# NeoStem to acquire Amorcyte



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NeoStem, Inc. (NYSE Amex: NBS) ("NeoStem" or the "Company"), an international biopharmaceutical company, announced the signing of a definitive merger agreement whereby NeoStem will acquire Amorcyte, Inc. ("Amorcyte"), a development stage cell therapy company focusing on novel treatments for cardiovascular disease. Amorcyte's lead product candidate, AMR-001, is ready to initiate a Phase II study for the treatment of acute myocardial infarction (AMI).

Of the approximately 800,000 Americans who suffer an AMI each year, twenty percent or 160,000 patients remain at risk to subsequently experience progressive deterioration in heart muscle function and as a consequence, an increase in major adverse cardiac events (MACE). AMR-001 targets treatment of this unmet medical need. Based on a comprehensive pre-clinical program which identified a mechanism of action with a highly purified homogeneous cell population, a Phase I study was completed. Results of the clinical study identified a therapeutic dose (biological threshold dose) that was associated with a significant improvement in perfusion>

AMR-001 is an autologous, bone marrow derived, pharmaceutical grade cell-based product that uses a cell population enriched for CD34+CXCR4+ cells. Studies have shown that these cells act as a natural repair mechanism, releasing from bone marrow and traveling to the damaged region of the heart following an AMI. Treatment with AMR-001 involves infusion of an active population of these cells directly into a patient’s heart via an intra-coronary catheter six to eleven days after an AMI (i.e., after the “hot (inflammatory) phase”) and as such complements the body’s natural rescue mechanism for those cells that face hypoxic stress (i.e., oxygen deprivation) as a result of an increased workload.

Unlike competitor cell therapy products being tested for cardiac repair post-AMI, NeoStem believes AMR-001 stands alone in its ability to claim all of the following attributes:

- a confirmed mechanism of action
- a cGMP (current good manufacturing practices) facility
- an established dose that exceeds the threshold of biological activity
- use of autologous cells that have no risk of rejection and are capable of integrating and providing local support, potentially for a prolonged period of time as demonstrated in pre-clinical animal experiments
- cells that are not expanded, thereby eliminating the potential concerns associated with such expansion
- composition of matter, methods and processes patents with long remaining life

To the Company's knowledge, this is the first stem cell trial in AMI ever conducted that prospectively established a significant relationship between dose and effect. NeoStem intends to enter the clinic for the start of the Phase II trial for AMR-001 no later than the

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first quarter of 2012 and to commence a Phase I study in congestive heart failure in 2012. The enrollment of this Phase II trial is estimated to complete within 12 months from start with data read-out 6 months after the last patient is treated.

The definitive merger agreement provides for the issuance of an aggregate of 6,821,283 shares of NeoStem common stock and warrants to purchase an aggregate of 1,881,008 shares of NeoStem common stock. An additional 4,092,768 shares of NeoStem stock will vest upon achievement of specified AMR-001 milestones. Amorcyte shareholders will receive additional consideration in the form of an earn out upon commercialization.


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- Live-cell microscopy reveals internal forces that direct cell migration


Holders of greater than 50% of Amorcyte's shares have agreed to vote in favor of the merger. The closing of the merger is subject to various conditions, including the approval by NeoStem and Amorcyte stockholders of the issuance of NeoStem's securities in the merger.

Dr. Robin L. Smith, CEO of NeoStem said, "We are excited to have reached this agreement with Amorcyte and to be in position to acquire this asset which is on the verge of commencing Phase II trials and which has a strong IP position that includes key issued patents for both composition of matter and method of use. We anticipate a seamless integration with our operations as PCT, our wholly-owned subsidiary, manufactured the cells for the AMR-001 Phase I clinical trial and has already been selected to manufacture AMR-001 for the Phase II trial."

"We are excited about the Phase 1 trial results and look forward to moving Amorcyte's lead product AMR-001 forward and toward commercialization through NeoStem," said Dr. Andrew Pecora, Chief Medical Officer of PCT and Chief Scientific Officer of Amorcyte. "Through NeoStem's preclinical VSEL platform, the Phase I-ready autoimmune disease product candidates of its Athelos subsidiary, and now through AMR-001, NeoStem seeks to fulfill the promise that an individual's own cells hold the potential to both heal and transform the way medicine is delivered."

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**Source:**
NeoStem, Inc.

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