AMP Quick Facts

Arch Therapeutics, Inc. (OTC.QB: ARTH)

Life Science
Medical Devices

OTC.QB:	**ARTH**
Last Price:	$0.22
June 23, 2014	
Fiscal Year:	9/30
Sector:	**Life Sciences**
Industry:	**Medical Devices**
Market Cap:	$16M
Shares Outstanding:	72M
Float:	28.65M
Addressable Market:	$4.5B
52 Week High:	$1.36
52 Week Low:	$0.11
Insider Ownership:	30%
Inst. Ownership:	12.8%
Avg. Daily Vol. (3 M):	83,000

For More Information please call:
Austin Gilbert:
A.M.P
678-736-5671

Arch Therapeutics, Inc. (OTC.QB: ARTH) is a Boston-based life sciences company that develops products to stop bleeding and control leaking during surgery and trauma care. Both bleeding and leaking are big problems for first responders and surgeons around the world, and if not well-controlled are major drivers of poor surgical outcomes, including patient mortality. Compared with currently-available products, Arch Therapeutics is developing its product to work better and with fewer side effects, and be very easy to prepare and apply, making it especially valuable in time-critical surgical and trauma applications.

Arch Therapeutics AC5 Surgical Hemostatic Device

Based on technologies originally developed at MIT for stem cell applications, Arch's flagship product is comprised of short chains of amino acids (called peptides) that self-assemble into sealing structures when exposed to blood or other internal body fluids. The product comes in a powered form and is mixed with water before use, making its very easy to transport, store, prepare, and use. The prepared product has the consistency of a light gel such as Purell hand sanitizer, and is transparent after application, a big benefit to surgeons.

Regulatory/Approval Pathway

Although still in the pre-clinical stage at this time, Arch's AC5 product is considered to be a medical device under U.S. and European law, making its approval process far more streamlined than would be the case were it considered a new drug. The Company believes that it will be approved for sale in Europe in 2015 and hopes to be approved in the United States shortly thereafter.

Expected regulatory path: Medical Device

- CE Mark EU (first focus)
- PMA USA

Formal biocompatibility studies and Planning clinical trial for 2014

- AC5 Surgical Hemostatic Device™ for surgical hemostasis
- Likely primary endpoint: ***Time to Hemostasis***

Target Markets

Arch Therapeutics, Inc. (OTC.QB: ARTH) serves the rapidly growing hemostatic agents and surgical sealants market, which is forecast to grow to over US$6 billion in 2017 from its 2013 size of US$4.5 billion.

- **Surgery** Arch Therapeutics plans to focus on surgery markets first, where its superior technology and cost-competitiveness should translate into a quick and large market penetration.
- **Trauma** The next likely focus of the Company's marketing efforts, the trauma market is very large, and is comprised of civilian and military first-responders.
- **Home Use** At some point, the product's low manufacturing cost and ease of use should allow it to compete in the home-use market, both domestically and abroad.

Competition

The available products include a wide variety of plant cellulose blends, polymers (Krazy Glue like products, as in Dermabond), and more expensive bioactive products that use the body's complicated coagulation pathway to function. Each product class entails its own problems, such as tissue adhesion and inflammation, which negatively affect healing and surgical outcome. ARTH is developing its product to avoid these common shortcomings and competes favorably with all available products in terms of cost, ease of use, and surgical outcome.

Progress and Completion of Significant 2014 Planned Milestones

1. *Select Notified Body for European regulatory pathway then confirm CE pathway with Notified Body*
2. *Complete Clinical Investigational Plan and Ethics Committee approval*
3. *Select new pipeline candidate and Expand intellectual property portfolio*
4. *Select GMP partner for clinical batch and Scale-up GMP manufacturing*
5. *Complete biocompatibility studies on AC5 Surgical Hemostatic Device™*
6. *Initiate AC5™ clinical trial*

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MANAGEMENT PARTNERS LLC

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678-736-5671

Contact: Austin Gilbert

AGilbert@AcornManagementPartners.com

Atlanta, Georgia U.S.A **New York, New York U.S.A.** **London, UK** **Singapore, Asia**