

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): May 9, 2013

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 350, 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 2.02. Results of Operations and Financial Condition.**

On May 9, 2013, NeoStem, Inc., a Delaware corporation (the “Company” or “NeoStem”), issued a press release consisting of a shareholder update letter, which also included certain results of the Company’s quarter ended March 31, 2013. A copy of this press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 2.02 by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

**Item 7.01 Regulation FD Disclosure.**

NeoStem, Inc. intends, from time to time, to present and/or distribute to the investment community and 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 attached hereto as Exhibit 99.2. NeoStem undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.2.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.2, shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by reference in such a filing.

*Forward Looking Statements*

This Current Report on Form 8-K, including Exhibit 99.1 and 99.2 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’s judgment regarding future events. Although the Company believes that 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 statement other than statements of historical fact included in the 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.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated May 9, 2013*
99.2	Slide presentation of NeoStem, Inc. dated May 2013*

\*Exhibit 99.1 and Exhibit 99.2 are furnished as part of this Current Report on Form 8-K.

**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

Dated: May 9, 2013

**NeoStem CEO's Letter to Shareholders**

NEW YORK, May 9, 2013 (GLOBE NEWSWIRE) --

Dear Shareholders,

We at NeoStem, Inc. (NYSE MKT: NBS) believe that cell therapy has the potential to radically change the face of how diseases are treated, leading to longer and, more importantly, higher quality lives. NeoStem is proud of its role at the forefront of this paradigm shift underway in medicine toward cell therapy - a shift away from treating disease with drugs and toward treating disease with our own cells; a shift away from treating symptoms and toward cures for the illnesses that cause the most suffering; a shift away from chemical drug development and toward looking inside ourselves to understand and then amplify our body's natural repair mechanisms.

NeoStem is becoming a leading player in cell therapy by vertically integrating the collection, storage and processing of cellular material and by developing, manufacturing, distributing, and delivering cell therapy products. We are taking advantage of the growth in the cell therapy industry both for our clients and for our internal pipeline. Our proprietary product development efforts target unmet medical needs in conditions that include cardiovascular disease (myocardial infarction and congestive heart failure), immune disorders (type 1 diabetes, steroid resistant asthma, organ rejection) and tissue repair (wounds, osteoporosis, macular degeneration and other indications).

**PreSERVE Phase 2 Clinical Trial**

We are very excited and encouraged by our cardiovascular program, which is advancing nicely in the clinic and which, we believe, is built upon strong intellectual property. As of April 30<sup>th</sup>, we have enrolled 108 patients into our AMR-001 Phase 2 PreSERVE clinical trial that treats patients who suffered a heart attack and we are on track to complete enrollment this year with data read out 6-8 months after the last patient is enrolled. We have shifted our expenditures to have a greater focus on investment in development of cell therapy products, spending \$3.2 million on research and development in Q1 2013.

**Amorcyte Intellectual Property Portfolio**

AMR-001 now has the benefit of 4 granted U.S patents, 5 patent grants outside of the U.S. and 30 additional patents pending around the world. In brief, our granted U.S. patents are as follows:

- U.S. Patent No. 7,794,705 covers a cell-based composition used to prevent deterioration of heart muscle post a heart attack. The composition contains a therapeutically effective amount of autologous mononuclear cells enriched for CD34 cells which further contain a subpopulation of biologically active CD34+/CXCR-4+ cells.
- With the grant of U.S. Patent 8,088,370, the AMR-001 product's use was extended beyond heart attack to treatment for any vascular injury caused by vascular insufficiency.
- Amorcyte's claims in U.S. Patent 8,343,485 similarly cover a cell-based therapy to repair a vascular injury caused by vascular insufficiency, but the product's CD34+ cell content limitation was greatly expanded in this patent to cover purities of almost any amount, and the product serum content was also expanded.
- Amorcyte's most recently granted patent (U.S 8,425,899) covers AMR-001 for the treatment of progressive myocardial injury due to vascular insufficiency, including the disease progression that leads to heart failure, together with claims that cover freezing cells and using them in a treatment regimen that includes multiple doses over time.

We are beginning the process of expanding applications for AMR-001 into other ischemic conditions such as congestive heart failure and traumatic brain injury.

**VSEL™ Technology Platform**

Additionally, we continue to develop our very small embryonic like (VSEL) stem cell technology, securing additional grant funding to support this initiative. Recent data supports that VSELS are pluripotent, meaning they can develop into cells of all three germ layers and, as such, would appear to have among the greatest potential for restorative healing of current cell based regenerative medicines in development. We are developing VSELS in pre-clinical models and expect this soon to be followed by an early clinical model to assess their therapeutic potential in wound care, bone regeneration and macular restoration.

In a recent study, VSEL treated wounds induced in the tail vein of an animal (cells applied in Fibrin spray) showed complete closure by Day 14 with organized tissue remodeling including skin as compared to untreated wounds that normally take up to 21

days to achieve this result. Furthermore, these studies showed that, compared to human mesenchymal stem cells, VSELS were 200% more potent with respect to achieving complete closure with organized tissue remodeling including skin.

In the eye model, when injecting VSELS into the sub-retinal area of the severe combined immunodeficiency (SCID) mouse eye, VSELS were shown to survive and integrate into the mouse sub-retinal space staining positive for photoreceptor markers suggesting the potential for using these cells to treat disorders creating vision loss.

NeoStem continues to receive grant awards to develop this important technology with the recent award of year two funds for a National Institute of Allergy and Infectious Diseases (NIAID) research grant exploring the development of VSEL Technology for radiation exposure.

### **Athelos**

NeoStem also continues to progress its T cell program with the goal of developing treatments for immune-mediated diseases, such as graft versus host disease (GVHD), autoimmune disorders (such as type 1 diabetes and multiple sclerosis) and allergic conditions that result from an imbalance between T-effector cells and T-regulatory cells (Treg). Treg therapy represents a novel approach for restoring immune balance by enhancing T-regulatory cell number and function (Chai, Jian-Guo et al, Journal of Immunology 2008; 180:858-869) and NeoStem holds exclusive rights to 21 issued patents and 3 patents pending related primarily to methods of isolating, purifying and expanding Tregs. Phase 1 work is ongoing globally under several independent physician INDs, including Dr. P. Trzonkowski, Dr. Jeffrey Bluestone and Dr. Rob Negrin, results of which will inform NeoStem's future clinical direction.

### **Progenitor Cell Therapy**

NeoStem also has a revenue generating arm of its business. Progenitor Cell Therapy (PCT), a contract development and manufacturing organization, generated over \$2.5 million in revenue in Q1 2013. We recently signed two new client contracts and continue to build this contract development and manufacturing business. PCT has provided services to over 100 clients in its more than 14-year history, and is the only contract manufacturing organization to have worked with a client's product (Dendreon, Inc.'s Provenge) through all of the phases of clinical trials and ultimately to FDA approval. PCT offers its clients and NeoStem cell processing and development capabilities on both the East and West Coasts of the U.S and is pursuing plans to expand internationally.

PCT has built a strong foundation of services that cater to the entire industry. This reduces our reliance on the success of internal development platforms by capturing greater revenues from a growing industry. Furthermore, PCT's manufacturing revenues should increase significantly as a client progresses through Phase 1, 2, and 3 trials and into commercialization where larger numbers of cells are needed. With our internal cell therapy expertise, we are able to cost-effectively develop cellular therapies for chronic unmet medical needs both for clients and for our own internal development activities. This uniquely positions us to follow the most promising technologies in the sector, informing us as we pursue technologies that may be of interest to us to co-develop or even acquire. Management is focused on growing the business through increased services and product offerings, including automation technologies geared toward improving efficiencies and lowering cost of goods.

### **Expanded Board**

We are also focused on developing a team that includes leaders in the industry as we look ahead to achieving the next level of our development. In this regard, we are pleased to have added the expertise of Stephen Potter who joined the NeoStem Board of Directors in February. Stephen has been involved with the cellular therapy industry since its early days and was most recently the Senior Vice President of Operations and Corporate Development for Osiris Therapeutics, Inc. where he worked as a member of the senior leadership that achieved one of the first FDA approvals of a stem cell therapy. Previously, he was Senior Vice President of Corporate and Business Development at Genzyme Corporation.

### **First Quarter Financial Results**

NeoStem ended the first quarter with \$9.3 million in cash and successfully completed a common stock offering in May 2013, that generated \$10.7 million of net proceeds to the Company. Net loss from continuing operations for Q1 2013 was \$8.9 million (or \$6.2 million when excluding non-cash charges - see reconciliation in appendix below) or \$.05 per share.

## Stem for Life Foundation

NeoStem, in partnership with The Stem for Life Foundation, The Pontifical Council for Culture of the Vatican, and STOQ International, hosted a successful historic three day event entitled *The Second International Vatican Adult Stem Cell Conference: Regenerative Medicine - A Fundamental Shift in Science & Culture*, which took place within the walls of The Vatican, April 11-13, 2013. Present at the conference was Dr. John Gurdon, keynote speaker and Nobel laureate, who echoed the sentiments of the many other prominent participants when he said, "I was particularly impressed by the thoughtful discussion of the ethical implications of adult stem cell science. These sessions opened my eyes to new dimensions of my work which will inform my future investigations."

Bill Hemmer, Anchor at the Fox News Channel and moderator of the second day of the conference, stated "(This was) a truly remarkable conference on the enormous potential and possibility of adult stem cells. The education and understanding of this science needs to be carefully considered. It could change all of our lives." Meredith Vieira, Special Correspondent for NBC News and moderator of the first day, said, "My husband, Richard, has been living with multiple sclerosis for 40 years, but our children, Ben, Gabe and Lily and I have shared some of that burden. Ultimately, chronic illness is a family affair, which is why we attended the Vatican conference as a family. We wanted to get a better understanding of stem cell research and the conference gave that to us. We listened to doctors, scientists and patients and came away with a strong sense of real hope, not just for Richard but for potentially millions of people. We understand there is a long road ahead, but through hard work and total commitment it may well lead to a better life for all of us."

At this conference, I was presented with the Key Founder's Award, on behalf of Stem for Life, by Cardinal Gianfranco Ravasi, President of the Pontifical Council for Culture, in recognition of the work we have accomplished in driving forward the joint initiative between the partners and in developing a conference that would receive worldwide media attention. The conference was covered widely by the press, including stories and interviews through outlets such as CNN.com, *The Wall Street Journal* print and radio network, Bloomberg TV, Fox News Channel, Fox News, Catholic TV, Vatican Radio, Catholic News Agency, EWTN, and more. Media coverage promoted the conference, but also helped to explain the Church's support for ethical research, highlighted the current progress occurring around the world in adult stem cell research and therapies, and told many of the stories of stem cell patients who spoke at or were honored at the conference. Other awardees included Dr. Silviu Itescu, CEO of Mesoblast (ASX:MSB), who received the Key Innovator Award, Dr. Sol Barer former CEO of Celgene Corp. (Nasdaq:CELG), who received the Key Visionary Award and Dr. W.E. Bosarge who received the Key Philanthropy Award.

As the regenerative medicine market continues to grow, NeoStem is uniquely positioned to capture the value of this market and lead the industry. We appreciate your continued conviction in the Company's agenda and will keep you posted on our progress. For more detailed information please review our investor PowerPoint at [www.neostem.com/NeoStem-Investor-Presentation.pdf](http://www.neostem.com/NeoStem-Investor-Presentation.pdf).

Regards,

Robin Smith, M.D., MBA

## Appendix

	Three Months Ended March 31, 2013
GAAP to NON-GAAP Reconciliation (millions)	
Net Loss from Continuing Operations	\$(8.9)
Equity-Based Compensation	\$2.20
Depreciation and Amortization	\$0.55
Changes in Fair Value of Derivative Liability	\$(0.01)
Net Loss from Continuing Operations Excluding Non-Cash Charges	\$(6.16)

## About NeoStem, Inc.

NeoStem, Inc. ("NeoStem" or the "Company") is a leader in the emerging cellular therapy industry. Our business model includes the development of novel proprietary cell therapy products as well as operating a contract development and

manufacturing organization ("CDMO") providing services to others in the regenerative medicine industry. The combination of a therapeutic development business and revenue-generating service provider business provides the Company with capabilities for cost effective in-house product development and immediate revenue and cash flow generation.

For more information, please visit: [www.neostem.com](http://www.neostem.com). To view the NeoStem investor presentation, please go to [www.neostem.com/NeoStem-Investor-Presentation.pdf](http://www.neostem.com/NeoStem-Investor-Presentation.pdf).

#### **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 strategy, including with respect to the Company's research and development and clinical evaluation efforts for cellular therapies, including with respect to AMR-001, the future of the regenerative medicine industry and the role of stem cells and cellular therapy in that industry and the Company's ability to successfully grow its contract development and manufacturing business. 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 11, 2013 and in the Company's periodic filings with the SEC. The Company's further development is highly dependent on future medical and research developments and market acceptance, which is outside its control.

CONTACT: NeoStem

Dr. Robin L. Smith

Chairman and CEO

Phone: +1-212-584-4174

Email: [rsmith@neostem.com](mailto:rsmith@neostem.com)

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# NeoStem<sup>®</sup>

Investor Presentation  
NYSE MKT: NBS  
May 2013





# Forward-Looking Statements

This presentation includes “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 our actual results, performance or achievements, 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 Annual Report on Form 10-K, 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 the future of the regenerative medicine industry and the role of stem cells and cellular therapy in that future, our ability to successfully develop and grow our business, including with regard to our research and development and clinical evaluation efforts and future marketing and sales in respect of AMR-001 and other cell therapies, the marketing and performance of our contract development and manufacturing business and our adult stem cell collection, processing and storage business 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 our 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, the funding of our clinical trials for AMR-001, and the commercialization of the relevant technology; (iii) our ability to build the management and human resources and infrastructure necessary to support the growth of our business; (iv) our ability to integrate our acquired businesses successfully and grow such acquired businesses as anticipated, including expanding our PCT business into Europe; (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 our business; (ix) whether any of our current or future patent applications result in issued patents, the scope of those 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 our current Phase 2 clinical trial of AMR-001; (xii) our ability to complete our Phase 2 clinical trial of AMR-001 (or initiate future trials) in accordance with our estimated timeline due to delays associated with enrolling patients due to the novelty of the treatment, the size of the patient population and the need of patients to meet the inclusion criteria of the trial or otherwise; and (xiii) the other factors discussed in “Risk Factors” and elsewhere in this presentation and in the Company’s other periodic filings with the Securities and Exchange Commission (the “SEC”) 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. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the Company undertakes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.



# Unsustainable Growth in US Health Care Costs

- \$2.7 Trillion Dollars is spent annually on health care costs (currently 18% of US GDP)<sup>1</sup>
- 80% of health care costs are associated with chronic conditions<sup>2</sup>
  - Cardiovascular disease costs over \$445B today  
Projected to increase to over \$1T by 2030<sup>3</sup>
  - Diabetes costs are over \$174B today  
Projected to increase to over \$300B by 2025<sup>4</sup>

*With an aging population, we need to move the paradigm from the treatment of chronic disease toward regenerative medicine and we believe NeoStem is part of that paradigm shift*



- 1) Center for Medicare and Medicaid
- 2) "Chronic disease and medical innovation in an aging nation" [www.silverbook.org](http://www.silverbook.org)
- 3) American Heart Association, Policy Statement January 24, 2011
- 4) American Diabetes Association

# Regenerative Medicine

- Repairing or replacing damaged tissue and restoring function
- Novel regenerative therapies hold the promise of transforming clinical outcomes and reducing overall healthcare costs
- The regenerative medicine market is estimated to grow to \$88 billion by 2014<sup>1</sup>

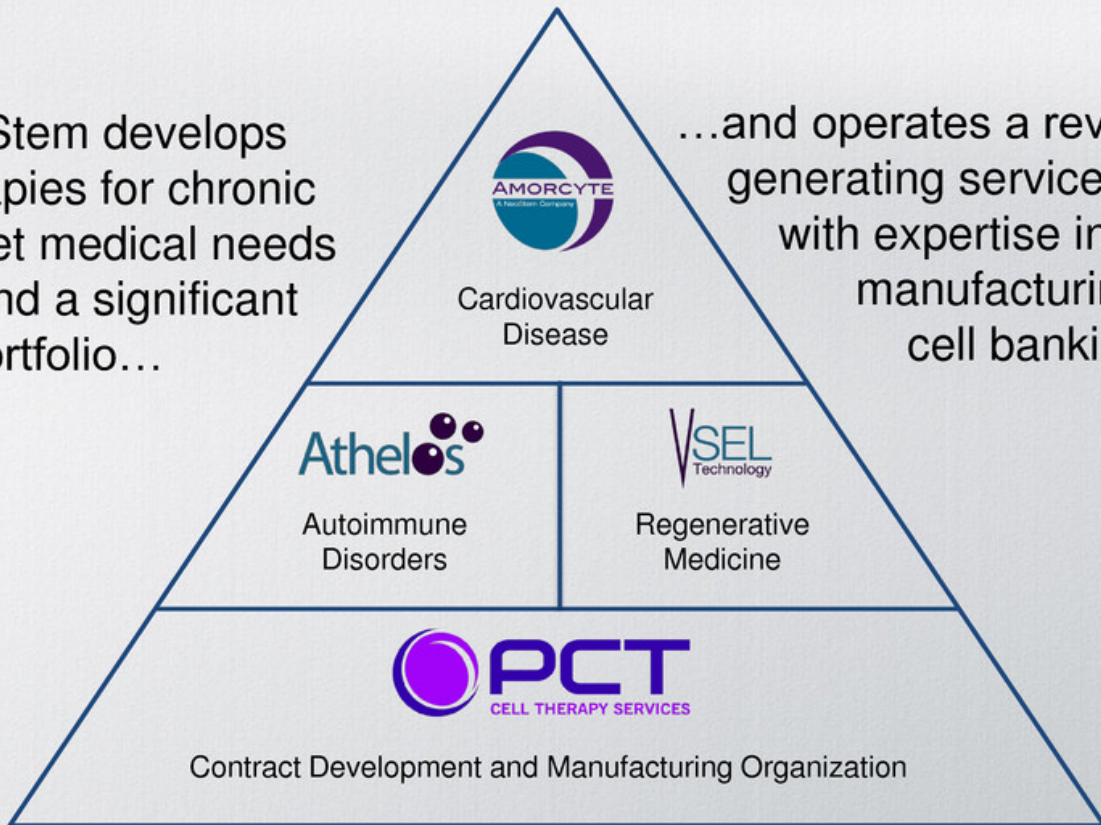


1) According to *The Regenerative Medicine Report*, MDB Capital Group, January 2011

# Developing Therapies on a Foundation of Manufacturing Expertise

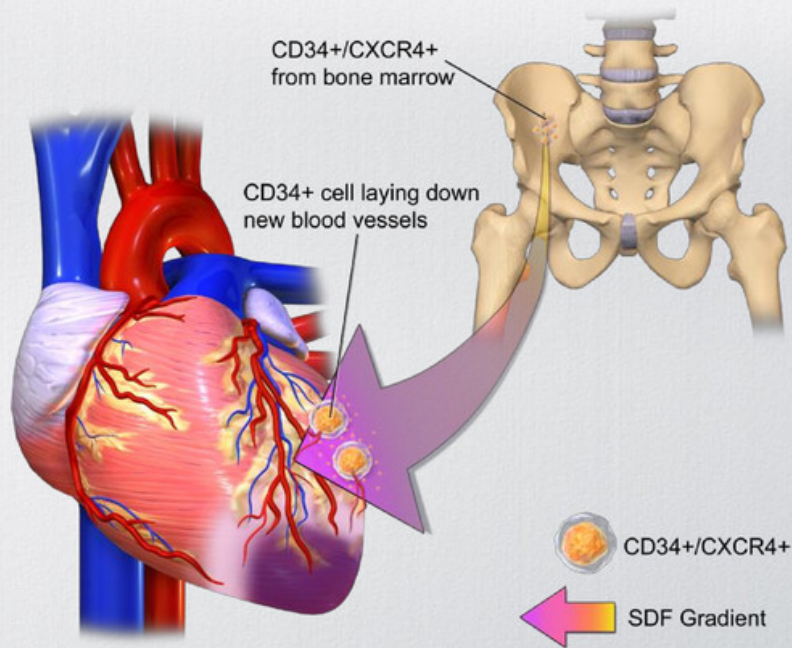
NeoStem develops therapies for chronic unmet medical needs around a significant IP portfolio...

...and operates a revenue generating service division with expertise in contract manufacturing and cell banking





# AMR-001 Brings Repair System to the Heart in Order to Preserve Function

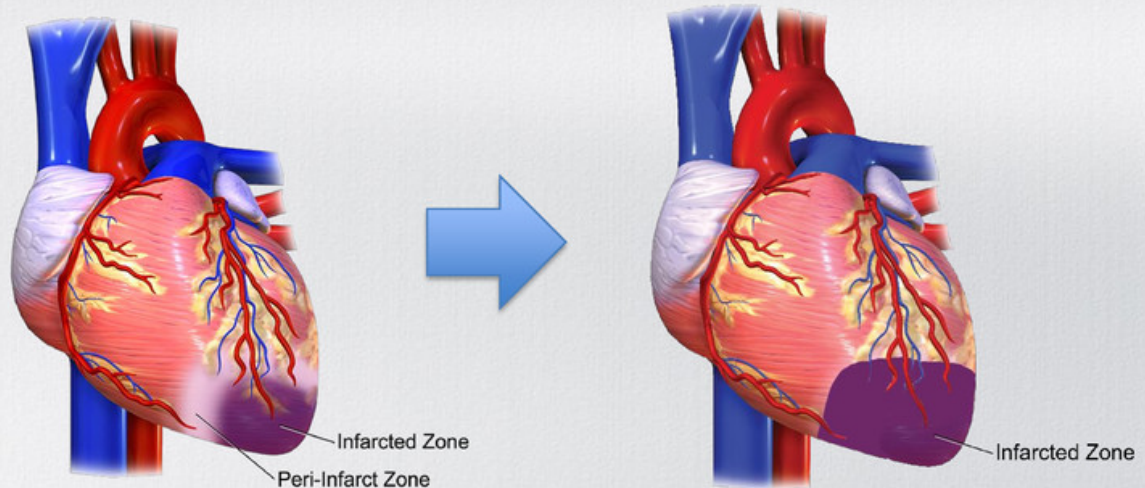


CD34<sup>+</sup>CXCR4<sup>+</sup> Cells are a natural repair mechanism





## The Peri-Infarct Zone Becomes the Infarct

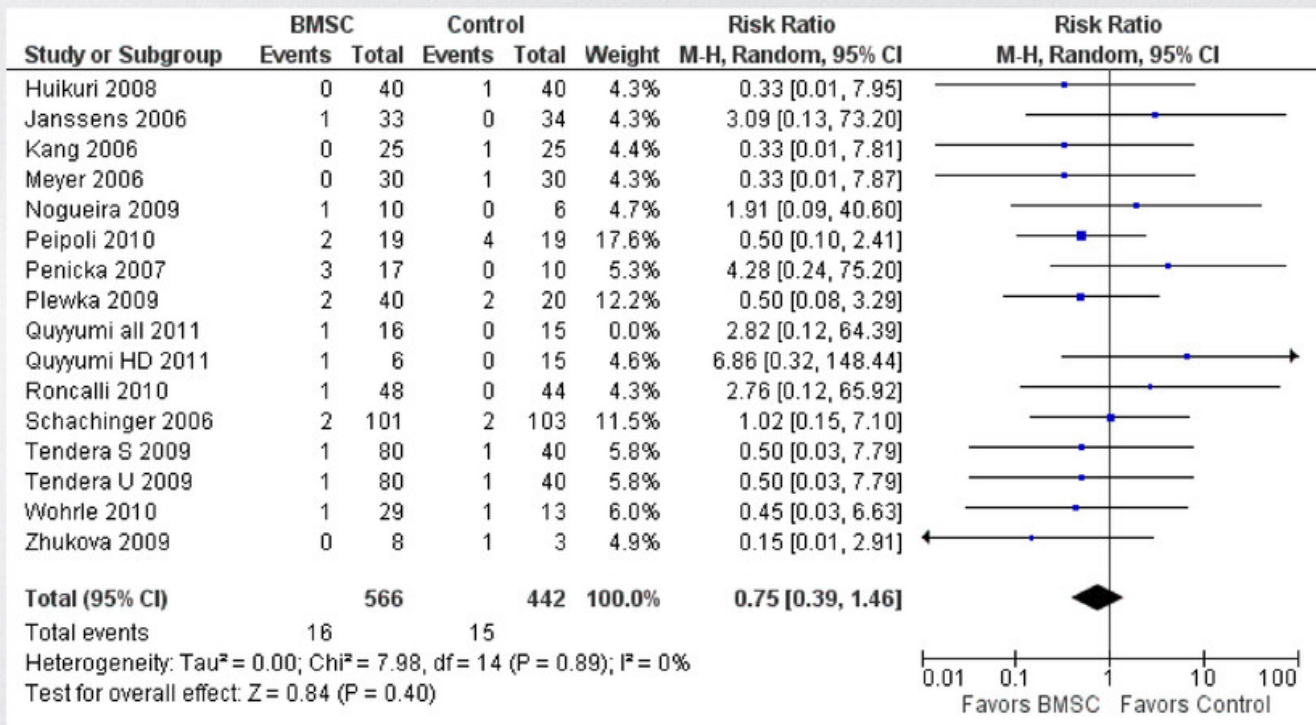


- A consequence of inadequate perfusion (microvascular insufficiency) is apoptosis and progressive cardiomyocyte loss in the peri-infarct zone, leading to infarct expansion
- STEMI patients are at risk of a progressive deterioration in heart muscle function that leads to arrhythmia, recurrent myocardial infarction, congestive heart failure and premature death



# Cochrane Collaboration Review

## Bone Marrow Derived Cells: Likely Safe and Positive Impact on Mortality

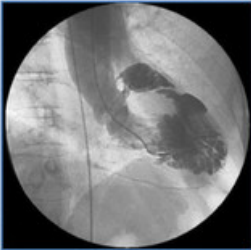




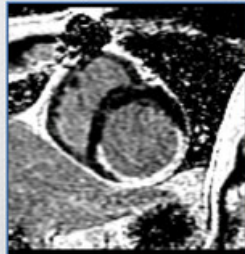
# Phase 1 Trial Design for AMR-001

<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, open-label)
<b>Number of Subjects</b>	N=31
<b>Number of Sites</b>	4 (incl. Emory University, Texas Heart Institute, Vanderbilt, Cincinnati)
<b>Geography</b>	United States
<b>Trial Duration</b>	6 months

Day 1: Ventriculography



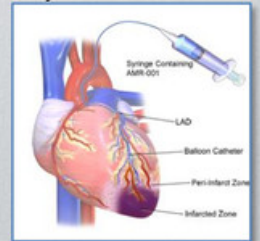
Day 4: CMR



Day 5-8:  
6-8 Hour Cell Separation Process



Day 6-10:  
Injection into the IRA

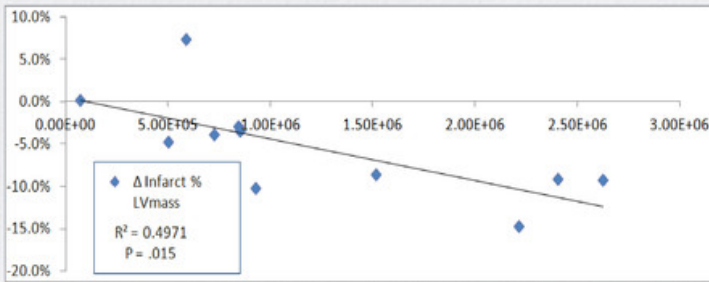




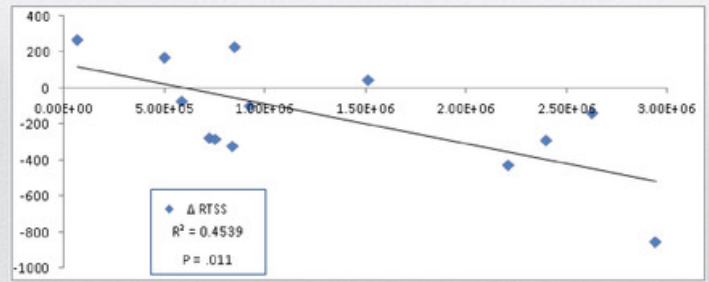


# Phase 1 Trial Results Summary

Dose Response Correlated with Mobile CD34+ Cells



Increasing doses of CD34+/ SDF-1 mobile cells reduced the size of the infarct region by CMR  
 $Y = \Delta \text{ Infarct \% LV Mass}$ ,  $X = \text{Dose of SDF1 mobile CD34 cells}$



Increasing doses of CD34+/ SDF-1 mobile cells reduced RTSS indicating improved perfusion  
 $Y = \Delta \text{ RTSS}$ ,  $X = \text{Dose of SDF1 mobile CD34 cells}$

RTSS (Hypoperfusion)

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

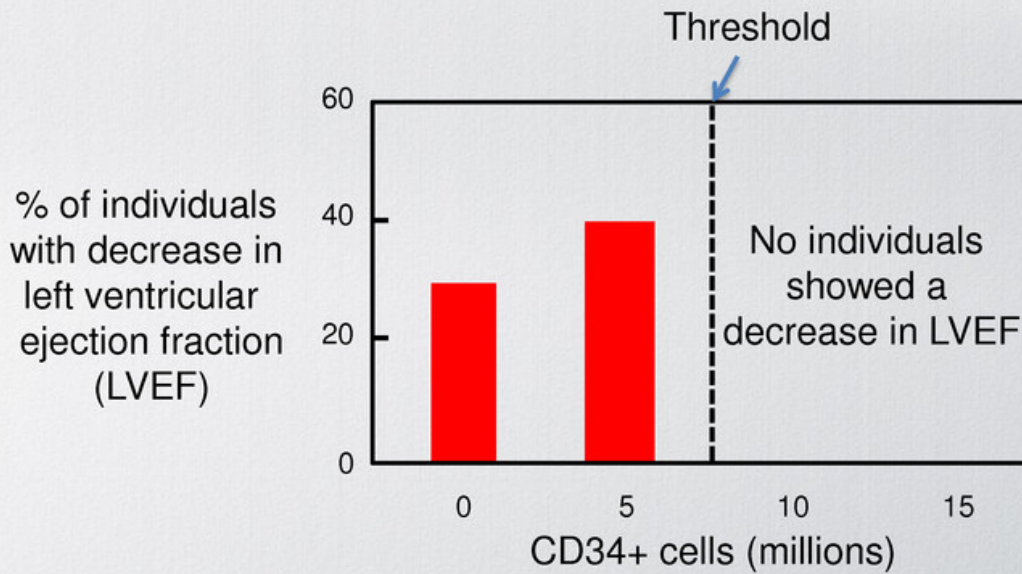
DSMB determined that no adverse events were related to therapy



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



# Effect of AMR-001 on Left Ventricular Function: Results of Phase 1 Trial



Quyyumi AmHtJ 2011 and data on file



# PreSERVE-AMI Phase 2 Study

**Indication** Post-AMI preservation of cardiac function

**Design** Double blinded, placebo controlled, randomized (1:1)

**Primary Endpoint** Change in cardiac perfusion (RTSS by SPECT) from baseline to 6 months

**Other Endpoints** Secondary endpoints to determine preservation of cardiac function and clinical events:  
CMR to measure LVEF, LVESV, LVEDV, regional myocardial strain, infarct/peri-infarct regional wall motion abnormalities, and infarct size (baseline and 6 months)  
Quality of Life measures: (KCCQ & SAQ)  
Reduction in cumulative MACE and other adverse clinical cardiac events at 6, 12, 18, 24, and 36 months

**Treatment** Single dose. Minimum dose for release  $\geq 10$ MM cells

**Location and Number of Subjects** United States, 50+ centers, 160 patients\*



\* If the number of evaluable patients in the trial is less than projected, NeoStem has authorization from the FDA to enroll up to 180 patients



# Expansion of Intellectual Property

- Broad and growing patent portfolio supports cardiac and other ischemic conditions
- 4 issued US composition of matter and methods patents:
  - U.S. 7,794,705: Issued 9/14/2010. Indication: Cardiac: Post AMI early and late
  - U.S. 8,088,370: Issued 1/3/2012. Indication: Any vascular injury: Post vascular insufficiency
  - U.S. 8,343,485: Issued 1/1/2013. Indication: Any vascular injury: Post vascular insufficiency
  - U.S. 8,425,899: Issued 4/23/2013. Indication: Progressive myocardial injury: Post AMI
- 5 issued OUS composition of matter and method patents:
  - Japan, South Africa, Malaysia, Philippines
- Patent Applications: 30 active US and OUS patents pending
- Issued and pending claims can be applied to other conditions caused by underlying ischemia, including: chronic myocardial ischemia post-AMI, congestive heart failure, critical limb ischemia and ischemic brain injury



# Scientific Advisory Board

**Andrew L. Pecora, MD, FACP, CPE**  
SAB Administrative Chairman

Chief Medical Officer, NeoStem  
Hackensack University Medical Center

---

**Eugene Braunwald, MD, FRCP**

Brigham & Women's Hospital

**Bernard J. Gersh, MD, ChB, DPhil, FRCP**

The Mayo Clinic

**Dean J. Kereiakes, MD, FACC**

The Christ Hospital Heart of Greater Cincinnati

**Douglas L. Mann, MD, FACC**

Washington University School of Medicine

**Emerson C. Perin, MD, PhD, FACC**

Texas Heart Institute

**Bertram Pitt, MD**

University of Michigan School of Medicine

**Arshed Quyyumi, MD, FRCP, FACC,**  
Principal Investigator, PreSERVE Trial

Emory University School of Medicine

**Edmund K. Waller, MD, PhD, FACP**

Emory University School of Medicine

**James T. Willerson, MD**

University Texas Health Science Center

**Joseph Wu, MD, PhD**

Stanford University School of Medicine





# What's Next?

## Congestive Heart Failure

US: Incidence – 660,000, Prevalence 5.8 million<sup>1</sup>

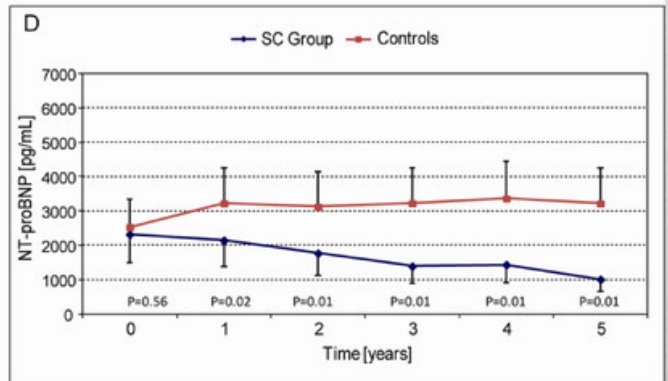
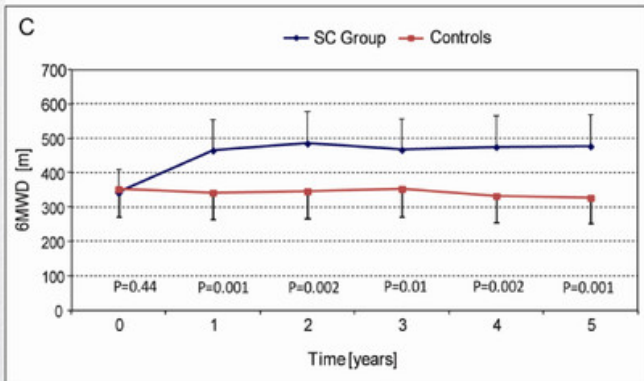
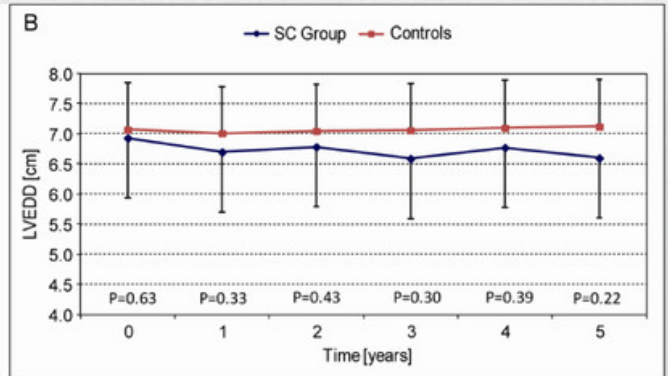
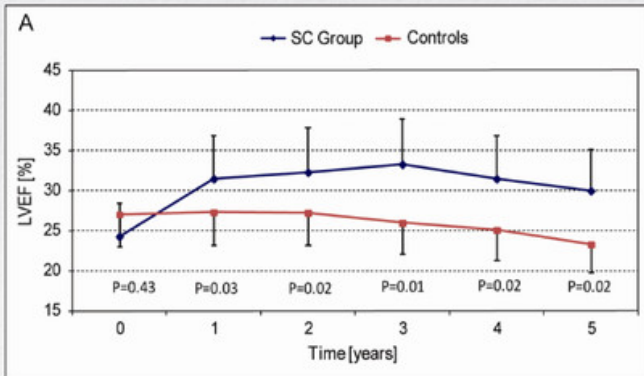
Worldwide: Prevalence – 20-23 million<sup>2</sup>



- 1) American Heart Association
- 2) Study by Case Western Reserve University



# Intracoronary Delivery of CD34+ Stem Cell Shows That Improvement in Physiologic and Clinical Status is Durable (to 5 years)

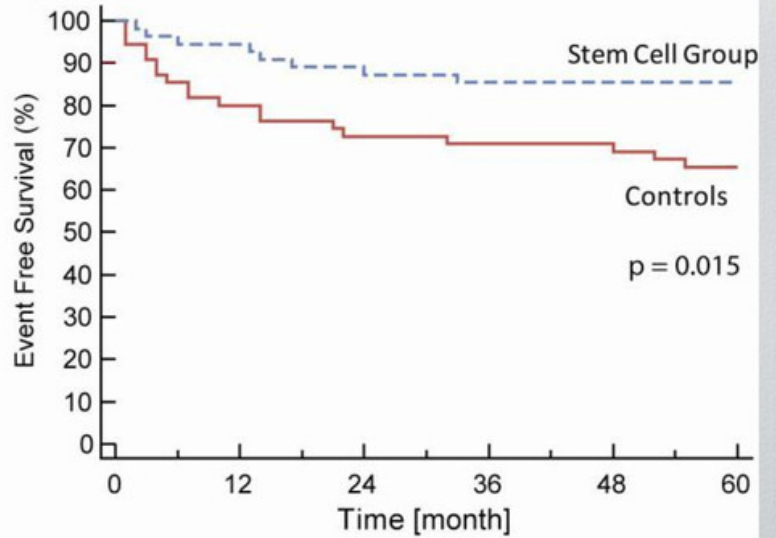
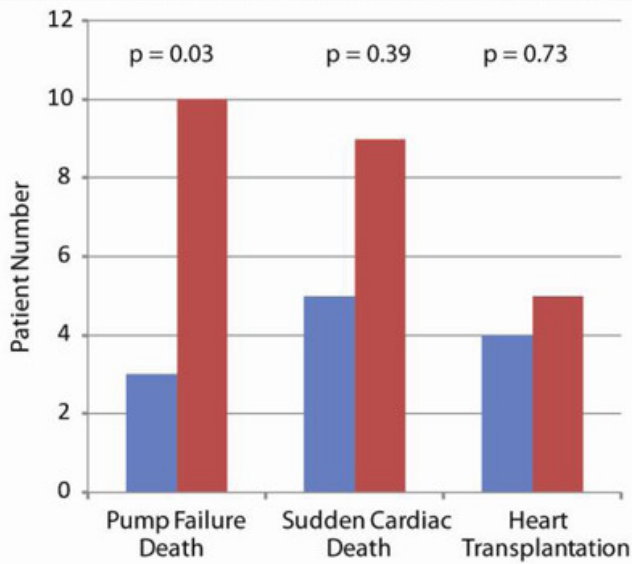


Adapted from Vrtovec et al, Circ Res published online Oct 12, 2012

■ Stem Cell Group  
■ Controls



# CD34+ Stem Cell Therapy Yields Meaningful Clinical Benefits in DCM




Adapted from Vrtovec et al, Circ Res published online Oct 12, 2012

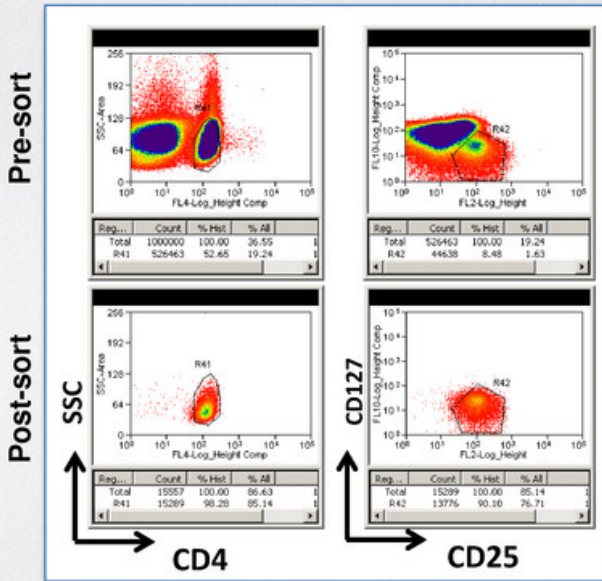
■ Stem Cell Group  
■ Controls



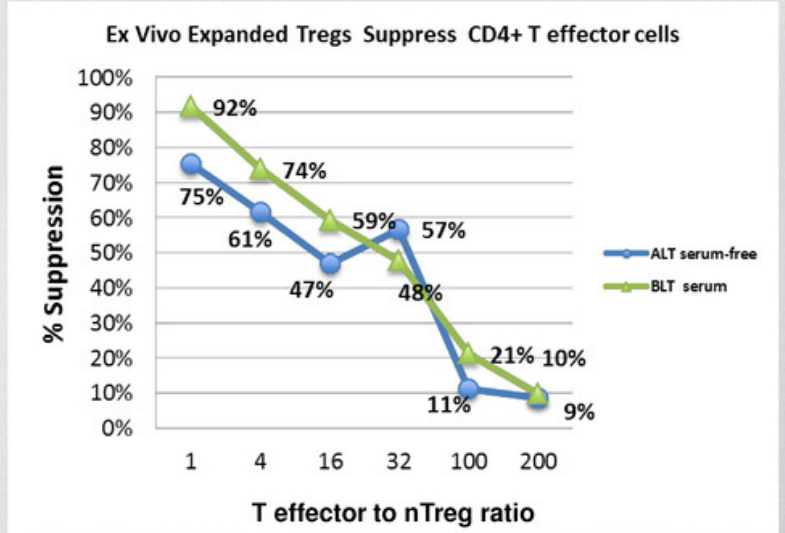
# Athelos<sup>®</sup> Treg Cells to Restore Immune Balance

- Partnership with Becton Dickinson, which owns 20% of Athelos 
- Immune-mediated diseases, such as graft-versus-host-disease (GVHD), autoimmune disorders, such as type 1 diabetes and multiple sclerosis, and allergic conditions, are a result of an imbalance between T-effector cells and T-regulatory cells (Treg)
- Treg therapy represents a novel approach for restoring immune balance by enhancing T-regulatory cell number and function<sup>1</sup>
- Phase 1 work is ongoing globally under several independent physician INDs, including Dr. P. Trzonkowski, Dr. Jeffrey Bluestone and Dr. Rob Negrin, results of which will inform NeoStem's future clinical direction
- Exclusive rights to 21 issued patents and 3 patents pending related primarily to methods of isolating, purifying and expanding Tregs

# Ex vivo Expanded Human Tregs Show Safety and Potential Efficacy in Early Clinical Trials



Post-sort *nTreg* : >90%



- Trzonkowski et al., First-in-man clinical results of the treatment of patients with graft versus host disease with human ex vivo expanded CD4+CD25+CD127- T regulatory cells . Clin. Immunol. 2009
- Di Ianni et al., Tregs prevent GVHD and promote immune reconstitution in HLA-haploidentical transplantation. Blood 2011
- Brunstein et al., Infusion of ex vivo expanded T regulatory cells in adults transplanted with umbilical cord blood: safety profile and detection kinetics. Blood 2011
- Marek-Trzonkowski et al., Administration of CD4+CD25highCD127- Regulatory T Cells Preserves  $\beta$ -Cell Function in Type 1 Diabetes in Children. Diabetes Care, 2012

## Athelos<sup>®</sup> Open Treg Trials

- Laport and Negrin, Stanford (NCT01660607) Phase I/II MAHCT w/ TCell Depleted Graft w/ Simultaneous Infusion Conventional and Regulatory T Cell (unpublished pers comm)
- Gitelman and Bluestone, UCSF (NCT01210664) T1DM Immunotherapy Using CD4+CD127lo/-CD25+ Polyclonal Tregs (unpublished pers comm)
- Bykovskaia, Russian State Medical University (NCT01446484) Treatment of Children With Kidney Transplants by Injection of CD4+CD25+FoxP3+ T Cells to Prevent Organ Rejection
- Brunstein, UMinn (NCT00602693 and NCT01163201) T-Regulatory Cell and CD3 Depleted Double Umbilical Cord Blood Transplantation in Hematologic Malignancies
- Lu, Nanjing Medical University, China, and Blazar, UMinn, USA (NCT01624077) Safety Study of Using Regulatory T Cells Induce Liver Transplantation Tolerance (Treg)



Source: Clinicaltrials.gov database



# Scientific Advisory Board

**Robert A. Preti, PhD,**  
SAB Administrative Chairman

Progenitor Cell Therapy

**Jeffrey Bluestone, PhD**

University of California, San Francisco, Diabetes Center

**David A. Horwitz, MD**

University of Southern California

**Robert Korngold, PhD**

Hackensack University Medical Center

**Robert S. Negrin, MD**

Stanford University

**David Peritt, PhD**

Hospira

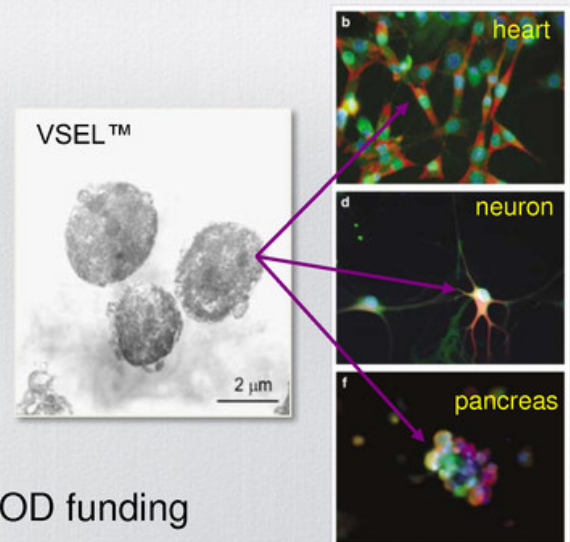
**Noel L. Warner, PhD**

BD Biosciences

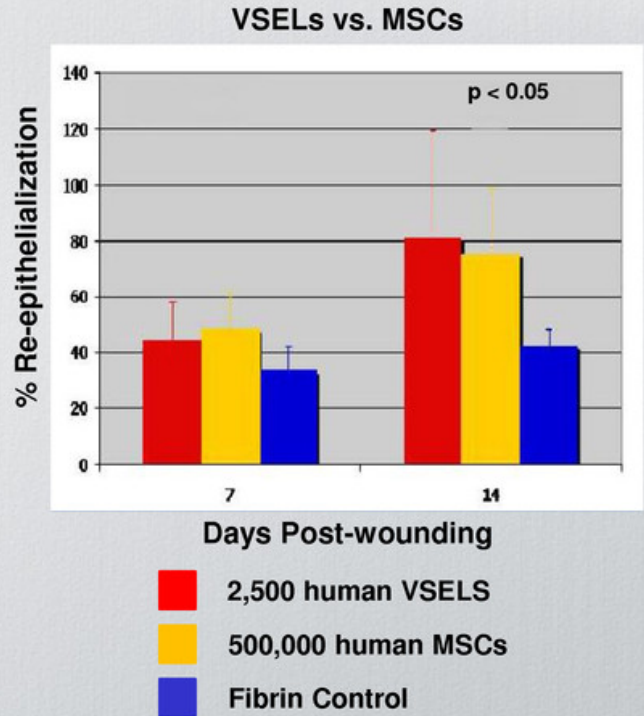
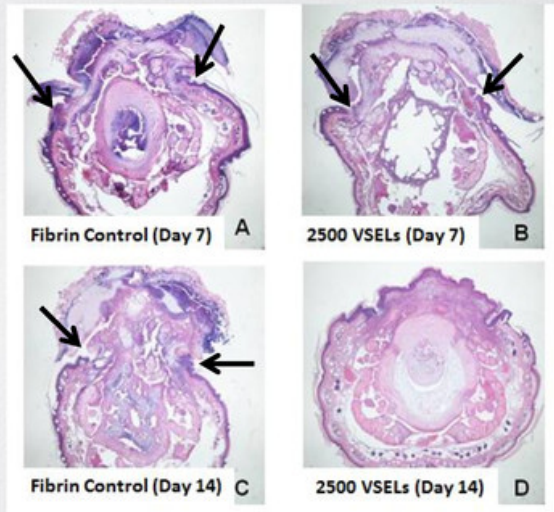


## VSELS – Adult Stem Cells

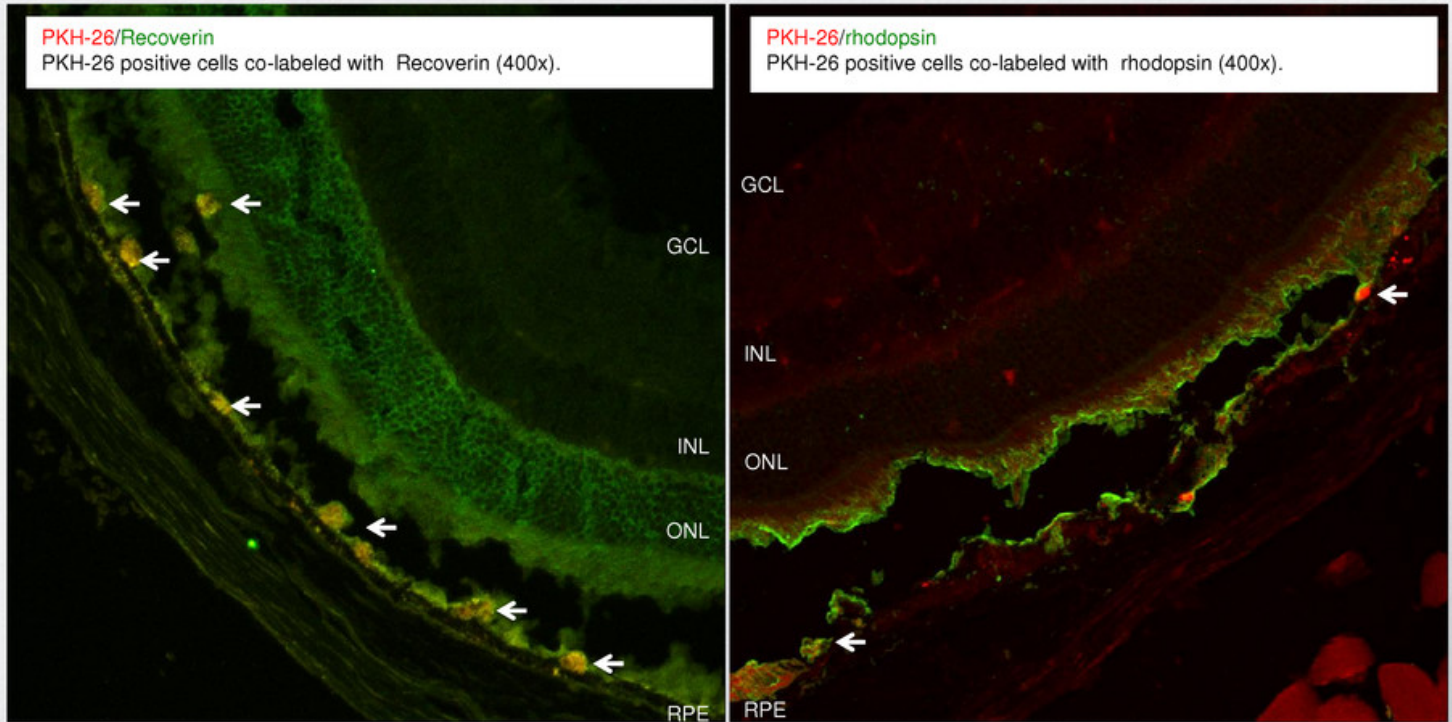
- Very small embryonic-like (VSELS™) stem cells are believed to be naturally pluripotent
- Animal models have demonstrated that highly enriched human VSELS are able to integrate, differentiate and potentially regenerate
- Treatment indications being explored include macular degeneration, osteoporosis, cardiac, acute radiation syndrome, and wounds
- Pre-clinical work financed largely by grants and DOD funding
  - **Total Active Grants Awarded:** \$4,596,676
  - **Total Grants Pending:** \$150,000
  - **Total Grants Planned for Submission:** \$6,150,000 (Spring 2013)  
- with institutions we have previously established a relationship
- NeoStem has 8 families of patents pending for method of treatment claims that dovetail with the indications that we are pursuing



# Human VSEs Accelerate Healing in a SCID Mouse Complex Tail Wound Model



# Human VSELs Injected into a Mouse Sub-Retinal Space Integrate and Show Differentiation Potential *in situ*







# Academic Collaborators

**Vincent Falanga, MD**

Roger Williams Medical Center

**Kameran Lashkari, MD**

Schepens Eye Institute, Harvard Medical School

**Song Li, PhD**

University of California, Berkeley

**Mariusz Ratajczak, MD, PhD, DSci**

University of Louisville

**Russel Tacihman, DMD, DMSc**

University of Michigan



Development and delivery of high quality, cost-efficient, and effective therapeutics can be leveraged by state-of-the-art manufacturing and regulatory expertise



- Experience with over
  - 100 Clients Served and Growing
  - 30,000 Products Manufactured
  - 18,000 Products Stored
  - 14,000 Products Shipped for Clinical Use
  - 50 US and EU Regulatory Filings Successfully Completed



*PCT Manufactured for Phase 1, 2 and 3 for  
Dendreon's FDA Approved  
Provenge® Product*



- cGMP/GLP Accredited and Certified Facilities



**Allendale, New Jersey** (30,000 ft<sup>2</sup>)  
ISO Class 7 / Class 10,000 suites  
ISO Class 6 / Class 1,000 suite



**Mountain View, California** (25,000 ft<sup>2</sup>)  
ISO Class 7 / Class 10,000 suites

- Large and small companies in the cell therapy space outsource services for all or part of their manufacturing needs to improve efficiencies and profitability and to reduce capital investment:



- PCT supports NeoStem's cell therapy development programs with
  - Lower costs for internal cell therapy development
  - Cash flow that can be reinvested toward growth and internal development activities
- Establish opportunities for early partnering relationships with goals of commercial manufacturing, equity participation and back-end royalties
- Automation initiatives focused on lowering cost of goods and increasing gross profits
- Initiatives being pursued to expand commercial manufacturing in the US and Europe

# Cell Therapy Manufacturing Customer Profiles

*Examples of Contract Services Potential from Conception to Commercialization\**

	Low Complexity Product	Medium Complexity Product	High Complexity Product
<b>Pre-clinical Drug Discovery Contracts</b>	12 to 18 Month Engagement \$50,000 to \$250,000	12 to 24 Month Engagement \$250,000 to \$500,000	24 to 36 Month Engagement \$500,000 to \$1,000,000
<b>Phase 1 Clinical Trial Manufacturing Contract</b>	6 to 12 Month Eng. 5 to 25 Units Produced \$250,000 to \$750,000	12 to 18 Month Eng. 25 to 50 Units Produced \$625,000 to \$1,250,000	12 to 24 Month Eng. 50 to 100 Units Produced \$1,000,000 to \$2,000,000
<b>Phase 2 Clinical Trial Manufacturing Contract</b>	12 to 18 Month Eng. 25 to 50 Units Produced \$625,000 to \$1,250,000	12 to 24 Month Eng. 100 to 200 Units Mfg. \$2,000,000 to \$4,000,000	18 to 36 Month Eng. 200 to 400 Units Mfg. \$3,000,000 to \$6,000,000
<b>Phase 3 Clinical Trial Manufacturing Contract</b>	12 to 18 Month Eng. 50 to 100 Units Produced \$1,000,000 to \$2,000,000	24 to 48 Month Eng. 200 to 400 Units Mfg. \$3,000,000 to \$6,000,000	24 to 48 Month Eng. 400 to 1,000 Units Mfg. \$4,000,000 to \$10,000,000
<b>Commercial Manufacturing Contract</b>	Est. Peak Annual Sales 2,500 to 5,000 Units <b>\$38M to \$75M / Yr.</b>	Est. Peak Annual Sales 10,000 to 25,000 Units <b>\$80M to \$200M / Yr.</b>	Est. Peak Annual Sales 25,000 to 50,000 Units <b>\$125 to \$250M / Yr.</b>

# NeoStem 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

**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

**Timothy C. Fong, PhD, MBA**  
VP, Technology & Product Development of PCT

- PhD in Immunology – UCLA, MBA – Saint Mary's College
- Recently Technical Director Cell Therapy at BD Biosciences
- Over 18 years experience in drug development; Has led R&D groups in cell and gene therapies from discovery research to clinical trials

**Jonathan Sackner-Bernstein, MD, FACC**  
VP of Clinical Development and Regulatory Affairs

- MD – Jefferson Medical College
- Internationally recognized clinical researcher in cardiology
- 20 years experience in clinical practice, medical research and healthcare management
- FDA background as past Associate Director for Technology and Innovation; Former CMO at Clinilabs, a clinical research organization

**Martin E. Schmieg**  
VP, Corporate Development

- BA – LaSalle University
- Expertise in bus dev for health care product and med tech companies
- Formerly President of Nuvilex, Inc., President and CEO of Freedom2, Inc.
- Selected transactions include multi-billion dollar sale of Advanced Bionics Corp. to Boston Scientific & development and market launch of the Cytoscan instrument



# NeoStem Board of Directors

<b>Robin Smith, MD, MBA</b> CEO & Chairman of the Board	<ul style="list-style-type: none"> <li>• MD – Yale; MBA – Wharton</li> <li>• Formerly President &amp; CEO IP2M, EVP &amp; CMO HealthHelp</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> (Independent)	<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>Drew Bernstein, CPA</b> (Independent)	<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>Martyn Greenacre, MBA</b> (Independent)	<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> (Independent)	<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>Stephen W. Potter, MBA</b> (Independent)	<ul style="list-style-type: none"> <li>• BS – University of Massachusetts; MBA - Harvard Business School</li> <li>• Experience – Biotech and pharma experience including Osiris Therapeutics (approval of Prochymal®, first-ever stem cell drug therapy), Genzyme, DuPont Pharmaceuticals, Booz Allen &amp; Hamilton</li> </ul>
<b>Eric Wei</b> Managing Partner, RimAsia Capital Partners	<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>



# Key Financial Metrics

**Revenue** \$2.5m (1Q 2013)

**Cash** \$9.3m (as of March 31, 2013)

**Additional Cash** \$10.7m (net proceeds from common stock offering in May 2013)

## **Total Stock and Equivalent Shares Outstanding** (as of May 9, 2013)

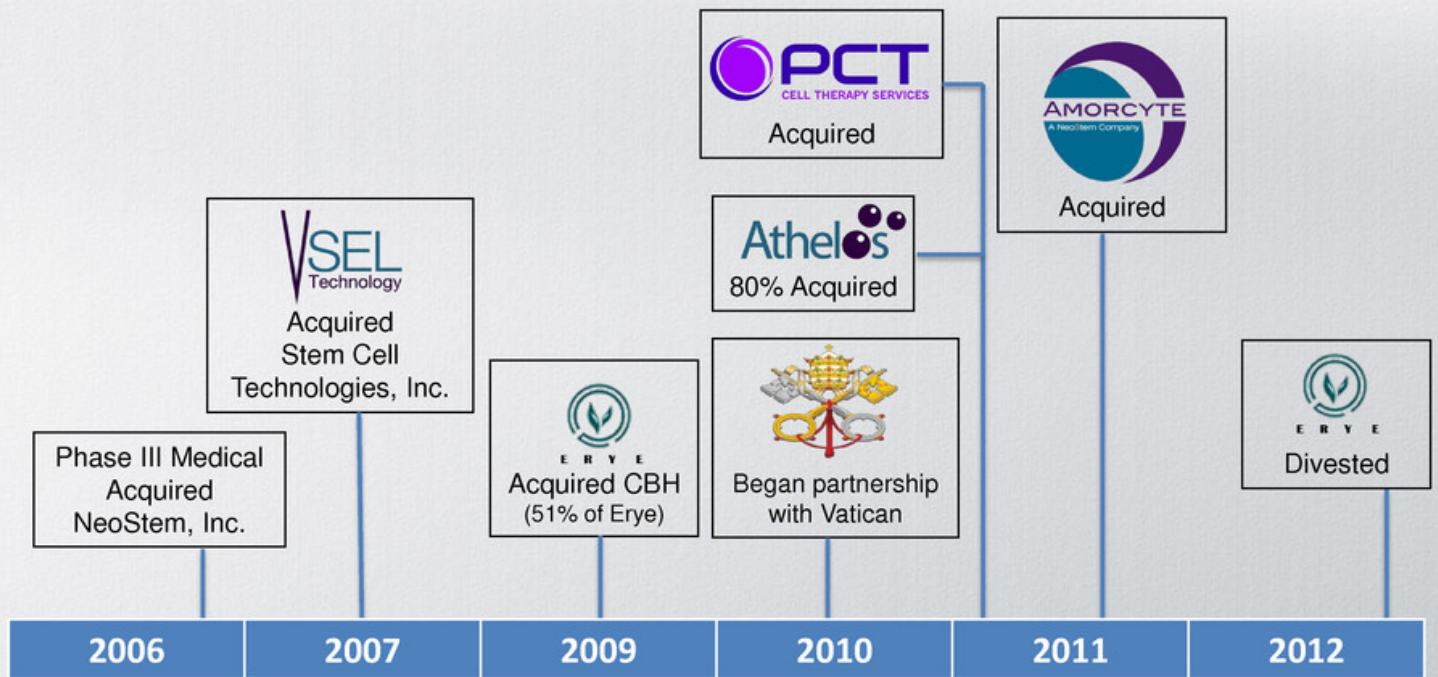
Common Shares 193.8m

Warrants 55.0m (avg. warrant exercise price of \$1.56)

Options 26.5m (avg. option exercise price of \$1.16)








# Accessed \$130 Million and Completed 5 M&A Transactions To Date



# NeoStem Milestones




- **Therapeutic Pipeline**

-  Complete enrollment PreSERVE-AMI Phase 2 trial
-  1<sup>st</sup> data readout 6-8 months after last patient enrolled
-  Progress towards Phase 1b/2a AMR-001 CHF trial
-  Progress towards VSEL™ human bone growth trials
-  Progress Treg cell program towards Phase 2 trial in type 1 diabetes

- **Commercial Operations** 

- Cell therapy automation project
- Manufacturing expansion into Europe
- US commercial manufacturing expansion
- Product/service expansion transaction(s)

# NeoStem is Built for Success in Regenerative Medicine

- Dynamic, experienced and nimble management with a proven track record of success with leadership that can execute
- Clinical and preclinical pipeline of cell therapies around a strong IP portfolio
  - Cardiovascular disease 
  - Autoimmune disorders 
  - Regenerative medicine 
- Recognized, state-of-the art contract development and manufacturing organization (East and West coast operations)



## Contact Information

**NeoStem, Inc.**  
**NYSE MKT: NBS**  
[www.neostem.com](http://www.neostem.com)

**Robin Smith, MD, MBA**  
***Chairman & CEO***  
Phone: (212) 584-4174  
Email: [rsmith@neostem.com](mailto:rsmith@neostem.com)

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