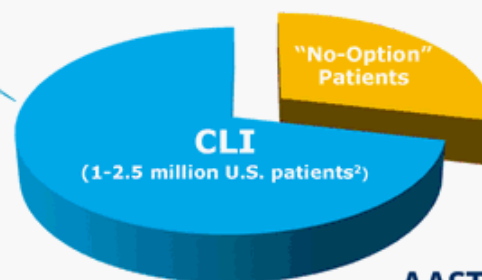


Limited Therapeutic Options

- No CLI therapy approved for no-option patients
 - Amputation - only option
- Within one year of diagnosis...
 - 25% will require amputation
 - 25% will die⁴
- Post-amputation mortality at 4 years as high as 76%³



Our Focus: 400,000 "No-Option" Patients⁴



AASTROM

Sources: (1)Schanzer A, Conte MS. Cardiovasc Med. 2010 June; (2) Yost ML. Critical Limb Ischemia. VOLUME 1 United States Epidemiology Prevalence, Market Opportunities and Analysis of the Two Most Common Comorbidities: Diabetes and Chronic Kidney Disease. 2007; (3)Hansen, Acta Orthop Scand 1998; (4)The SAGE GROUP 2007 and Allie et al. Eurointervention. 2005 May

■ ■ Brief Overview: Study Design

- ❖ Original Protocol: Up to 150 patients in a prospective, controlled, **randomized, double-blind study**
 - Based on positive 1st interim (February 2010), stopped enrollment at 86 randomized patients
 - 72 Patients enrolled, randomized, and eligible for treatment were analyzed
 - Enrollment criteria:
 - Age 18-90 yrs old
 - Diagnosed with CLI and no option for revascularization
 - Wounds rate 3 or less on Wagner scale
- ❖ Randomized 2:1 to Treatment vs Control
- ❖ Total 12 month follow-up (visits every 3 months)



2nd Interim, November'10: Efficacy and Safety Data Evaluated

- Patients: All enrolled, randomized, treated and completing 6-month follow-up
- Evaluations:
 - ❖ Time to first occurrence of treatment failure (TTF)
 - Major amputation of treated leg
 - All-cause mortality
 - Doubling of wound size from baseline
 - *De novo* gangrene
 - ❖ Amputation-free survival (AFS)
 - Major amputation of treated leg
 - All-cause mortality
 - ❖ Adverse events





Results

Interim Analysis November 2010
6-month evaluation



■ ■ Patient Demographics – ITT population

Parameter	TRC N = 48	Control N = 24
% Male	71	58
Age (mean, range)	69 (34-90)	67 (40-85)
% Current, % Past smokers	17, 67	38, 46
% Current, % Past alcohol	44, 23	29, 33
BMI (mean, range)	26.9 (14-38)	28.1 (18-40)
Creatinine mg/dL (mean, range)	1.2 (0.5-2.8)	1.1 (0.5-1.6)
N (%) prior below talus amputation	8 (17)	2 (8)
N (%) with known Diabetes	21 (44)	15 (63)

ITT population: Total 72 patients randomized, and eligible for treatment, 6-month evaluation



Disposition of Treated Patients at 6 month Interim

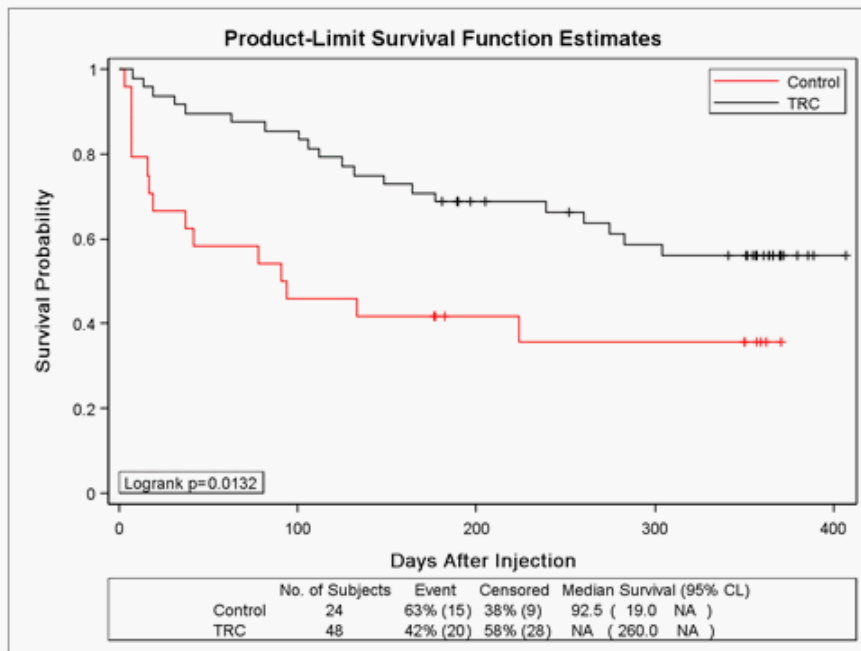
	TRC N = 48	Control N = 24
Completed	34 (71)	18 (75)
Died	3 (6)	1 (4)
Withdrew	6 (13)	0 (0)
-w/endpoint*	3 (6)	0 (0)
-w/o endpoint	3 (6)	0 (0)
Continuing	5 (10)	5 (21)

* All 3 patients had a major amputation



Time to First Occurrence of Treatment Failure: ITT

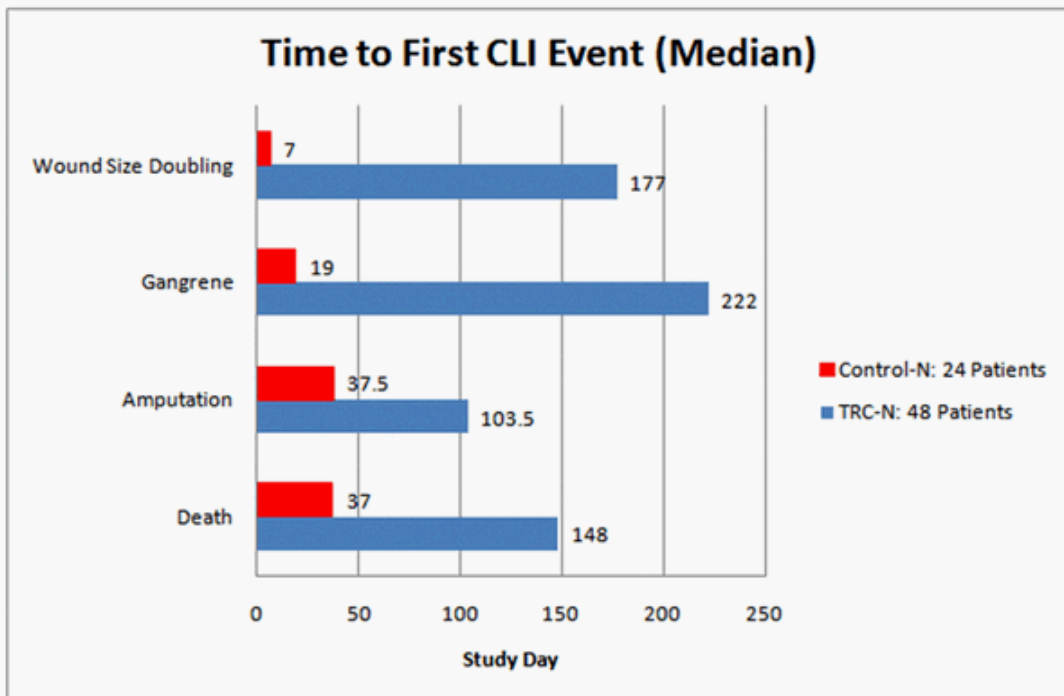
Population, 2nd Interim



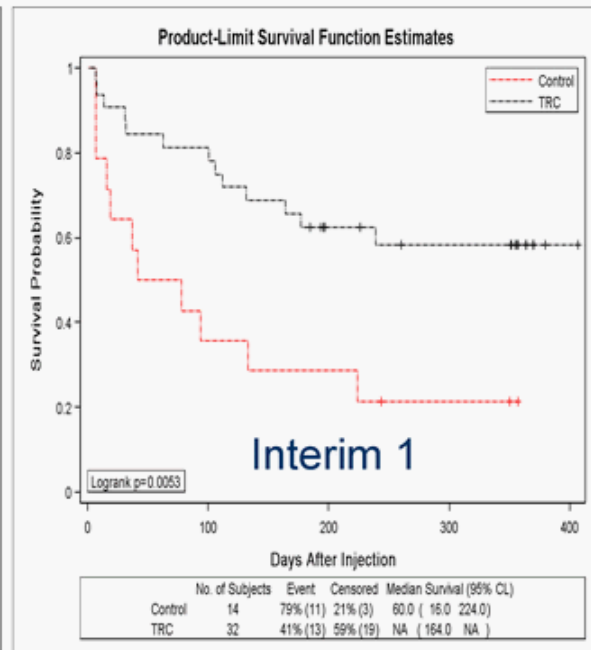
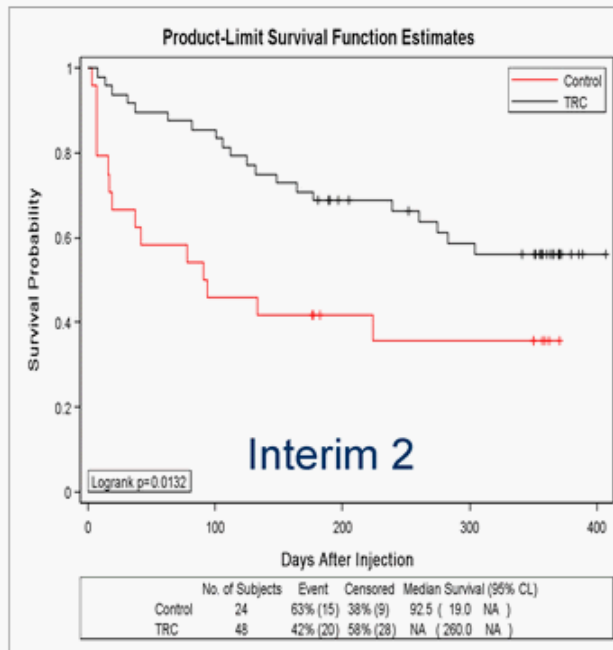
56% risk reduction: HR 0.44 (0.22-0.86)



Aastrom's Therapy Prolongs Time to the First CLI Event



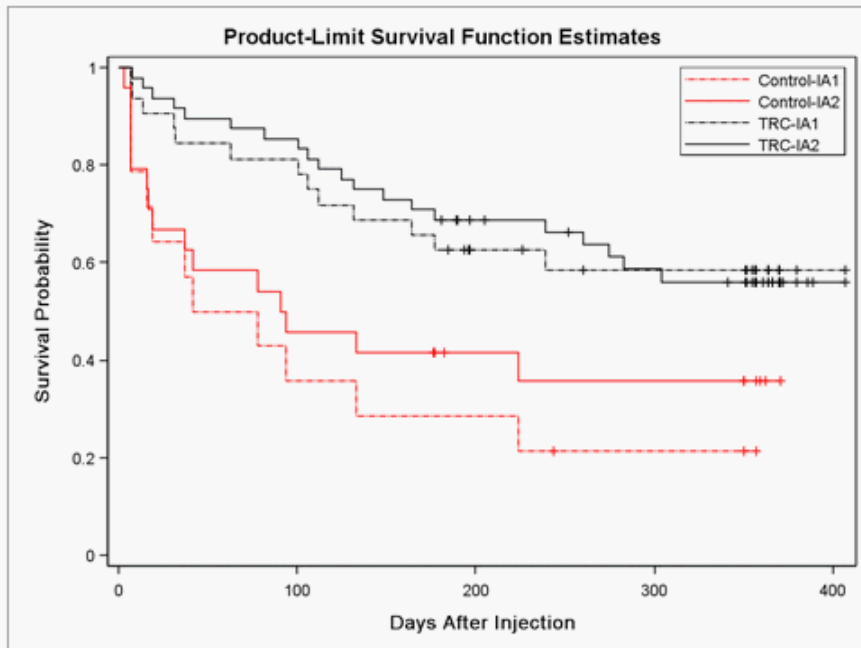
Time to Treatment Failure: Comparison of Interim Analyses



Similar shape, p value as 2nd IA

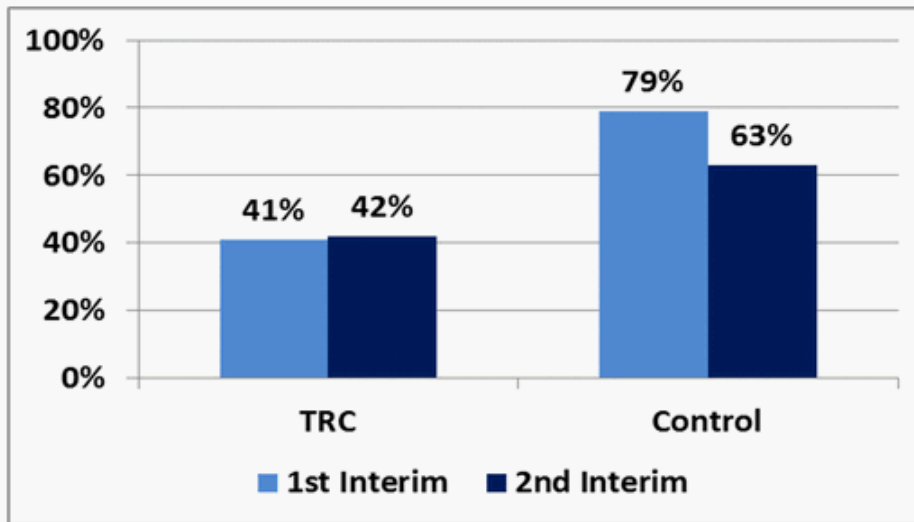


Time to Treatment Failure: Comparison of Interim Analyses



Similar treatment event rate for both interim analyses
Control event rate differs slightly

■ ■ Treatment Failure: Rates for 1st and 2nd Interim Analyses



Similar Treatment Event Rate for Both Interim Analyses
Control Event Rate Differs Slightly



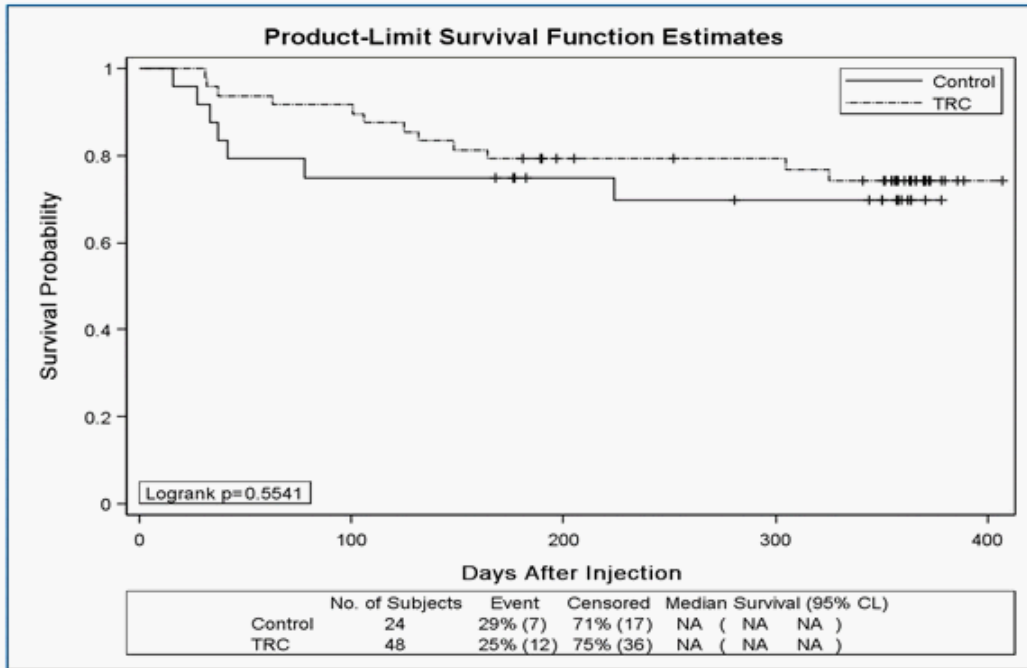
Composite Event Rates – 1st & 2nd Interims

N (%) with Event	TRC			Control		
	1 st Interim * N = 32	2 nd Interim N = 16	Total N = 48	1 st Interim * N = 14	2 nd Interim N = 10	Total N = 24
Amputation	8 (25)	2 (13)	10 (21)	6 (43)	0 (0)	6 (25)
De novo Gangrene	5 (16)	1 (6)	6 (13)	2 (14)	3 (30)	5 (21)
Wound size doubling from BL	6 (19)	3 (19)	9 (19)	5 (36)	2 (20)	7 (29)
Death	1 (3)	2 (13)	3 (6)	1 (7)	0 (0)	1 (4)

* Some patients included in the 1st Interim Analysis experienced their event after the time of the 1st interim analysis (between the 1st and 2nd interim analyses)



Amputation-Free Survival: ITT population, 2nd Interim

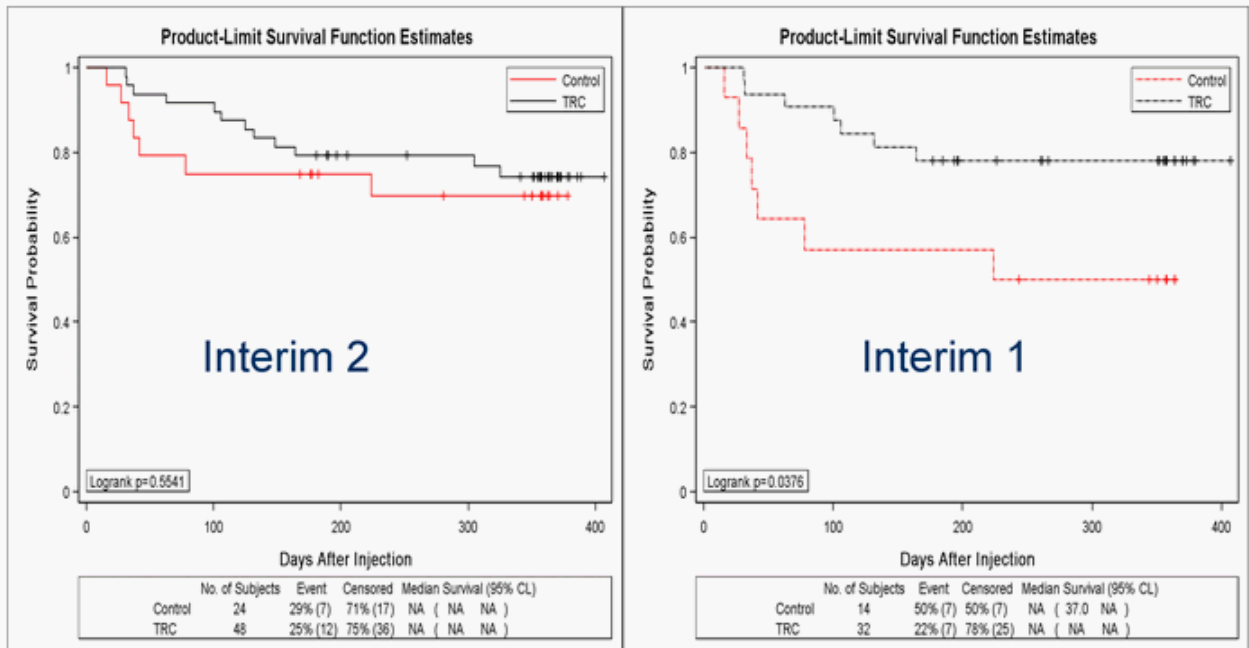


24% risk reduction: HR 0.76 (0.30-1.92)



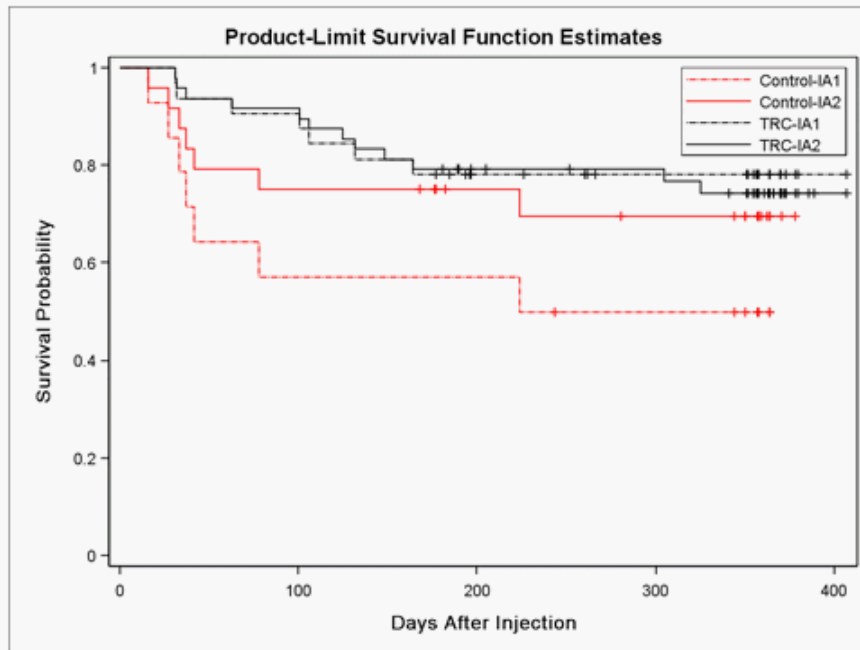
Amputation Free Survival:

Comparison of Interim Analyses 1 and 2



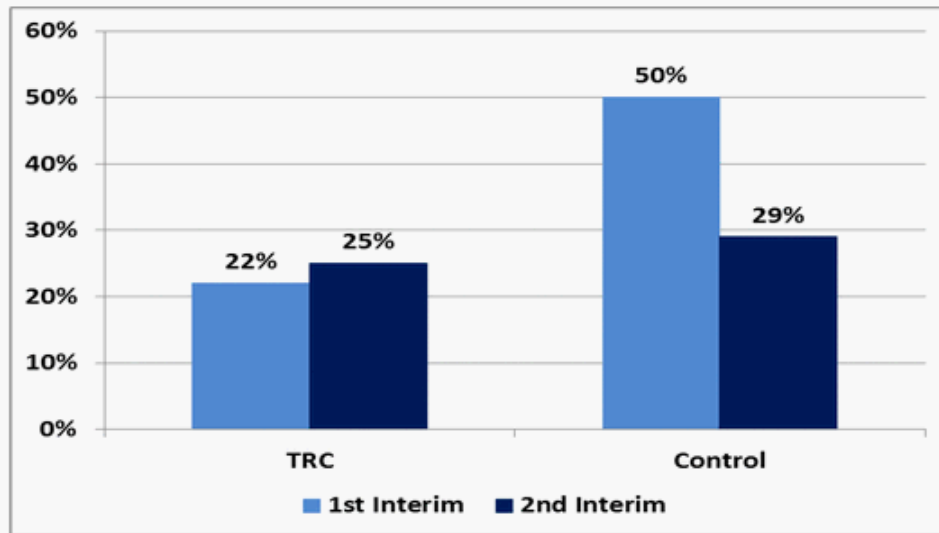
Dissimilar shape, p value IA 1 vs IA 2

Amputation Free Survival: Comparison of Interim Analyses



Similar Treatment Event Rate for Both Interim Analyses
Control Event Rate Markedly Different

Amputation Free Survival – Rates for 1st and 2nd Interim Analyses



Similar Treatment Event Rate for Both Interim Analyses
Control Event Rate Differs Markedly

■ ■ Typical Event Rates in No-Option CLI Trials:

Author	N	AFS Event Rate	Time Period
Horie et al. (2010) G-CSF mobilized PBMNC	140	43%	1 year
Nikol et al. (2008) Talisman 201 Placebo	56	51.8%	1 year
Brass et al. (2006) Circulase Placebo	177	17.5%	6 months
Onodera et al. (2010) BM-MNC or M-PBMNC	185	27-34%	2 year
Matoba et al. (2008) BM-MNC	74	31-38%	1 year

Usual AFS event rates are \approx 30-40%



■ ■ Differences in Baseline Characteristics: IA 1 and IA 2

Parameter	TRC		Control	
	1 st Interim N (%)	2 nd Interim N (%)	1 st Interim N (%)	2 nd Interim N (%)
Treated Patients	32	16	14	10
Male	25 (78)	9 (56)	8 (57)	6 (60)
Female	7 (22)	7 (44)	6 (43)	4 (40)
Baseline Physical Examination				
Previous Amputation on Treated Side	5 (16)	3 (19)	2 (14)	0 (0)
Wound	18 (56)	11 (69)	9 (64)	7 (70)
Medications				
ASA	25 (78)	12 (75)	11 (79)	9 (90)
Statin	24 (75)	14 (88)	11 (79)	10 (100)
ACE Inhibitors	11 (34)	4 (25)	5 (36)	7 (70)

■ ■ Safety Evaluation:

■ ■ Safety Overview: All Aspirated Patients

Safety Parameter	TRC N = 53	Control N = 24
N (%) with Adverse Events	46 (87)	22 (92)
N (%) Serious Adverse Event	23 (43)	12 (50)
N (%) withdrawal due to AE	1 (2)	0 (0)
N (%) Deaths *	3 (6)	1 (4)

* An additional TRC treated patient died after the study completed.



Safety Overview: All Aspirated Patients;

■ ■ AEs in $\geq 10\%$ of Patients

Preferred Term N (%)	TRC N = 53	Control N = 24
Pain in extremity	17 (32)	4 (17)
Gangrene	6 (11)	6 (25)
Cellulitis	5 (9)	6 (25)
Skin Ulcer	7 (13)	4 (17)
Localized infection	5 (9)	3 (13)
Nausea	5 (9)	3 (13)

■ ■ Summary: RESTORE-CLI 6-Month Interim Analysis

1. Continued evidence of an excellent safety profile
2. Time to treatment failure continues to be statistically significant ($p = 0.0132$)
 - > All events of this composite (amputation, death, doubling in wound size and *de novo* gangrene) are delayed in comparison to the placebo group
3. 24% reduction in event rate for amputation and death (although unlike interim analysis 1, not statistically significant)
 - > Control event rate changed from 1st interim



■ ■ Impact on Phase 3 Plans

- ❖ Improved Phase 3 sample size understanding
 - Phase 3 Interim Analysis planned to reassess sample size estimates
- ❖ Improved understanding of key design issues
- ❖ Continuing the work to support the Phase 3 program launch in the 1st half of 2011

■ ■ Next Steps:

- ❖ Awaiting FDA Feedback from SPA (submitted 10/18/2010)
- ❖ Finalize the protocols based on their response
- ❖ Ensure FDA agreement with production of Aastrom's expanded autologous cell therapy (CMC amendment)
- ❖ Launch Phase 3 studies





"Astrom would like to thank all of the patients, clinical coordinators, and investigators for contributing to and participating in the Astrom Phase 2b, RESTORE-CLI trial."





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Aastrom Presents Positive Second Interim Analysis of
Phase 2b RESTORE-CLI Clinical Trial

Company continues its plans to rapidly move into a Phase 3 program in 2011

Ann Arbor, MI, November 18, 2010 (1:45pm ET) — Aastrom Biosciences, Inc. (NASDAQ: ASTM), a leading developer of expanded autologous cellular therapies for the treatment of severe cardiovascular diseases, today announced that an interim analysis of all 86 patients enrolled in the company's Phase 2b RESTORE-CLI clinical trial shows that the study achieved both its primary safety endpoint and primary efficacy endpoint of time to first occurrence of treatment failure. The findings related to time to first occurrence of treatment failure were statistically significant ($p=0.0132$). Further analyses show a clinically meaningful reduction of 56% in treatment failure events. The RESTORE-CLI trial is the largest fully controlled cell-therapy study ever conducted in critical limb ischemia (CLI).

This interim analysis includes results from all 86 patients who were randomized and enrolled in the trial, 72 of whom were eligible for treatment and have completed at least six months of follow-up and 62 of whom completed 12 months of follow-up. Analysis of the data for amputation-free survival, a secondary measure which the study was not powered to demonstrate, showed a clinically meaningful reduction in event rates of 24%, but did not show statistical significance ($p=0.5541$). Importantly, analysis of the data between the interim results shows similar treatment event rates (22-25%) for the treated group, but an unexpected reduction in event rates for the control group from 50% to 29%.

In February 2010, Aastrom reported results from an interim analysis of data from this trial that showed a statistically significant clinical benefit favoring Aastrom's autologous cellular therapy for the first 46 patients enrolled in the trial, in both time to first occurrence of treatment failure (a composite endpoint consisting of major amputation of treated leg, all-cause mortality, doubling of total wound surface area from baseline and *de novo* gangrene; $p=0.005$) and amputation-free survival ($p=0.038$).

Results of the second interim analysis were presented today in a non-CME satellite session of the VEITHsymposium™ in New York City by principal investigator Richard Powell, M.D.,

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chief of vascular surgery at Dartmouth-Hitchcock Medical Center in Lebanon, NH. An archived webcast of the presentation will be available at www.aastrom.com/investor.cfm.

“I am very optimistic about the treatment response rates we have seen in patients in this trial so far. These interim data suggest that there is a clear and clinically meaningful therapeutic effect at work in treated patients. I look forward to examining the benefits of this treatment in the context of a larger Phase 3 study,” said Dr. Powell.

The two interim analyses were done to provide information to support the design and execution of Aastrom’s Phase 3 CLI program. In October, Aastrom announced plans to initiate a Phase 3 CLI clinical development program under special protocol assessments (SPA) with a Fast Track designation by the FDA.

“We believe these interim results provide further evidence supporting the use of our autologous cell therapy to treat patients with this devastating disease,” said Tim Mayleben, president and CEO of Aastrom Biosciences. “As expected, these data provide essential guidance as we refine and finalize the sample sizes and patient selection criteria for our Phase 3 program.”

About Aastrom Biosciences

Aastrom Biosciences is an emerging biotechnology company developing expanded autologous cellular therapies for use in the treatment of severe cardiovascular diseases. The company’s proprietary cell-processing technology enables the manufacture of mixed-cell therapies expanded from a patient’s own bone marrow and delivered directly to damaged tissues. Aastrom has advanced its cell therapies into late-stage clinical development, including a planned Phase 3 clinical program for the treatment of patients with critical limb ischemia and two ongoing Phase 2 clinical trials in patients with dilated cardiomyopathy. For more information, please visit Aastrom’s website at www.aastrom.com.

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This document contains forward-looking statements, including without limitation, statements concerning employment opportunities, clinical trial plans and progress, objectives and expectations, clinical activity timing, intended product development, disease treatment and progression, operating results, spending activities, patient symptoms and responses to treatment, treatment options and expected timing of collecting and analyzing treatment data, all of which involve certain risks and uncertainties. These statements are often, but are not always, made through the use of words or phrases such as “anticipates,” “intends,” “estimates,” “plans,” “expects,” “we believe,” “we intend,” and similar words or phrases, or future or conditional verbs such as “will,” “would,” “should,” “potential,” “could,” “may,” or similar expressions. Actual results may differ significantly from the expectations contained in the forward-looking statements. Among the factors that

- more -

may result in differences are the inherent uncertainties associated with clinical trial and product development activities, regulatory approval requirements, competitive developments, and the availability of resources and the allocation of resources among different potential uses. These and other significant factors are discussed in greater detail in Aastrom's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. These forward looking statements reflect management's current views and Aastrom does not undertake to update any of these forward-looking statements to reflect a change in its views or events or circumstances that occur after the date of this release except as required by law.