Bio-AMD Inc. (BIAD) $0.15

BIAD **Bio-AMD, Inc.**

Common Stock
SEC Reporting - Current

OTCQB

0.1485 ⬆ 0.0134 (9.92%)

Real-Time Best Bid & Ask
No Inside Bid/Offer

Previous Close	Daily Range	Volume	Average Vol (30d)
0.1351	0.1485 - 0.1485	750	36,750
Open	**52wk Range**	**Dividend**	**Net Dividend Yield**
0.1485	0.02 - 0.30	N/A	N/A

Trade Data Delayed 15 minutes. Trade Time Jun 19, 2015

Bio-AMD Advances Revolutionary Monitors for both Wafarin/Coumadin Users and Heart Attack Victims.

Blood Coagulation Monitor (COAG).

Bio-AMD Holdings is a development stage company, formed in February 2010, which, through its operating subsidiary, Bio Alternative Medical Devices Ltd. ("Bio-Medical"), principally operates in the Medical Point of Care ("POC") diagnostic space. Where context requires, reference to Bio-AMD Holdings also includes reference to Bio-Medical. Bio-AMD Holdings owns a portfolio of patent applications on technologies, which it expects to enable it to develop **highly accurate, low cost, hand held electronic diagnostic devices** capable of reading certain third party assays.

Since 2010 Bio-AMD Holdings has been developing its technology **into three initial product types 1)** a digital strip reader targeted initially into the "over the counter" female well-being market (including digital pregnancy, ovulation and fertility testing, **2)** a blood coagulation device and **3)** early stage development work into a POC immunoassay detection system based on magnetic nanoparticle manipulation for the detection of heart attacks.

Background

Patients with cardiac problems are often on life-long oral anticoagulation therapy, for example Warfarin or Coumadin. Frequent testing and careful monitoring of the medicine or blood clotting agents is a necessity to minimize the risks of fatal hemorrhaging.

Anticoagulant or blood-thinning therapy is prescribed for people who have undergone replacement or mechanical heart valve surgery, have irregular heartbeats such as atrial fibrillation, or have had heart attacks. Other types of patients who might be using the drug and this monitoring system include who have, or are trying to prevent, blood clots in veins or pulmonary embolism (a blood clot in the lungs.)

However, current testing for PT/INR is both costly (to the healthcare provider since tests are normally performed in the lab) and time consuming.

Bio-AMD is currently developing a new **hand-held meter** device using combined magnetic/optical detection sensors, with a unique for micro-fluidic strip using very low blood volume. A patent for the Bio-AMD blood coagulation meter and technology has been filed. Bio-AMD's COAG POC system is based on their **disposable microfluidic strip** (meaning they intend on making the "real" money on the strips vs device sales when launched). During 2013 they further developed the strip design to incorporate multi-chambers, incorporating a novel locking mechanism that allows for the control of

fluid flow through the strip. This is expected to allow the testing of coagulation immunoassays that utilize multiple reagents, and is subject to a new patent application.

The hand-held device features:

- ✓ Lab accuracy to give patient day to day control of anti-coagulant intake
- ✓ State of the art digital electronics and embedded software
- ✓ Unique blood detection design (blood and plasma)
- ✓ Very low volume whole blood sample required ("finger-stick")
- ✓ Fast response test result
- ✓ Temperature control with direct strip measurement
- ✓ External power supply and battery
- ✓ USB connection for data output
- ✓ Internal memory
- ✓ Easy to use

Interestingly, in December of 2014, it was reported that one of the leaders in the field **Alere (NYSE: ALR)** which makes the INRatio device came under regulatory scrutiny and their "volutary recall" in May of 2014 was upgraded to Class I status (having the potential to cause death or permanent injury) due to inaccurate test results. This means that some patients may be at risk for spontaneous bleeding.

It goes without saying that a patient's life depends on accurate measurements. And that was what the Alere products failed to provide. There were **19,000 reports of "adverse events"** over a one-year period – which included three deaths.

In Alere's 10Q they stated, "Cardiometabolic net product sales and services revenue decreased by $21.7 million, or 5%, to **$441.6 million for 2014**, from $463.3 million for 2013, primarily as a result of a decline in sales of our Alere INRatio2 PT/INR professional test strip in the U.S. due to the voluntary recall. The company transitioned customers from the recalled Alere INRatio2 PT/INR Professional Test Strip to the Alere INRatio PT/INR Test Strip, which was not included in the recall.

Then coincidently (?) in December of 2014, in the same month of the Alere recall -- Bio-AMD announced a billion dollar Japanese based company called **Sysmex Corporation**, would jointly conduct a feasibility study for the potential development of their POC COAG system including a reader device

with disposable test strips for PT-INR assays and potentially new future assays in the field of hemostasis. Sysmex Corporation with 7,000 employees is a world leader in clinical laboratory systemization and solutions, including laboratory diagnostics, laboratory automation and clinical information systems.


Hisashi Ietsugu
Chairman and CEO

Serving customers for more than 40 years, Sysmex focuses on technological leadership in diagnostic science and information tools that make a difference in the health of people worldwide.

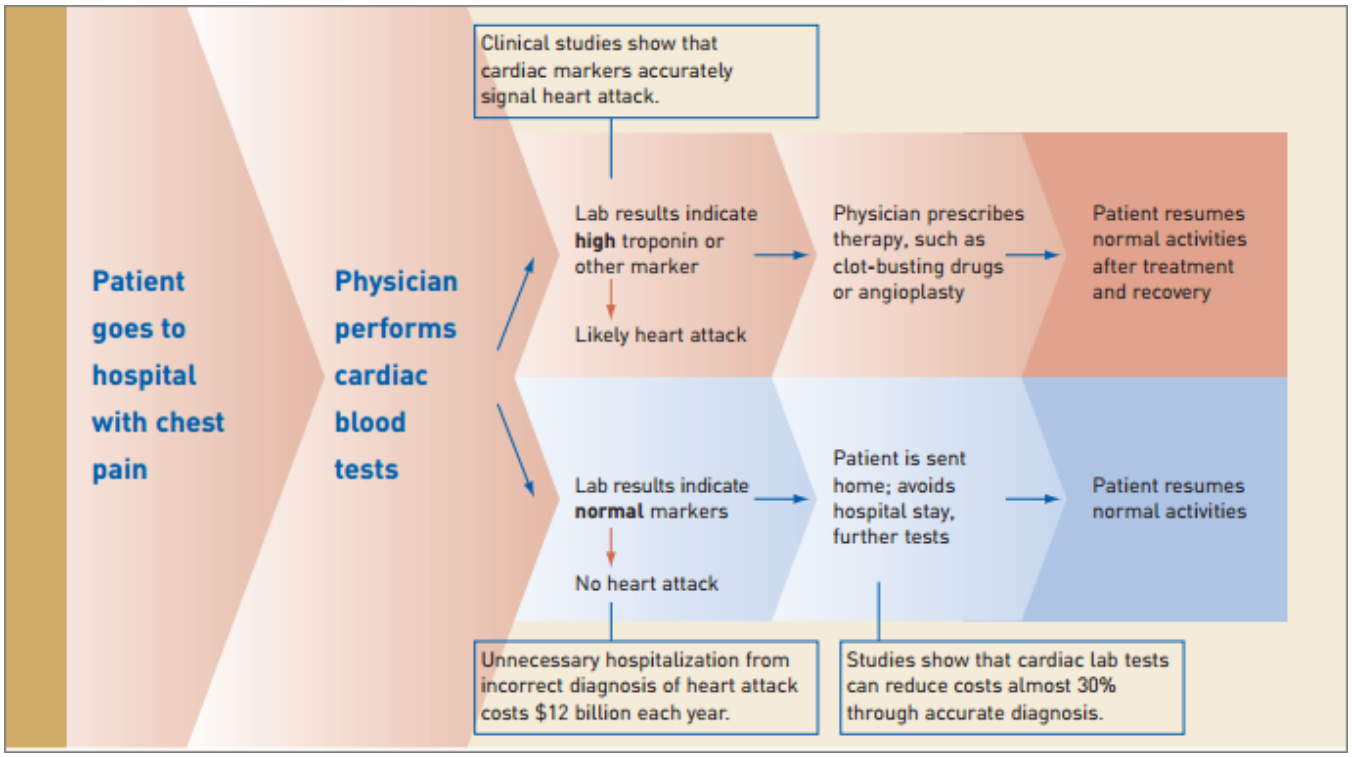
Sysmex will own all intellectual property developed by either party in connection with the Study, and will reimburse Bio-AMD Ltd. for costs and expenses incurred in connection with the project development. An expense advance of approximately $980,000 was made to Bio-AMD Ltd. If Sysmex determines the feasibility study to be successful and decides to progress with the Research, further cost reimbursements will be made during the term of the Agreement linked directly to milestone criteria and deliverables to be agreed by both parties. Yes, a little vague, but still huge news. We expect the benefit associated with the product development, would be worth many times the $980,000 they received.

In 2013, the POC (point of care) coagulation market for PT/INR measurement was estimated to be worth approximately US$ **870 million globally** and projected to grow to an estimated US$ 1.1 billion by 2017. The market is dominated by a small number of major players including Alere, Roche, Siemens and Philips who have either developed products internally or have acquired exclusive rights to license appropriate **technologies from smaller companies**.

Not surprisingly, the share price took off and we decided (hoped) to initiate coverage on a pull back, which it recently has. The **shares ran from $0.07 to a peak of $0.30** and has since retreated in half offering new investors an excellent entry point, in our opinion.

Heart Attack Monitor (MIDS)

What are cardiac biomarkers?



Cardiac biomarkers are substances that are **released into the blood** when the heart is damaged or stressed. Measurements of these biomarkers are used to help diagnose acute coronary syndrome (ACS) and cardiac ischemia, conditions associated with insufficient blood flow to the heart.

When blood flow to the heart is blocked or significantly reduced for a longer period of time (usually for more than 30-60 minutes), it can cause heart cells to die and is called an acute myocardial infarction (AMI or heart attack). This leads to death of the affected portion of heart muscle with permanent damage and scarring of the heart and sometimes can cause sudden death by causing irregular heart contractions (arrhythmia). Unstable angina and AMI are together called acute coronary syndrome since they are both due to a very acute decrease in blood flow to the heart.

Bio-AMD plans to develop an immunoassay platform **initially for the cardiac marker POC** (*point of care, like even in an ambulance*) testing market, which are measured to evaluate heart function. The detection of these markers are used to diagnose myocardial infarction and its severity, **typically troponin** (cTnI or cTnT), myoglobin and creatine kinase MB isoenzyme (CK-MB). Due to their increased sensitivity and specificity compared with CK-MB and other conventional biomarkers, troponins have been the preferred choice for the diagnosis of heart attacks.

Test	Cardiac Marker Starts to Increase	Reaches Peak Level	Total Duration	Enzyme from...
CK	4–8 hours	—	48–72 hours	Heart, Brain, Skeletal Muscle
CK-MB	3–4 hours	12–24 hours	48 hours	Heart
Myoglobin	1–2 hours	4–6 hours	24 hours	Heart, Skeletal Muscle
Troponin	3–6 hours	12–24 hours	1 week	Heart

The MIDS POC platform, in early stage development, incorporates what they believe to be a novel microfluidic strip design (including multi-chamber), combining magnetic nanoparticle manipulation and a double detection technique using bespoke Hall Effect sensors coupled with the unique Bio-AMD optical sensor. **It is anticipated that the system can increase significantly the sensitivity and accuracy of the test result, bringing laboratory quality results to the POC setting.** The company is not aware that this method is being used in products currently being offered in the market, or in development.

Troponin tests are primarily ordered to help diagnose a heart attack and rule out other conditions with similar signs and symptoms. Either a troponin I or troponin T test can be performed; usually a laboratory will offer one test or the other. The concentrations are different, but they basically provide the same information. Troponin I and troponin T are proteins found in heart muscle and are **released into the blood** when there is damage to the heart.

Their ultimate aim is to commercialize a product for the multiple cardiac marker testing market currently estimated by BCC Research to be worth US **$1.3 billion globally** in 2013 (including device, reagent and supply sales), and is expected to rise to $2.4 billion by 2018.

In October 2014, the Company received an offer of a funding assistance award from Innovate UK, the UK's Government supported innovation agency, in the amount of 36,655 for a **"Proof of Market"** report for our MIDS technology. A third party research company, Inventya Ltd., based in the UK, is leading an extensive market research project, working with Bio-AMD, into the potential for MIDS specifically into the cardiac marker POC testing market. This will include a survey of key buyers, competitor analysis likely commercialization strategies.

The 70 page report (essentially a "will this product sell" report), **was released June 1st**.

Again, similar to the COAg product, the "real money" will be in the testing, not in the testing device.

Patients go to the emergency room more **than 6 million times each year** because of chest pain. But because heart attack can be difficult to diagnose—

✓ …roughly 2-10% of patients who are actually experiencing a heart attack are sent home.

✓ …some $12 billion is spent every year on inappropriately hospitalizing patients **who are not** actually

experiencing a heart attack.

✓ …the costs of cardiac lab tests are miniscule compared to the total costs of misdiagnosis.

Studies show that cardiac lab tests help physicians diagnose heart attack accurately and promptly. Accurate diagnosis means more appropriate care, earlier discharge for patients who are at no risk, and cost-savings.

The following table summarizes several studies.

	Tests used in study	Results for patient	Cost Savings	
			Length of stay reduced...	Total costs reduced...
	More frequent use of **CK, CK-MB, myoglobin,** and **troponin** tests[1]	Better accuracy, faster diagnosis	33%	29%
	CK-MB tests[2]	More accurate diagnosis	44%	
	More frequent **CK-MB tests** for complicated cases[3]	Earlier discharge from hospital	8.3%	"The potential impact is tremendous when the difference [in LOS] is multiplied by the millions of cardiac patients seen in the US each year."
	Troponin[4]	More accurate diagnosis	2 days	
	Troponin[5]	Earlier discharge	✓ 8.5% increase in number of patients who did not have a heart attack discharged the day after admission ✓ 50% increase in number of patients diagnosed with confirmed heart attack	Earlier discharge for patients=107 saved hospital bed days
	Troponin[6]	Diagnoses concluded no heart attack or low-risk		Lower drug, lab, hospitalization costs

When is a test it ordered?

A troponin test will usually be ordered when a person with a suspected heart attack first comes into the emergency room, followed by a series of troponin tests performed over several hours.

A heart attack may be suspected and testing done when a person has signs and symptoms such as those listed below. Note that not everyone will experience chest pain, and women are more likely than men to have sign and symptoms that are not typical.

- Chest pain, discomfort and/or pressure (most common)
- Rapid heart rate, skipping a beat

- Shortness of breath and/or difficulty breathing
- Fatigue
- Nausea, vomiting
- Cold sweat
- Lightheaded
- Undue fatigue
- Pain in other places: back, arm, jaw, neck, or stomach

In people with stable angina, a troponin test may be ordered when:

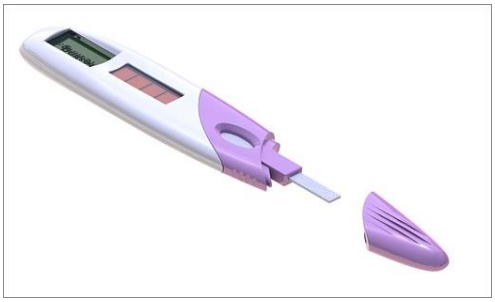
- Symptoms worsen
- Symptoms occur when a person is at rest
- Symptoms are no longer eased with treatment

These are all signs that the angina is becoming unstable, which increases the risk of a heart attack or other serious heart problem in the near future.

We suggest readers look at the "Proof of market" report, which clearly delineates the need for Bio-AMD's MIPS device.

Digital Strip Reader.

Finally, Bio-AMD has a **Digital Strip Reader** and the company's first stage of its corporate strategy has been to develop a universal digital strip reader (DSR) capable of reading a variety of lateral flow strips to detect differing conditions.



DSR technology platform can read and quantify traditional chromatography based, nitro-cellulose, lateral-flow immunoassay tests, predicated on what they believe to be a **unique optical sensor arrangement**. The DSR comprises a proprietary design incorporating sensors, diagnostics, display and power management capabilities. A key feature of their DSR technology is that its platform can be adapted and applied to numerous and disparate lateral flow diagnostic tests.

The DSR has a wide range of applications. The company has focused their commercial efforts initially on a next generation pregnancy test for "Over The Counter" and home use. They intend to expand into

related product areas including ovulation & fertility in the near future. The DSR platform can also be adapted for other immunoassay test and they are currently exploring other potential areas such as cholesterol (lifestyle testing), cardiac markers, drugs of abuse and infectious diseases e.g. HIV, syphilis, H. Plyori, Chlamydia.

- ✓ Key features of the DSR platform include:
- ✓ New technology and new IP (patents filed)
- ✓ Unique interlocked cartridge cap
- ✓ Unique Quad Solar Cell light sensor array
- ✓ Clear digital LCD output to minimize errors
- ✓ Environmentally friendly – No batteries or chemicals (fully disposable)
- ✓ High sensitivity (semi-quantitative measurement)
- ✓ Tolerance free system
- ✓ Low manufacturing cost (higher profit margin)
- ✓ Ability to read any lateral flow strip including those using color change
- ✓ Easy to use

Management.

(From the most recent 10K)

Thomas Barr: Mr. Barr has served as our chief executive officer since December 2008 and as a director of ours since December 2006. He has served as a director of WL since May 2009. He has expertise in corporate management, corporate governance and SEC reporting matters. He has been actively involved in the development of our corporate strategies including those involving our WL and Bio-AMD subsidiaries. He served as our Vice President of Alternative Fuels Operations from December 2006 until December 2008.

From December 21, 2010 through the present, Mr. Barr has served as a director of Imperial Resources, Inc., a US public company engaged in oil and gas exploration and development. From January 2005 to April 2007, Mr. Barr acted as a consultant to small and medium sized private and public enterprises regarding prospective funding, investor and public relations strategy, collateral creation, website development and public market quotation. From December 2001 to December 2004, Mr. Barr served as a consultant to EasyScreen PLC, a fully listed London Stock Exchange company, at which Mr. Barr's main duties were to draft and implement corporate statements. While serving as a consultant to

EasyScreen PLC, Mr. Barr was an integral part of the team involved in several private placement funding rounds prior to the company's acquisition. From January 1996 to November 2001 Mr. Barr was a private analyst and investor in publicly quoted stocks. From 1981 to 1996, Mr. Barr worked in the North Sea as a professional saturation diver involved in oil and gas field sub-sea construction. Mr. Barr obtained a BSc from Stirling University, Scotland, in 1981. Mr. Barr is a citizen of the United Kingdom. We took into account of his prior experience in operating public and private enterprises in corporate management, development of corporate strategies, private placement funding and SEC reporting matters and believe Mr. Barr's past experience in these fields gives him the qualifications and skill to serve as our Chief Executive Officer and Director.

Robert Galvin: Mr. Galvin has served as our chief financial officer and treasurer since December 2008 and as a director of ours since June 2009. He also served as our secretary from December 2008 to June 2010. He has expertise in corporate finance and accounting, mergers and acquisitions, divestitures, and capital raising. He is a founding partner in the ARM Partnership, a corporate and financial advisory firm that specializes in small cap, venture backed fast growth businesses. He is also a co-founder, director and shareholder of Bio-AMD.

He has served as a director of WL since July 7, 2010 and is also a shareholder of WL. From February 1996 to March 2002, he was a Director at Andersen Corporate Finance, prior to which Mr. Galvin worked in the commercial banking division of Barclays Plc. He has a first class honors degree BA (hons), and is an Associate of the Chartered Institute of Bankers. Mr. Galvin is a citizen of the United Kingdom. We took into account of his prior experience in corporate finance and accounting, mergers and acquisitions, divestitures, and capital funding and believe Mr. Galvin's past experience in these fields gives him the qualifications and skill to serve as our Chief Financial Officer and Director.

David Miller: Mr. Miller has served as our president since June 2009, as our secretary since June 2010 and as a director of ours since December 2008. He has served as a director of WL from May 2009 until July 7, 2010. He has expertise in corporate management, development of business plans and strategies, sales and human resources matters. He has had an active role in the development of our WL business. He has been providing consultancy services to a venture capital provider since January 2009. From January 2006 through December 2008 he was the Sales Development Director for DX Group Ltd., which is a provider of specialized business mail and delivery services.

From September 1999 through September 2005, Mr. Miller was the Sales and Marketing Director for MailSource UK Ltd. From 1978 through 1999, Mr. Miller was employed by Barclays Bank PLC, where his positions included Head of Regional Sales, South East Region, and Regional Sales Manager, Thames Valley Region. He is an Associate of the Chartered Institute of Bankers. Mr. Miller is a citizen of the United Kingdom. We took into account of his prior experience in corporate management, development of business plans and strategies, sales and human resources matters and believe Mr.

Miller's past experience in these fields gives him the qualifications and skill to serve as our President and Director.

Summary.

Bio-AMD (BIAD) is an incredibly undervalued opportunity for long-term speculative investors. With 44 million shares outstanding as of May 8th, the market is giving this promising technology platform little to no appreciation of their potential, with a market valuation of only $6 million.

COAG. We feel strongly that the technology has been vetted by Symex's involvement and near $1 million investment. Even if the technology was "half-baked," we feel that Sysmex saw an opportunity with Alere's stumble, to get a foothold into the market which is estimated to be worth near $1 billion. With sales of $1.7 billion for Sysmex, this is an attractively large and new market for Sysmex and we feel comfortable that they will be using their full research and development capabilities, to get this product to market. We feel highly confident about that.

The market growth for a COAG device is driven by the rising number of patients using anti-coagulation therapy, improved re-imbursement levels from health authorities following growing clinical evidence supporting the use of such testing and strong patient demand for patient self-testing. The company has performed initial in-house bench tests at their laboratory, which, when compared against the current "best in market" devices, produces comparable results which they believe validates the feasibility of their design. Now with Sysmex's backing, we believe that the question isn't if COAG will get to market, but rather when.

MIDS: Like with COAG, the technology will require the company to partner with a much larger company with the requisite capital resources and skills including distribution and sales channels, and ideally global marketing expertise in cardiac testing. The "Proof of Market" report will no doubt be used to seek out and enlist a partner with the required deep-pockets to get it to market. We fully anticipate that news of signing a new partner, would likely send the stock considerably higher, much like the COAG announcement did.

We believe that the Bio-AMD MIDS technology has considerable potential to create a next generation of POC test devices. Their proposed method aims to bring together biology, chemistry, nano-fluidics, and electronics and, "lab-on-chip" technology together into what we believe can be unique, economically viable products.

Target partners are those who we believe their technology will fit strategically within their existing portfolio either as a complement to a product line, as a replacement technology or as a new product initiative.

Bio-AMD in our opinion has three more “shots on goal.” The first was the COAG Sysmex announcement, the second would be a MIDS partnering agreement.

The third and fourth catalysts which in our opinion can have a ten-fold magnitude effect on the share price over a partnering agreement, would be news of their partners announcing the release of a product into the market. And we can assure investors, while there can be no assurances of an actual commercial release – that is far better to be a shareholder before such news rather than after. Far better.

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