

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): January 25, 2012

NEOSTEM, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware  
(State or Other Jurisdiction  
of Incorporation)

001-33650  
(Commission  
File Number)

22-2343568  
(IRS Employer  
Identification No.)

420 Lexington Avenue, Suite 450, New York, New York 10170  
(Address of Principal Executive Offices)(Zip Code)

(212) 584-4180  
Registrant's Telephone Number

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 (see General Instruction A.2. below):

- 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))
-

**Item 7.01. Regulation FD Disclosure.**

NeoStem, Inc. (“NeoStem” or the “Company”) intends, from time to time, to utilize at various industry and other conferences a slide presentation. The slide presentation is accessible on NeoStem’s website at [www.neostem.com](http://www.neostem.com) and is being furnished as Exhibit 99.1 hereto. NeoStem undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

The information in this Current Report on Form 8-K under Item 7.01 is being furnished pursuant to Item 7.01 of Form 8-K. In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including, without limitation, Exhibit 99.1, shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information in this Current Report on Form 8-K, including, without limitation, Exhibit 99.1, shall not be incorporated by reference into any filing or other document pursuant to the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing or document.

**Item 8.01 Other Events**

On January 25, 2012, Amorcyte, LLC, a wholly-owned subsidiary of the Company, issued a press release announcing the enrollment of the first patient in its PreSERVE Phase 2 trial of AMR-001, its lead product candidate for the treatment of acute myocardial infarction. A copy of this press release is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated into this Item 8.01 by reference.

***Forward Looking Statements***

This Current Report on Form 8-K, including Exhibit 99.1 hereto, contains “forward-looking” statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are typically preceded by words such as “believes,” “expects,” “anticipates,” “intends,” “will,” “may,” “should,” or similar expressions, although some forward-looking statements are expressed differently. Forward-looking statements represent the Company’s management judgment regarding future events. Although the Company believes the expectations reflected in such forward-looking statements are reasonable, the Company can give no assurance that such expectations will prove to be correct. All statements other than the statements of historical fact included in this Current Report on Form 8-K are forward-looking statements. The Company cannot guarantee the accuracy of the forward-looking statements, and you should be aware that the Company’s actual results could differ materially from those contained in the forward-looking statements due to a number of factors, including the statements under “Risk Factors” contained in the Company’s reports filed with the Securities and Exchange Commission (the “SEC”).

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**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
99.1	Slide presentation of NeoStem, Inc., dated January 2012
99.2	Press Release dated January 25, 2012

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**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.

**NEOSTEM, INC.**

By: /s/ Catherine M. Vaczy  
Name: Catherine M. Vaczy, Esq.  
Title: Vice President and General Counsel

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Dated: January 26, 2012

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# NeoStem, Inc. ("NBS")

## Investor Presentation

*January 2012*

**NeoStem**<sup>®</sup>  
YOUR CELLS • YOUR USE • YOUR LIFE  
[WWW.NEOSTEM.COM](http://WWW.NEOSTEM.COM)



## Forward-Looking Statements

Included in this presentation are "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995, as well as historical information. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of NeoStem, Inc. and its subsidiaries (collectively, the "Company"), or industry results, to be materially different from anticipated results, performance or achievements expressed or implied by such forward-looking statements. When used in this presentation, statements that are not statements of current or historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words "plan," "intend," "may," "will," "expect," "believe," "could," "anticipate," "estimate," or "continue" or similar expressions or other variations or comparable terminology are intended to identify such forward-looking statements, although some forward-looking statements are expressed differently. Additionally, statements regarding our ability to successfully develop, integrate and grow the businesses at home and abroad, including with regard to the Company's research and development efforts in cellular therapy, its adult stem cell and umbilical cord blood collection, processing and storage business, contract manufacturing and process development of cellular based medicines, and the pharmaceuticals manufacturing operations conducted in China, the future of regenerative medicine and the role of stem cells in that future, the future use of stem cells as a treatment option and the role of VSEL™ Technology in that future and the potential revenue growth of such businesses, are forward-looking statements. Our future operating results are dependent upon many factors and our further development is highly dependent on future medical and research developments and market acceptance, which is outside our control. Forward-looking statements, including with respect to the successful execution of the Company's strategy, may not be realized due to a variety of factors and we cannot guarantee their accuracy or that our expectations about future events will prove to be correct. Such factors include, without limitation, (i) our ability to manage the business despite operating losses and cash outflows; (ii) our ability to obtain sufficient capital or strategic business arrangements to fund our operations and expansion plans, including meeting our financial obligations under various licensing and other strategic arrangements and the successful commercialization of the relevant technology; (iii) our ability to build the management and human resources and infrastructure necessary to support the growth of the business; (iv) our ability to integrate the Company's acquired businesses successfully and grow such acquired businesses as anticipated; (v) whether a large global market is established for our cellular-based products and services and our ability to capture a share of this market; (vi) competitive factors and developments beyond our control; (vii) scientific and medical developments beyond our control; (viii) our ability to obtain appropriate governmental licenses, accreditations or certifications or comply with healthcare laws and regulations or any other adverse effect or limitations caused by government regulation of the business; (ix) whether any of our current or future patent applications result in issued patents and our ability to obtain and maintain other rights to technology required or desirable for the conduct of our business; (x) whether any potential strategic benefits of various licensing transactions will be realized and whether any potential benefits from the acquisition of these licensed technologies will be realized; (xi) the results of our development activities, including the timing, enrollment, outcome and/or results of any clinical trials; (xii) our ability to successfully divest our 51% ownership of our Erye subsidiary; (xiii) factors regarding our business and initiatives in China and, generally, regarding doing business in China, including through our variable interest entity structure, including (a) costs related to funding these initiatives, (b) the successful application under Chinese law of the variable interest entity structure to the Company's business, which structure the Company is relying on to conduct its business in China, (c) the ability to integrate the Company and the business operations in China successfully, (d) the need for outside financing to meet capital requirements, and (e) the ability of the Company to realize on its investment in Erye through distributions, divestiture or other strategic alternatives and the value to be realized given recent regulatory and other developments in China; and (xiv) other risk factors disclosed in the Company's definitive proxy statement filed September 16, 2011 and in the Company's periodic filings with the Securities and Exchange Commission which are available for review at [www.sec.gov](http://www.sec.gov) under "Search for Company Filings."

All forward-looking statements attributable to us are expressly qualified in their entirety by these and other factors. We undertake no obligation to update or revise these forward-looking statements, whether to reflect events or circumstances after the date initially filed or published, to reflect the occurrence of unanticipated events or otherwise, except to the extent required by federal securities laws.

The contents of this PowerPoint presentation reflect the merger of Amorocyte, Inc., a clinical stage therapeutics company pursuing cell-based therapies for cardiovascular diseases, with and into a wholly-owned subsidiary of NeoStem, which closed on October 17, 2011.



# NeoStem, Inc.

(AMEX: NBS)

*Leader in the Development and Manufacture of Cellular Therapies*

Strategic combination of revenues including stem cell therapies, contract manufacturing and stem cell services

## Clinical Development



## Manufacturing & Services



NeoStem  
www.neo-stem.com



# Cell Therapy Has Already Shown Promise Towards Unmet Therapeutic Needs

21,036 Cell Therapy Trials; 3,856 Stem Cell Therapy Trials; 1,065 Immunotherapy Trials\*

## Central Nervous System



Reverse neurological damage

- ALS
- Spinal cord injury
- Stroke
- Neuro-degenerative

## Cardiovascular Disease



Neo-vascularization and repair of damaged tissue

- Prevent heart failure post STEMI
- Restore failing heart function
- Improve areas of vascular insufficiency

## Musculoskeletal



Rebuild bone and repair cartilage

- Disc repair
- Cranial facial
- Osteoporosis
- Reconstruction post trauma

## Autoimmune Diseases



Reset the immune system

- Provide exquisite control of glucose and insulin level (diabetes)
- Immune tolerance regimens to combat autoimmunity
  - MS
  - Lupus
  - Osteoarthritis
- GvHD
- Solid organ rejection

## What Does This Mean For Investors?

\* Source: Clinicaltrials.gov (note not all enrolling)





## NeoStem's Approach

NeoStem is uniquely positioned for success with a strategic combination of revenues and a pipeline of cell based therapies focused on transforming chronic disease.

### Therapeutics Development

- Autologous Stem Cell based Therapeutic for Cardiovascular Disease (Amorcyte)
- T-Regulatory Program for Auto-Immune Disorders, GVHD & Solid Organ Rejection (Athelos)
- Regenerative Medicine Program Using Autologous VSELs™



### Revenues

#### Services Division

Contract  
Manufacturing  
(PCT)  
&  
Family Stem  
Cell Banking

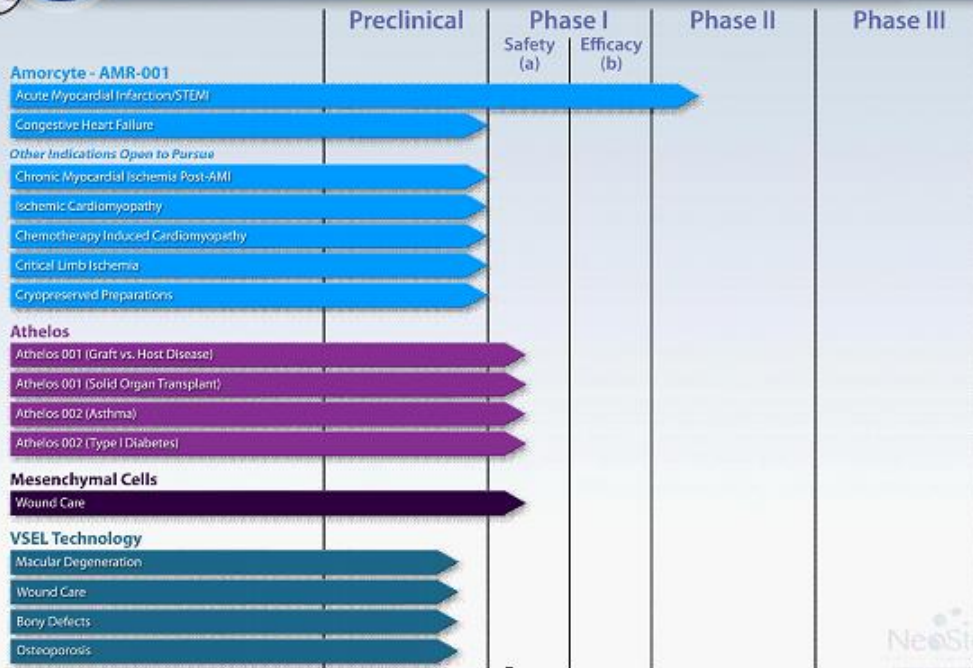


## Clinical Development



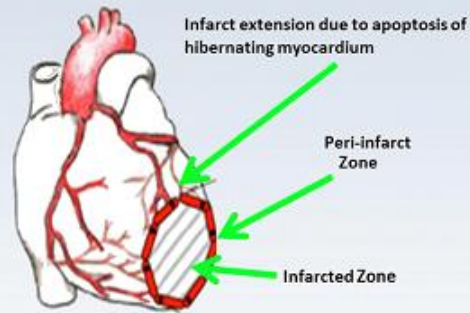


# NeoStem's Cell Therapeutics Pipeline



## Clear Unmet Medical Need for AMI Patients

- Of the approximately 800,000 annual AMI patients in the U.S., 20% (160,000) are STEMI, and **are at risk to experience progressive deterioration in heart muscle function leading to:**
  - Premature Death
  - Recurrent Myocardial Infarction
  - Congestive Heart Failure
- A consequence of inadequate perfusion (microvascular insufficiency) is hibernating cardiomyocytes and progressive cardiomyocyte loss due to apoptosis



### References:

American Heart Association  
Quyyumi AA et al 2011, American Heart Journal; 161(1) 98-105



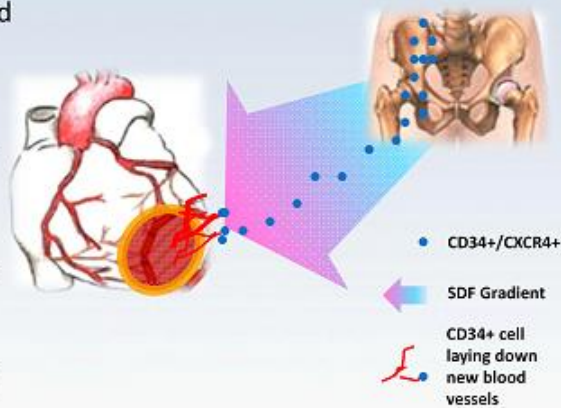
- AMR-001 is an autologous bone marrow derived pharmaceutical grade therapeutic intended to preserve heart muscle function and limit MACE and other adverse clinical events following an acute myocardial infarction.
- Pharmaceutical grade: Defined identity, purity, potency, relevant biologic stability (mobility in an SDF-1 gradient), sterility and dose threshold in our Phase 1 clinical trial.
- Confirmed mechanism of action: Based on SDF-1 mediated mobility.
- Dominant IP position with both composition of matter and method patents through 2028.
- Manufacturing and logistics cost, including transportation, will allow for attractive commercial margins.
- Existing manufacturing capacity expected to be available for first two years of commercialization (PCT).
- Early pharmacoeconomic study supports value of AMR-001.



## Cell Type: CD34<sup>+</sup>CXCR4<sup>+</sup> Cells are a Natural Repair Mechanism

The body attempts to rescue damaged tissue to prevent ventricular remodeling:

- A distress signal (HIF) is induced by hypoxia in the peri-infarct zone
- HIF induces synthesis of SDF-1 which mobilizes CD34<sup>+</sup>CXCR4<sup>+</sup> cells
- The mobilized cells are trophic to the peri-infarct zone, preventing apoptosis through paracrine effects and effecting neoangiogenesis



AMR-001: Highly purified (CD34<sup>+</sup>) and active (CXCR4<sup>+</sup>) cell population





## AMR-001 Phase 1 Clinical Trial Completed

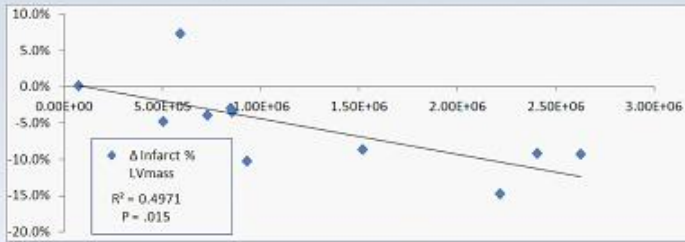
<b>Indication</b>	Post-AMI with LVEF $\leq$ 50% and wall motion abnormality in the myocardium of the IRA
<b>Primary Endpoint</b>	Safety in post-AMI patients
<b>Other Endpoints</b>	RTSS* (Perfusion); LVEF; ESV; SDF mobility
<b>Key Inclusion Criteria</b>	Confirmation of ST Elevation MI; Ejection fraction $\leq$ 50% 96 hours post stenting
<b>Dosing Frequency</b>	Single dose
<b>Groups and Randomization</b>	3 dose cohorts (5, 10, 15 million cells, randomized 1:1)
<b>Number of Subjects</b>	N=31
<b>Number of Sites</b>	4
<b>Geography</b>	United States
<b>Trial Duration</b>	6 months

Quyyumi AA et al 2011, American Heart Journal; 161(1) 98-105

\*RTSS: Resting Total Severity Score - a measure of hypoperfusion (lack of perfusion)

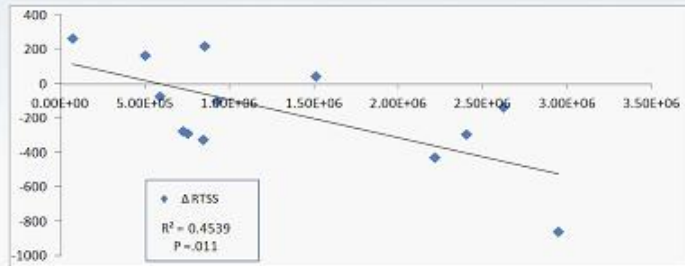
## Dose Response Established

Y =  $\Delta$  Infarct % LV Mass, X = Dose of SDF1 mobile CD34 cells



**Increasing doses of AMR-001 reduced the size of the infarct region by CMR**

Y =  $\Delta$  RTSS, X = Dose of SDF1 mobile CD34 cells



**Increasing doses of AMR-001 reduced RTSS indicating improved perfusion**

Quyyumi AA et al 2011, American Heart Journal; 161(1) 98-105





## Threshold Dose for Efficacy Established

### RTSS (Hypoperfusion)

*Baseline correlates with infarct size*

Cohort	Base Line	6 months	Delta	% Change
Control	259.0	273.5	+14.5	+5.6
5M Cells	714.2	722.0	+7.8	+1.1
10M Cells	998.6	635.8	-362.8	-36.4
15M Cells	584.0	462.0	-122.0	-20.9

**Patients dosed  $\geq$  the threshold dose of 10 million cells showed significant improvement in perfusion**

DSMB determined that no adverse events were related to therapy

Quyyumi AA et al 2011, American Heart Journal; 161(1) 98-105  
RTSS: Resting Total Severity Score



# Subgroup Analyses: Additional Cardiac Function Test Results

Amorcyte-AMR 001

## RTSS (Hypoperfusion)

		6 month			
		Base Line	6 Mo.	Δ	% Δ
Below Threshold		385.4	398.1	+12.6	+3.3
Above Threshold		814.3	558.6	-255.8	-31.4 (p=0.01)*

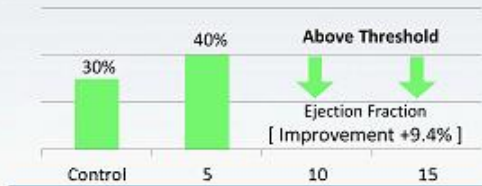
## Ejection Fraction

		6 month			
		BL	6 Mo.	Δ%	% Δ
Below Threshold		51.0	51.8	0.7	+1.3
Above Threshold		48.2	52.7	+4.5	+9.4

## End Systolic Volume

		6 month			
		BL	6 Mo.	Δml	% Δ
Below Threshold		77.7	81.3	+3.6	+4.6
Above Threshold		94.1	88.4	-5.7	-6.1

## Drop in Ejection Fraction



The overall composite data and Individual scores (RTSS, ESV, EF) support potential best in class product

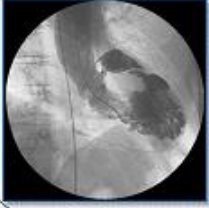
\* Threshold 10m cells or more

Quyyumi AA et al 2011, American Heart Journal; 161(1) 98-105

## Phase 2 PreSERVE AMI Trial Using AMR-001

- Patient presents with chest pain + STEMI
- All enrolled patients receive a stent
- If ejection fraction (EF)  $\leq$  48% (96 hours post stenting), patient is enrolled in trial & randomized for treatment

Ventriculography



Day 1

CMR



Day 4

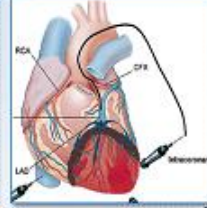
- Patient bone marrow harvested
- CD34<sup>+</sup>CXCR4<sup>+</sup> cells isolated using proprietary technology
- Intracoronary infusion of CD34<sup>+</sup>CXCR4<sup>+</sup> cell product (treatment arm) or media (control arm)

6-8 Hour Cell Separation Process



Day 5-8

Injection into the IRA



Day 6-10

### 6 Months Follow-up: Cardiac function measures by SPECT MPI and MRI with MACE Follow-up

Primary endpoint of RTSS and a host of secondary measures to assess the impact of AMR-001 on infarct size and cardiac function. These will include left ventricular ejection fraction (LVEF), (preservation and change), end systolic and end diastolic volumes, regional myocardial strain and regional wall motion. QOL will be measured by the Kansas City Cardiomyopathy Questionnaire (KCCQ) and the Seattle Angina Questionnaire (SAQ) administered at baseline, 6 and 12 months post randomization. Clinical outcomes include major adverse cardiac events (MACE) and changes in NYHA classification at 6 months, one year, 18 months, two years and three years. MACE are defined as cardiac mortality, hospitalization for worsening heart failure and recurrent acute myocardial infarction (AMI). In addition, clinical events including ventricular arrhythmias requiring intervention, acute coronary syndrome (ACS), and revascularization (PCI, CABG) will be assessed at 6 months, one year, 18 months, two years and three years. All-cause mortality will be assessed as will be the number of days alive and out of the hospital at 6 and 12 months.



## PreSERVE AMI Trial Phase 2 Clinical Plan

<b>Indication</b>	Post-AMI Preservation of Cardiac Function
<b>Primary Endpoint</b>	Increased Cardiac Perfusion (RTSS) measured by SPECT at baseline and 6 months
<b>Other Endpoints</b>	A composite of endpoints will be used to determine overall cardiac function (including preservation of LVEF and prevention of adverse remodeling) and Quality of Life (KCCQ & SAQ*)
<b>Safety</b>	Reduction in cumulative MACE and other adverse clinical cardiac events at 6, 12, 18, 24, and 36 months
<b>Dosing Frequency</b>	Single dose
<b>Dosing and Randomization</b>	Minimum dose for release $\geq 10$ m cells Randomized 1:1 treatment to sham placebo control
<b>Number of Subjects</b>	160 patients
<b>Number of Sites</b>	34
<b>Geography</b>	United States
<b>Data Readout</b>	18 months from initiation (12 month accrual and 6 month follow-up): Perfusion, cardiac function, QOL* and other clinical events

\* KCCQ: Kansas City Cardiomyopathy Questionnaire  
SAQ: Seattle Angina Questionnaire



## Pharmacoeconomic Impact

- Adverse left ventricular remodeling after STEMI results in an average medical burden of  $\geq$  \$50K per patient, per year of life
- If a patient's LVEF declines below 40%, then the cost per year escalates for the balance of the patient's lifetime
- AMR-001 is designed to prevent a decline in LVEF, thereby limiting adverse left ventricular remodeling and its negative consequences
- Pricing will allow strong commercial margins while significantly reducing costs to the health care system

Therapy	Stem Cell Product Acquisition Charge		Total Cost of Therapy
	US	International	
Bone Marrow	\$26,090	\$41,555	\$125,000 - 150,000
Peripheral Blood (PBSC)	\$25,620	\$41,645	\$85,000 - \$125,000
Cord Blood Transplant	\$34,045	\$43,025	\$150,000 - 300,000
Provenge®	\$93,000 (3Trt)		Not Available
AMR-001	TBD	TBD	TBD



## Additional Potential Indications for AMR-001

- AMR-001 platform can be applied to other conditions resulting from underlying ischemia

- Chronic myocardial ischemia post-AMI
- Congestive heart failure
- Critical limb ischemia
- Cryopreserved preparations of AMR-001 for future vascular insufficiency



- Broad and growing patent portfolio supports cardiac and other ischemic conditions

- AMR-001: Composition of matter patent (2028)
- 7,794,705: Issued 9/14/2010. Indication: Cardiac: Post AMI early and late
- 8,088,370: Issued 1/3/2012. Indication: Any tissue: Post ischemic injury

## Athelos: T-reg Cells - Restoring Immune Balance

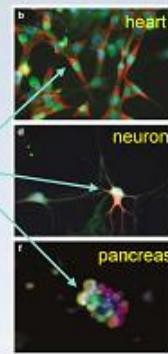
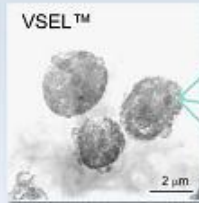


- Partnership with Becton Dickinson which owns 20% of the Athelos subsidiary
- Immune mediated diseases, such as GVHD, autoimmune diseases and allergic diseases, are a result of an imbalance between T-effector cells and T-regulatory cells (T-reg)
- T-reg therapy represents a novel approach for restoring immune balance by enhancing T-regulatory cell number and function
- T-reg cells are collected by apheresis, isolated using surface markers (for example: CD4+, CD25+, FoxP3+), activated and expanded *ex vivo* approximately 500 fold in 20 days<sup>1</sup>
- Phase 1 work is ongoing globally under several independent physician INDs, results of which will inform NeoStem's future clinical direction

1) Chai, Jian-Guo et al, *Journal of Immunology* 2008; 180:858-869

## VSEL™ Pluripotent Adult Stem Cells

- VSEL™ (Very Small Embryonic-Like) technology is NeoStem's proprietary adult stem cell technology platform
- Believed to be naturally pluripotent – no manipulation required
- iPSCs (induced pluripotent stem cells) are recognized as manipulated and destroyed by the immune system (even as an autologous product)
- VSELS™ have been shown in animal research to home to sites of injury, up-regulate angiogenesis, down-regulate inflammation (the "paracrine effect"), AND, importantly, go one step further and differentiate into target cell types



VSELS™ potentially represent the most regenerative adult stem cell as they are pluripotent, autologous, "natural," and have powerful paracrine effects





## Manufacturing & Services



## Progenitor Cell Therapy (PCT): Commercial Scale Manufacturing

PCT

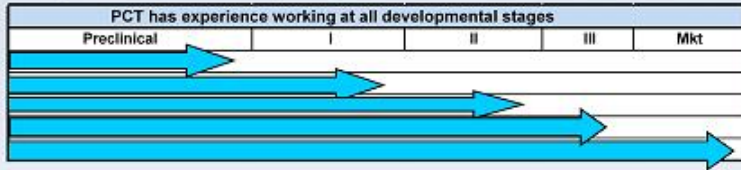
- Recognized industry leader in commercial cell therapy manufacturing
- Manufactured 30,000+ cell therapy product procedures and delivered 6,000+ cell therapies to patients worldwide for more than 100 clients
- 50,000 square feet of cGMP manufacturing capability located in North America and China
- Large scale manufacturing for clients allows lower costs for internal cell therapy development
- Diversified revenue stream from cell therapy manufacturing contracts



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# PCT's Extensive CMO Pipeline

- PCT has experience with virtually every cell type including dendritic cells (7 years of manufacturing for Dendreon's Provenge®)
- Establish early partnering relationships with goals of commercial manufacturing, equity participation and *back-end royalties*

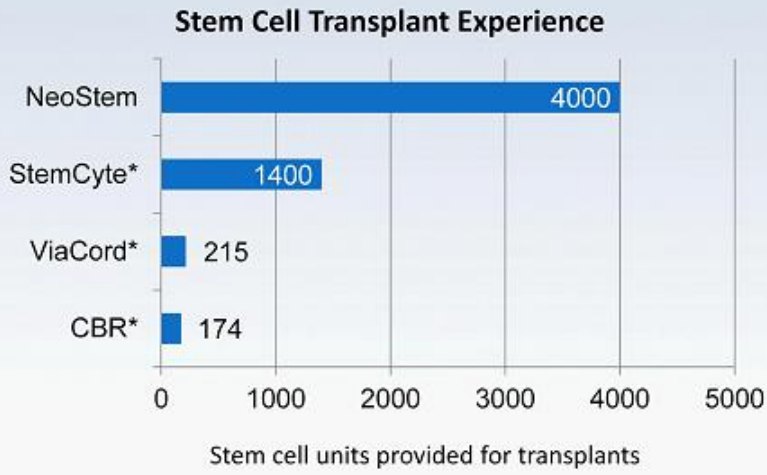


- Active companies in the cell therapy space include:



## Additional Revenue-Generating Businesses

NeoStem Family Storage - Stem cell collection and storage for infants and adults



\*Source - Information derived from StemCyte.com 10-2011, ViaCord.com 10.2011, and Cordblood.com 10-2-11

## Suzhou Erye – a Significant Asset

### Own 51% of Chinese generic therapeutics company, Suzhou Erye location Suzhou, China

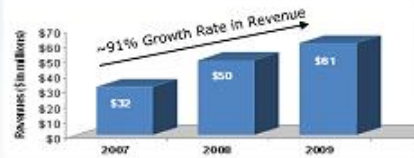
#### Suzhou Erye

- **Vertically-integrated manufacturer of generic antibiotic products and APIs with extensive distribution throughout China**
  - Multiple cGMP-certified production lines
  - Extensive distribution network throughout PRC
  - No significant customer concentration

#### Market Opportunity

- **Pharmaceutical market forecasted to reach \$78 billion by 2013**
  - Construction of 30,000 new hospitals, clinics and healthcare centers
  - New Rural & Urban Cooperative Medical Insurance System – at least 90% of the population covered by 2011

- **70% of current drug portfolio covered by the National Insurance Drug List; number of products covered expected to increase**
- **Revenue more than doubled from 2007 to 2010; new facility expected to double capacity**





## Financials, Milestones & Key Executives



## Financial Highlights

### Key Metrics as of September 30, 2011

<b>Revenue</b>	\$56.0m (nine months ended 9/30/11)
<b>Cash Position</b>	\$15.6m*
<b>Net Loss Excluding Non-Cash Charges</b>	\$10.0m (nine months ended 9/30/11)*
<b>Total Stock and Equivalent Shares</b>	
Common Shares	100.4m
Options	17.7m (avg. option exercise price is \$1.73)
Warrants	35.2m (avg. warrant exercise price is \$2.41)
Series E Preferred Stock	4.7m

\*See Appendix for GAAP to Non-GAAP reconciliation





## Recent and Expected Milestones

### Recent Accomplishments:

- Expansion of intellectual property beyond cardiovascular disease to all of vascular insufficiency
- Manufacturing contract that includes ownership in the client company, *back end royalty* of the product being produced and locked in commercial manufacturing
- First patient enrollment in PreSERVE AMI Phase 2 trial

### Expected Milestones:

- Start of AMR-001 trial in congestive heart failure (2012)
- Athelos - data read-out from investigator sponsored P1 trials in GVHD, diabetes, solid organ transplant, and asthma (2012)
- Monetization of 51% ownership in Suzhou Erye (2012)
- Additional government research grants
- Business development or M&A activity





## Expected NeoStem Events (over 12 months)

The Divestiture of Erye

Amorcyte – Clinical progress on Phase 2 STEMI “Preserve” trial

Amorcyte: Expanding IP and its implications on the space

Amorcyte: CHF trial begins

NeoStem & Amorcyte: EU strategy

BD Opportunities

Athelos: Move into the clinic in one selected “target” indication (GvHD, SOT, Asthma)

VSEL's: The promise to move regenerative medicine to tissue regeneration

Non-Dilutive Capital: DOD and other funding opportunities

PCT News Flow: revenues, contracts and partnerships



## Key Executives

**Robin Smith, MD, MBA**  
*CEO & Chairman of the Board*

- MD – Yale; MBA – Wharton
- Formerly President & CEO IP2M (HC multimedia), EVP & CMO HealthHelp (radiology management)
- Trustee of NYU Medical Center; Chairman of the Board of NYU Hospital for Joint Diseases (through November 2009) and Stem for Life Foundation

**Larry May**  
*Chief Financial Officer*

- BS Business Administration – University of Missouri
- Formerly Treasurer & Controller at Amgen; SVP Finance & CFO at BioSource Intl
- Extensive experience building accounting, finance and IT operations

**Jason Kolbert, MBA**  
*VP of Strategic Business Development*

- BS Chemistry – SUNY New Paltz, MBA - University of New Haven
- 17 years experience on Wall Street as Research Analyst in biotechnology in US and Asia
- 6 years in the pharmaceutical industry with Schering-Plough in Japan

**Andrew Pecora, MD, FACP**  
*Chief Medical Officer*

- MD – University of Medicine and Dentistry of New Jersey
- Chief Innovations Officer, Professor and Vice President of Cancer Services at John Theurer Cancer Center at Hackensack University Medical Center

**Robert Preti, PhD**  
*President and Chief Scientific Officer of PCT*

- PhD and MS in Cellular Biology / Hematology - New York University
- One of the country's leading authorities on cell engineering and the principal investigator for a number of clinical trials relating to stem cell transplantation
- 10 years experience as Director of Hematopoietic Stem Cell Processing & Research Laboratory

**Jian Zhang**  
*General Manager, Suzhou Erye Pharmaceuticals Co., Ltd*

- Joined Erye in 2003; extensive experience in the Chinese pharmaceutical industry
- Degree in Finance and Accounting from Central Television University
- Certified Public Accountant in China



# Questions



## Patents and Patent Applications

- **Composition of matter patents granted for Athelos (2023) & AMR-001 (2028)**
- **NeoStem's patent estate includes:**
  - Over 30 issued patents
  - Over 90 pending patent applications
  - Composition of matter and methods claims
  - Geographic breadth of filings including North America, Europe, Asia, Australia, Israel and South Africa
- **Cell therapy focus of NeoStem's IP includes:**
  - Immunology
  - Cardiology
  - Orthopedic
  - Wound healing
  - Age related tissue restoration
  - Stem cell isolation, collection and Storage
  - VSEL pluripotent stem cell discovery and applications

## NeoStem: Ideally Positioned for the Year Ahead



**Clinical Philosophy is a Differentiating Factor**



**Internal CMO: Cost-Effective Manufacturing Solution for Internal Development, Potential for Positive Cash Flow, Manufacturing Currency Allows Royalty Deals, Risk Diversification.**



**Dominant Landscape IP**



**China Manufacturing: Enhances NeoStem's Attractiveness in the Industry**



**Vatican Initiative: Opens "Unique Opportunities" for discussion with multiple parties from Political, Media, Business and Retail Leaders**



## Board of Directors

### NeoStem Board Members

<b>Robin Smith, MD, MBA</b> <i>CEO &amp; Chairman of the Board</i>	<ul style="list-style-type: none"> <li>MD – Yale; MBA – Wharton</li> <li>Formerly President &amp; CEO IP2M (HC multimedia), EVP &amp; CMO HealthHelp (radiology management)</li> <li>Experience - Trustee of NYU Medical Center; Chairman of the Board of NYU Hospital for Joint Diseases (through November 2009) and Stem for Life Foundation</li> </ul>
<b>Richard Berman</b> <i>(Independent)</i>	<ul style="list-style-type: none"> <li>Over 35 years of venture capital, management, M&amp;A experience</li> <li>Experience – Current Board of Directors of Apricus Biosciences, Easylink Services International, Inc., Advaxis, Inc., Broadcaster, Inc., National Investment Managers</li> </ul>
<b>Draw Bernstein, CPA</b> <i>(Independent)</i>	<ul style="list-style-type: none"> <li>BS – University of Maryland Business School</li> <li>Licensed in State of New York; member AICPA, NYSSCPA and NSA</li> <li>Experience – Bernstein &amp; Pinchuk LLP (member of BDO Seidman Alliance); PRC auditing; 200+ real estate transactions with \$3B+ aggregate value; accountant and business advisor</li> </ul>
<b>Edward Geehr, MD</b> <i>(Independent)</i>	<ul style="list-style-type: none"> <li>BS – Yale University; MD – Duke University</li> <li>Experience – Abraxis Bio-Science; Allez Spine; IPC-The Hospitalist Company</li> </ul>
<b>Martyn Greenacre, MBA</b> <i>(Independent)</i>	<ul style="list-style-type: none"> <li>BA – Harvard College; MBA – Harvard Business School</li> <li>Experience – Board and executive positions for multiple biopharmaceutical companies; Former CEO of Delsys Pharmaceutical Corporation and Zynaxis Inc; Chairman of the Board of BMP Sunstone Corporation</li> </ul>
<b>Steven Myers</b> <i>(Independent)</i>	<ul style="list-style-type: none"> <li>BS Mathematics – Stanford University</li> <li>Experience – Founder/Chairman/CEO SM&amp;A (competition management services); career in aerospace and defense sectors supporting DoD &amp; NASA programs</li> </ul>
<b>Andrew Pecora, MD, FACP</b>	<ul style="list-style-type: none"> <li>MD – University of Medicine and Dentistry of New Jersey</li> <li>Experience – Chief Innovations Officer, Professor and Vice President of Cancer Services at John Theurer Cancer Center at Hackensack University Medical Center, and Managing Partner of the Northern New Jersey Cancer Center</li> </ul>
<b>Mingsheng Shi</b> <i>Chairman of the Board of Suzhou Eye Pharmaceutical</i>	<ul style="list-style-type: none"> <li>BSc Economics &amp; Management – Party School of the Communist Party of China</li> <li>Professional title of Senior Economist</li> <li>Extensive experience in pharmaceutical industry in China</li> </ul>
<b>Eric Wei</b> <i>Managing Partner, RimAsia Capital Partners</i>	<ul style="list-style-type: none"> <li>BS Mathematics &amp; Economics – Amherst College; MBA – Wharton</li> <li>Experience – Founder/Managing Partner of RimAsia Capital Partners (private equity); Peregrine Capital, Prudential Securities, Lazard Freres, Citibank; Gilbert Global Equity Partners Crimson Asia Capital Partners</li> </ul>





## Amorcyte Scientific Advisory Board

<b>Eugene Braunwald, MD, FRCP</b>	<ul style="list-style-type: none"> <li>• Brigham &amp; Women's Hospital</li> </ul>
<b>Bernard J. Gersh, MD, ChB, DPhil, FRCP</b>	<ul style="list-style-type: none"> <li>• The Mayo Clinic</li> </ul>
<b>Dean J. Kereiakes, MD, FACC</b>	<ul style="list-style-type: none"> <li>• The Christ Hospital Heart of Greater Cincinnati</li> </ul>
<b>Douglas L. Mann, MD, FACC</b>	<ul style="list-style-type: none"> <li>• Washington University School of Medicine</li> </ul>
<b>Andrew L. Pecora, MD, FACP, CPE</b>	<ul style="list-style-type: none"> <li>• Chief Medical Officer, NeoStem</li> <li>• Hackensack University Medical Center</li> </ul>
<b>Carl J. Pepine, MD</b>	<ul style="list-style-type: none"> <li>• University of Florida College of Medicine</li> </ul>
<b>Emerson C. Perin, MD, PhD, FACC</b>	<ul style="list-style-type: none"> <li>• Texas Heart Institute</li> </ul>
<b>Bertram Pitt, MD</b>	<ul style="list-style-type: none"> <li>• University of Michigan School of Medicine</li> </ul>
<b>Arshed Quyyumi, MD, FRCP, FACC</b>	<ul style="list-style-type: none"> <li>• Principal Investigator, Phase II</li> <li>• Emory University School of Medicine</li> </ul>
<b>Edmund K. Waller, MD, PhD, FACP</b>	<ul style="list-style-type: none"> <li>• Emory University School of Medicine</li> </ul>
<b>James T. Willerson, MD</b>	<ul style="list-style-type: none"> <li>• University Texas Health Science Center</li> </ul>
<b>Joseph Wu, MD, PhD</b>	<ul style="list-style-type: none"> <li>• Stanford University School of Medicine</li> </ul>



## Athelos Scientific Advisory Board

<b>Robert A. Preti, PhD, Chairman</b>	<ul style="list-style-type: none"><li>• Progenitor Cell Therapy</li></ul>
<b>Bruce Blazar, MD</b>	<ul style="list-style-type: none"><li>• University of Michigan Masonic Cancer Center</li></ul>
<b>Jeffrey Bluestone, PhD</b>	<ul style="list-style-type: none"><li>• University of California, San Francisco, Diabetes Center</li></ul>
<b>David A. Horwitz, MD</b>	<ul style="list-style-type: none"><li>• University of Southern California</li></ul>
<b>Carl June, MD</b>	<ul style="list-style-type: none"><li>• Perelman School of Medicine, University of California</li></ul>
<b>Robert Korngold, PhD</b>	<ul style="list-style-type: none"><li>• Hackensack University Medical Center</li></ul>
<b>Wayne A. Marasco, MD, PhD</b>	<ul style="list-style-type: none"><li>• Dana-Farber Cancer Institute</li></ul>
<b>Robert S. Negrin, MD</b>	<ul style="list-style-type: none"><li>• Stanford University</li></ul>
<b>David Peritt, PhD</b>	<ul style="list-style-type: none"><li>• Hospira</li></ul>
<b>Camillo Recordi, MD</b>	<ul style="list-style-type: none"><li>• University of Miami Diabetes Research Institute</li></ul>
<b>Noel L. Warner, PhD</b>	<ul style="list-style-type: none"><li>• BD Biosciences</li></ul>





# Appendix

## GAAP to Non-GAAP Reconciliations for the nine months ended September 30, 2011

**Cash Position Reconciliation**

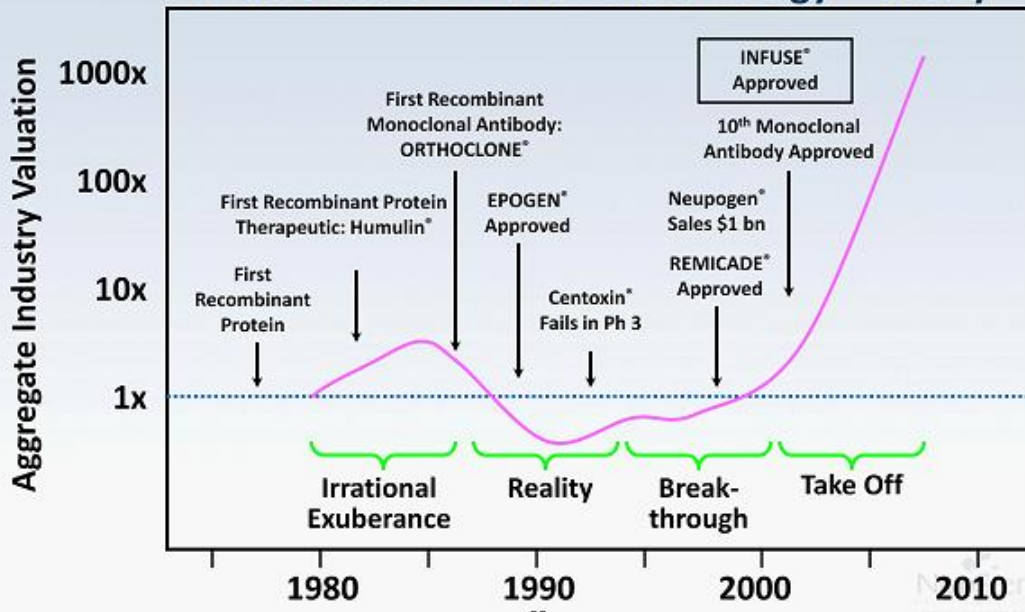
Cash & cash equivalents	\$ 11,713,338
Short term investments	555
Restricted cash	1,427,827
Cash included in Other Assets (represents cash held in escrow as security associated with Preferred Series E obligations, with maximum lock up through May 2013)	2,500,000
<b>Cash Position</b>	<b>\$ 15,641,720</b>

**Net Loss Excluding Non-Cash Charges Reconciliation**

Net Loss	\$ (27,728,736)
<b>Non cash charge adjustments per Cash Flow Statement:</b>	
Common stock, stock options and warrants issued	8,164,814
Depreciation and amortization	6,754,953
Amortization of preferred stock discount and issuance cost	1,903,703
Changes in fair value of derivative liability	(1,661,049)
Write off of acquired in-process research and development	1,150,000
Loss on disposal of assets	396,635
Non-cash interest expense	328,425
Contributions paid with common stock	607,363
Bad debt expense	50,024
<b>Net Loss Excluding Non-Cash Charges</b>	<b>\$ (10,033,868)</b>

# Evolution of a Paradigm Shift

## Value Creation in the Biotechnology Industry



# AMR-001 Advantages in the Landscape

	AMORCYTE	Exate	Adherys / Angiovech	Meoblasts / Cephaleon	Cytod	Oculis	Aestrum	Aldagen	Beaver
Clinical Development Stage	PII	PII	PI	PI	PII	PII	PII	PI	PII
Field of Use	AMI	AMI	AMI	AMI	AMI	AMI	HF	HF	CM
Defined Mechanism of Action	✓	✓			✓			✓	✓
Autologous	✓	✓			✓		✓	✓	✓
Potential Toxicities / Safety Signals				✓		✓	✓		
Centralized Manufacturing	✓	✓	✓	✓		✓	✓	✓	✓
cGMP Defined Product	✓		✓	✓		✓	✓	✓	✓
Threshold Dose	✓	✓	✓	✓					✓
Cells Expanded			✓	✓		✓	✓		
Strong IP	✓								

AMI = Acute Myocardial Infarction  
 HF = Heart Failure  
 CMI = Chronic Myocardial Ischemia

## AMR-001 Advantages

- Functionality of CD34<sup>+</sup>CXCR4<sup>+</sup> cells
- Confirmed mechanism of action
- cGMP processing and manufacturing that stabilizes the CD34<sup>+</sup>CXCR4<sup>+</sup> cells
- Potency, viability, stability, sterility, and variability assays
- Threshold dose established at 10 million cells
- Dominant IP
  - composition of matter
  - methods and processes
  - catheter delivery



## To Be Successful You Must Demonstrate Ability to Reduce Cost, Time and Risk of Cell Therapy Development

- Autologous vs. allogeneic
- Patient-specific vs. multi-patient use
- Sources of cells: bone marrow derived, adipose, IPS, embryonic, etc.
- Fresh vs. cryopreserved
- Shelf-life from sourcing to therapy (logistics considerations)
- Changes control through scale-up (SOPs and Manufacturer)
- Pharmacoeconomic studies

### These Variables Directly Effect:

- Regulatory pathway
- Time of development
- Cost of clinical trials
- Affordability / cost of goods
- Reimbursement
- Adoption by medical community

# Capturing the Paradigm Shift to Cell Based Therapy

## THE NEW ERA OF REGENERATIVE MEDICINE

Dozens of biotech companies and university labs are developing ways to replace or regenerate failed body parts. Here are a few of the projects:



### BONE

Bone-growth factors or stem cells are inserted into a porous material cut to a specific shape, creating new jaws or limbs. A product that creates shinbones is in clinical trials.

**COMPANIES:** Creative Biomolecules, Orquest, Sulzer Orthopedics Biologics, Genetics Institute, Osiris Therapeutics, Regeneron.



### SKIN

Organogenesis' Apligraf, a human-skin equivalent, is the first engineered body part to win FDA approval, initially for leg ulcers. Other skins are in the works for foot ulcers and burns.

**COMPANIES:** Organogenesis, Advanced Tissue Sciences, Integra LifeSciences, LifeCell, Ortic International.



### PANCREAS

Insulin-manufacturing cells are harvested from pigs, encapsulated in membranes, and injected into the abdomen. The method has been tested in animals and could be in human trials in two years.

**COMPANIES:** BioHybrid Technologies, Neocrin, Circe Biomedical



### HEART VALVES, ARTERIES, AND VEINS

A 10-year initiative to build a heart has just started. Genetically engineered proteins have been successfully used to regrow blood vessels.

**COMPANIES:** Organogenesis, Advanced Tissue Sciences, Genetech, LifeCell, Regenesis.

DATA: BUSINESS WEEK, DRUG & MARKET DEVELOPMENT REPORTS



### SALIVA GLANDS

Proteins called aquaporins that allow cells to secrete water are used to recreate saliva glands damaged by disease or radiation. Glands are also being engineered to secrete healing drugs. The technique has proven successful in mice.

**COMPANIES:** None yet.

### URINARY TRACT

Cartilage cells are taken from the patient, packed into a lay matrix, and injected into the weakened ureter, where they bulk up the tissue walls to prevent urinary backup and incontinence. The method is in late-phase clinical trials.

**COMPANIES:** Regenesis, Integra LifeSciences.

### BLADDER

Doctors at Children's Hospital in Boston have grown bladders from skin cells and implanted them in sheep. They are about to try the same process on a patient.

**COMPANIES:** Regenesis.

### CARTILAGE

A product is already on the market that regrows knee cartilage. A chest has been grown for a boy and a human ear on a mouse.

**COMPANIES:** Genzyme Tissue, Biomatrix, Integra LifeSciences, Advanced Tissue Sciences, Regen Biologics, Osiris Therapeutics.



### TEETH

Enamel matrix proteins are used to fill cavities. It works in dogs; human trials are a few years away.

**COMPANIES:** Biora, Atria Laboratories, Creative BioMolecules.



### BREAST

In preclinical studies, several companies have been able to create a cosmetic nipple by inserting a ball of cartilage. Researchers are now trying to grow a whole cosmetic breast.

**COMPANIES:** Regenesis, Integra LifeSciences.



### LIVER

A spongy membrane is built up and then seeded with liver cells. Organs the size of a dime have been grown, but a full-size liver could take 10 years due to its complexity.

**COMPANIES:** Advanced Tissue Sciences, Human Organ Sciences, Organogenesis.



### SPINAL CORD NERVES

Scientists are investigating nerve-growth factors, injecting them at the site of damage to encourage regeneration or seeding them along biodegradable filaments and implanting them. Rats have been made to walk again.

**COMPANIES:** Acorda, Regeneron, CytoTherapeutics, Guilford Pharmaceuticals.





## Contact Information

### **NeoStem, Inc. (NYSE AMEX: NBS)**

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## **Amorcyte, a NeoStem Company, Enrolls First Patient in PreSERVE Phase 2 Trial for Acute Myocardial Infarction**

NEW YORK, Jan. 25, 2012 /PRNewswire/ -- Amorcyte, LLC, a NeoStem, Inc. company (NYSE Amex: NBS)("NeoStem" or the "Company") today announces the enrollment of the first patient in the Amorcyte PreSERVE Phase 2 trial for acute myocardial infarction. The study is a multicenter, randomized, double-blind, placebo-controlled clinical trial to evaluate the safety and efficacy of infarct-related artery infusion of AMR-001, an autologous bone marrow derived cell therapy enriched for CD34+ cells. AMR-001 is administered 5 to 11 days post-stent placement in patients diagnosed with an ST segment elevation myocardial infarction with ejection fraction less than or equal to 48%, as determined by cardiac magnetic resonance imaging measured after recovery from myocardial stunning. Approximately 160 subjects, age 18 and older, will be randomized 1:1 between the treatment group and control group. Progenitor Cell Therapy, LLC, also a NeoStem company, will support the manufacturing, product supply, and logistics for the trial.

Dr. Arshed Quyyumi, Professor of Medicine at Emory University and the lead principal investigator in the study said, "We are thrilled to begin evaluating AMR-001, a CD34+ cell therapy, in these patients. We look forward to Phase 2 trial confirmation of the biologic activity of AMR-001 demonstrated in the Phase 1 trial and hope to provide patients with significant clinical benefit and an enriched quality of life."

"The first patient enrollment signals a key advance in our efforts in the trial," said Dr. Andrew L. Pecora, Chief Medical Officer of NeoStem. "We are on track to enroll the targeted 160 patients over the next year or so with first data follow-up six months after the last patient is enrolled."

AMR-001 represents the first compound in this class of cell therapies to have a highly defined cell population and an identified biologically effective therapeutic dose, both of which tie back to the biological mechanism of action that the outcomes of the current study are intended to demonstrate. The Amorcyte therapy is being developed initially for the preservation of heart muscle function for approximately 160,000 American patients who sustain a heart muscle damaging STEMI annually.

Dr. Pecora further added, "Even with current best clinical practices, this group faces a significant chance of adverse outcomes, including premature death. Our goal is to create significant pharmacoeconomic value by reducing the associated costs of adverse outcomes often seen in these patients. We feel AMR-001 has the potential to address a substantial unmet medical need."

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For more information on the clinical trial please visit [www.amorcyte.com](http://www.amorcyte.com) or view the NeoStem corporate presentation at [www.neostem.com/investor-relations/](http://www.neostem.com/investor-relations/).

About NeoStem, Inc. and Amorcyte, LLC, a NeoStem company

NeoStem, Inc. ("NeoStem") is a leader in the development and manufacture of cell therapies. NeoStem has a strategic combination of revenues, including that which is derived from the contract manufacturing services performed by Progenitor Cell Therapy, LLC, a NeoStem company. That manufacturing base is one of the few cGMP facilities available for contracting in the burgeoning cell therapy industry, and it is the combination of PCT's core expertise in manufacturing and NeoStem's extensive research capabilities that positions the company as a leader in cell therapy development. Amorcyte, LLC, also a NeoStem company, is developing a cell therapy for the treatment of cardiovascular disease. Amorcyte's lead compound, AMR 001, represents NeoStem's most clinically advanced therapeutic and is open for enrollment in a Phase 2 trial for the preservation of heart muscle function after a heart attack. Amorcyte expects to begin a Phase 1 clinical trial in 2012 for AMR-001 for the treatment of patients with congestive heart failure. Athelos Corporation also a NeoStem company is developing a T-cell therapy for a range of autoimmune conditions with our partner Becton-Dickinson. NeoStem's pre-clinical assets include its VSEL™ Technology platform for regenerative medicine, which NeoStem believes to be an endogenous pluripotent non-embryonic cell that has the potential to change the paradigm of cell therapy as we know it today.

For more information on NeoStem and Amorcyte, please visit [www.neostem.com](http://www.neostem.com) and [www.amorcyte.com](http://www.amorcyte.com)

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements reflect management's current expectations, as of the date of this press release, and involve certain risks and uncertainties. Forward looking statements include statements herein with respect to the successful execution of the Company's business and medical strategy, including with respect to the development of AMR-001 and other cell therapies, about which no assurance can be given. The Company's actual results could differ materially from those anticipated in these forward- looking statements as a result of various factors. Factors that could cause future results to materially differ from the recent results or those projected in forward-looking statements include the "Risk Factors" described in the Company's definitive proxy statement filed with the Securities and Exchange Commission on September 16, 2011 and in the Company's periodic filings with the Securities and Exchange Commission. The Company's further development is highly dependent on future medical and research developments and market acceptance, which is outside its control.

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