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Amarantus
BioScience

Amarantus Reports Second Quarter 2015 Financial Results and Business Overview

SAN FRANCISCO and GENEVA, Aug. 17, 2015 (GLOBE NEWSWIRE) --[Amarantus BioScience Holdings, Inc.](#) (OTCQX:AMBS), a biotechnology company developing therapeutic and diagnostic product candidates in orphan indications and neurology, announced financial results for the second quarter ended June 30, 2015. The Company also highlighted recent corporate and clinical development achievements for its Therapeutics Division and its wholly-owned subsidiary, Amaranthus Diagnostics, Inc.

SECOND QUARTER 2015 AND RECENT HIGHLIGHTS

Corporate

- Commenced trading on the [OTCQX Marketplace](#) as part of the path to progress to a national stock exchange listing;
- Completed a [capital restructuring](#) in order to meet share price requirements in preparation for a national exchange listing

Amarantus Therapeutics

- *Engineered Skin Substitute (ESS): Autologous full thickness skin replacement product for severe burns*
 - Signed a Cooperative Research and Development Agreement (CRADA) with the U.S. Army Institute of Surgical Research and Rutgers, The State University of New Jersey to [expand the development of ESS for the treatment of deep partial- and full-thickness burn wounds in adult patients](#) (ClinicalTrials.gov Identifier: NCT01655407);
 - Completed the acquisition of Cutanogen Corporation from Lonza Walkersville, Inc. (Lonza), a subsidiary of Lonza Group Ltd., thereby securing [full ownership and exclusive worldwide license to intellectual property rights associated with ESS](#); and
 - Engaged Lonza via a long-term services [agreement to manufacture ESS under Good Manufacturing Practices for human clinical trials](#), and subsequent commercial distribution.
- *Eltoprazine: Parkinson's disease levodopa-induced dyskinesia (PD-LID), adult ADHD, and Alzheimer's aggression*
 - [Commenced enrollment](#) and [initiated dosing](#) in the Phase 2b multi-center, 60-subject, double-blind, placebo-controlled, four-way crossover, dose range finding clinical study for the treatment of PD-LID (ClinicalTrials.gov Identifier: NCT02439125);
 - Announced the publication of [data on long-term efficacy and elucidating the](#)

- [mechanism of action of eltoprazine](#) in an animal model of PD-LID;
 - Announced the [issuance of the U.S. patent covering proprietary methods of administration](#) for eltoprazine for the treatment of Parkinson's disease;
 - Presented [data from the Phase 1/2a clinical study](#) of eltoprazine in PD-LID at the 19th International Congress of Parkinson's Disease and Movement Disorders; and
 - Completed Phase 2b [clinical investigator meetings in both the United States and European Union](#).
- *MANF: Mesencephalic-astrocyte-derived neurotrophic factor*
 - Announced the successful delivery and distribution of [MANF in a preclinical model to brain areas involved in Parkinson's disease](#), further solidifying the rationale for its development as a potential disease-modifying treatment for PD;
 - Entered into a [cGMP manufacturing agreement with Catalent Biologics for clinical-grade production of MANF](#) to enable program advancement into human clinical studies in retinitis pigmentosa (RP), retinal artery occlusion and Parkinson's disease;
 - Presented positive preclinical data showing [MANF preserves the light-sensing function of photoreceptor cells](#) at the leading ophthalmology conference ARVO 2015;
 - Received a Notice of Allowance for the U.S. patent application covering compositions of matter and methods of use related to [proprietary manufacturing processes for synthetic MANF and its administration](#) for protein therapy and cell therapy; and
 - Received [European Union Orphan Drug Designation \(ODD\) for MANF](#) for the treatment of RP, complementing the U.S. ODD obtained in December 2014.

"The completion of the acquisition of Cutanogen from Lonza this quarter is a significant milestone for Amaranthus Therapeutics. ESS is a potentially revolutionary solution for the treatment of severe burns that has demonstrated initial human proof-of-concept in an investigator-initiated setting," commented Joseph Rubinfeld, Ph.D., member of the Amaranthus Board Directors. "Our collaboration with the U.S. Army is an important part of the expansion plan for the clinical development program of ESS. We expect to focus on the regulatory strategy for ESS in the weeks ahead."

Amarantus Diagnostics, Inc. (a wholly owned subsidiary of Amaranthus BioScience Holdings, Inc.)

- Established a [Strategic Advisory Committee for Amaranthus Diagnostics](#) comprising three seasoned, results-driven life science and healthcare industry leaders with expertise in commercializing molecular diagnostics to focus on advancing and deriving the full value of the company's diagnostics business.
- *LymPro Test[®] for the diagnosis of Alzheimer's disease (AD)*
 - Presented [data demonstrating that LymPro met primary and secondary endpoints in the blinded, multi-center LP-002 clinical study](#) that confirms LymPro's Fit-For-Purpose use in AD Clinical Trials at the 2015 Alzheimer's Association International Conference[®]; and
 - Advanced business development activities with the pharmaceutical industry for

Investigational Use Only (IUO) [LymPro Test](#) biomarker services.

- *MSPrecise*[®] for the diagnosis of multiple sclerosis (MS)
 - Published data in the Journal *GENE* from a clinical study demonstrating that [MSPrecise supports identification of multiple sclerosis patients with 84% accuracy and performs well in identifying MS among a broad cohort of potential neurological diseases](#); and
 - Reported preliminary data from a blood-based version of MSPrecise showing it has [statistically significant sensitivity and specificity for classifying presentation of MS](#).
- *Georgetown Assays for the diagnosis of AD*
 - Continued to explore the potential of the emerging AD IUO blood diagnostics market through the one-year, exclusive option agreement with Georgetown University to license patent rights for [blood based biomarkers for AD and memory loss](#).

"The addition of ESS to our product portfolio adds a first-in-class regenerative medicine platform to our pipeline. The advancement of Eltoprazine into Phase 2b clinical development represents a significant achievement as we establish clinical and regulatory excellence at Amaranthus Therapeutics," added David A. Lowe, Ph.D., member of the Amaranthus Board of Directors. "As we round out 2015 we expect to see additional momentum in our strategy for Amaranthus Diagnostics under the guidance of our newly appointed Strategic Advisory Committee tasked with realizing the full value from our neuro-diagnostics business."

EXPECTED NEAR-TERM MILESTONES

- Obtain an up-listing to a national stock exchange to position the Company for an appreciation in value and enabling the expansion of its current shareholder base;
- Initiate the U.S. military study under the ESS CRADA at the first surgical facility site;
- Enroll the first patient in the Phase 2 study of ESS for the treatment of severe burns;
- Accelerate the path to commercialization for ESS by establishing a dialogue with regulatory authorities before the end of 2015;
- Announce top-line results from the ESS Phase 2 severe burn study in 2016;
- Expand the eltoprazine Phase 2b program in PD-LID in Europe in 3Q 2015;
- Complete patient enrollment for the ongoing Phase 2b study in 1Q 2016;
- Report topline results from the Phase 2b clinical study of eltoprazine in PD-LID in 1H 2016;
- Submit an IND application for MANF for the treatment of retinitis pigmentosa;
- Continue to advance pre-clinical studies for MANF in other orphan ophthalmological indications and Parkinson's disease;
- Advance MSPrecise and the LymPro Test into CLIA validation studies in parallel later this year in preparation for launch under CLIA designation to market to the broader medical community in the United States; and
- Execute one of the strategic options for the Amaranthus Diagnostics, including a potential sale, co-development or spin-off opportunities, to derive the significant value from the Company's premier neuro-diagnostics business.

"The company has evolved significantly over the course of the past year with the expansion

and advancement of our therapeutics pipeline and the continued traction towards commercialization with Amaranthus Diagnostics. This progress has been integral in enabling us to build a strong foundation for the company to advance to our next stage of growth," added Gerald E. Commissiong, President & CEO of Amaranthus Bioscience Holdings. "We have taken several important steps to prepare the company for an uplisting on a national exchange. We continue working in earnest to achieve that goal as quickly as possible as it remains the priority and focus of our team, and we intend to continue to engage the NASDAQ Capital Market to complete this important objective."

SECOND QUARTER 2015 FINANCIAL SUMMARY

Research and development costs for the three months ended June 30, 2015 increased \$617,000 to \$2,257,000 from \$1,640,000 for the three months ended June 30, 2014, primarily due to increase in clinical related costs and research arrangements.

General and administrative expenses increased \$1,238,000 to \$3,339,000 for the three months ended June 30, 2015 from \$2,101,000 for the three months ended June 30, 2014, primarily due to increased spending on Lonza Option payments, acquisition costs and other professional services, including consulting costs.

For the three months ended June 30, 2015, other income (expense) decreased \$158,000 to an expense of \$126,000 from \$284,000 in three month period ended June 30, 2014. Interest expense increased from the prior year quarter \$55,000 and change in fair value of warrant and derivative liability decreased \$193,000.

Net loss for the three months ended June 30, 2015 was \$5,722,000 as compared to a net loss of \$4,025,000 for the three month period ended June 30, 2014 with the increase in loss driven by research and development expense, consulting, Lonza Option payments, professional services and acquisition costs.

For the six months ended June 30, 2015 research and development costs increased \$2,577,000 to \$4,734,000 from \$2,157,000 for the six months ended June 30, 2014, primarily due to increase in clinical related costs and research arrangements.

General and administrative expenses increased \$4,180,000 to \$7,400,000 for the six months ended June 30, 2015 from \$3,220,000 for the six months ended June 30, 2014 primarily due to increased spending on consulting, Lonza Option payments, acquisition costs and other professional services.

For the six months ended June 30, 2015, other income (expense) decreased \$4,022,000 to an expense of \$168,000 from \$4,190,000 in the six month period ended June 30, 2014. Interest expense and loss on issuance of warrants decreased \$541,000 and \$3,867,000, respectively. Change in fair value of warrant and derivative liability increased \$473,000 to \$0 for the six months ended June 30, 2015.

Net loss for the six months ended June 30, 2015 was \$12,302,000 as compared to a net loss of \$9,567,000 for the six month period ended June 30, 2014 with the increase in loss driven by research and development expense, consulting, Lonza Option payments, professional services and acquisition costs.

As of June 30, 2015, the Company had total current assets of \$784,000 consisting of \$315,000 in cash and cash equivalents and \$386,000 in prepaid expenses and other current assets, and \$83,000 in deferred funding fees.

Amarantus Bioscience Holdings, Inc

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(in thousands, except share and per share data)

	June 30,	December
	2015	31,
	<u>2015</u>	<u>2014</u>
	(Unaudited)	(Audited)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 315	\$ 214
Deferred financing fees	83	—
Prepaid expenses and other current assets	386	198
Total current assets	<u>784</u>	<u>412</u>
Restricted cash	204	204
Property and equipment, net	150	145
Intangible assets, net	10,245	1,497
Total assets	<u>\$ 11,383</u>	<u>\$ 2,258</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued expenses	\$ 4,729	\$ 3,502
Accounts payable - Regenicin	—	2,550
Related party liabilities and accrued interest	255	252
Accrued interest	139	25
Note Payable	2,850	—
Total current liabilities	<u>7,973</u>	<u>6,329</u>
Total liabilities	<u>7,973</u>	<u>6,329</u>
Stockholders' equity (deficit)		
Convertible preferred stock, \$0.001 par value, 10,000,000 shares authorized:		
Series A, \$0.001 par value, 250,000 shares designated, -0- shares issued and outstanding as of June 30, 2015 and December 31, 2014	—	—
Series B, \$0.001 par value, 3,000,000 shares designated, -0- shares issued and outstanding as of June 30, 2015 and December 31, 2014	—	—
Series C, \$0.001 par value, 750,000 shares designated, 750,000 shares issued and outstanding as of June 30, 2015 and December 31, 2014	1	1
Series D, \$1,000 stated value; 1,300 shares designated; 350 and 1,299 issued and outstanding as of June 30, 2015 and December 31, 2014, respectively; aggregate liquidation preference of \$350	315	1,169
Series E, \$1,000 stated value; 13,335 shares designated, 7,722 and 4,500 issued and outstanding as of June 30, 2015 and December 31, 2014 respectively; aggregate liquidation preference of \$7,722	6,950	4,050

Series G, \$5,000 stated value; 10,000 shares designated; 1,087 and 0 issued and outstanding as of June 30, 2015 and December 31, 2014, respectively; aggregate liquidation preference of \$5,435	4,950	—
Common stock, \$0.001 par value, 13,333,333 authorized; 7,084,970 and 5,614,605 shares issued and outstanding at June 30, 2015 and December 31, 2014, respectively	7	6
Additional paid-in capital	62,637	45,886
Accumulated deficit	(71,450)	(55,183)
Total stockholders' equity (deficit)	<u>3,410</u>	<u>(4,071)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 11,383</u>	<u>\$ 2,258</u>

Amarantus Bioscience Holdings, Inc

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(in thousands, except share and per share data)

	Three Months Ended June 30, 2015	Three Months Ended June 30, 2014	Six Months Ended June 30, 2015	Six Months Ended June 30, 2014
Net sales	\$ —	\$ —	\$ —	\$ —
Operating expense:				
Research and development	2,257	1,640	4,734	2,157
General and administrative	3,339	2,101	7,400	3,220
	<u>5,596</u>	<u>3,741</u>	<u>12,134</u>	<u>5,377</u>
Loss from operations	(5,596)	(3,741)	(12,134)	(5,377)
Other income (expense):				
Interest expense	(126)	(71)	(168)	(709)
Loss on issuance of common stock	—	—	—	(67)
Loss on issuance of warrants	—	—	—	(3,867)
Other expense	—	(20)	—	(20)
Change in fair value of warrant & derivative liabilities	—	(193)	—	473
Total other income (expense)	(126)	(284)	(168)	(4,190)
Net loss	<u>\$ (5,722)</u>	<u>\$ (4,025)</u>	<u>\$ (12,302)</u>	<u>\$ (9,567)</u>
Preferred stock dividend	\$ 3,187	\$ 26	\$ 4,016	\$ 52
Net loss attributable to common stockholders	\$ (8,909)	\$ (4,051)	\$ (16,318)	\$ (9,619)

Basic and diluted net loss per common share	<u>\$ (1.08)</u>	<u>\$ (0.83)</u>	<u>\$ (2.13)</u>	<u>\$ (2.11)</u>
Basic and diluted weighted average common shares outstanding	<u>8,230,225</u>	<u>4,893,491</u>	<u>7,652,163</u>	<u>4,551,050</u>

About Amaranthus BioScience Holdings, Inc.

Amarantus BioScience Holdings (OTCQX:AMBS) is a biotechnology company developing treatments and diagnostics for diseases in the areas of neurology and orphan diseases. AMBS' Therapeutics division has development rights to eltoprazine, a small molecule currently in a Phase 2b clinical program for Parkinson's disease levodopa-induced dyskinesia with the potential to expand into adult ADHD and Alzheimer's aggression. The Company has an exclusive worldwide license to intellectual property rights associated to Engineered Skin Substitute (ESS), an orphan drug designated autologous full thickness skin replacement product in development for the treatment of severe burns currently preparing to enter Phase 2 clinical studies. AMBS owns the intellectual property rights to a therapeutic protein known as mesencephalic-astrocyte-derived neurotrophic factor (MANF) and is developing MANF as a treatment for orphan ophthalmic disorders, initially in retinitis pigmentosa (RP). AMBS also owns the discovery of neurotrophic factors (PhenoGuard™) that led to MANF's discovery.

AMBS' Diagnostics division owns the rights to MSPrecise®, a proprietary next-generation DNA sequencing (NGS) assay for the identification of patients with relapsing-remitting multiple sclerosis (RRMS), and has an exclusive worldwide license to the Lymphocyte Proliferation test (LymPro Test®) for Alzheimer's disease, which was developed by Prof. Thomas Arendt, Ph.D., from the University of Leipzig, and owns further intellectual property for the diagnosis of Parkinson's disease (NuroPro®).

For further information please visit www.Amarantus.com, or connect with the Company on [Facebook](#), [LinkedIn](#), [Twitter](#) and [Google+](#).

Forward-Looking Statements

Certain statements, other than purely historical information, including estimates, projections, statements relating to our business plans, objectives, and expected operating results, and the assumptions upon which those statements are based, are forward-looking statements. These forward-looking statements generally are identified by the words "believes," "project," "expects," "anticipates," "estimates," "intends," "strategy," "plan," "may," "will," "would," "will be," "will continue," "will likely result," and similar expressions. Forward-looking statements are based on current expectations and assumptions that are subject to risks and uncertainties which may cause actual results to differ materially from the forward-looking statements. Our ability to predict results or the actual effect of future plans or strategies is inherently uncertain. Factors which could have a material adverse effect on our operations and future prospects on a consolidated basis include, but are not limited to: changes in economic conditions, legislative/regulatory changes, availability of capital, interest rates, competition, and generally accepted accounting principles. These risks and uncertainties should also be considered in evaluating forward-looking statements and undue reliance should not be placed on such statements.

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