#### 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): March 15, 2015

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):

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o 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.

On Monday, March 16, 2015, NeoStem, Inc., a Delaware corporation (the "Company" or "NeoStem"), issued a press release announcing that updated efficacy and safety results from the one-year follow-up for its Phase 2 PreSERVE AMI study and additional analyses of certain functional tests were presented at ACC.15, the American College of Cardiology's 64<sup>th</sup> Annual Scientific Session and Expo, in San Diego, California. A copy of the press release is attached hereto as Exhibit 99.1. The data as presented by Dr. Arshed A. Quyyumi, the Lead Principal Investigator of our PreSERVE AMI Study, at the ACC Expo, is also attached hereto as Exhibit 99.2.

Additionally, NeoStem 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 and is attached hereto as Exhibit 99.3. NeoStem undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.3.

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 Exhibits 99.1, 99.2 and 99.3, 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 Exhibits 99.1 and 99.3 hereto, contain "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 March 16, 2015*	
99.2	Pre-SERVE AMI ACC Expo Slide Presentation*	
99.3	Slide presentation of NeoStem, Inc. dated March 2015*	

\*Exhibits 99.1, 99.2 and 99.3 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:General Counsel

Dated: March 16, 2015

### NeoStem Announces PreSERVE AMI Clinical Trial One-Year Follow-Up Results

#### Results support previous observation of dose-dependent signals across multiple endpoints

New York, NY (March 16, 2015) - NeoStem, Inc. (NASDAQ:NBS), a biopharmaceutical company developing novel cell based personalized medicine therapies, announced today the presentation of updated efficacy and safety results from the one-year follow-up for its Phase 2 PreSERVE study and additional analyses of certain functional tests at ACC.15, the American College of Cardiology's 64<sup>th</sup> Annual Scientific Session and Expo, in San Diego, California. The one-year follow-up results are defined as all data accumulated until the last patient enrolled completed 12 month follow-up. Thus, the results actually represent data from patients with a median follow-up of 18 months.

The PreSERVE study is NeoStem's clinical trial evaluating NBS10 which is being developed to treat damaged heart muscle following an acute myocardial infarction. One-year follow-up safety data collected thus far supports the trial's 6 month results presented at the American Heart Association's Scientific Sessions in November 2014. The ACC presentation contained updated safety and exploratory efficacy data and additional analyses conducted on left ventricular ejection fraction (LVEF) data. Clinical Endpoint Committee adjudication of major adverse cardiac events (MACE) was performed on the 6 month data reported previously and was not performed for new events (occurring between 6 and 12 months). The next prescribed adjudication of MACE is currently planned at the end of patient follow-up. At 12-month follow-up, no meaningful safety or tolerance differences were observed between treatment and control groups. In this updated analysis, no additional deaths were reported in the treatment or control groups beyond those previously reported in the six month analysis. In addition, in post hoc subset analyses based on the number of cells patients received, serious adverse event (SAE) frequency continues to show numerical improvement at all cell doses when compared to control.

No additional SPECT data were collected at one year follow-up. As an exploratory measure of efficacy, PreSERVE looked at reduction of infarct size at six months. Patients receiving 20 million cells or more experienced a decrease in infarct size of 41% vs 24% for patients in the control group.

Based on the one-year follow-up results, the company and its scientific advisors believe that the study results suggest:

- Intracoronary administration of autologous CD34+ cells appears safe and well-tolerated;
- A signal for a mortality benefit; and
- A signal for reduction in the frequency of serious adverse events (SAEs) in higher dose groups.

"We believe that these data, when coupled with the six month data on MACE and LVEF that we previously reported, are encouraging and show the possibility that higher doses of CD34 cells may provide benefit to patients post-STEMI," said Dr. Douglas Losordo, Chief Medical Officer of NeoStem. "Further consideration of these data, in consultation with our medical advisory board, should lead us to a determination of the next steps for the development of this program in the second half of 2015."

"While small in number, we are encouraged by the fewer mortality events observed for treated patients versus control patients as of the date of this 12 month follow-up. In addition, we are very encouraged by the persistence of reduced serious adverse event rates and evidence for improved infarct healing and left ventricular function," said Dr. Arshed A. Quyyumi, Professor of Medicine at Emory University and Lead Principal Investigator of the PreSERVE AMI study, who made the presentation at ACC.15. "In addition,

the failure of SPECT imaging to document changes at the 6 month interim analysis, despite signs of clinical benefit in multiple parameters, suggests that this technique is not applicable in this setting."

These highlights should be read in conjunction with a full and complete copy of the data as contained in the ACC presentation, which data can be viewed by visiting the NeoStem website at <u>www.Neostem.com/media/events/</u> and on the Securities and Exchange Commission website at <u>www.sec.gov</u>.

### About NeoStem's Ischemic Repair Program

NeoStem is developing CD34 cell-based therapies to address damage to tissue caused by ischemia. Ischemia occurs when the supply of oxygenated blood in the body is restricted. The Company's Ischemic Repair Program seeks to reverse the damage caused by this restriction through the development and formation of new blood vessels. The Program's lead product candidate in this area is NBS10, a chemotactic hematopoietic stem cell product comprised of autologous bone marrow-derived CD34/CXCR4 cells selected to treat damaged heart muscle following AMI (severe heart attack). NBS10 is thought to work by increasing microvascular blood flow in the heart muscle via the development and formation of new blood vessels, thereby reversing the restriction of blood supply caused by a heart attack and rescuing at-risk cardiac tissue from eventual cell death.

### About the PreSERVE AMI Clinical Trial

PreSERVE AMI is a randomized, double-blind, placebo-controlled clinical trial of intracoronary infusion of autologous CD34 cells in patients with left ventricular dysfunction post-ST elevation myocardial infarction (STEMI). The trial included 161 subjects at 60 sites in the United States, randomized 1:1 between treatment and placebo arms. Eligible patients presented with acute STEMI, had successful stenting of the infarct-related artery and had left ventricular dysfunction 4 days after AMI. Primary endpoints include occurrence of SAEs and MACE (defined as cardiovascular death, re-infarction, heart failure hospitalization, and coronary revascularization) through 3 year follow-up, and 6-month change in myocardial perfusion (RTSS) measured quantitatively by gated SPECT myocardial perfusion imaging. Secondary endpoints include cardiovascular magnetic imaging resonance (CMR) to measure left ventricular ejection fraction (LVEF), left ventricular end-systolic volume (LVESV), left ventricular end-systolic diameter (LVEDV). Infarct size (baseline and six months) was an exploratory endpoint.

### About NeoStem, Inc.

NeoStem is a biopharmaceutical company pursuing the preservation and enhancement of human health globally through the development of novel cell based personalized medicine therapeutics that prevent, treat or cure disease. The Company is developing therapies based on three platform technologies (immune-oncology, ischemic repair and immunomodulation) with a lead, late-stage (Phase 3, 2 and 2, respectively) clinical program for each. The combination of a rich therapeutics pipeline and an externally recognized in-house center for cell therapy process development and manufacturing has created an organization with unique capabilities for accelerated and efficient product development. <u>www.neostem.com</u>

### Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forwardlooking 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, the Company's ability to develop and grow its business, the successful development of cellular therapies with respect to the Company's research and development and clinical evaluation efforts in connection with the Company's Targeted Immunotherapy Program, Ischemic Repair Program , Immune Modulation Program and other cell therapies, especially NBS10, the future of the regenerative medicine industry and the role of stem cells and cellular therapy in that industry, and the performance and planned expansion of the Company's contract development and manufacturing business as well as its efforts to expand its capabilities into the cell therapy tools market. 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 ("SEC") on March 2, 2015, and in the Company's other 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 of its control. While 6 month and 12 month data have been collected, those data are subject to ongoing analysis, and results reported at this time are preliminary. There can be no assurance that further analysis may not reveal negative, or less promising, results.

CONTACT: NeoStem, Inc. Eric Powers Manager of Communications and Marketing Phone: +1-212-584-4173 Email: epowers@neostem.com

### PreSERVE-AMI: A Randomized, Double-Blind, Placebo Controlled Clinical Trial of Intracoronary Infusion of Autologous CD34+ Cells (NBS10) in Patients with Left Ventricular Dysfunction Post STEMI

Arshed Quyyumi<sup>1</sup>, Dean Kereiakes<sup>2</sup>, David Shavelle<sup>3</sup>, Timothy Henry<sup>4</sup>, Ali Denktas<sup>5</sup>, Ahmed Abdel-Latif<sup>6</sup>, Catalin Toma<sup>7</sup>, Gregory Barsness<sup>8</sup>, Stephen Frohwein<sup>9</sup>, Richard Schatz<sup>10</sup>, Martin Cohen<sup>11</sup>, Charles Davidson<sup>12</sup>, Nabil Dib<sup>13</sup>, Marc Klapholz<sup>14</sup>, Gary Schaer<sup>15</sup>, Alejandro Vasquez<sup>16</sup>, Andrew Pecora<sup>17</sup>, Thomas Moss<sup>17</sup>, Pamela Hyde<sup>17</sup>, Anna Maria Kanakaraj<sup>17</sup>, Le Dich<sup>17</sup>, Vitaly Druker<sup>17</sup>, Candice Junge<sup>17</sup>, Robert Preti<sup>17</sup>, Douglas Losordo<sup>17</sup>

<sup>1</sup>Emory Clinical Cardiovascular Research Institute, Cardiology Division, Emory University School of Medicine, Atlanta, GA <sup>2</sup>The Christ Hospital Heart and Vascular Center, Cincinnati, OH <sup>3</sup>University of Southern California, Los Angeles, CA <sup>4</sup>Cedars-Sinai Heart Institute, Los Angeles, CA <sup>5</sup>Baylor College of Medicine/Michael E Debakey VA Medical Center, Houston, TX <sup>6</sup>University of Kentucky, Lexington, KY <sup>7</sup>University of Pittsburgh Medical Center, Pittsburgh, PA <sup>8</sup>University of Pittsburgh Medical Center, Pittsburgh, PA <sup>9</sup>Emory St. Josephs Hospital, Atlanta, GA <sup>10</sup>Scripps Health, La Jolla, CA <sup>11</sup>Westchester Medical Center, Valhalla, NY <sup>12</sup>Bluhm Cardiovascular Institute Northwestern Memorial Hospital, Chicago, IL <sup>13</sup>Heart Sciences Center, Gilbert, AZ <sup>14</sup>Rutgers University, New Jersey Medical School, Newark, NJ <sup>15</sup>Rush University Medical Center, Chicago, IL <sup>16</sup>Huntsville Hospital, Huntsville, AL <sup>17</sup>Neostem Inc., New York, NY

www.clinicaltrials.gov Identifier: NCT01495364

# The PreSERVE AMI Study: Funding Sources & Disclosures

### **Conflict of Interest Disclosures**

Quyyumi: NeoStem Advisory Board member

### **Funding Source**

Study funded by NeoStem, Inc.

# Background

- Recent meta-analysis of unselected bone marrow mononuclear cell therapy after STEMI suggest that there may be no impact on LVEF changes and MACE<sup>1</sup>
- Clinical studies evaluating the therapeutic potential of cells selected for CD34 expression have demonstrated a consistent favorable impact on outcomes<sup>2-5</sup>
- Phase 1 study of autologous CD34+ cells (NBS10) provided initial evidence of feasibility and safety and suggested a threshold dose of 10 million CD34 cells for bioactivity<sup>6</sup>

1. Gyongyosi M et al. Circ Res 2015: CIRCRESAHA.114.304346. 2. Vrtovec B et al Circ Res. 2013 Jan 4;112(1):165-73. 3. Lezaic L et al. J Card Fail 2015; 21: 145-152. 3. Losordo DW et al. Circ Res. 2011 Aug 5;109(4):428-36. 4. Losordo DW et al. Circ Cardiovasc Interv. 2012 Dec;5(6):821-30.5. Poglajen G et al. Circ Cardiovasc Interv. 2014 Aug;7(4):552-9. 6. Quyyumi AA et al; Am Heart J. 2011 Jan;161(1):98-105.



# **PreSERVE Study Design**

DESIGN	Randomized (1:1), Phase 2, double blind, placebo controlled trial in patients with acute STEMI and low LVEF
PRIMARY ENDPOINTS	<ul> <li>Incidence rates of SAEs and MACE</li> <li>Change in myocardial perfusion (RTSS) measured quantitatively by gated SPECT MPI at 6 months</li> </ul>
KEY SECONDARY ENDPOINTS	LVEF – change from baseline and preservation at 6 months
KEY EXPLORATORY ENDPOINTS	Change from baseline in infarct size; hospitalization
STUDY SIZE	161 patients, 60 centers in United States
TREATMENT	Single dose CD34+ cells via infarct related artery with minimum dose for release ≥10M (million) ±20%
CONTROL	Matching infusion with placebo

# **PreSERVE: Eligibility**

### **INCLUSION CRITERIA**

- Acute ST elevation myocardial infarction.
- Stenting within 3 days of chest pain
- LVEF ≤48% by CMR or ≤45% by SPECT after 4 days
- Wall motion abnormality associated with the target lesion
- NYHA heart failure class I, II or III.

### **EXCLUSION CRITERIA**

- STEMI > 4 days before stenting.
- Cardiogenic shock
- Severe aortic stenosis.
- Re-occlusion of the infarct related artery (IRA) prior to the infusion.

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 Planned revascularization during the next 6 months.

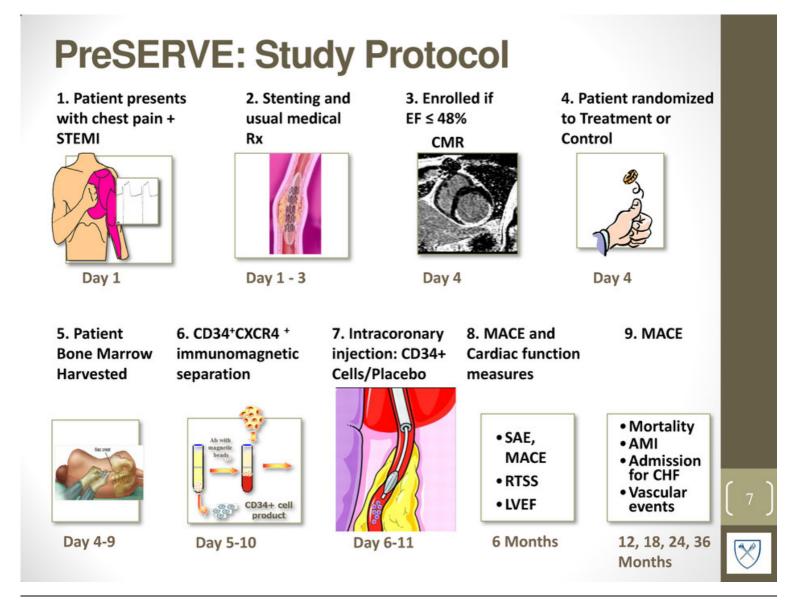
## **PreSERVE Sites**

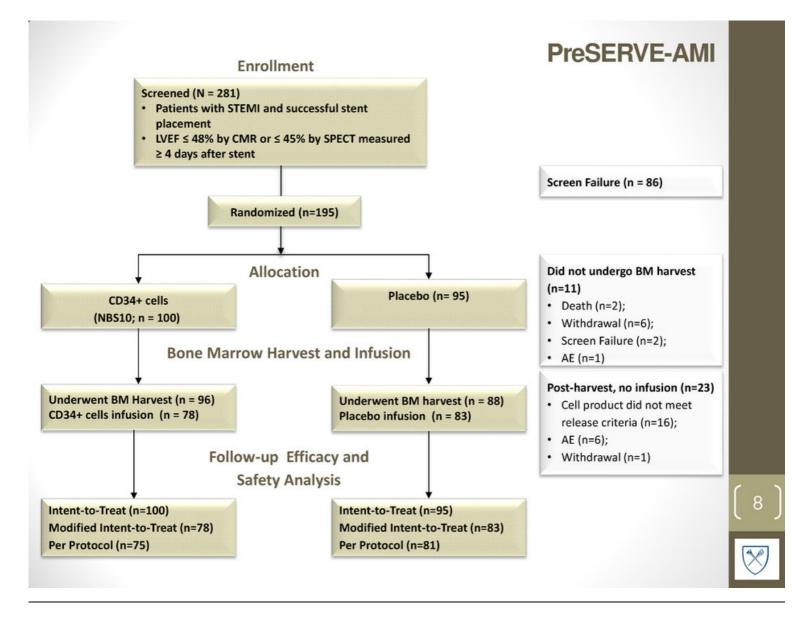
Investigator Name Arshed Quyyumi Alejandro Vasquez **Dean Kereiakes** Marc Klapholz Kenichi Fujise Nandish Thukral **Gary Schaer Robert Iwaoka** 

Ahmed Abdel-Latif Vijaykumar Kasi Vernon Anderson **Roger Gammon Stephen Frohwein Tim Henry Richard Schatz** Tanvir Bajwa Nabil Dib **Catalin Toma** Michael Tamberella Pradyumna Tummala **Charles Davidson Gregory Barsness** Virender Sethi **Tarek Helmy David Shavelle** Fadi El-Ahdab Martin Cohen Gerald Koenig **Carl Pepine** Vincent Pompili **Robert Frankel** Mark Vesely

Site Emory Heart Center Research The Christ Hospital UMDNJ-Newark Univ. Texas - Galveston Methodist San Antonio Rush University Medical Center Presbyterian CVI Research U. of Kentucky, Gill Heart Institute Orlando Health U. of Texas HSC - Houston Austin Heart PLLC St Joseph's Research Institute Minneapolis Heart Scripps-La Jolla Aurora Health Mercy Gilbert Medical Center **UPMC** Presbyterian CaroMont Heart Northeast Georgia Heart Center Northwestern University Mayo Clinic - Minnesota Hackensack University University of Cincinnati Keck School of Medicine-USC CV Group Central Lynchburg Westchester Medical Center Henry Ford University of Florida-Gainesville Ohio State University Maimonides Medical Center-Brooklyn University of Maryland

Investigator Name	Site	
	Detroit Receiving/Harper	
Theodore Schreiber	Hospital	
Mazen Abu-Fadel	U. of Oklahoma HSC	
Emerson Perin	Texas Heart Institute	
David Fortuin	Mayo Clinic - Arizona	
	Stony Brook University	
Luis Gruberg	Hospital	
Charles Lambert	Florida Hospital	
	University of Alabama-	
Massoud Leesar	Birmingham	
Joseph Wu	Stanford University	
Howard Eisen	Drexel University	
Lawrence Barr	Advocate Health Elm Hurs	
Buddhadeb Dawn	Kansas U. Medical Center	
Amit Patel	University of Utah	
Christopher Gange	MetroWest Medical Center Miriam Hospital	
Paul Gordon		
Richard Rothschild	St. John's Regional Hospita	
Peter Kerwin	Advocate Health Oakbrook	
Hitinder Gurm	U. Michigan	
Michael Imburgia	Louisville Cardiology	
Kimberly Skelding	Geisinger Medical Center	
Vijay Iyer	Buffalo General Hospital	
	Stern Cardiovascular	
Frank McGrew	Foundation/Baptist Hospita	
Zachary Hodes	St. Vincent Medical Group	
Augusto Prichard	Medstar Heart Institute	
	UVA Health System	
Michael Ragosta	Cardiology Research	
	Cardiology Associates	
Barry Bertolet	Research LLC	
	Detroit Clinical Reseach	
Majid Qazi	Center PC	
Paul Huang	Swedish Medical Center	





## **Baseline Characteristics**

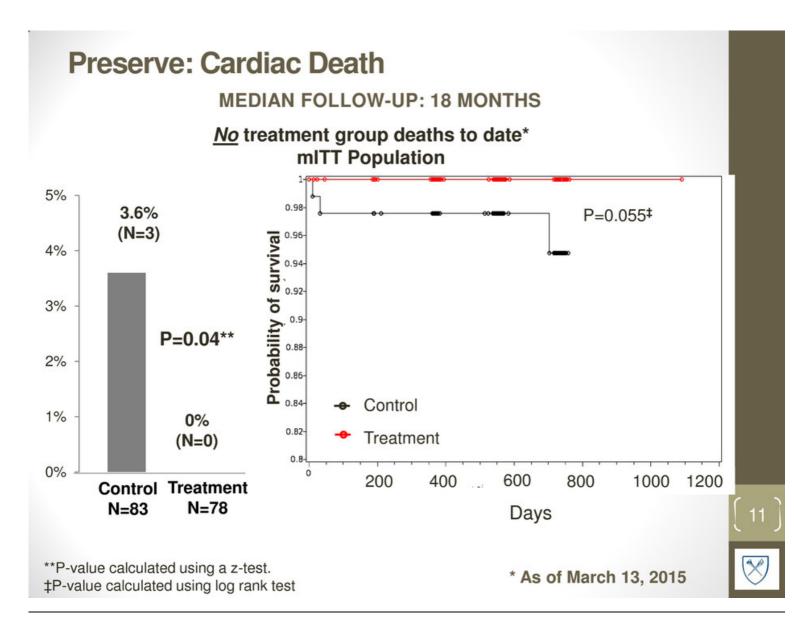
	Treated NBS10 (N=78)	Placebo (N=83)	P-value*
Demographics			
Age; mean ± SD	57.1 ± 10.1	56.4 ± 10.1	0.65
Female; n (%)	12 (15%)	17 (20%)	0.4
Race; White, n (%)	56 (72%)	62 (75%)	0.87
CV Risk Factors			
Hypertension (%)	53 (68%)	56 (67%)	0.80
Diabetes (%)	27 (35%)	19 (23%)	0.1
Hyperlipidemia (%)	13 (17%)	17 (20%)	0.82
NYHA Class*; mean ± SD	$1.8 \pm 0.6$	$1.9 \pm 0.7$	0.59
CV Medical History			
Prior CABG; n(%)	2 (3%)	2 (2%)	0.95
Prior PCI; n(%)	15 (19%)	15 (18%)	0.85
Prior CHF; n(%)	11 (14%)	11 (13%)	0.88
Prior MI; n(%)	13 (17%)	15 (18%)	0.34
Index AMI/PCI			
Infarct size (grams); mean ± SD	33.8 ± 17.4	38.6 ± 19.5	0.16
Pre-discharge LVEF (%); mean ± SD	34.3 ± 7.3	34.1 ± 8.4	0.90
LVEDV index; mean ± SD	98.0 ± 25.6	91.9 ± 20.8	0.12
LVESV index; mean ± SD	61.2 ± 23.6	58.5 ± 19.9	0.46
Time from symptoms to stent (min); mean ± SD	931 ± 1277	569 ± 864	0.041
Time from stent to infusion (days); mean ± SD	9.3 ± 1.23	9.4 ± 1.43	0.60

\*P-values for quantitative characteristics are based on a t-test. P-values for categorical characteristics are based on a Chi-square test.

## **PreSERVE Status**

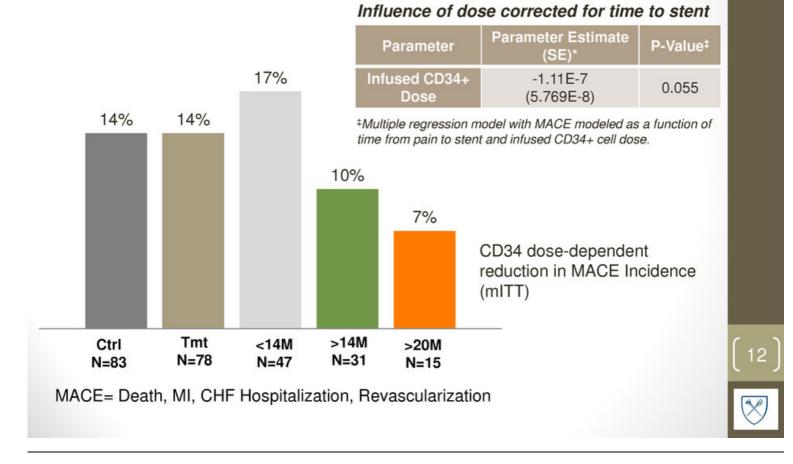
- One year follow-up completed for all subjects in December 2014
  - Median follow-up time: 18 months
- Primary endpoints and key secondary endpoints after all subjects completed 6 months follow-up (one year median follow-up) presented at AHA

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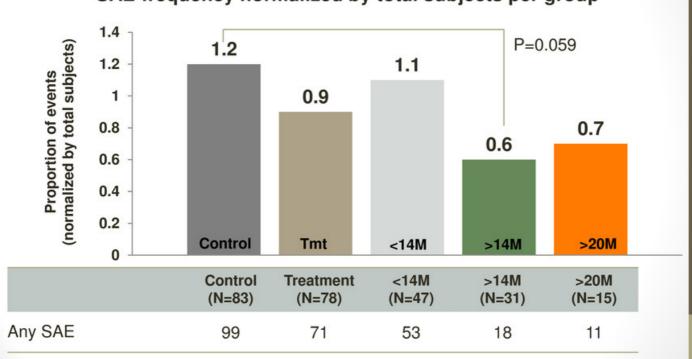
## PreSERVE: Major Adverse Cardiovascular Events

### **MEDIAN FOLLOW-UP: 12 MONTHS**



## **PreSERVE: Serious Adverse Events**

MEDIAN FOLLOW-UP: 18 MONTHS (mITT)



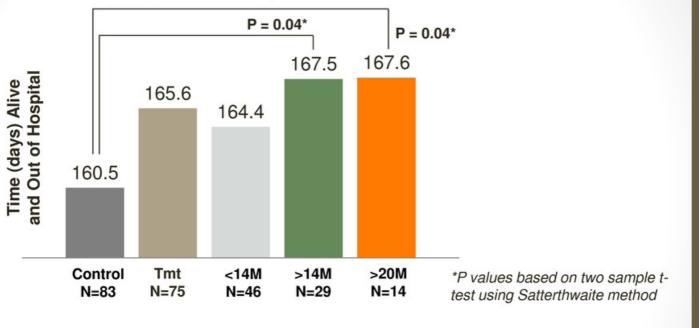
SAE frequency normalized by total subjects per group

SAE = any untoward medical occurrence that results in death or is life-threatening \*P values based on two sample t-test using Satterthwaite method. P=NS for tmt, <14M and >20M vs control.

## **PreSERVE: Hospitalization during Follow-**

up

**MEDIAN FOLLOW-UP: 12 MONTHS** 



Parameter	Parameter Estimate (SE)*	P-Value*
CD34+ Cell Dose	1.6E-7(8.0E-7)	0.053
Time to Stent	1.3E-4(5.2E-4)	0.8

ANCOVA with time alive and out of hospital as outcome, cell dose, and time to stent as covariate



## **PreSERVE: Myocardial Perfusion**

SPECT Resting Total Severity Score (RTSS) Change from Baseline to 6 months (mITT)

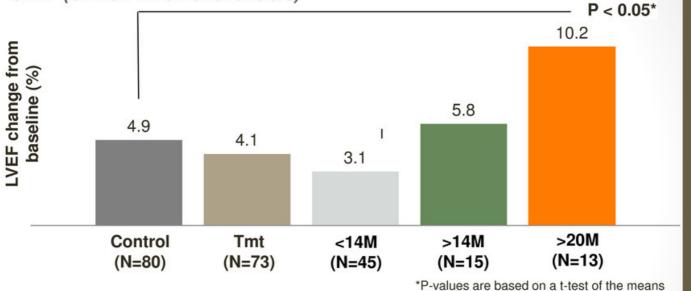
	Placebo	CD34	P-value
RTSS Mean Change from Baseline (±SD)	-149.6 ± 221.1	-142.7 ± 257.8	NS

- Improvement in clinically relevant endpoints not mirrored by change in SPECT perfusion
  - Results indicate that SPECT myocardial perfusion is not a suitable surrogate

## **PreSERVE: Left Ventricular Ejection Fraction**

Change from Baseline to 6 months (mITT)

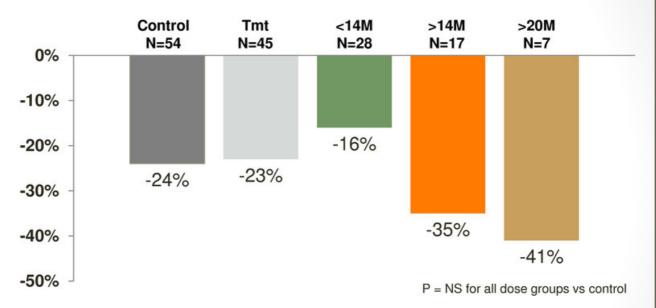




### Influence of dose corrected for time to stent

Parameter	Parameter Estimate (SE)	P-Value	
CD34+ Cell Dose	2.21 (1.084)	0.045 <sup>†</sup>	[ 16 ]
CD34+ CXCR4+ cell Dose	4.8E-7 (2.1E-7)	0.062 <sup>‡</sup>	
Multiple regression† and ANOVA‡ models			$\otimes$

### PreSERVE: Infarct Size Change from Baseline to 6 months(CMR only; mITT)



### Influence of dose corrected for time to stent

Parameter	Parameter Estimate (SE)	P-Value
CD34+ cell Dose	-1.4E-6 (5.9E-7)	0.02

ANCOVA with infarct size change from baseline as outcome, infarct size at baseline, cell dose, and time to stent as covariate

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# **PreSERVE** Sites

**Investigator Name** Arshed Quyyumi Alejandro Vasquez **Dean Kereiakes** Marc Klapholz Kenichi Fujise Nandish Thukral Gary Schaer **Robert Iwaoka** 

Ahmed Abdel-Latif Vijaykumar Kasi Vernon Anderson **Roger Gammon Stephen Frohwein Tim Henry Richard Schatz** Tanvir Bajwa Nabil Dib **Catalin Toma** Michael Tamberella Pradyumna Tummala **Charles Davidson Gregory Barsness** Virender Sethi **Tarek Helmy David Shavelle** Fadi El-Ahdab Martin Cohen Gerald Koenig **Carl Pepine** Vincent Pompili **Robert Frankel** Mark Vesely

Site Emory Heart Center Research The Christ Hospital UMDNJ-Newark Univ. Texas - Galveston Methodist San Antonio Rush University Medical Center Presbyterian CVI Research U. of Kentucky, Gill Heart Institute Orlando Health U. of Texas HSC - Houston Austin Heart PLLC St Joseph's Research Institute Minneapolis Heart Scripps-La Jolla Aurora Health Mercy Gilbert Medical Center **UPMC** Presbyterian CaroMont Heart Northeast Georgia Heart Center Northwestern University Mayo Clinic - Minnesota Hackensack University University of Cincinnati Keck School of Medicine-USC CV Group Central Lynchburg Westchester Medical Center Henry Ford University of Florida-Gainesville Ohio State University Maimonides Medical Center-Brooklyn University of Maryland

Investigator Name	Site	
	Detroit Receiving/Harper	
Theodore Schreiber	Hospital	
Mazen Abu-Fadel	U. of Oklahoma HSC	
Emerson Perin	Texas Heart Institute	
David Fortuin	Mayo Clinic - Arizona	
	Stony Brook University	
Luis Gruberg	Hospital	
<b>Charles Lambert</b>	Florida Hospital	
	University of Alabama-	
Massoud Leesar	Birmingham	
Joseph Wu	Stanford University	
Howard Eisen	Drexel University	
Lawrence Barr	Advocate Health Elm Hun	
Buddhadeb Dawn	Kansas U. Medical Cente	
Amit Patel	University of Utah	
Christopher Gange	MetroWest Medical Cente	
Paul Gordon	Miriam Hospital	
<b>Richard Rothschild</b>	St. John's Regional Hospit	
Peter Kerwin	Advocate Health Oakbroo	
Hitinder Gurm	U. Michigan	
Michael Imburgia	Louisville Cardiology	
Kimberly Skelding	Geisinger Medical Cente	
Vijay Iyer	Buffalo General Hospital	
	Stern Cardiovascular	
Frank McGrew	Foundation/Baptist Hospit	
Zachary Hodes	St. Vincent Medical Grou	
Augusto Prichard	Medstar Heart Institute	
	UVA Health System	
Michael Ragosta	Cardiology Research	
	Cardiology Associates	
Barry Bertolet	Research LLC	
-	Detroit Clinical Reseach	
Majid Qazi	Center PC	
Paul Huang	Swedish Medical Center	

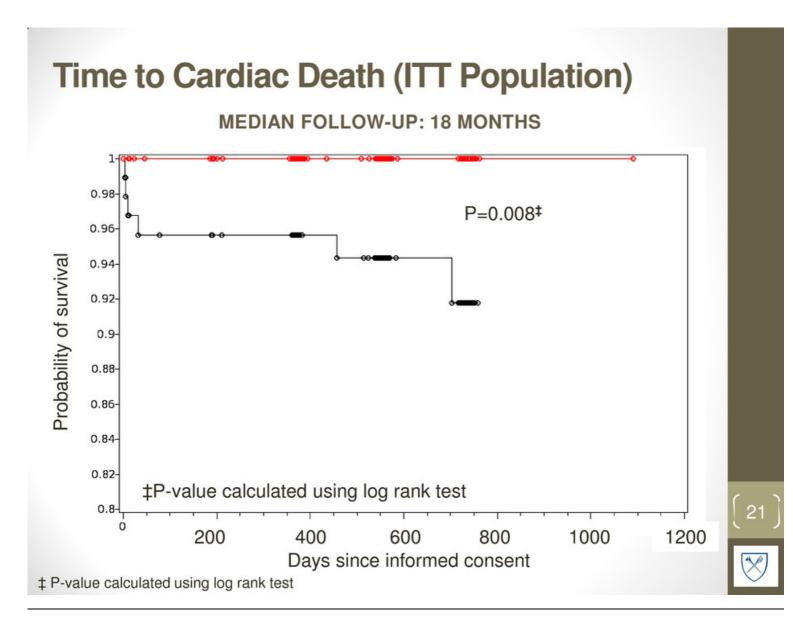
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# Thank you for your attention



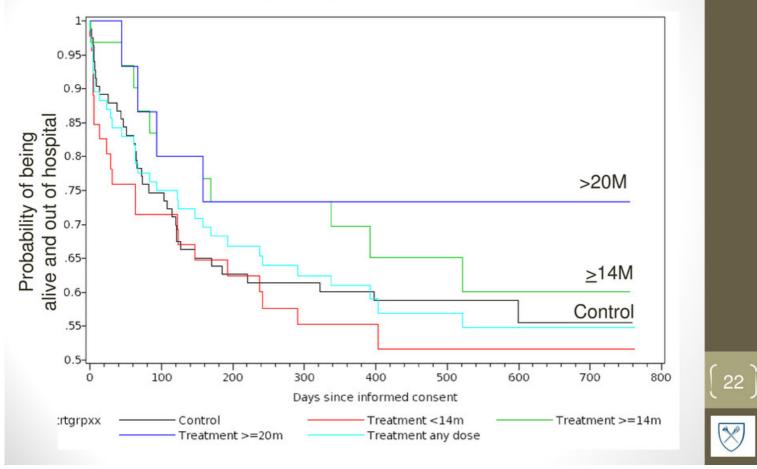
# BACK UP SLIDES

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# Time to First Hospitalization (mITT)

**MEDIAN FOLLOW-UP: 12 MONTHS** 





David J. Mazzo, PhD Chief Executive Officer March 2015

## Forward-looking statements

This pres ins "forward-looking" statements within the meaning of the Private S 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 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. We remind readers that forward-looking statements are merely predictions and therefore inherently subject to uncertainties and other factors and involve known and unknown risks that could cause the actual results, performance, levels of activity or our achievements or industry results, to be materially different from any future results, performance levels of activity or our achievements or industry results expressed or implied by such forward-looking statements. Such forward looking statements appear in this presentation. Factors that could cause our actual results to differ materially from anticipated results expressed or implied by forward-looking statements include, among others.

- · 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 product candidates in our development programs for our Targeted Cancer Immunotherapy Program, our Ischemic Repair Program and our Immune Modulation Program, and the commercialization of the relevant technology; • our ability to build and maintain the management and human resources infrastructure necessary to
- support the growth of our business.
- · our ability to integrate our acquired businesses successfully and grow such acquired businesses as anticipated, including expanding our PCT business internationally; • whether a large global market is established for our cellular-based products and services and our
- ability to capture a meaningful share of this market; scientific and medical developments beyond our control;
- our ability to obtain and maintain, as applicable, appropriate governmental licenses, accreditations
  or certifications or comply with healthcare laws and regulations or any other adverse effect or

tions caused by government regulation of our business;

· 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; our ability to commercialize products without infringing the claims of third party patents;
- whether any potential strategic or financial benefits of various licensing agreements will be realized;
- the results of our development activities, especially:
   the results of our planned Intus Phase 3 clinical trial of NBS20 being developed to treat metastatic melanoma
- . the results of our PreSERVE Phase 2 clinical trial of NBS10 being developed to treat acute myocardial infarction for which we released initial data on November 17, 2014 and for which all 6 and 12 month data has been collected; however it is subject to ongoing analysis, and currently reported results, although promising, are preliminary and there can be no assurance that further analysis may not reveal negative, or less promising, results;
- · our ability to complete our other planned clinical trials (or initiate other trials) in accordance with our estimated timelines 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
- the other factors discussed in "Risk Factors" in our Form 10-K filed with the Securities and Exchange Commission ("the SEC") on March 2, 2015, and elsewhere in the Annual Report on Form 10-K.

The factors discussed herein, including those risks described in Item 1A. "Risk Factors" in the Company's Annual Report on Form 10-K filed with the SEC on March 2, 2015 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 under "Search for Company Filings" could cause actual results and developments to be materially different from those expressed or implied by such statements. 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.

## **NeoStem financial metrics**

MARKET METRICS		FINANCIAL METRICS	
MARKET CAPITALIZATION <sup>1</sup>	\$150.0 M	<b>REVENUE<sup>3</sup></b>	\$17.9M (FY 2014)
STOCK PRICE <sup>2</sup>	\$3.90	CASH <sup>4</sup>	\$26.3M
52 WEEK RANGE <sup>2</sup>	\$3.08 - \$7.75	COMMON SHARES	38.3 M
<b>FLOAT<sup>1</sup></b>	33.7M	OUTSTANDING <sup>1</sup> WARRANTS <sup>1</sup> 3.5 M	2 E M
INSIDER HOLDINGS <sup>1</sup>	12.1%	WARRAN15*	3.5 M (avg. warrant exercise price of \$14.12)
		OPTIONS <sup>1</sup>	6.4 M (avg. option exercise price of \$7.44)

1. As of March 12, 2015 (based on shares outstanding on March 12, 2015)

As of March 12, 2015
 For the year ended December 31, 2014

4. As of December 31, 2014 (includes cash, cash equivalents and marketable securities)

## Transforming cells into therapies



### NeoStem's PCT: Industry-recognized single source premier services

### Center of excellence for process development, engineering and manufacturing



**PRODUCT &** 

PROCESS

DEVELOPMENT



MANUFACTURING



**ENGINEERING &** 

AUTOMATION





LOGISTICS STORAGE & DISTRIBUTION

EXPERT CONSULTATION & REGULATORY SUPPORT

NeoStem !

## At a glance

Highly experienced management and scientific team

Proprietary platform technologies yielding a diversified, balanced pipeline targeting critical unmet needs in large global markets and near-term development milestones

Immunotherapy platform applicable across multiple solid tumors with Fast Track and Orphan Drug Designations and a SPA for a phase 3 study in metastatic melanoma

Cell therapy platform applicable in multiple cardiovascular indications with ongoing Phase 2 study for acute myocardial infarction – compelling and consistent interim results

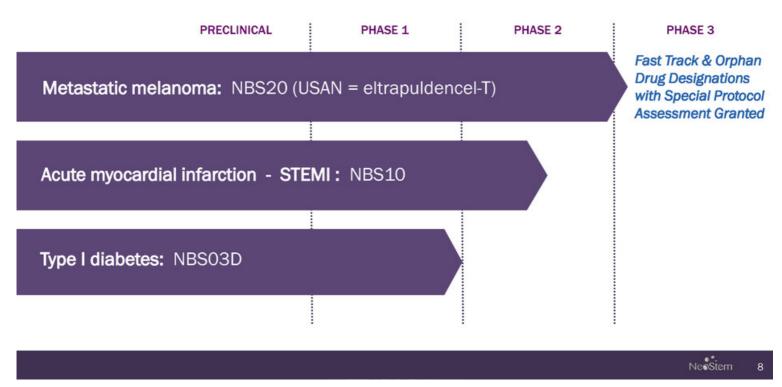
Immunomodulation therapy platform targeting autoimmune disorders with FDA cleared phase 2 study in adolescents with type I diabetes

Internal center of excellence (PCT) with bicoastal facilities and proven capabilities innovating discovery, development, manufacturing and delivery of cell-based therapies

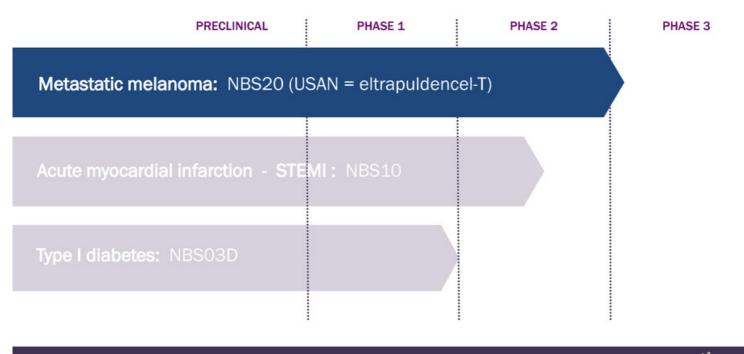
## Experienced executive team

David J. Mazzo, PhD Chief Executive Officer	Over 30 years experience in all aspects of large and emerging global biotech/biopharma company operations and successful international drug development
Robert S. Vaters, MBA President and Chief Financial Officer	Over 25 years financial and management experience in a variety of healthcare, biotechnology, biologics, medical device and pharmaceutical companies
Douglas W. Losordo, MD Chief Medical Officer	A leader in cell therapy research and development and renowned cardiologist with noteworthy academic and industry credentials
Robert A. Preti, PhD President of NeoStem's PCT	A leading authority on cell-based therapy engineering with unique development and commercialization experience
Robin L. Smith, MD, MBA Executive Chairman	Extensive background in healthcare, business development and management; led NeoStem 2006-2014

## Robust, diversified and balanced pipeline



## Robust, diversified and balanced pipeline





### NBS20: (USAN = eltrapuldencel-T) Metastatic melanoma

Fast Track designation Orphan Drug designation Special Protocol Assessment



## Stage III recurrent/stage IV metastatic melanoma

#### PREVALENCE AND UNMET MEDICAL NEED

~20,000 estimated new cases per year in U.S.1

- ~10,000 deaths per year in U.S.1
- ~15% five-year survival rate<sup>2</sup>
- ~\$1 billion U.S. market size<sup>3</sup>

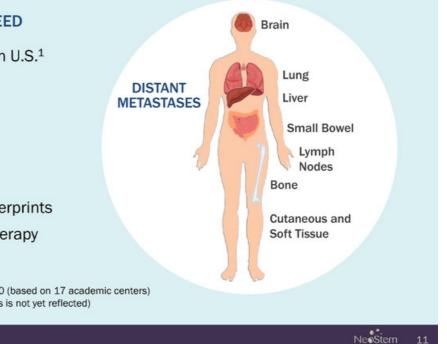
Numerous non-synonymous mutations

- · Unique patient-specific antigenic fingerprints
- Ideal target for autologous immunotherapy

2. For Stage IV metastatic melanoma - AJCC Cancer Staging 2010 (based on 17 academic centers)

(Five year data for recently approved melanoma immunotherapies is not yet reflected)

3. GBI Research - 2013



<sup>1.</sup> American Cancer Society, 2014 SEER

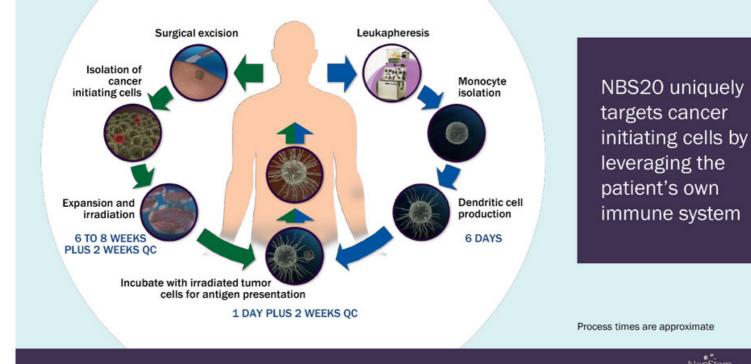
## Current metastatic melanoma therapies insufficient

CURRENTLY APPROVED THERAPIES	2 Year Survival	
DTIC (GENERIC) JC0 1999, JC0 2000	9-20%	4%
INTERLEUKIN-2 (PROMETHEUS LABS) JCO 2002	25%	15%
IPILIMUMAB (BMS) NEJM 2010	24%	20%
ANTI-PD1 <sup>1</sup> (BMS AND MERCK) Clin Oncol 2014	40-50%	N/A
VEMURAFENIB (ROCHE) Engl J Med 2012	Est. 20%	N/A
THERAPEUTIC CANDIDATES		
T-VEC (AMGEN - P3) Clin Oncol 2013	40%	N/A
TUMOR INFILTRATING LYMPHOCYTES (LION - P2) Clin Cancer Res 2011	40%	29%

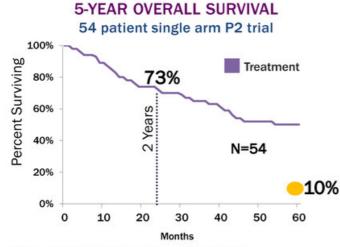
1. Includes both nivolumab and pembrolizumab

2. Survival rates for patients with Stage IV (distant metastatic disease), calculated from time of treatment

## Preparation of NBS20 - stimulating immune response



## Phase 2: multiple trials; consistent, compelling data



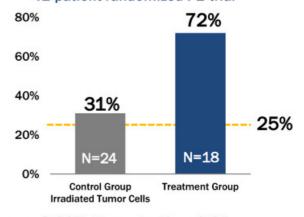
50% observed 5-year survival rate

Treatment considered safe and generally well tolerated — Minor local injection site reactions

Dillman, et al. Cancer Biother Radiopharm 2009

Historical control for distant metastases: Balch J Clin Oncol 2009

2-YEAR OVERALL SURVIVAL 42 patient randomized P2 trial



#### p = 0.007; Hazard ratio = 0.27

Treatment considered safe and generally well tolerated — Minor local injection site reactions Dillman, et al. *Journal Immunotherapy* 2012

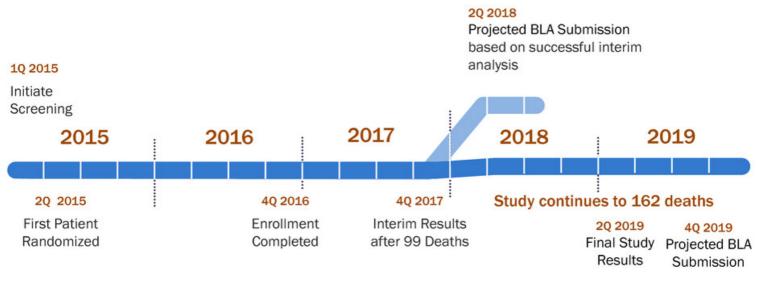
--- Historical control for distant metastases

# The Intus study: phase 3 with SPA and orphan drug and fast track designations



DESIGN	Single randomized, double blind, placebo controlled trial for stage III recurrent or stage IV metastatic melanoma for registration
PRIMARY ENDPOINT	Overall survival
POWERING	80% power to detect 37.5% reduction in risk of death
RELATION TO STANDARD THERAPIES	Adjunctive (clinical practice based trial)
STUDY SIZE	Planned 250 eligible patients across approximately 50 sites (US, Canada, Australia, New Zealand)
TREATMENT	Autologous dendritic cells loaded with antigen from proliferating autologous tumor cells + GM-CSF
CONTROL	Peripheral blood mononuclear cells obtained from pheresis product + GM-CSF

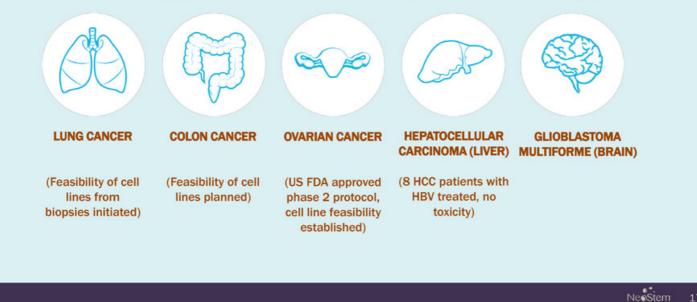
## Timeline to BLA



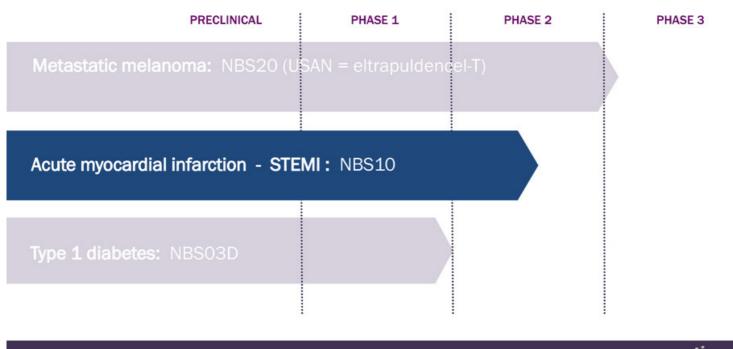
Total trial cost to earliest projected BLA: ~\$45 million

## Multi-billion dollar lifecycle opportunity

### Potential application across multiple solid tumor types



## Robust, diversified and balanced pipeline





# NBS10: ST segment elevation myocardial infarction (STEMI)

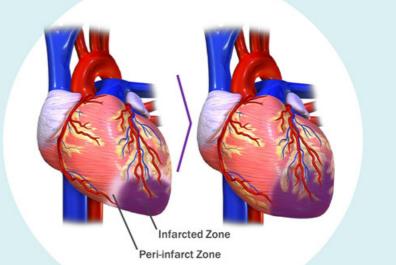


## Acute myocardial infarction (STEMI)

#### PREVALENCE AND UNMET MEDICAL NEED

STEMI patients are at high risk of progressive deterioration in heart muscle function leading to Major Adverse Cardiac Events (MACE)

~65,000 STEMI patients/year in U.S. (successfully stented) later experience heart failure<sup>1</sup>

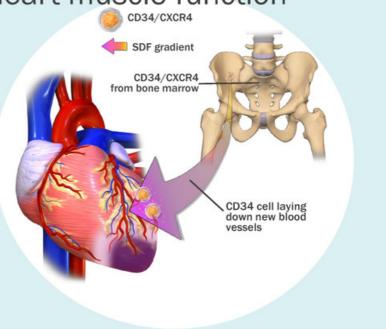


1. Pedersen, Journal of the American College of Cardiology, 2014 and NeoStem modeling

# NBS10 – Leveraging the body's natural repair mechanism to preserve heart muscle function

CD34+ cells have been shown to induce the development of new blood vessels, preventing tissue death by improving blood flow

NBS10 = CD34+ cells extracted from the patient's bone marrow, treated to maximize potency and then delivered directly to the infarct site via a routine catheter lab procedure



## PreSERVE study: enrolled phase 2 study in follow-up

DESIGN	Randomized (1:1), Phase 2, double blind, placebo controlled trial for post-AMI (STEMI) patients
PRIMARY ENDPOINTS AND KEY SECONDARY ENDPOINT	Change in cardiac perfusion from baseline to 6 months (exploratory) Incidence rates of SAEs and MACE (regulatory – AMI) LVEF change from baseline to 6 months (regulatory – heart failure)
KEY INCLUSION CRITERIA	Confirmation of ST Elevation MI; ejection fraction $\leq$ 48% at day 4 by CMR; state-of-the-art care post stenting
STUDY SIZE	161 patients, 60 centers in United States
TREATMENT	Single dose via infarct related artery with minimum dose for release $\geq$ 10M (million) ±20% CD34+ cells. Actual dose determined by intrinsic number of cells in marrow and processing success rate
CONTROL	Matching infusion with placebo
	Nessiem

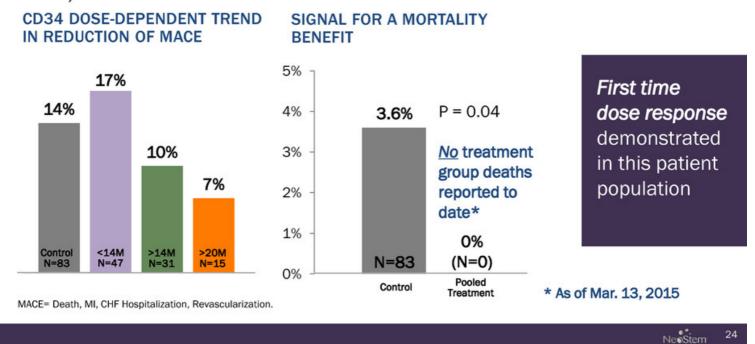
## PreSERVE 6 & 12-month interim conclusions\*

	<ul> <li>Signal for a mortality benefit (12 month data)</li> </ul>
-	Signal for reduction in frequency of SAEs in higher dose groups (12 month data)
•	CD34 cell dose-dependent trend in improvement of left ventricular ejection fraction and reduction in infarct size
-	No correlation between experimental endpoint of perfusion and treatment

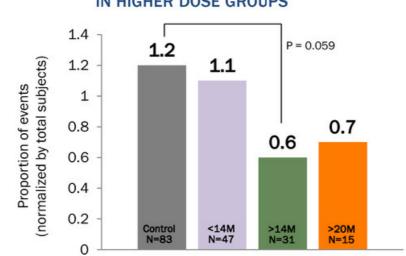
Results inform regarding important design parameters for next development steps

\*Based on data collected at 6 months except where noted

## PreSERVE: MACE incidence (median follow-up 12 mos)



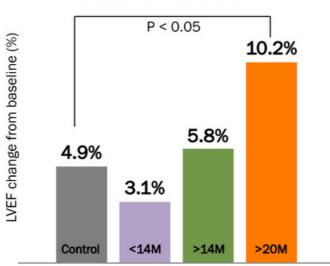
## PreSERVE: SAE incidence (median follow-up 18 mos)



#### SIGNAL FOR REDUCTION IN FREQUENCY OF SAES IN HIGHER DOSE GROUPS

*First time dose response* demonstrated in this patient population

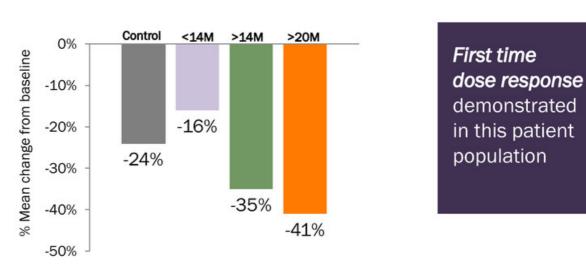
## PreSERVE: LVEF change from baseline at 6 mos.



#### CD34 CELL DOSE-DEPENDENT TREND IN IMPROVEMENT OF LVEF

*First time dose response* demonstrated in this patient population

## PreSERVE: Infarct size change (baseline to 6 mos.)



#### CD34 CELL DOSE-DEPENDENT TREND IN REDUCTION OF INFARCT SIZE

## Next steps for ischemic repair program

#### STEMI NEXT DEVELOPMENT STEPS

- March 2015: One-year data
- 2H 2015: Determine next development steps based on PreSERVE interim results and consultation with medical advisors (potentially Phase 2B/3 trial)
- · March 2016: Two-year data
- March 2017: Three-year data, end of study

#### NEXT POTENTIAL DEVELOPMENT STEPS IN OTHER INDICATIONS

- Phase 2 in chronic heart failure
- · Phase 2 in critical limb ischemia

## Multi-billion dollar lifecycle opportunity

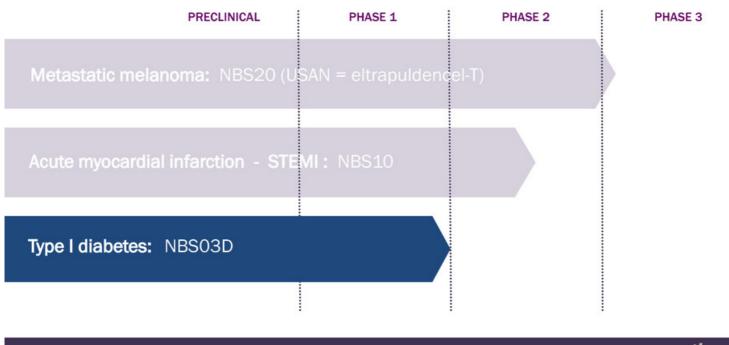
Potential application across several cardiovascular indications





CHRONIC HEART FAILURE CRITICAL LIMB ISCHEMIA

## Robust, diversified and balanced pipeline





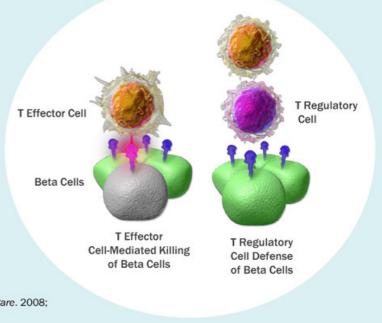
### NBS03D: Diabetes Mellitus Type-1 (T1D)



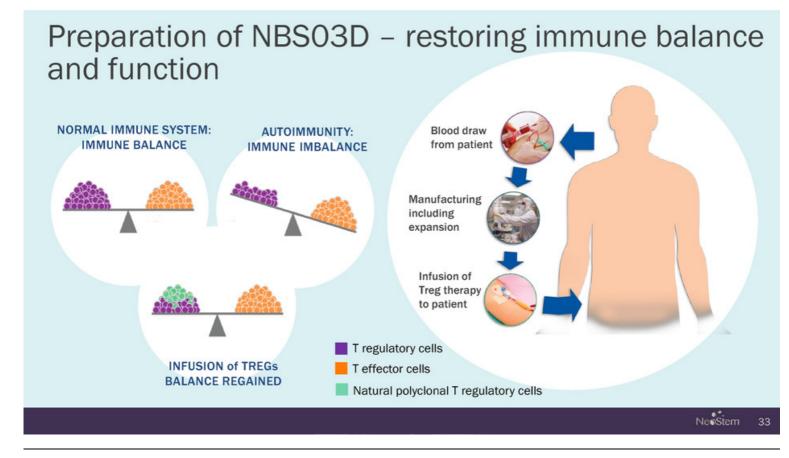
# Diabetes Mellitus Type-1 (T1D): an autoimmune disease

#### PREVALENCE AND UNMET MEDICAL NEED

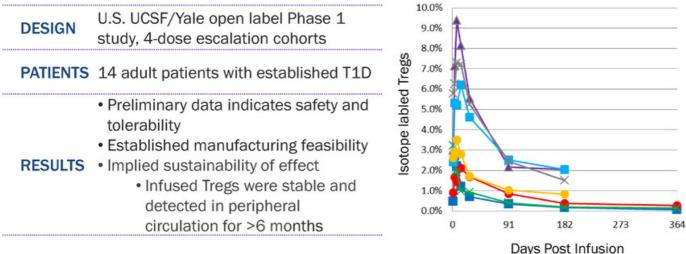
- 18,000 children under 20 in U.S. with new onset T1D per year  $^{1}$
- 3% annual growth rate worldwide<sup>2</sup>
- No curative treatments for T1D, only lifelong insulin therapy
- Diabetes is leading cause of kidney failure, new cases of adult blindness and nontraumatic lower-limb amputations



- 1. Hamman RF, et al. Diabetes Care. 2014; Sosenko JM, et al. Diabetes Care. 2008;
- Palmer JP. Diabetes/metabolism research and reviews. 2009
- 2. The DIAMOND Project Group. Diabetic Medicine. 2006;23:857-866.



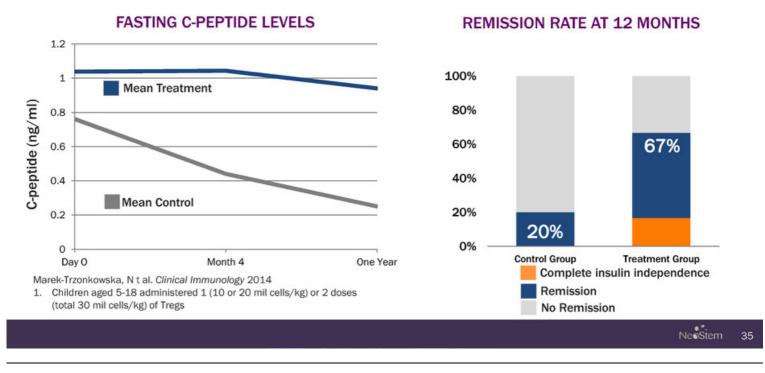
## Regulatory T Cell therapy appears to be safe and well tolerated in adults<sup>1</sup>



Each Line Corresponds to an Individual Subject

1. Gitelman et al, American Diabetes Association Abstract, 2014

# Regulatory T Cell therapy preserves beta cell function in children<sup>1</sup>

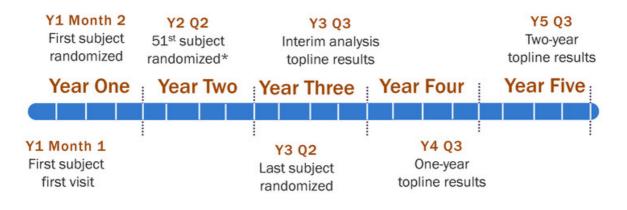


## The Trutina study: phase 2 in adolescents with $T1D^1$

DESIGN	Double blind, placebo controlled, randomized (1:1:1) for adolescent patients with recent onset T1D ages 12 to 18
	Preservation of C-peptide at 52 weeks in comparison to placebo
POWERING	80% power to detect 50% attenuation of the decline in mixed meal tolerance test stimulated c-peptide in comparison to placebo, adjusted for baseline
STUDY SIZE	111 subjects to be enrolled across ~11 US sites
TREATMENT	2 dose groups of NBS03D (single dose autologous ex-vivo expanded polyclonal T Regulatory cell therapy): 10 and 20 million cells/kg
CONTROL	Matching infusion

1. Study cleared by FDA to proceed based on efficacy data in children establishing prospect of direct benefit

## Trutina study timeline

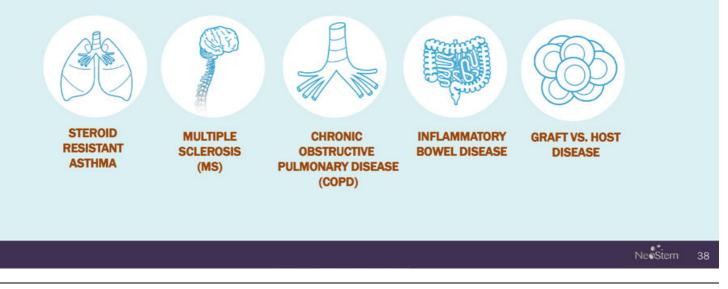


Expected cost of trial: ~\$22.5 million

\*One-year visit of 51st subject triggers interim analysis

## Multi-billion dollar lifecycle opportunity

### Potential application across multiple autoimmune and allergic diseases



### Investment summary

Highly experienced management and scientific team

 Proprietary platform technologies yielding a diversified, balanced pipeline targeting critical unmet needs in large global markets and near-term development milestones

Immunotherapy platform applicable across multiple solid tumors with Fast Track and Orphan Drug designations and a SPA for a phase 3 study in metastatic melanoma

Cell therapy platform applicable in multiple cardiovascular indications with ongoing Phase
 2 study for acute myocardial infarction – compelling and consistent interim results

✓ Immunomodulation therapy platform targeting autoimmune disorders with FDA cleared phase 2 study in adolescents with type I diabetes

✓ Internal center of excellence (PCT) with bicoastal facilities and proven capabilities innovating discovery, development, manufacturing and delivery of cell-based therapies



**Corporate Presentation** 

### Transforming **Personalized Medicine**

#### **Contact:**

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