



AMRI Acquires Whitehouse Laboratories Investment Community Presentation

December 15, 2015

Forward-Looking Statements



This presentation may contain projections, estimates and other forward-looking statements that involve a number of risks and uncertainties, including those discussed in the Company's filings with the Securities and Exchange Commission. While this presentation represents management's current judgment on the future direction of the Company's business, such risks and uncertainties could cause actual results to differ materially from any future performance suggested herein. The Company undertakes no obligation to release publicly the results of any revisions to these forward-looking statements to reflect events or circumstances arising after the date hereof.

NASDAQ: AMRI

Transaction Highlights



Consideration

- \$54 million cash
- An additional \$2 million in shares of AMRI common stock, contingent upon Whitehouse achieving certain 2015 targets

Financing

- Funded with cash on hand and revolving line of credit
- Additional capital available to support our growth strategy

Financial Impact

- Accretive to non-GAAP earnings per share in 2016

Leadership

- COO Mark Stier to remain as site head
- Whitehouse Labs to become part of DDS business unit

Whitehouse Labs Business Highlights



- Privately owned testing and consulting services company, founded in 2002
- Based in Lebanon, NJ; close proximity and access to the corporate US headquarters of many global life science companies
- 2015 estimated revenue of \$10 million; adjusted EBITDA of \$6 million;
 - Double digit annual revenue growth 2013 - 2015
- Provides turnkey solution for life sciences and pharma companies
 - Comprehensive array of testing services from materials, containers, analytical chemistry, drug delivery systems, packaging, distribution, and stability
- Established reputation for rigorous quality assurance protocols and technical excellence
 - No quality system deficiencies ever noted by FDA; no 483s issued



Whitehouse Labs Business Highlights (cont.)



- A market leader in qualification testing, a critical function for all aspects of pharmaceutical development and manufacturing
- Global vendor approval and included in NDA and ANDA filings as specified testing lab
 - 20+ MSAs in place with major pharmaceutical manufacturers
 - 80+ quality agreements
- Experienced scientific staff at the forefront of container closure integrity testing and highly respected by U.S. regulatory officials
- Attractive value proposition to clients
 - Outperforms the large TICs in terms of quality, CCIT technical/validation expertise, expedited testing capabilities, and unsurpassed customer service at competitive price points

Strategic Benefits of the Transaction



- Strategically extends AMRI's analytical service offerings in rapidly expanding area of outsourcing services
 - AMRI now has a comprehensive package of testing and analytical service offerings
 - Supports all our business units and a majority of our customers' testing needs
- Access to large, diverse customer base for future growth
 - Over 250 customers with high retention rates
 - Diverse revenue stream
 - Cross selling and revenue synergy opportunities for both companies
- Central New Jersey location provides AMRI with a great talent base and a strategic location for future growth
- Whitehouse Labs can grow further and faster with AMRI
 - Dedicated sales support
 - Revenue synergies

Favorable Industry Dynamics for Testing and Analytical Services

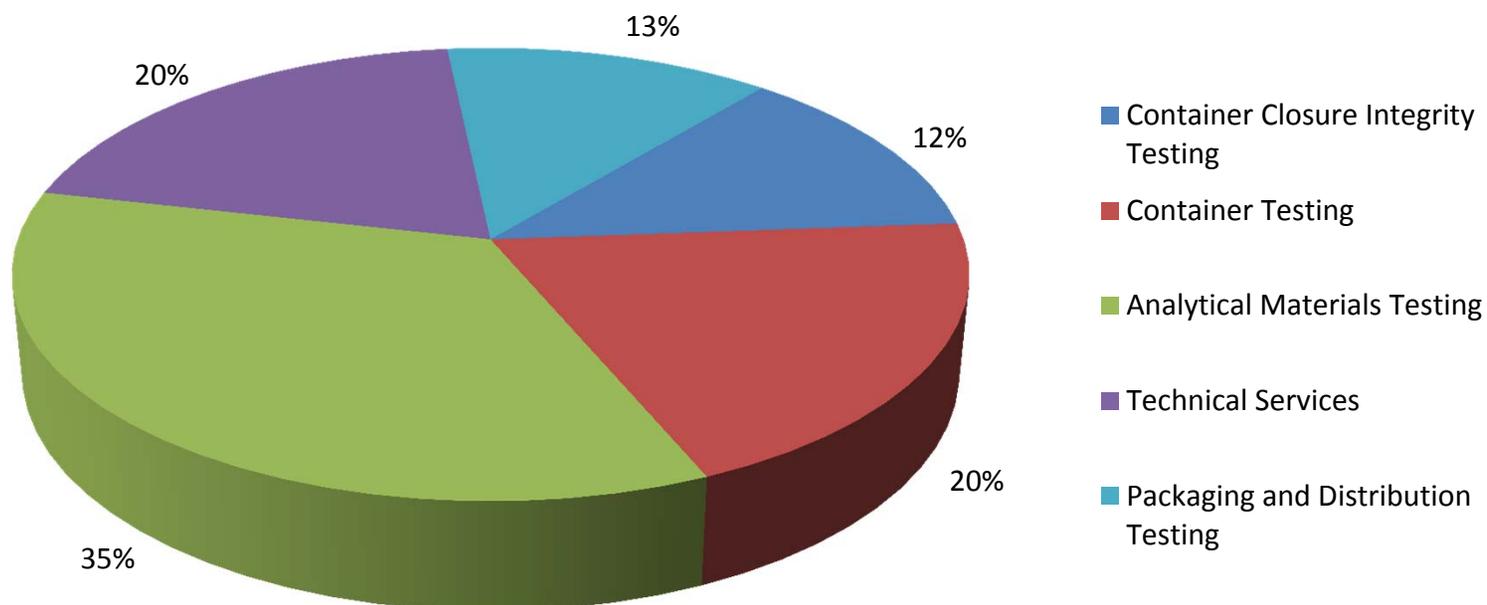


- Increased outsourcing of testing services
 - Increasing government regulation and complexity of testing
 - Mounting demand for independent verification
 - Reduced capital outlays and expenses associated with maintaining in-house laboratory
- Increased regulation and continually evolving standards and complexity of testing modalities favoring those with expertise
 - Proliferation of biologics and innovative drug delivery devices
 - Pressures to accelerate time to market for new products is necessitating faster testing turn-around times

Diverse Revenue Mix



Whitehouse Labs 2014 Revenue Segmented by Testing Division



Whitehouse Labs Testing Services



Container Closure Integrity Testing

- USP <1207> tests
- Leak test method validation specific to container & product type
- Helium mass spec leak testing
- Laser-based headspace analysis
- Mass flow leak detection
- Vacuum decay, high voltage leak detection & seal scan testing
- Residual seal force training
- Parenteral vial capping optimization

Packaging and Distribution Testing

- ISO 11607 packaging validation – integrity & strength testing
- Real time, accelerated aging & environmental conditioning
- Packaging materials – physical & identification tests
- Shipment monitoring
- Packaged product testing – performance, utility & leakage
- Label adhesion & legibility – bar code quality
- ASTM & ISTA package distribution simulation testing
- Cold chain / thermal testing

Technical Services Testing

- ISO 11608: needle-based injections for medical use
- Cleaning validations (swabbing, analysis)
- Unit dose
- Extractables and leachables
- Mechanical testing
- Stability

Analytical Materials Testing

- Full monograph testing per USP, EP, BP, JP, FCC, ACS, AOCS
- Elemental impurities USP<232>, USP <233>, and UP <2232>
- Residual solvents as per USP <467>, organic volatile impurities
- DSC and FTIR – HPLC, GC, ICP, ICP/MS
- Method verification and validation – analytical method transfer
- Heavy metals and trace impurities – atomic absorption & ICP
- Product QC, release testing, and stability storage
- Dissolution and disintegration

Container Testing

- USP glass testing
- USP plastic containers
- USP container performance testing
- USP elastomeric closure testing
- USP biological reactivity
- Comprehensive EP & JP container testing

Whitehouse Labs Container Closure Integrity Testing



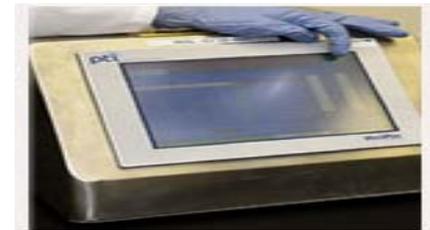
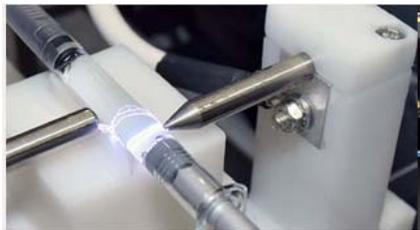
A recognized leader in the container closure integrity testing, Whitehouse Laboratories offers state-of-the art solutions including in-depth method development and validation.

WHL's CCIT laboratory is equipped with modern leak detection technologies including vacuum decay package leak detection, high voltage leak detection (HVLD), helium leak detection (HeLD), laser-based headspace analysis, and airborne ultrasound/seal-scans providing tests that offer more reliability, accuracy, and sensitivity via more current deterministic methods versus older probabilistic methods such as dye and microbial ingress.

Management believes that it is the only outsourced provider to house all of these advanced technologies in one facility. WHL's team of experts utilize state of the art technologies to offer leak test method development and validation in a fully accredited, cGMP environment.

- **CCIT capabilities**

- USP <1207> testing experts
- Leak test method validation specific to container & product type
- Vacuum decay, high voltage leak detection & seal scan testing
- Laser-based headspace analysis
- Mass flow leak detection
- Helium mass spec leak testing
- Residual seal force testing
- Parenteral vial capping optimization



Technical Services



A growing proportion of revenue generated from this division pertains to testing related to drug delivery devices. Devices tested include auto injectors, syringes, needles, catheters, and unique drug delivery products and packages.

Combination medical devices represent a unique set of risk factors and are subject to numerous regulatory guidelines that cover both drug and medical device standards. While these new and unique systems are a convenience to the end-user, there are many steps in the development, manufacturing and distribution cycle that pose compliance concerns. For example, the transport environment with pressure changes combined with shock and vibration can result in unacceptable plunger movement, excessive drug product contact with needle surface, and a host of other scenarios – all are problematic for “first dose” performance and as such robust testing is necessary to ensure not only compliance but also functional use.

- **Whitehouse Analytical Laboratories offers comprehensive and expert technical services for drug delivery and medical device testing**
 - ISO 11608: Needle-based injections for medical use
 - Cleaning validations (swabbing, analysis)
 - Developing and validating analytical methods
 - Compound specific methods
 - Total organic compounds
 - Extractables and leachables
 - GC/MS, HPLC, GC and ICP methodology
 - Modify & validate routine or controlled extractable procedures for routine extractables testing or product release
 - Product storage and production retains with complaint resolution testing
 - cGMP ICH stability and storage programs during clinical trials, NDA, aNDA submissions, and management of retain samples
 - Flexible conditions, photostability studies per ICH Q1B
 - Mechanical testing
 - Physical properties: dimensional, inspection, and functional
 - Unit dose
 - USP <698> deliverable volume
 - USP <755> minimum fill
 - USP <905> uniformity of dosage units

Whitehouse Labs Packaging & Distribution Testing Services



Since first formally opening in August of 2010, the Packaging and Distribution Testing Department has been a source of growth for Whitehouse Laboratories. Building upon existing relationships with pharmaceutical clients, the department has expanded to serve other sectors, such as medical device and biotechnology.

Having an integrated lab, capable of supporting product launch from development to market is a key asset for the business unit. The Package Lab, in conjunction with the other company divisions, offers clients a unique opportunity to have one unified vendor to meet many of their packaging qualification requirements.

- **Packaging testing services**

- Whitehouse Laboratories provides testing as required to assist with the validation of terminally sterilized medical device packaging systems. With a staff of industry experts in aging, performance, strength, and integrity testing for sterile barrier (SBS) packaging.
- ISO 11607 packaging validation - integrity & strength testing
- Real time, accelerated aging & environmental conditioning
- Packaging materials - physical and identification tests
- Packaged product testing - performance, utility & leakage
- Label adhesion & legibility - bar code quality
- Technical experts in package testing



Whitehouse Labs Packaging & Distribution Testing Services



The core competencies of the Packaging and Distribution Testing Department are currently focused on testing primary and secondary packaging for pharmaceutical product development and medical device packaging qualifications. The Department occupies a true niche - cGMP testing capabilities in an ISTA certified facility that is also DEA licensed.

The laboratory is centrally located on the East Coast - a location not well served by the current contract testing market and a hot bed of pharma activity. Additionally, management is particularly excited about the opportunity to further penetrate the consumer products sector.

• **Distribution tests**

- ASTM and ISTA package distribution simulation testing
 - Distribution simulation testing – shock, vibration, compression, and environmental stress (temperature, humidity, and pressure)
- Real time, accelerated aging & environmental conditioning
 - Altitude simulation testing can be performed up to 100,000 feet
- Shipment monitoring
 - With Lansmont Savers™, WHL can monitor shipments for shock, vibration, temperature, humidity, and pressure
 - Testing will show exactly what a product is exposed to in order to adequately package it
- Cold chain / thermal testing
 - High performance Cincinnati Sub Zero Environmental Chambers
 - Evaluate temperature controlled packaging
 - Ensure that products remain within their specified safe temperature range
 - Ramp and soak through winter and summer profiles

Whitehouse Labs Analytical Materials Testing



Whitehouse Labs is a comprehensive analytical testing laboratory that offers USP-NF, EP, FCC and JP Monograph testing for many raw materials used in pharmaceuticals, personal care products, and cosmetics.

- ➔ *Full monograph testing per USP, EP, BP, JP, FCC, ACS, AOCS*
- ➔ *Method verification and validation - analytical method transfer*
- ➔ *Elemental impurities USP <232>, USP <233> and USP <2232>*
- ➔ *Heavy metals and trace impurities - atomic absorption & ICP*
- ➔ *Residual solvents as per USP <467>, organic volatile impurities*
- ➔ *Product QC, release testing and stability storage*
- ➔ *DSC and FTIR - HPLC, GC, ICP/MS*
- ➔ *Dissolution and disintegration*

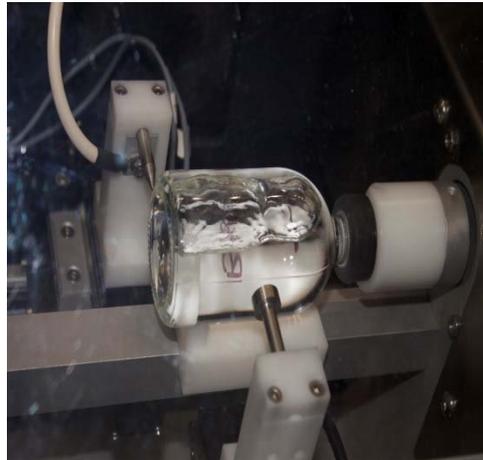


Whitehouse Labs Container Testing



A recognized leader in container qualification testing, WHL can assist with all required USP, EP, and JP testing for all container systems. An experienced and dedicated “container” staff is available to advise and consult to ensure complete compliance to FDA requirements. Container types routinely tested include:

- *USP glass testing*
- *USP plastic containers*
- *USP container performance Testing*
- *USP elastomeric closure testing*
- *USP and biological reactivity*
- *Comprehensive EP & JP container testing*
- *Label adhesion & legibility*



About AMRI



Albany Molecular Research Inc. (AMRI) is a global contract research and manufacturing organization that has been working with the Life Sciences industry to improve patient outcomes and the quality of life for more than two decades. With locations in North America, Europe and Asia, our key business segments include Discovery and Development Services (DDS), Active Pharmaceutical Ingredients (API), and Drug Product Manufacturing. Our DDS segment provides comprehensive services from hit identification to IND, including expertise with diverse chemistry, library design and synthesis, *in vitro* biology and pharmacology, drug metabolism and pharmacokinetics, as well as natural products. API Manufacturing supports the chemical development and cGMP manufacture of complex API, including potent, controlled substances, biologics, peptides, steroids, and cytotoxic compounds. Drug Product Manufacturing supports pre-clinical through commercial scale production of complex liquid-filled and lyophilized parenteral formulations. For more information about AMRI, please visit our website at www.amriglobal.com or follow us on Twitter (@amriglobal).

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