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Amarantus Announces Preclinical Development Timeline for MANF Therapeutic

SUNNYVALE, Calif.-- Amarantus BioScience Holdings, Inc. (OTCQB: AMBS), a biotechnology company discovering and developing treatments and diagnostics for diseases associated with neurodegeneration and apoptosis, today provided a timeline of key activities and milestones related to the preclinical development of MANF (Mesencephalic-Astrocyte-derived Neurotrophic Factor). The Company is currently focused on developing MANF across three broad categories: Parkinson's disease and Traumatic Brain Injury; large systemic applications such as Ischemic Heart Disease and Diabetes; and orphan indications.

“We plan to move forward on a number of fronts this year with MANF, leading potentially to one or more Investigational New Drug (IND) filings in 2014,” said Gerald E. Commissiong, President and Chief Executive Officer of Amarantus. “The pace and scope of activities outlined today reflect the unique properties of MANF, the positive results reported earlier this year in neuroprotective and neurorestorative animal models of Parkinson’s disease and supportive data from the published literature.”

The upcoming activities related to Amarantus’ Parkinson’s disease program include:

- Create mammalian GMP production processes for MANF; the Company has sourced the expertise for these activities, and has started development of the supporting analytical and bioanalytical assays;
- Form a partnership agreement in the third quarter of 2013 with a firm specializing in Convection-enhanced delivery (CED) of drugs to the brain;
- Initiate non-human primate pharmacology studies in Parkinson's disease models in the second half of 2013 in order to establish an appropriate dosing regimen for human clinical studies;
- Potentially evaluate MANF gene therapy based upon upcoming developments in the field of neurotrophic factors for Parkinson’s disease, and the Company’s current patent position whereby the Company owns exclusive rights to MANF gene therapy applications in all vector systems.

Additional planned activities are expected to include:

- Conduct pharmacokinetic and pharmacodynamic (PK/PD) studies, with data available in the third quarter of 2013, to evaluate the biological properties of MANF when administered systemically, with data to be released as it becomes available;
- Conduct pharmacology studies in traumatic brain injury, ischemic heart disease, diabetes and certain other animal models in the third quarter of 2013, with data to be released as it becomes available;

- Evaluate MANF in a variety of animal models of orphan diseases in the third quarter of 2013 that represent significant market opportunities, and where there is limited or very limited competition;
- Initiate MANF toxicology studies upon development of a master cell bank of MANF protein material as one of the final pre-IND steps;
- File an IND in 2014.

“Based on our progress with these preclinical activities and the interest and level of data in specific indications, we will seek to partner with biopharmaceutical companies or appropriate not-for-profit disease foundations in order to accelerate our development program and assist in recruiting patients for future clinical studies,” said Mr. Commissiong. “We will prioritize our clinical development programs based upon the outcome of the pharmacology studies that will begin in the third quarter of 2013 for the indications outlined here today. We intend to give highest priority to those indications where we have a shorter path to market, and where non-dilutive financing is available to support further development. Fortunately for the Company, it is likely that many of the pre-clinical studies will have applications across indications, meaning we will get the advantage of a particular set of data enabling multiple indications.”

The Company will seek to gain ‘Breakthrough,’ ‘Fast Track’ and/or ‘Orphan Drug Designation’ status with the FDA where the Company believes the data generated justifies such a designation, potentially significantly reducing the time to market for MANF and/or improving the potential economic outcome for the Company.

The Company believes MANF could address the following very significant market opportunities:

- Parkinson’s disease: $1 billion
- Traumatic Brain Injury: $200 million
- Ischemic Heart Disease: $2 billion
- Diabetes: $2 billion
- Orphan diseases: $2 billion

Large pharmaceutical companies have shown significant interest in neurotrophic factors for Parkinson's disease for over two decades. In 1993, Amgen acquired Synergen for $262 million shortly after Synergen successfully completed studies using GDNF as a protein therapeutic in animal models of Parkinson's disease. In 2007, Genzyme entered into a $150 million partnership with Ceregene to gain access to ex-U.S. marketing rights to Neurturin after Ceregene successfully completed a Phase 1 clinical study demonstrating safety for Neurturin as a gene therapy product. Ceregene is expected to announce data on a recently completed Phase 2 study this quarter.

The acute ischemic heart disease market represents an $8 billion market worldwide. The chronic ischemic heart disease market represents a $30 billion market. One of the key unmet medical needs in the ischemic heart disease market is limiting ischemia/reperfusion associated with myocardial infarction, the area where MANF has shown significant promise in the published literature.

Diabetes represents a $28 billion market worldwide. One of the key unmet needs in the diabetes market is improving beta cell function, an area where MANF is believed to hold

promise.

A prime example of a successful orphan strategy is Genzyme, who was successful in turning its orphan drug strategy into a $20.1 billion buyout by Sanofi Aventis in 2011. Another example of a successful orphan strategy is FerroKin Biosciences, which was successfully acquired by Shire for $325 million in early 2012 with only $27 million in paid-in-capital and a virtual staff of seven employees. In 2011, Alexion Pharmaceuticals reported $783 million in revenue based on sales of its only product Soliris, a drug that treats a population of approximately 10,000 patients in the U.S. and Western Europe.

About Mesencephalic-Astrocyte-derived Neurotrophic Factor (MANF)

MANF (Mesencephalic-Astrocyte-derived Neurotrophic Factor) is a protein that corrects protein misfolding, one of the major causes of apoptosis (Programmed Cell Death). Mesencephalic-Astrocyte-derived Neurotrophic Factor (MANF) is believed to have broad potential because it is a naturally-occurring protein produced by the body for the purpose of reducing and preventing apoptosis (in response to injury or disease), via the unfolded protein response. By manufacturing MANF and administering it to the body, Amarantus is seeking to use a regenerative medicine approach to assist the body with higher quantities of MANF when needed. Amarantus is the front-runner and primary holder of intellectual property (IP) around MANF, and is initially focusing on the development of MANF-based protein therapeutics. MANF's current lead indication is Parkinson's disease with additional focus on Traumatic Brain Injury (TBI). Future indications may include myocardial infarction and certain rare and ultra-rare orphan diseases where MANF is currently being evaluated.

About Amarantus

Amarantus is a development-stage biotechnology company founded in January 2008. The Company is focused on developing unique products and proprietary technologies for the potential treatment and/or diagnosis of Parkinson's disease, Traumatic Brain Injury, Ischemic Heart Disease and other human diseases. The Company owns the intellectual property rights to Mesencephalic-Astrocyte-derived Neurotrophic Factor ("MANF") and is developing MANF-based products as treatments for neurological disorders where there is a significant unmet medical need. The Company also is a Founding Member of the Coalition for Concussion Treatment (#C4CT), a movement initiated in collaboration with Brewer Sports International seeking to raise awareness of new treatments in development for concussions and related nervous-system disorders. For further information please visit www.Amarantus.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about the possible progress of the MANF technology in testing for Parkinson’s disease, statements about expectations, plans and prospects of the development of Amarantus' diagnostic product candidates for Alzheimer’s and Parkinson’s disease, traumatic brain injury, ischemic heart disease, diabetes, and unspecified Orphan indications; and the potential market size for the LymPro test for Alzheimer’s disease. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including the risks associated with development of therapeutic drug candidates, as well as

the risks, uncertainties and assumptions relating to the development of Amarantus' new product candidates, including those identified under "Risk Factors" in Amarantus' most recently filed Annual Report on Form 10-K and Quarterly Report on Form 10-Q and in other filings Amarantus periodically makes with the SEC. Actual results may differ materially from those contemplated by these forward-looking statements Amarantus does not undertake to update any of these forward-looking statements to reflect a change in its views or events or circumstances that occur after the date of this presentation.

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Source: Amarantus BioScience Holdings, Inc.