

Company Description



Biomoda, Inc is an Albuquerque, New Mexico-based In-Vitro Diagnostics company that develops assays to detect cancer. Biomoda's cell-targeting technology is based on Tetrakis Carboxyphenyl Porphine (TCPP) which was developed at St. Mary's Hospital in Colorado and Los Alamos National

Laboratory in New Mexico. Their lead product is a non-invasive lung cancer screening test called CyPath[®]. Currently, Lung cancer claims more lives than any other type of cancer in the United States. But despite this, there is currently no technology approved for routine lung cancer screening in the United States resulting in only 40% of patients diagnosed with lung cancer surviving 1 year after being diagnosed and the 5-year survival rate is only 14%.

Lung Cancer Detection Stages and Deaths

According to the U.S. National Cancer Institute 2009 SEER data, lung cancer is the leading cause of cancer death among both men and women in the U.S. with more people dying annually of lung cancer (159,390 deaths) than of colon, breast, and prostate cancers combined (49,920, 40,610 and 27,360 deaths respectively). Approximately 80% of malignant tumors of the lung are due to Non-Small Cell Lung Cancer (NSCLC) with the remainder being Small-Cell Lung Cancer (SCLC).

Only 20%-25% of NSCLC patients are diagnosed early (Stage Ia/Ib). Unfortunately, approximately 65%-80% of patients are diagnosed with unresectable (non-operable) NSCLC resulting in an overall 5-year survival rate of only 14% for all types and stages of lung cancer. Another benefit of early detection is that while overall mortality rates from surgical removal ranges from 1.3% to 11.6%, the mortality rate is lower among patients undergoing smaller resections.

Non-Small Cell Lung Cancer (NSCLC)	
Detection Stage	5-Year Survival
Stage Ia	82%
Stage Ib	68%
Stage IIa	50%
Stage IIb	40%
Stage IIIa	29%
Stage IIIb	15%
Stage IV	3-5 months

Source: Sat Sharma, MD, FRCPC, Bruce Maycher, MD, "Lung Cancer, Non-Small Cell" Medscape/eMedicine

Despite the poor overall survival due to late diagnosis, the U.S. Agency for Healthcare Research and Quality (AHRQ) convened the U.S. Preventive Services Task Force (USPSTF) concluded that *"the evidence is insufficient to recommend for or against screening asymptomatic persons for lung cancer with either low dose computerized tomography (LDCT), chest x-ray (CXR), sputum cytology, or a combination of these tests."* Their specific rationale was stated as *"The USPSTF found fair evidence that screening with LDCT, CXR, or sputum cytology can detect lung cancer at an earlier stage than lung cancer would be detected in an unscreened population; however, the USPSTF found poor evidence that any screening strategy for lung cancer decreases mortality. Because of the invasive nature of diagnostic testing and the possibility of a high number of false-positive tests in certain populations, there is potential for significant harms from screening. Therefore, the USPSTF could not determine the balance between the benefits and harms of screening for lung cancer."*

However, these conclusions were made based on the cost/benefit of combining X-ray imaging technologies with sputum cytology. Those studies using sputum cytology were done using Pap stain with a microscope to determine whether abnormal cells are present rather than using florescent biomarkers such as Biomoda's CyPath[®]. In addition, Biomoda's CyPath[®] is intended for use without the need for X-ray imaging technologies.

Reference Materials
U.S. Preventive Services Task Force - Lung Cancer Screening Recommendation Statement http://www.uspreventiveservicestaskforce.org/3rduspstf/lungcancer/lungcanrs.htm
U.S. Preventive Services Task Force - Lung Cancer Screening Summary and Update http://www.uspreventiveservicestaskforce.org/3rduspstf/lungcancer/lungsum.htm
American Cancer Society Guidelines for the Early Detection of Cancer http://www.cancer.org/docroot/PUB/content/PUB_3_8X_American_Cancer_Society_Guidelines_for_the_Early_Detection_of_Cancer_update_2001.asp

The main difficulty in finding an acceptable diagnostic screening test for lung cancer is the need for a relative inexpensive test that also has acceptable levels of sensitivity and specificity. The relevant statistical definitions are as follows:

Sensitivity: the percentage of people with lung cancer who are correctly identified as having lung cancer by the diagnostic test.

- True Positive: people with lung cancer correctly diagnosed as having lung cancer
- False Positive: Healthy people incorrectly identified as having lung cancer

Specificity: the percentage of healthy people who are correctly identified as not having lung cancer by the diagnostic test.

- True Negative: Healthy people correctly identified as healthy
- False Negative: people with lung cancer incorrectly identified as healthy

Chest X-rays (CXR) would be the most economical of diagnostic tools for lung cancer except it has a false-positive rate of up to 74% which requires additional (and unnecessary) testing using low-dose computerized tomography (LDCT). Yet, even LDCT has a high false-positive rate of up to 41% requiring high-resolution computerized tomography (HRCT) which is more expensive. Recent criticism of the high level of radiation exposure experienced by patients undergoing CT scans might have a large effect on their use despite the higher sensitivity. *The New York Times* recently reported on March 28, 2010 that the radiation experienced by a patient undergoing a CT scan can be up to 400 times greater than the radiation experienced in a standard chest X-ray.¹

The American College of Radiology Imaging Network (ACRIN) is currently conducting large-scale imaging trials in lung cancer to more accurately calculate sensitivity, specificity and mortality as follows:

American College of Radiology Imaging Network - Current Lung Cancer Imaging Studies
COMPLETED - ACRIN PROTOCOL 6654 (See NLST Below) Source: http://www.acrin.org/TabID/145/Default.aspx
Main Objective: To determine whether lung cancer screening using low-dose helical CT reduces lung cancer-specific mortality relative to screening with chest radiographs in a high-risk cohort.
Participants: Current or former cigarette smokers between the ages of 55 and 74 years without a history of lung cancer.
ACRIN PROTOCOL 6668 / RTOG 0235 Source: http://www.acrin.org/TabID/155/Default.aspx
Main Objective: The primary purpose of this study is to determine if the SUV measurement from FDG-PET imaging shortly after treatment is a useful predictor of long-term clinical outcome (survival) after definitive chemoradiotherapy.
Participants: Eligible patients are those older than 18 years with AJCC clinical stage IIB/III non-small cell lung carcinoma who are being planned for definitive concurrent chemoradiotherapy (inoperable disease).
ACRIN PROTOCOL 6678 Source: http://www.acrin.org/TabID/162/Default.aspx
Main Objectives: <ul style="list-style-type: none"> ▪ To test whether a metabolic response, defined as a $\geq 25\%$ decrease in peak tumor SUV post-cycle 1 of chemotherapy, provides early prediction of treatment outcome (tumor response and patient survival). ▪ To determine the test-retest reproducibility of quantitative assessment of tumor FDG uptake by SUVs. ▪ To evaluate in an exploratory analysis the time course of treatment induced changes in tumor FDG uptake. ▪ To evaluate in an exploratory analysis changes in tumor volume during chemotherapy by multislice CT.
Participants: Eligible participants for this trial are patients with advanced NSCLC (for Groups A and B: Stage IIIB with pleural effusion or Stage IV, who are scheduled to undergo palliative chemotherapy; for Group C, Stages IIIA, IIIB, or IV, with unspecified therapy) who meet the eligibility criteria. Patients with previously treated NSCLC may participate so long as they meet the eligibility criteria.

Reference Materials

¹Harris, Gardiner. "Scientists Say F.D.A. Ignored Radiation Warnings - NYTimes.com." *The New York Times - Breaking News, World News & Multimedia*. 28 Mar. 2010. Web 21 Apr. 2010.

<http://www.nytimes.com/2010/03/29/health/policy/29fda.html>

National Lung Screening Trial (NLST) by the National Cancer Institute

In November 2010, the National Cancer Institute (NCI) announced the initial results from the National Lung Screening Trial (NLST) screening over 53,000 current and former heavy smokers ages 55 to 74 and found that low-dose helical computed tomography (LDCT) had 20% fewer lung cancer deaths compared to standard chest X-ray screening (354 deaths vs. 442 deaths or 1.32% vs. 1.65%).

While a 20% reduction in lung cancer deaths using LDCT screening is an improvement over X-ray screening, investors should note the high false-positive rates (see table below) require additional and unnecessary testing. The high cost of using LDCT to improve the death rate from 1.65% to 1.32% may not be economically viable to be used as a primary lung cancer screening tool.

Results of National Lung Screening Trial (NLST) Presented at RSNA 2010								
Screening Results	Low Dose Helical CT				Chest X-Ray			
	Round 1	Round 2	Round 3	Total	Round 1	Round 2	Round 3	Total
Patients Screened	26,314	24,718	24,104	75,136	26,049	24,097	23,353	73,499
# Initial Positives	7,193	6,902	4,054	18,149	2,387	1,482	1,175	5,044
% Initial Positives	27.3%	27.9%	16.8%	24.2%	9.2%	6.2%	5.0%	6.9%
# Initial Positives	7,193	6,902	4,054	18,149	2,387	1,482	1,175	5,044
# Actual Lung Cancer	270	168	211	649	136	65	78	279
% True Positive	3.8%	2.4%	5.2%	3.6%	5.7%	4.4%	6.6%	5.5%
# No Lung Cancer	6,923	6,734	3,843	17,500	2,251	1,417	1,097	4,765
% False Positive	96.2%	97.6%	94.8%	96.4%	94.3%	95.6%	93.4%	94.5%

Source: Denise R. Aberle, MD, "National Lung Screening Trial-Trial Design and Initial Results", RSNA 2010

In addition, recent criticism of the high level of radiation exposure experienced by patients undergoing CT scans remains a concern. The total whole body effective dose that is ultimately delivered via a CT scan is calculated as a weighted average of the dose to each organ and is therefore higher for a low-dose lung CT scan, about 1.5 mGy as compared to a chest X-ray which delivers only about 0.02 mGy. The *New York Times* reported on March 28, 2010 that the radiation experienced by a patient undergoing a CT scan can be up to 400x greater than the radiation experienced in a standard chest X-ray.

In fact, the NCI itself cautions *"The possible disadvantages of helical CT include the cumulative effects of radiation from multiple CT scans; surgical and medical complications in patients who prove not to have lung cancer but who need additional testing to make that determination; and risks from additional diagnostic work-up for findings unrelated to potential lung cancer, such as liver or kidney disease. In addition, the screening process itself can generate suspicious findings that turn out not to be cancer in the vast majority of cases, producing significant anxiety and expense. These problems must, of course, be weighed against the advantage of a significant reduction in lung cancer mortality."*

We believe that Biomoda's CyPath[®] non-invasive lung cancer screening test, if successful, would represent a much safer, cheaper and more accurate (sensitivity & specificity) lung cancer screening test than LDCT.

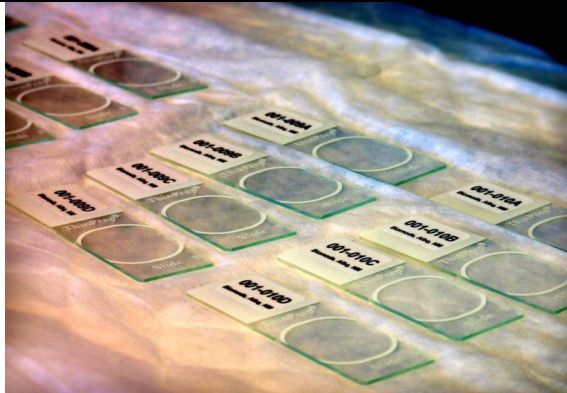
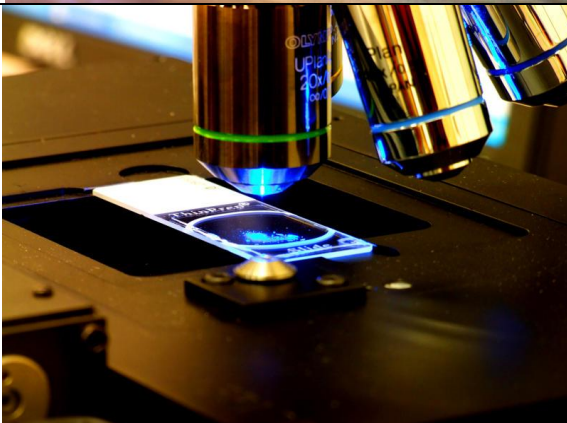

Reference Materials
National Cancer Institute Press Release http://www.cancer.gov/newscenter/pressreleases/NLSTresultsRelease
National Cancer Institute Question and Answer http://www.cancer.gov/newscenter/qa/2002/nlstqaQA
National Lung Cancer Screening Trial Design http://radiology.rsna.org/content/early/2010/10/28/radiol.10091808.full
New York Times CT Article http://www.nytimes.com/2010/03/29/health/policy/29fda.html

CyPath® Assay Lung Cancer Screening Technology

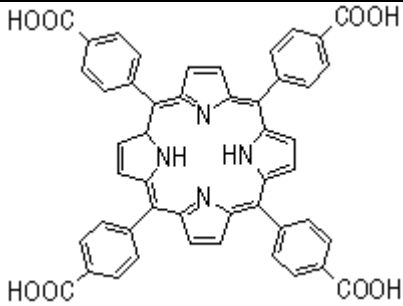
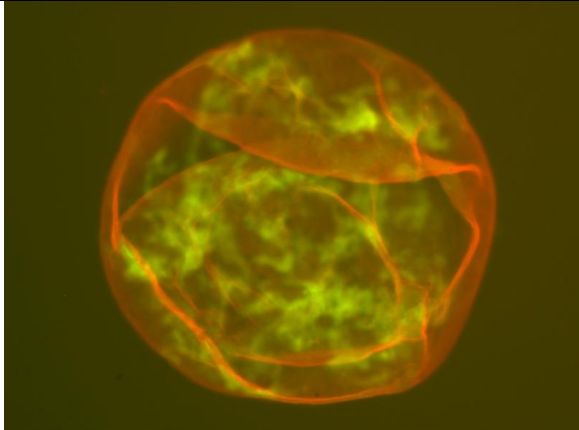
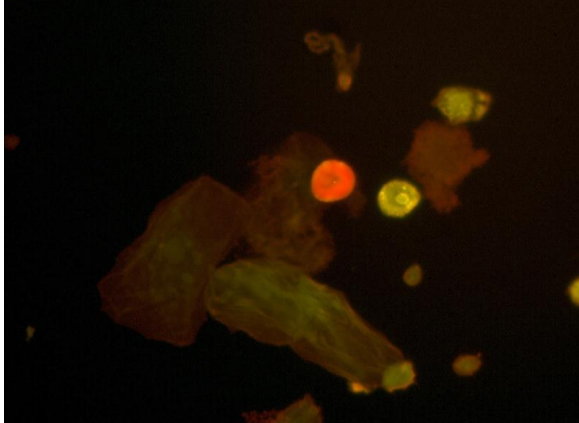
Biomoda's CyPath® assay for early lung cancer detection is an easy, non-invasive test of deep lung sputum. At the doctor's office, the patient receives an Acapella® device (sold by Smiths Medical) and a collection cup. The deep lung sputum sample is collected over 3 days with a triple morning cough procedure, and the patient returns the collection cup to the doctor's office or a laboratory drop-off point. At the laboratory, the sample is processed onto a microscope slide containing a monolayer of the patient's cells which are prepared using labeling reagents containing CyPath® and viewed with an ultraviolet microscope utilizing a special filter. The lab technician detects the presence of fluorescing red cells and other cellular metrics through computer computational analysis.

The preparation of the slides starts with the separation of the cells from the mucous and other cellular debris found in the sputum. This allows the lab technician to then apply a monolayer of the cells from the sputum onto a slide for labeling with the TCCP reagent. Once the appropriate amount of time has been reached for slide immersion in the reagent, the slides are rinsed, air dried and cover slipped.

The slide, now completed, is observed underneath an ultraviolet light utilizing a fluorescent microscope containing a special filter called a fluorescein isothiocyanate (FITC) filter. Normal cells appear white, green-yellow or pale orange in color and are transparent in appearance. Cancer cells appear dark crimson red and are opaque. This is due to the fact that the TCCP molecules bound to the malignant cells fluoresce at 650nm when excited by certain ultraviolet light. The presence of fluorescing red cells and other cellular metrics are evaluated under the microscope and the results are interpreted based on the characteristics of the cells on each slide.

TCCP	
<p>Sputum samples are prepared at Biomoda's laboratory. The cells are separated from the mucous and other cellular fragments and a slide is prepared with a monolayer of the cells.</p>	
<p>The slides are then treated with the TCCP labeling solution and examined under an ultraviolet fluorescent microscope.</p>	
<p>The lab technician detects the presence of fluorescing red cells and other cellular metrics through computer computational analysis</p>	

Source: Biomoda Inc.

5,10,15, 20-Tetrakis (Carboxyphenyl) Porphine (TCCP)	
	<p>5,10,15, 20-Tetrakis (Carboxyphenyl) Porphine (TCCP) has the chemical formula $C_{48}H_{30}N_4O_8$ and a porphyrin ring chemical composition</p>
	<p>It is proposed that TCCP binds to LDL receptors that are over exposed on the surface of malignant cells.</p>
	<p>Porphyrin ring derivatives including TCCP fluoresce when exposed to certain wavelengths of UV light. Malignant cells treated with TCCP fluoresce red (seen in center of photo) effectively identifying them from healthy tissue.</p>

Source: Biomoda Inc.

Specifically CyPath[®] is 5,10,15, 20-Tetrakis (Carboxyphenyl) Porphine (TCPP), a synthetically manufactured porphyrin. It is proposed that the binding CyPath[®] to malignant cells is a cell surface phenomenon where the TCPP binds to over expressed low density lipoprotein (LDL) receptors on neoplastic disease. There has been evidence before of other porphyrin's affinity to malignancies.

Discoveries and studies in the late 1940's that 1948 provided evidence that lipophilic and amphiphilic porphyrins have an affinity for neoplastic tissue, but the reasoning for this affinity was not clear.² Later studies have proposed a mechanism of action that explains this affinity that involves the binding of lipophilic and amphiphilic porphyrins to serum lipoproteins, in particular, low-density lipoproteins (LDLs).³ Some studies have proposed that an LDL can bind anywhere from 25-130 porphyrin molecules.⁴ It has also been demonstrated that the recognition of LDLs by their cell surface receptor is unaltered by the binding of porphyrins, providing an excellent mechanism for the localization of porphyrins in LDL receptor over-expressing neoplastic disease.⁵

Studies at the Department of Neurosurgery, Institute of Clinical Medicine, at the University of Tsukuba, Japan have also highlighted the connections between porphyrin rings and LDL receptors in cancer. Using flow cytometry, the scientists examined the simultaneous uptake of

porphyrin and low-density lipoprotein (LDL) by 4 established cell lines of glioma and normal fibroblasts. The results indicated porphyrin and LDL showed competitive conjugation with the LDL receptor, further supporting the theory that porphyrin uptake occurs via the LDL receptor.⁶

Reference Materials

²Figge, F.H.J., Weiland, G.S., Manganiello, L.O.J. 1948 Cancer detection and therapy. Affinity of neoplastic, embryonic and traumatized tissues for porphyrins and metalloporphyrins. *Proc. Soc. Exp. Biol. Med.* 68:640-641

³Kessel, D. 1986. Porphyrin-lipoprotein association as a factor in porphyrin localization. *Cancer Lett.* 33:183-188.

⁴Osterloh, J., Graca, M., Vincente, H. 2002 Mechanisms of porphyrinoid localization in tumors.. *J Porphyrins Phthalocyanines.* 6:305-324

⁵de Smidt, P. C., Versluis, A.J., van Berkel, T.J.. 1993. Properties of incorporation, redistribution, and integrity of porphyrin-low-density lipoprotein complexes. *Biochemistry.* 32:2916-2922.

⁶Nakajimad, Susumu, Isao Sakatac, Tadao Nosea, Kei Nakaia, Tetsuya Yamamotoa, Fumiyo Yoshidab, Akira Matsumuraa, and Yasushi Shibataa. "Competitive Uptake of Porphyrin and LDL via the LDL Receptor in Glioma Cell Lines: Flow Cytometric Analysis." *Cancer Letters* 166.1 (2001): 79-87. *Cancer Letters.* 10 May 2001. Web. 20 Apr. 2010. http://www.tulips.tsukuba.ac.jp/dspace/bitstream/2241/90828/1/CL_166-1.pdf

Acapella® Vibratory PEP Therapy System

While the pilot trial utilized the Lung Flute® (sold by Medical Acoustics LLC) for sputum sample collection, we anticipate that for the pivotal trial, Biomoda instead will use the FDA-cleared Acapella® device which combines high frequency oscillation and positive expiratory pressure (PEP) in a single unit. A lever with a magnet on the end is inside the device which intermittently interrupts the air flow causing a vibration in the lungs. A dial at one end adjusts the amount of resistance. When exhaling through the Acapella valve, the air flow moves the lever back and forth. The number and size of lever movements or frequency is based on the resistance of the air flow. There are 2 color-coded types (green for high-flow, blue for low) and both can adjust the frequency and flow resistance by turning the adjustment dial. The Acapella® is sold under the Portex brand of Smiths Medical, a division of Smiths Group (LSE:SMIN).



Source: Smiths Medical

The physical action of the Acapella facilitates mucus clearing with vibration and pressure causing lung secretions to thin and become expelled. It is the endothelial cells found in the secretions or sputum that Biomoda tests for neoplastic disease using their CyPath® technology.

Porphyrin Use in Oncology

PHOTOFRIN®

The image displays three chemical structures of porphyrin derivatives, showing various substituents like methyl, sodium acetate, and sodium propionate groups. Below the structures is a photograph of a Photofrin injection vial and its packaging box, which includes the text: 'PHOTOFRIN (porfimer sodium) For Injection 75 mg Single Use Vial For Intravenous Use Only'. To the right of the photograph is a microscopic image showing red fluorescent structures, likely representing the porphyrin-based photosensitizer.

Source: Axcan Pharma Inc.

Porphyrin-based therapeutics have been approved for oncology indications in the past. Through a process called photodynamic therapy (PDT) porphyrin based photosensitizers are used in conjunction with specific wavelengths of visible and near-infrared light to destroy the diseased tissues to which the photosensitizer is bound. The light excites the photosensitizer from its ground state which in turn reacts with oxygen found in the tissue, creating oxygen free radical species that destroy the cells they come into contact with.

An example of one of these already approved photosensitizers is Photofrin® made by Canadian, privately held Axcan Pharma Inc. Photofrin® is a liquid formulation of porfimer sodium for intravenous injection. Porfimer sodium consists of an assortment of oligomers of up to eight porphyrin rings attached by either ether or ester linkages.

The cytotoxic effects of Photofrin® are light and oxygen dependent. Photofrin® is administered systemically via intravenous injection. Clearance of the photosensitizer from a variety of tissues occurs over 40-72 hours, but tumors, skin, and organs of the reticuloendothelial system (liver and spleen) retain Photofrin® for a longer period.

As with Biomoda's CyPath® technology, Photofrin's affinity to malignancies seems to be related to the increase in LDL receptors on the cell surface.⁷

Once bound to the malignant lesions, the tumor is selectively bombarded with 630nm wavelength laser light. This specific wavelength of light excites the photosensitizer which in turn creates the reactive oxygen species that destroy the surrounding tissue.

Photofrin[®] has been approved by the FDA for the treatment of Esophageal Cancer, Endobronchial Cancer, and High-Grade Dysplasia in Barrett's Esophagus. We believe the approval of Photofrin[®] in these indications represents validation for the possible tumor targeting ability of Porphyrin ring-based compounds. Although TCPP and porfimer sodium are different molecules, they share very similar physical chemical characteristics, we believe that they have very similar chemical properties when it come to targeting malignancies.

Reference Materials

⁷Polonovski, J., JP Reyftmann, L. Dubertret, R. Santus, S. Goldstein, JC Mazière, P. Morlière, and C. Candide. "In Vitro Interaction of the Photoactive Anticancer Porphyrin Derivative Photofrin II with Low Density Lipoprotein, and Its Delivery to Cultured Human Fibroblasts." FEBS Lett. 207.1 (1986): 133-38. U.S. National Library of Medicine, National Institutes of Health. Web. 21 Apr. 2010.

<http://www.ncbi.nlm.nih.gov/pubmed/2945739>

Clinical Trials

In March 2009, Biomoda received Institutional Review Board (IRB) approval for its pilot Phase II clinical study. The study is in partnership with the New Mexico Department of Veterans Services and is designed to screen up to 520 high-risk New Mexican veteran participants, "20 pack-year" smokers (individuals who have smoked one pack a day for 20 years or two packs a day for 10 years) for lung cancer.

Update:

On March 30, 2011 Biomoda released top line results from their pilot study showing Sensitivity, or proportion of actual positives which are correctly identified, was 77%. Specificity, or proportion of negatives which are correctly identified, was 58%. The overall accuracy of the assay to correctly classify groups of study participants into the cancer or high-risk cohorts was 81.3%. These results were statistically significant with a p-value of less than 0.001 determined by Receiver Operating Characteristic (ROC) analysis of the sensitivity and specificity. Adequate sputum samples were collected from 113 individuals in the high-risk cohort but 11 were dismissed because of either the presence of suspect nodules, or they could not be reached to confirm that they did not develop lung cancer. The remaining 102 samples comprising the intent-to-treat group were compared to samples from 26 individuals in the positive control arm, who had confirmed lung cancer and had not yet begun treatment for their disease. Each of the deep-lung sputum samples were processed into 12 slides and treated with CyPath[®] labeling solution and viewed under a fluorescent microscope for the presence of fluorescing cells. The 12 slides prepared from each patient sample represent about 600,000 cells out of the millions of cells contained in the total sputum sample. The pilot study was able to show proof of concept that CyPath[®] is able to identify quantitative differences between the high-risk and the cancer cohorts of the study.

Biomoda is now investigating new techniques to improve the sensitivity and specificity of the CyPath[®] assay. Sputum sample collection methods are being evaluated to improve sample quality. Flow cytometry is also being investigated as a method to increase the quantity of cellular analysis to evaluate the entire deep-lung sputum sample. Process automation and optimization, including definition of cell matrices for quantitative measurement, morphological analysis and differentiation between dysplastic cells and cancer cells, are under review for a future pivotal trial launch.

PHASE I/II HUMAN CLINICAL TRIAL PROTOCOL

Title	Sputum Labeling Utilizing Synthetic Meso Tetra (4-Carboxyphenyl) Porphine (TCPP) for Detection of Lung Cancer
# of Patients	520 (male and female)
Trial Design	Interventional, Diagnostic, Single Blind (Investigator), Non-Randomized, Historical Control, Parallel Assignment
Ages	18 Years and Older
Endpoints	Primary: Efficacy (Clinical Sensitivity and Specificity)
Cohort 1:	Heavy Smoker: Defined as 20 pack years or greater (e.g., 1 pack/day for 20 years or 2 packs/day for 10 years).
Cohort 2:	Known Lung Cancer: Recently diagnosed with Stage I - IV lung cancer with either central (bronchogenic) or peripheral tumor location, and prior to surgery or other therapy for the cancer; Participants with a central or peripheral pulmonary recurrence of lung cancer following primary therapy may also be enrolled. Sputum samples for this cohort may be collected at or after a diagnostic bronchoscopy.
Inclusion	Male or female Veterans Study Participants must be willing to provide primary care physician contact information and agree to have medical

	information released if indicated
	Meet requirements of one of the two cohorts in the study
Exclusion	Severe obstructive lung disease
	Angina with minimal exertion
	Pregnancy
	Have or have had cancer other than lung cancer
	Worked in the mining Industry
Investigators	Constance Dorian, BS Biology (Study Director)
	Lara Patriquin, MD- Radiology Associates of Albuquerque
	Thomas Bauer, MD- Helen F Graham Cancer Center, Christiana Care

Source: ClinicalTrials.gov NCT00894127

Pending assay optimization and finalization, Biomoda plans to file an Investigational Device Exemption (IDE) with the FDA to review the pivotal Phase III study protocol. Study sites, Principal investigator and a CRO have been identified for this proposed larger trial.

Biomoda plans to move forward with conducting the larger pivotal multi-site study in preparation for a Premarket Approval Application (PMA) filing with the FDA. The primary endpoint in the study design has been proposed as the identification of 50 asymptomatic patients from a high-risk “20 pack-year” smoker patient population. Depending on the prevalence rate of lung cancer in this population the number of patients in this trial could range from 2,000 to 3,500 people.

On November 15th, 2010 Biomoda announced an alliance with Quintiles Global Central Laboratories to help refine the automated image recognition system for measuring the photon emission rate and cell morphology of CyPath®-stained cells to detect early stage lung cancer. Under the terms of the agreement, Quintiles will review CyPath®-stained slides and pap-stained slides to analyze the cell matrices and help Biomoda further calibrate the “signature” of cancer and other aberrant cells that have been labeled with the CyPath® solution.

In further preparation, Biomoda announced on December 1st, 2010 that they have selected RCRI, Inc., to be the Contract Research Organization (CRO) for the proposed pivotal clinical trial of the CyPath® diagnostic for early detection of lung cancer. RCRI will support the CyPath® pivotal clinical trial by providing Biomoda with a comprehensive suite of clinical study services, including project management, site identification, recruitment, data management, statistical design and reimbursement strategy.

Supporting Studies

Biomoda Internal Studies

In June 2008, Biomoda conducted an in-house validation study of the CyPath® Lung Cancer screening assay. The study was initiated with an approved protocol and informed consent that was reviewed and approved by a duly constituted Institutional Review Board (IRB). The study compared the sputum samples from 27 different patients; 15 heavy smoker patients with lung cancer, and 12 normal or healthy patients with no history of smoking or lung cancer.

IN HOUSE VALIDATION STUDIES	
# of Patients	27 (male and female)
Ages	18 Years and Older
Endpoints	Primary: Efficacy (Clinical Sensitivity and Specificity)
Cohort 1:	15 Heavy Smoker with Known Lung Cancer: Defined as 20 pack years or greater (e.g., 1 pack/day for 20 years or 2 packs/day for 10 years).
Cohort 2:	12 Normal Patients: Defined as those who have never smoked and do not have a history or diagnosis of lung cancer
Exclusion	Severe obstructive lung disease
	Angina with minimal exertion
	Uncontrolled Asthma
	Those on supplemental oxygen
Investigator	Biomoda

Source: Biomoda Inc.

RESULTS		
Sample	Number of Patients	Number of Positive for Fluorescence
Normal	12	0
Lung Cancer	15	15

Source: Biomoda Inc.

The results from this study showed 100% specificity (12/12) and 100% sensitivity (15/15) for the CyPath Assay Technology

St. Mary's/Los Alamos Laboratory Collaborative Studies

St. Mary's Hospital and the Isotope and Nuclear Chemistry Division of the Medical Radioisotopes Research Program at Los Alamos National Laboratory conducted four preliminary studies prior to application of a patent for 5,10,15,20-tetrakis (4-carboxyphenyl) porphine (TCPP).

In the first study, the localization of TCPP versus 3 other porphyrin's with known tumor uptake to cancerous cells was examined. The experiment looked at two different sputum samples, both from Uranium miners. The test subject had confirmed squamous cell lung carcinoma, the control subject had no confirmed cancer, but did suffer from chronic obstructive pulmonary disease (COPD). The goals of this study were to:

- Compare different sputum processing procedures including investigating optimal incubating time of cells for porphyrin uptake
- Compare TCPP uptake to other porphyrins with known tumor affinity
- Compare TCPP uptake in both test and control samples, and verify the TCPP localization to malignant sputum cells.

Results:

- Sputum samples processed with alcohol and carbowax or alcohol (no carbowax) had a larger number of cells free of the mucus than samples processed with phosphate buffered saline (PBS) or unprocessed (raw) samples.
- Sputum samples which had been incubated with TCPP had the greatest number of cells fluorescing (greatest porphyrin uptake) as compared with the three other porphyrins studied. The fluorescent intensity (brightness) of the cells that had localized porphyrin was also greater in samples processed with TCPP than in samples processed with the other porphyrins.
- When sputum cells were incubated with porphyrin for 24 hours and then washed with PBS, the porphyrin remained attached to the cells.
- When porphyrin uptake in the test and control samples was compared, the porphyrin uptake in the control cells was considerably lower than the uptake in the test samples. In addition, the fluorescence intensity of the few control cells that did fluoresce was lower than the fluorescence intensity of the test cells. The most dramatic difference between uptake of porphyrin by test and control sputum cells was seen in samples incubated with TCPP.
- After first staining neoplastic cells in the samples using the PAP, researchers re-examined samples and determined that TCPP fluorescence was seen in every neoplastic cell identified on sputum samples.

The second study was designed to evaluate the localization of TCPP in different lung cancer patients with different types of lung cancer. Sputum samples from 12 uranium miners with differing medical histories were examined for TCPP localization. Eight of the twelve patients had lung cancer, based on medical history and previous PAP staining. These subjects were confirmed for disease by biopsy. There were a variety of lung cancers including three squamous cell lung cancers, three oat cell (small cell) lung cancers, one adenocarcinoma, and one advanced metastatic lymphoma that had spread to the lung. The remaining four patients had been judged free of disease by PAP staining, but had not been biopsied.

The samples were blinded and labeled with the TCPP compound. Researchers analyzed the samples for number of fluorescent cells then multiplied that number by a subjective number between one and four that represented the brightness

of the cells that were fluorescent compared to the cells with only “background” levels of fluorescence. The resulting number gave the sample an assigned a fluorescence index (FI).

The preliminary results showed that 11 out of 12 samples with the highest FI values were from cancer patients, and the lowest FI values were found in controls or normal samples. One exception was found in a sample that had a FI similar to the known cancer patients, but had been labeled as a control. Upon further investigation, prompted by the TCPP results, another PAP stain analysis, determined that this subject had been previously misdiagnosed by PAP stain cytopathology, and consequently had lung cancer. This correction, the addition of one more control or normal sample and one additional cancer sample yielded these results.

FLUORESCENT INDEX (FI)		
Cancer Patients	Number of Patients	FI (mean)
Squamous cell	5	83.5
Adenocarcinoma	1	68.0
Small cell carcinoma	3	42.7
Metastatic lymphoma	1	>150.0
Non-cancerous	4	15.2

Source: Biomoda Inc.

The FI of sputum from cancer patients was 3x to 8x greater than from control or normal samples, making disease more easily distinguishable from healthy tissue. This was best exemplified by TCPP ability to identify the false negative that the initial PAP stain test let through. The results from this blinded study also showed 100% specificity (4/4) and 100% sensitivity (10/10).

The third and fourth studies were conducted to determine whether TCPP would also localize in human lung cancer cells grown in tissue culture and whether flow cytometry could be used to identify lung cancer cells which have localized the TCPP. A study was done in both a human squamous lung cancer cell line as well as a human small cell (oat cell) lung carcinoma cell line. Both of these studies yielded positive results for localization and use in flow cytometry. US Patent # 5,162,231 (*Method of using 5,10,15,20-tetrakis (carboxyphenyl) porphine for detecting cancers of the lung*) was awarded based on the results of these four studies.⁸

Reference Materials

⁸Cole, Dean A., David C. Moody, III, Edward L. Ellinwood, and Gerard M. Klein. Method of Using 5,10,15,20-tetrakis(carboxyphenyl)porphine for Detecting Cancers of the Lung. Patent 5,162,231. 10 Nov. 1992. Web. 21 Apr. 2010 <http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fmetahtml%2FPTO%2Fsearch-bool.html&r=1&f=G&l=50&co1=AND&d=PTXT&s1=5,162,231.PN.&OS=PN/5,162,231&RS=PN/5,162,231>

Other Markets

While currently TCPP and the CyPath[®] platform is being developed for the detection of Lung Cancer, the system of malignancy detection can easily be adapted to other types of cancers. Bladder cancer incidence, like lung cancer, has a strong correlation to individuals that smoke. It has been reported that nearly half of all bladder cancer cases in males are in smokers or those who used to smoke.⁹ Other studies have discovered a linear relationship between smoking and bladder cancer risk, and that quitting smoking leads to a better risk profile when it comes to developing the disease.¹⁰ The CyPath[®] platform can easily be adapted as a diagnostic tool for the detection of bladder cancer by testing the endothelial cells found in urine with TCPP in the same fashion as the lung cells are tested in from the sputum in lung cancer. By changing the sample collection the technology can be applied to many different types of cancer (*see table on right*).

Adaptability of CyPath Technology	
Cancer	Sample Collection
Lung	Sputum
Cervical	Traditional Brushing
Breast	Ductal Lavage
Colorectal	Stool
Bladder	Urine
Circulating Tumor Cells (CTC)	Blood

Source: Biomoda Inc. and LifeTech Capital

TCPP could also have possible applications outside of the realm of diagnostics. The technology could be developed as surgical marker that could be used by surgeons to aid in the resection of tumors. The boundary between malignant and healthy tissue when removing a tumor can be very difficult to identify, causing surgeons to often remove more healthy tissue than needed during the procedure. A topical TCPP solution applied in the operating room may act as an accurate aid to the doctor by binding to the cancer cells and fluorescing under UV light, and thus provide the surgeon with a clear image of the tissue to be removed.

There are possible therapeutic uses for TCPP in oncology as well. Porphyrin rings, as found in hemoglobin, are able to carry heavy metal atoms, or other molecule in their center. In the case of hemoglobin, the porphyrin ring carries iron in its center which allows the transport of both oxygen and carbon dioxide, and other gases through the bloodstream. This empty pocket inside TCCP could carry a radioactive molecule or other therapeutic, directly targeting cancer cells. There has been experimentation with TCCP in this area already by the scientists at Los Alamos National Laboratory. They attached a radioactive form of copper to TCPP called Cu67, to target cancerous cells directly. Biomoda has also conducted some internal preliminary studies using gold nanoparticles with a piezo coating and a tuned laser to destroy cancer cells in a targeted fashion very similar to the mechanism found in Photo Dynamic Therapy (see *Porphyrin use in Oncology*).

While all of these new markets are potential future products for the company, we have not yet included them in our financial models. However, should the development pathways become more certain, they could represent potential upside.

Reference Materials

⁹ACS : What Are the Risk Factors for Bladder Cancer? *American Cancer Society: Information and Resources for Cancer: Breast, Colon, Prostate, Lung and Other Forms*. Web. 27 Apr. 2010.
http://www.cancer.org/docroot/CRI/content/CRI_2_4_2X_What_are_the_risk_factors_for_bladder_cancer_44.asp

¹⁰Boffetta P (2008). "Tobacco smoking and risk of bladder cancer". *Scand J Urol Nephrol Suppl* **42** (S218): 45–54. Web. 23 Apr. 2010. <http://informahealthcare.com/doi/abs/10.1080/03008880802283664>

Intellectual Property

Biomoda has a number of patents and patent applications as shown below. We expect additional patent applications will be filed in the future as development progresses.

SELECTED BIOMODA U.S. INTELLECTUAL PROPERTY FILINGS			
NUMBER	DESCRIPTION	FILED	ISSUED
6,838,248	Compositions and Methods for Detecting Pre-Cancerous Conditions in Cell and Tissue Samples Using 5, 10, 15, 20-Tetrakis (Carboxyphenyl) Porphine	November 19, 2001	January 4, 2005
7,384,764	Method for Prognosing Response to Cancer Therapy with 5, 10, 15, 20-Tetrakis (Carboxyphenyl) Porphine	September 2, 2004	June 10, 2008
12/133,855	Compositions and Methods of Making 5, 10, 15, 20-Tetrakis (Carboxyphenyl) Porphine	June 5, 2008	Pending
61/226,646	System and Method for Analyzing Samples Labeled with 5, 10, 15, 20-Tetrakis (4-Carboxyphenyl) Porphine	July 17, 2009	Pending
SELECTED BIOMODA INTERNATIONAL INTELLECTUAL PROPERTY FILINGS			
NUMBER	COUNTRY	FILED	ISSUED
2,429,526	Canada	November 28, 2006	Allowed
01987011.2	Europe	November 19, 2001	Pending
4307070	Japan	November 19, 2001	May 15, 2009
2008-266490	Japan	October 15, 2008	Pending
PA/a/2003/004406	Mexico	November 19, 2001	Allowed
2002239269	Australia	December 4, 2008	December 4, 2008

Source: U.S. Patent and Trademark Office & Biomoda Inc.

Competition

Biomoda believes that CyPath[®] represents a superior methodology as compared to other diagnostic modalities currently in use and under development (*see below*). CyPath's potential combination of a non-invasive, inexpensive and accurate assay would make it suitable for lung cancer screening.

Competitive Technologies			
Type	Description	Pros	Cons
CyPath [®] Biomoda	Molecular marker-based assay used on non-invasively collected body fluids.	Early lung and bladder cancer diagnostic, low cost with high sensitivity/specificity. Ease of use. Non-invasive.	Pathologist identifies the presence of cancer cells in an onco-labeled sample by color under UV light.
Proteomics	Modeling protein expression for diagnostic purposes.	Can develop possible therapy routes.	In early stages of R&D. Commercial applications questionable. High cost.
Biomarkers	Engineered antibodies for detecting specific cell types or antigens	Commercialized in the form of kits like the PSA test.	High cost to manufacture and store. Requires refrigeration. Not for early detection.
Cytology Stains (PAP)	A complicated staining procedure for cellular evaluation. Used for diagnosing cervical cancer.	Established infrastructure supporting cervical diagnosis. Low cost at \$45 to \$60.	Not proven to be effective for early detection of lung and bladder cancer. Low accuracy (64%) assay variability.
Genomics	Models gene expression for diagnostic purposes.	Can develop possible therapy routes.	Multiple expression paths, difficult to deduce a definitive result. High cost at \$1,000+.
Cancer Byproducts (Breath analysis)	Cancer cells produce metabolic byproducts. Example: methylation.	Non-invasive.	Still in early stages of R&D. Uses complicated equipment. Costs undisclosed or unknown.
Radiology-Computer Tomography (Spiral CT)	Advanced X-ray technology.	Currently being used to stage lung tumors.	Cannot confirm if cancer is present, but will identify abnormalities in lung. Not practical for screening large populations. Radiation exposure. High cost at \$500 to \$1,500.
Radiology-Positron Emission Tomography (PET)	An advanced imaging technology based on the emission of positrons from an injected-metabolized imaging agent.	High-resolution images.	Cannot confirm if cancer is present, but will identify abnormalities in lung. Not considered early detection. Radiation exposure. High cost at \$850 to \$4,000.
Bronchoscopy	Based on fiber optics and image capture.	View lesions in situ.	Requires an invasive procedure and complicated equipment. High cost at \$1,000+.

Source: Biomoda Inc.

Management

Maria Zannes, Chief Executive Officer, Chairman: Prior to her work with Biomoda, Zannes was president of the Energy Recovery Council, a national waste-to-energy trade group in Washington, D.C., for 10 years and consulted for private clients in the medical, environmental and energy industries. She is a research associate with Columbia University Earth Engineering Center and co-founder of two research centers at Columbia. She previously held managerial positions at ECOS Corporation, a subsidiary of Burlington Environmental, and Wheelabrator Technologies, Inc., a subsidiary of Waste Management. Zannes is licensed to practice law in Washington state and New Mexico.

John J. Cousins, President, Chief Financial Officer and Director: John Cousins has 25 years of management experience. He also serves as Biomoda's Chief Financial Officer and has 10 years experience as a public company CFO. Mr. Cousins began his career as an electronics engineer, and he has worked for the ABC Television Network and Ampex. He has also been an entrepreneur and owned and operated his own businesses. Mr. Cousins holds undergraduate degrees from the Massachusetts Institute of Technology and Boston University. He earned an MBA from the Wharton School of Business at the University of Pennsylvania.

Constance Dorian, Vice President of Technical Operations: Constance Dorian has 20 years experience in the design and development of in-vitro diagnostic assays, clinical studies, quality control, prepared slides, quality assurance, product support programs, product improvement programs, cost reduction programs, contract negotiations, inventory control, and production planning following FDA Guidelines. She holds a degree in biology from San Diego State University.

Gordon Bennett, Fluorescence Microscopist: Gordon Bennett has a B.S. in physics as well as a J.D. from the University of New Mexico. His background is in photonics and electronics. Previously, he served as an adjunct faculty member at the College of Santa Fe and has held the Chair in Photonics and Biophotonics at Central New Mexico Community College in Albuquerque, New Mexico. He is currently a member of the Optical Society of America and the New Mexico State Bar.

Angela Montoya, Research Associate: Angela Montoya holds science degrees from the University of New Mexico. Her expertise is in the coordination, conduction, and analysis of environmental and clinical research. She is currently working towards an M.S. in Health Education.

Tim Zannes, General Counsel: Tim Zannes is a partner in the Zannes Firm. He previously ran a private investigation firm in New Mexico after leaving a position with the Albuquerque City Attorney's Office. He worked for the firm of Lambros and Lambros in Cleveland, Ohio. Mr. Zannes attended the University of North Carolina and the University of New Mexico where he earned his JD degree.

Verrity Gershin, Director of Administration: Verrity Gershin has 11 years of experience in accounting, corporate filings and corporate administrative support. Ms. Gershin assisted with Biomoda's initial public offering and provides assistance on compliance with federal securities law. Ms. Gershin holds a bachelors degree from the University of New Mexico.

BOARD OF DIRECTORS

Maria Zannes, Director and Corporate Secretary: Maria Zannes brings more than 30 years of experience in the environmental and energy industries where she worked in multiple capacities, including federal lobbyist and company president. Formerly president of a national waste-to-energy trade group in Washington, D.C., Ms. Zannes currently consults for private clients in the medical and environmental industries. Ms. Zannes was a legislative aide and press secretary to U.S. Rep. Charles Wilson (D-Texas) after leaving her home state of New Mexico where she began her career as a journalist. Ms. Zannes is licensed to practice law in Washington State and New Mexico.

David Lambros, Director: David Lambros was the elected law director of Brook Park, Ohio, and presently serves as the law director of the Village of Valley View and the Village of Kelley's Island, Ohio. As law director, Mr. Lambros serves as chief legal counsel to cities negotiating with corporations and businesses, and is an expert in municipal law. Mr. Lambros has practiced law for more than 25 years and served on various boards, including Commerce Exchange Bank and Southwest General Hospital. Mr. Lambros presently is a director on the Systems Board at Southwest General Hospital, a multi-million dollar company.

Lewis White, Director: Lewis White is Chief Executive Officer and Director of New Energies Nebraska, LLC, a subsidiary of Standard Alcohol Company. Previously, Mr. White was CEO of Los Hojas Corporation and owned a successful childcare business for 20 years. He has also been a real estate investor, principal of a food services business catering to niche markets and an employee of the State of Nebraska. Mr. White earned a business administration degree from the University of Nebraska at Omaha. He is a major shareholder in Biomoda.

MEDICAL ADVISORY BOARD

Thomas Bauer, MD, is Chief of Thoracic Surgery at Helen F Graham Cancer Center in Newark, Delaware, and Principal Investigator of the Biomoda Phase II clinical trial currently underway. Dr. Bauer is Principal Investigator of three additional lung cancer screening trials through I-ELCAP and one breath test screen. He has two other current academic appointments (Jefferson Medical College and Arcadia University). Dr. Bauer has authored dozens of peer- and nonpeer-reviewed publications and abstracts. He serves on many committees and programs and belongs to dozens of associations.

Dan Merrick, MD, is known for his work in anatomic and clinical pathology, and molecular genetic pathology. He has published several papers on lung cancer and is an expert on sputum cytology. Dr. Merrick graduated from the University of Washington Medical School.

Tim Kennedy, MD, is associated with the University of Colorado and specializes in internal medicine, pulmonology and cytopathology. He is an expert in sputum cytology. Dr. Kennedy has authored many peer-reviewed publications, belongs to dozens of professional societies and serves on many committees. He has held faculty positions at the University of Arizona and University of Colorado Health Sciences Center.

Ramesh Gopal, MD, is a board-certified radiation oncologist serving as Medical Director of radiation treatment at the M.D. Anderson Cancer Center satellite at the Presbyterian Kaseman Hospital in Albuquerque, New Mexico.

Lara Patriquin, MD, is a Principal Investigator for Biomoda's Phase II clinical trial. Dr. Patriquin is a radiologist at Radiology Associates and Presbyterian Hospital.

Steve Groshong, MD, PhD, is a pathologist at the National Jewish Hospital in Denver and Assistant Professor at the University of Colorado, Denver.

SCIENTIFIC ADVISORY BOARD

Marty Jacobson, PhD, is an Adjunct Professor of microbiology at Mesa State College in Colorado and a scientist at the Saccomanno Institute, St. Mary's Hospital in Grand Junction, Colorado. He has published dozens of scientific papers.

Srinivas Mukkamala, PhD, is an Adjunct Professor at the New Mexico Institute for Mining and Technology. His research focus is on information assurance, digital forensics, knowledge mining, applied soft computing techniques, bioinformatics, information and network security practices.

David Faguy, PhD, is an Adjunct Assistant Professor, Department of Molecular Genetics and Microbiology, at the University of New Mexico School of Medicine. He has published numerous peer-reviewed research publications.

CLINICAL ADVISORY BOARD

Richard Phillips, MSPH, PhD, is a Principal Consultant in medical device development at Quintiles Consulting. Previously, he worked in the FDA's Office of Device Evaluation, serving as a first-line scientific reviewer in the Chemistry and Toxicology Branch, Division of Clinical Laboratory Devices, and then as Chief, Anesthesiology and Defibrillator Devices Branch, Division of Cardiovascular, Respiratory and Neurological Devices. Before joining FDA, Dr. Phillips worked for three in-vitro diagnostic device companies as Director of Clinical Research/Clinical Affairs. Dr. Phillips is a Diplomate of the American Board of Forensic Toxicology and the author of numerous papers in clinical chemistry, analytical and forensic toxicology, and in-vitro diagnostic devices. He is a member of the American Association for Clinical Chemistry, Association of Clinical Scientists, Clinical Ligand Assay Society, Society of Forensic Toxicologists, and the American Academy of Forensic Sciences. Dr. Phillips earned his BS in biology and chemistry from Marian University, his MSPH from the University of North Carolina, Chapel Hill, and his PhD from Indiana University.

Richard Holcomb, PhD, is an Associate Senior Consultant with Quintiles. Dr. Holcomb works with clients in the medical device, pharmaceutical, biologic and biotechnology industries to develop and implement preclinical and clinical development plans, with special emphasis on medical devices regulated by the FDA. Dr. Holcomb has a B.S. in mathematics from Michigan Technological University, an MS and a PhD in biometry from the University of Minnesota.

Tom Zimmerman, Contract Research Organization (CRO) Project Advisor with Alquest, Inc., has 25 years experience in clinical laboratory operations and management. He is an expert in laboratory logistics, data management, point-of-care issues, quality assurance and validation. Mr. Zimmerman has worked for Nichols Institute Reference Laboratories, SmithKline Beecham Clinical Laboratories, Focus Diagnostics, Medtox Laboratories, ViroMed Laboratories, and Mayo Medical Laboratories/Clinical Trial Services where he was senior analyst programmer and operations administrator for Core Laboratory Services. Tom earned his BA from St. Cloud State University in Minnesota.

Risks

Some of the operational and financial risks to Biomoda Inc. are:

- **Need to Raise Additional Funds:** Per their 10-Q filing, *“Biomoda currently is insolvent and will remain insolvent until new funding is secured. The Company is investigating all means of funding, including restructuring. Management believes that Biomoda’s technology is sound and can be developed to commercialization if funding for research and clinical trials can be secured. Management will continue to work despite lack of funds to procure investment, and the Company is in conversations with several investment funds to resolve the current financial situation and continue forward with technology and commercial development. Biomoda currently has obligations of approximately \$1,000,000. The anticipated capital needs for the next 12 months are \$2,000,000, for a total capital raise of \$3,000,000. This amount is planned to fund the optimization work leading to the pivotal trial.”* We are uncertain if Biomoda can successfully raise funds in a timely manner or in a sufficient amount to continue development work.
- **FDA and Regulatory risks:** All of Biomoda Inc.’s products are ultimately reliant on approvals by the U.S. FDA and other national regulatory bodies. There can be no guarantee of timely or definite FDA or other national regulatory body approvals for any of their pipeline products.
- **Partnerships:** Biomoda Inc. is reliant on partners to successfully develop, conduct clinical trials and prepare regulatory filings for its products. Failure of Biomoda Inc.’s existing or future partners to perform satisfactorily or in a timely fashion could adversely impact the company’s financial position.
- **Patent Litigation:** Third-party claims of infringement of intellectual property could require Biomoda Inc. to spend time and money on defending their intellectual property rights up to and including adverse judgments against Biomoda.
- **Small-Capitalization and Liquidity:** Biomoda Inc. currently trades on the OTC Bulletin Board which may result in both lower trading volume and liquidity possibly leading to large spreads and high volatility in the stock price. Investors should note that small-cap stocks have additional risks that may result in trading at a discount to their peers. Investors should also note the higher probability of financial default and higher degree of financial distress inherent in the small-cap segment of the market. However, we believe Biomoda Inc. will pursue a listing on the Nasdaq or AMEX exchanges sometime in the future which could result in higher trading volume and liquidity.
- **Sector Rotation:** Biomoda Inc. is a small biotechnology diagnostic development company often kept in a portfolio with similar companies. In such cases, a significant event for one company may have a material impact on the valuation of all similar companies regardless of their unique qualities.

Biomoda Inc.
Consolidated Income Statement

FYE DEC 31st

	2008	1Q09	2Q09	3Q09	4Q09	2009	1Q10	2Q10	3Q10	4Q10	2010	1Q11	2Q11
U.S.	0	0	0	0	0	0	0	0	0	0	0	0	0
Europe	0	0	0	0	0	0	0	0	0	0	0	0	0
Total Revenues	0	0	0	0	0	0	0	0	0	0	0	0	0
Cost of Goods Sold	0	0	0	0	0	0	0	0	0	0	0	0	0
Gross Profit	0	0	0	0	0	0	0	0	0	0	0	0	0
Research & Development, Net of Grants	91,308	(5,059)	16,389	44,489	(51,539)	4,280	47,950	111,622	118,122	132,947	410,641	154,129	66,704
Professional Fees	192,226	40,928	27,452	26,899	136,169	231,448	111,347	64,597	46,936	38,053	260,933	79,538	(7,247)
Depreciation and Amortization	52,205	16,114	7,168	6,085	6,161	35,528	6,230	2,703	3,348	8,243	20,524	8,816	9,462
Sales & Marketing	0	0	0	0	0	0	0	0	0	0	0	0	0
General and Administrative	978,192	42,612	52,394	346,213	176,922	618,141	264,367	258,752	531,701	226,620	1,281,440	217,527	171,273
Total Operating Expenses	1,313,931	94,595	103,403	423,686	267,713	889,397	429,894	437,674	700,107	405,863	1,973,538	460,010	240,192
Income from Operations	(1,313,931)	(94,595)	(103,403)	(423,686)	(267,713)	(889,397)	(429,894)	(437,674)	(700,107)	(405,863)	(1,973,538)	(460,010)	(240,192)
Other Income	118	0	0	0	0	0	0	0	0	0	0	0	0
Gain on Extinguishment of Debt	1,043,925	0	0	0	0	0	0	0	0	0	0	0	0
Gain on Sale of Assets	0	0	0	0	0	0	2,068	0	0	120	2,188	0	3,000
Unrealized Gain (Loss) on Warrants	0	0	0	0	0	0	(1,323,549)	1,777,070	593,285	946,986	1,993,792	(93,745)	(2,802,732)
Unrealized Gain (Loss) on Options	0	0	0	0	0	0	(7,083)	12,336	3,089	10,250	18,592	(441)	4,568
Unrealized Gain (Loss) Note Conversion	0	0	0	0	0	0	0	0	0	(90,221)	(90,221)	(190,732)	401,319
Other Income	0	0	0	0	0	0	0	0	0	244,479	244,479	0	0
Interest Income	0	0	0	0	0	0	0	201	51	296	548	84	0
Interest Expense	(45,375)	(3,399)	(3,967)	(3,967)	(4,559)	(15,892)	(3,958)	(3,934)	(673,477)	(170,252)	(851,621)	(157,965)	(247,289)
Total Other Income/Expense	998,668	(3,399)	(3,967)	(3,967)	(4,559)	(15,892)	(1,332,522)	1,785,673	(77,052)	941,658	1,317,757	(442,799)	(2,641,134)
Income Before Tax	(315,263)	(97,994)	(107,370)	(427,653)	(272,272)	(905,289)	(1,762,416)	1,347,999	(777,159)	535,795	(655,781)	(902,809)	(2,881,326)
Provision for Income Taxes [1]	0	0	0	0	0	0	0	0	0	0	0	0	0
Net Income (Loss)	(315,263)	(97,994)	(107,370)	(427,653)	(272,272)	(905,289)	(1,762,416)	1,347,999	(777,159)	535,795	(655,781)	(902,809)	(2,881,326)
EPS - Diluted	(\$0.00)	(\$0.00)	(\$0.00)	(\$0.01)	(\$0.00)	(\$0.01)	(\$0.02)	\$0.02	(\$0.01)	\$0.01	(\$0.01)	(\$0.01)	(\$0.03)
Shares Outstanding - Diluted	72,607,361	77,008,922	77,023,153	75,917,329	76,812,264	76,690,417	80,100,033	87,600,579	91,331,420	92,936,886	88,366,234	92,954,664	103,015,895

Balance Sheets

	12/31/08	12/31/09	12/31/10	6/30/11
Assets:				
Cash and Marketable Securities	\$36,854	\$20,041	\$248,770	\$5,830
Grants Receivable	184,124	0	0	0
Deferred Charges	0	9,573	23,740	13,740
Other Receivables	0	0	0	35,000
Prepaid Expenses & Other	0	0	2,708	1,271
Total Current Assets	\$220,978	\$29,614	\$275,218	\$55,841
Accounts/Grants Receivable- Unbilled	81,797	0	0	0
Property and Equipment, Net	1,984	0	11,849	10,998
Deferred Charges	0	26,325	16,752	11,967
Patents and Trademarks, Net	114,576	113,645	161,815	174,267
TOTAL ASSETS	\$419,335	\$169,584	\$465,634	\$253,073
Liabilities:				
Accounts Payable	\$289,199	\$506,068	\$250,425	\$372,480
Advances from Stockholders	201,643	215,142	228,640	232,015
Short-term Debt	90,873	114,978	112,520	131,839
Accrued Liabilities	0	0	0	259,078
Convertible note	0	0	169,942	39,451
Deferred Liability	0	0	0	0
Derivative Liabilities- Warrants	0	0	0	0
Derivative Liabilities- Options	0	25,415	0	0
Total Current Liabilities	\$581,715	\$861,603	\$761,527	\$1,034,863
NON-CURRENT LIABILITIES				
Derivative liabilities- Warrants	0	0	787,081	3,589,323
Derivative liabilities- Stock Options	0	0	5,975	1,848
Derivative liabilities- Note Conversion	0	0	741,589	35,138
Long-term Debt	162,110	120,477	73,109	51,346
Stockholders' Equity	(324,490)	(812,496)	(1,903,647)	(4,459,445)
TOTAL LIAB. & EQ	\$419,335	\$169,584	\$465,634	\$253,073

NOTES

[1] As of December 31, 2010, Biomoda had a net operating loss carry forward of \$9,365,000

DISCLOSURES



Ratings and Price Target Changes over Past 3 Years

Initiated April 30, 2010 – Strong Speculative Buy - Price Target \$1.00
 Update March 31, 2011 – Strong Speculative Buy - Price Target \$0.40
 Downgrade May 17, 2011 – Avoid/Sell - Price Target N/A

Analyst Certification: We, Stephen M. Dunn and William D. Dawson, the authors of this research report certify that a.) All of the views expressed in this report accurately reflect our personal views about any and all of the subject securities or issuers discussed b.) No part of our compensation is directly or indirectly related to the specific recommendations or views expressed in this research report and c.) We may be eligible to receive other compensation based upon various factors, including total revenues of the Firm and its affiliates as well as a portion of the proceeds from a broad pool of investment vehicles consisting of components of the compensation generated by investment banking activities, including but not limited to shares of stock and/or warrants, which may or may not include the securities referenced in this report.

DISCLOSURES

Does the Analyst or any member of the Analyst's household have a financial interest in any securities of the Company?	NO
Does the Analyst or any member of the Analyst's household or Firm serve as an officer, director or advisory board member of the Company?	NO
Has the Analyst or any member of the Analyst's household received compensation directly or indirectly from the Company in the previous 12 months?	NO
Does the Firm or affiliates beneficially own ≥1% of the Company's common stock?	NO
Has the Firm or affiliates received investment banking services compensation in previous 12 months?	YES
Has the Firm or affiliates received non-investment banking securities-related services compensation in previous 12 months?	NO
Does the Firm or affiliates expect to receive or intend to seek investment banking compensation in next 3 months?	YES
Has the Firm or affiliates received non-securities services compensation in previous 12 months?	NO
Does the Firm or affiliates make a market in the Company's securities?	NO

The Firm and/or its directors and employees may own securities of the company(s) in this report and may increase or decrease holdings in the future. The Firm, its officers, directors, analysts or employees may effect transactions in and have long or short positions in the securities (or options or warrants with respect thereto) mentioned herein. The Firm may effect transactions as principal or agent in the securities mentioned herein.

Ratings Definitions: 1) **Strong Buy:** the stock is expected to appreciate and produce a total return of at least 40% over the next 12-18 months; 2) **Buy:** the stock is expected to appreciate and produce a total return of at least 20% over the next 12-18 months; 3) **Strong Speculative Buy:** the stock is expected to appreciate and produce a total return of at least 40% over the next 12-18 months but **the volatility and investment risk is substantially higher** than our "Strong Buy" recommendation; 4) **Speculative Buy:** the stock is expected to appreciate and produce a total return of at least 20% over the next 12-18 months but **the volatility and investment risk is substantially higher** than our "Buy" recommendation; 5) **Neutral:** the stock is fairly valued for the next 12-18 months; 6) **Avoid/Sell:** the stock is expected to decline at least 20% over the next 12-18 months and should be avoided or sold if held; 7) **Under Review:** the previous rating and/or price target is suspended due to a significant event which now requires additional analysis and the previous rating and/or price target cannot be relied upon; 8) **Not Rated:** the stock has too much business or financial uncertainty to form an investment conclusion or is currently in the process of being acquired and 9) **Restricted:** coverage cannot be initiated or has been temporarily suspended to comply with applicable regulations and/or firm policies in certain circumstances such as investment banking or an advisory capacity involving the company.

LifeTech Capital Research	Research Coverage	Investment Banking	FINRA RULE 2711	Research Coverage	Investment Banking
Ratings Distribution	% of Total	% of Total	Ratings Distribution	% of Total	% of Total
Strong Buy	17%	50%	Buy	83%	50%
Strong Speculative Buy	67%	50%	Hold/Neutral	8%	100%
Buy	0%	0%	Sell	8%	100%
Speculative Buy	0%	0%	Total	100%	58%
Neutral	8%	100%			
Avoid/Sell	8%	100%			
Under Review	0%	0%			
Not Rated	0%	0%			
Restricted	0%	0%			
Total	100%	58%			

Legal Disclaimer

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