BIOANALYTICAL SYSTEMS INC
Form 10-K/A
May 02, 2012

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K/A

(Amendment No. 2)

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 for the fiscal year ended September 30, 2011.
OR

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 for the transition period from _____ to _____.

Commission File Number 000-23357

BIOANALYTICAL SYSTEMS, INC.

(Exact name of the registrant as specified in its charter)

INDIANA (State or other jurisdiction of incorporation or organization)	35-1345024 (I.R.S. Employer Identification No.)
2701 KENT AVENUE WEST LAFAYETTE, INDIANA (Address of principal executive offices)	47906 (Zip code)

(765) 463-4527

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to section 12(g) of the Act: Common Shares

Indicate by checkmark if the registrant is a well-known seasoned issuer, as defined by Rule 405 of the Securities Act. YES ¨ NO x

Indicate by checkmark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES ¨ NO x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES x NO ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES x NO ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of “large accelerated filer,” “accelerated filer,” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer ¨	Non-accelerated filer ¨	Smaller Reporting Company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). YES o NO x

Based on the closing price on the NASDAQ Global Market on March 31, 2011, the aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was $8,090,000. As of December 22, 2011, 6,945,631 of registrant's common shares were outstanding.

Documents Incorporated by Reference

None

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EXPLANATORY NOTE

This Amendment No. 2 on Form 10-K/A (the "Amendment") amends the Annual Report on Form 10-K of the Bioanalytical Systems Inc. Company ("we", "us", "our", or the "Company") for the fiscal year ended September 30, 2011, originally filed with the Securities and Exchange Commission (the "SEC") on December 29, 2011 (the "Original Filing"). We are filing this Amendment in response to an SEC comment letter received on March 6, 2012, revising the Clients section of Part I, Item I to include material terms of our Preferred Provider Agreement. In addition, in connection with the filing of this Amendment and pursuant to the rules of the SEC, we are including with this Amendment certain currently dated certifications. Accordingly, Item 15 of Part IV has also been amended to reflect the filing of these currently dated certifications.

This Form 10-K/A does not attempt to modify or update any other disclosures set forth in the Original Filing, except as required to reflect the additional information included in Part III of this Form 10-K/A. Additionally, this Form 10-K/A, except for the additional information included in Part III, speaks as of the filing date of the Original Filing and does not update or discuss any other Company developments subsequent to the date of the Original Filing.

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PART I

This Report may contain "forward-looking statements," within the meaning of Section 27A of the Securities Act of 1933, as amended, and/or Section 21E of the Securities Exchange Act of 1934, as amended. Those statements may include, but are not limited to, discussions regarding our intent, belief or current expectations with respect to (i) our strategic plans; (ii) our future profitability, liquidity and capital resources; (iii) our capital requirements; (iv) industry trends affecting our financial condition or results of operations; (v) our sales or marketing plans; or (vi) our growth strategy. Investors in our common shares are cautioned that reliance on any forward-looking statement involves risks and uncertainties, including the risk factors contained beginning on page 13 of the Report. Although we believe that the assumptions on which the forward-looking statements contained herein are based are reasonable, any of those assumptions could fail to project actual events and, as a result, the forward-looking statements based upon those assumptions could prove to be significantly different from actual results. In light of the uncertainties inherent in any forward-looking statement, the inclusion of a forward-looking statement herein should not be regarded as a representation by us that our plans and objectives will be achieved. We do not undertake any obligation to update any forward-looking statement.

(Dollar amounts in thousands, except per share data, unless noted otherwise.)

ITEM 1 - BUSINESS

General

We are an international contract research organization providing drug discovery and development services. Our clients and partners include pharmaceutical, biotechnology, academic and government organizations. We apply innovative technologies and products and a commitment to quality to help clients and partners accelerate the development of safe and effective therapeutics and maximize the returns on their research and development investments. We offer an efficient, variable-cost alternative to our clients' internal product development programs. Outsourcing development work to reduce overhead and speed drug approvals through the Food and Drug Administration ("FDA") is an established alternative to in-house development among pharmaceutical companies. We derive our revenues from sales of our research services and drug development tools, both of which are focused on determining drug safety and efficacy. The Company has been involved in the research of drugs to treat numerous therapeutic areas for over 35 years since its formation as a corporation organized in Indiana in 1974.

We support the preclinical and clinical development needs of researchers and clinicians for small molecule and large biomolecule drug candidates. We believe our scientists have the skills in analytical instrumentation development, chemistry, computer software development, physiology, medicine, analytical chemistry and toxicology to make the

services and products we provide increasingly valuable to our current and potential clients. Our principal clients are scientists engaged in analytical chemistry, drug safety evaluation, clinical trials, drug metabolism studies, pharmacokinetics and basic research from small start-up biotechnology companies to many of the largest global pharmaceutical companies. We are committed to bringing scientific expertise, quality and speed to every drug discovery and development program to help our clients develop safe and effective products.

Industry Overview

Drug discovery and development is the process of creating drugs for the treatment of human disease. The drug discovery process aims to identify potential drug candidates, while the drug development process involves the testing of these drug candidates in animals and humans to meet regulatory requirements. Discovering and developing new drugs is an extremely expensive, complex, high-risk and time-consuming process. Multiple industry sources estimate the fully capitalized cost of developing and commercializing a new pharmaceutical product ranges from $800 million to over $1 billion. In addition, it generally takes between 10 and 15 years to develop a new prescription drug and obtain approval to market it in the United States.

The drug development services industry provides independent product development services to pharmaceutical, biotechnology companies, and government organizations. This industry has evolved from providing limited clinical trial services in the 1970s to a full-service industry today characterized by broader relationships with clients and by service offerings that encompass the entire drug development process, including preclinical evaluations, study design, clinical trial management, data collection, biostatistical analyses, regulatory consulting, clinical laboratory and diagnostic services, pre- and post-approval safety analysis, product registration and post-approval support.

Over the past 25 years, technological advances, as well as the emergence of the biotechnology industry, have dramatically changed the drug discovery process. New and improved technologies have evolved such as ultra high-throughput screening, new in vitro and in vivo preclinical profiling techniques and the gene-based drug research commonly referred to as genomics. The objective of these innovations is to find more drug targets and to screen chemical compounds against targets much more quickly, with literally millions of compounds possible. This process is expected to produce many more molecules having the ability to affect biological activity. These molecules then need to be tested quickly and economically to determine their viability as potentially safe and effective drug candidates.

Trends Affecting the Drug Discovery and Development Industry

Our services and products are marketed globally to pharmaceutical, medical research and biotech companies and institutions engaged in drug research and development. The research services industry is highly fragmented among many niche vendors led by a small number of larger companies; the latter offer an ever-growing portfolio of start-to-finish pharmaceutical development services. Our products are also marketed to academic and governmental institutions. Our services and products may have distinctly different clients (often separate divisions in a single large pharmaceutical company) and requirements. We believe that all clients are facing increased pressure to outsource facets of their research and development activities and that the following factors will increase client outsourcing:

Accelerated Drug Development

Clients continue to demand faster, more efficient, more selective development of an increasing pool of drug candidates. Consequently, our clients require fast, high-quality service in order to make well-informed decisions to quickly exclude poor candidates and speed development of successful ones. The need for additional development capacity to exploit more opportunities, accelerate development, extend market exclusivity and increase profitability drives the demand for outsourced services.

Increase in Potential New Drug Candidates

While research and development spending and the number of drug candidates are increasing, the time and cost required to develop a new drug candidate also have increased. Many pharmaceutical and biotechnology companies do not have sufficient internal resources to pursue development of all of these new drug candidates on their own. Consequently, these companies are looking to the drug discovery and development services industry for cost-effective, innovative and rapid means of developing new drugs.

Cost Pressures of Introducing New Drugs

Market forces, healthcare reform and other governmental initiatives place significant pressures on pharmaceutical and biotechnology companies to reduce drug prices. In addition, increased competition as a result of patent expiration, market acceptance of generic drugs, and governmental and privately managed care organization efforts to reduce healthcare costs have added to drug pricing pressures. The industry is responding by consolidating, streamlining operations, decentralizing internal discovery and development processes, and minimizing fixed costs. In addition, increased pressures to differentiate products and justify drug pricing are resulting in an increased focus on healthcare economics, safety monitoring and commercialization services. Moreover, pharmaceutical and biotechnology companies are attempting to increase the speed and efficiency of internal new drug discovery and development processes.

Patent Expiration

As exclusivity ends with patent expiry, drug companies defend their proprietary positions against generic competition with various patent extension strategies. Both the drug company creating these extensions and the generic competitors should provide additional opportunities for us.

Alliances

Strategic alliances allow pharmaceutical companies to share research know-how and to develop and market new drugs faster in more diverse, global markets. We believe that such alliances will lead to a greater number of potential drugs in testing, many under study by small companies lacking broad technical resources. Those small companies can add shareholder value by further developing new products through outsourcing, reducing risk for potential allies. Clients seek realistic business partnerships with their service provider in an effort to ensure that costs are controlled as their development programs progress. We have long-standing business relationships with many pharmaceutical companies and continue to offer flexible services and adapt to our client's requirements.

Mergers and Acquisitions

Consolidation in the pharmaceutical industry is commonplace. As firms blend personnel, resources and business activities, we believe they will continue to streamline operations and minimize staffing, which may lead to more outsourcing. Consolidation may result in a disruption in the progress of drug development programs as merging companies rationalize their respective drug development pipelines.

Biotechnology Industry and Virtual Drug Company Growth

The U.S. biotechnology industry has grown rapidly over the last decade and has emerged as a key client segment for the drug discovery and development services industry. In recent years, this industry has generated significant numbers of new drug candidates that will require development and regulatory approval. Many biotechnology drug developers do not have in-house resources to conduct development. Many new companies choose only to carry a product to a developed stage sufficient to attract a partner who will manufacture and market the drug. Because of the time and cost involved, these companies rely heavily on CROs to conduct research for their drug candidates.

Unique Technical Expertise

The increasing complexity of new drugs requires highly specialized, innovative, solution-driven research not available in all client labs. We believe that this need for unique technical expertise will increasingly lead to outsourcing of research activity.

Data Management and Quality Expertise

Our clients and the FDA require more data, greater access to that data, consistent and auditable management of that data, and greater security and control of that data. We have made significant investments in software throughout our contract services groups to optimize efficiency and ensure compliance with FDA regulations and market expectations.

Changes in the Regulatory Environment

The drug discovery and development process is heavily regulated by the FDA and its Center for Drug Evaluation and Research. Recent product safety concerns, increases in drug and general healthcare costs and the emergence of importation issues have placed the FDA and other regulatory agencies under increased scrutiny. The war on terror, the risk of global vaccine shortages and the threat of new potential pandemics have elevated the FDA's focus on research in the areas of bioterrorism and vaccine development. As a result of these and other events, drug safety, cost and availability are under intense monitoring and review by Congress, the FDA and other government agencies. In 2007, primarily in response to the FDA's handling of postmarket data and recent drug safety concerns, the FDA Act was signed into law. In addition to reauthorizing and amending various provisions that were scheduled to expire, this Act provided the FDA with new regulatory authority to require drug sponsors to run post-approval studies and clinical trials and develop and implement risk evaluation and mitigation strategies. It is also likely that additional legislation will be passed that will impact the FDA and drug development and approval process in the United States. The FDA Act, continued drug safety issues and future legislation could have a lasting and pronounced impact on the drug discovery and development industry.

Globalization of the Marketplace

Foreign firms rely on independent development companies with experience in the U.S. to provide integrated services through all phases of product development and to assist in preparing complex regulatory submissions. Domestic drug firms are broadening product availability globally, demanding local regulatory approval. We believe that domestic service providers with global reach, established regulatory expertise, and a broad range of integrated development services will benefit from this trend.

Our Solution

We address the needs of the pharmaceutical and biotechnology industries, as well as academic, non-profit and government organizations, for drug discovery and development by providing integrated services to help our clients maximize the return on their research and development investments. Our application of innovative technologies and products and our commitment to quality throughout the drug discovery and development process offer our clients a way to identify and develop successful drugs and devices more quickly and cost-effectively. We have obtained significant drug development expertise from more than 35 years of operation.

The Company's Role in the Drug Development Process

After a new drug candidate is identified and carried through preliminary screening, the development process for new drugs has three distinct phases.

1) The ***preclinical phase*** includes safety testing to prepare an Investigational New Drug ("IND") application for submission to the FDA. The IND must be accepted by the FDA before the drug can be tested in humans. Once a pharmacologically active molecule is fully analyzed to confirm its integrity, the initial dosage form for clinical trials is created. An analytical chemistry method is developed to enable reliable quantification. Stability and purity of the formulation are also determined.

Clients work with our preclinical services group to establish pharmacokinetics (PK), pharmacodynamics (PD) and safety testing of the new drug. These safety studies range from dose ranging studies, that involve acute safety monitoring of drugs and medical devices to chronic, multi-year oncogenicity and reproductive toxicity studies. Dose level confirmation is provided by our pharmaceutical analysis group. Bioanalyses of blood sampled under these protocols by our bioanalytical services group provide pharmacokinetic and metabolism data that is used with the safety and toxicity information to determine the exposure required to demonstrate toxicity. A no effect level is then established for the drug and sets the basis for future dose levels in further safety testing and clinical phase I studies. Upon successful completion of preclinical safety studies, an IND submission is prepared and provided to the FDA for review prior to human clinical trials.

Many of our products are designed for use in discovery and preclinical development. The Culex® family of robotic automated dose delivery and blood and other biofluids sampling and physiological parameters measurement systems enable researchers to quickly and cost effectively determine PK/PD profiles of drugs in large and small animal models. The Culex system allows experiments on freely moving conscious animals from early research for therapeutic target validation to lead optimization of compounds. Using the Culex system, researchers are able to automatically dose and sample in-vivo to develop pharmacokinetic and pharmacodynamic profiles of drugs during early screening in

rodents and other animals quickly and cost effectively. Our bioanalytical services group utilizes our depth of expertise in liquid chromatography with detection by mass spectrometry as a mainstay of our bioanalytical laboratories to support research, preclinical and clinical programs. We also offer bioanalytical services that utilize electrochemistry, spectrophotometric (UV/Vis or fluorescence) and Corona Discharge detection as options. We have invested heavily in robotics and mass spectrometry systems. Application of this technology allows us to rapidly develop and validate methods for new compounds and obtain information suitable for regulatory submission.

2) The ***clinical phase*** further explores the safety and efficacy of the substance in humans. The sponsor conducts Phase I human clinical trials in a limited number of healthy individuals to determine safety and tolerability. Bioanalytical assays determine the availability and metabolism of the active ingredient following administration. Expertise in method development and validation is critical, particularly for new chemical entities.

Exhaustive safety, tolerability and dosing regimens are established in sick humans in Phase II trials. Phase III clinical trials verify efficacy and safety. After successful completion of Phase III trials, the sponsor of the new drug submits a New Drug Application ("NDA") or Product License Application ("PLA") to the FDA requesting that the product be approved for marketing. Early manufacturing demonstrates production of the substance in accordance with FDA Good Manufacturing Practices ("GMP") guidelines. Data are compiled in an NDA, or for biotechnology products a PLA, for submission to the FDA requesting approval to market the drug or product. Our bioanalytical work per study grows rapidly from Phase I through Phase III. Phase II and III studies take several years, supported by well-proven, consistently applied analytical methods. It is unusual for a sponsor to change laboratories during these phases unless there are problems in the quality or timely delivery of results.

Our services include evaluation of bioequivalence and bioavailability to monitor the rate and extent to which a drug is available in the body and to demonstrate that the availability is consistent between formulations. We additionally offer support and testing services in clinical sample development, release and stability.

3) The ***Post-approval phase*** follows FDA approval of the NDA or PLA. This includes production and continued analytical and clinical monitoring of the drug. The post-approval phase also includes development and regulatory approval of product modifications and line extensions, including improved dosage forms. The drug manufacturer must comply with quality assurance and quality control requirements throughout production and must continue analytical and stability studies of the drug during commercial production to continue to validate production processes and confirm product shelf life. Samples from each manufactured batch must be tested prior to release of the batch for distribution to the public.

We also provide services in all areas during the post-approval phase, concentrating on bioequivalence studies of new formulations, line extensions, new disease indications and drug interaction studies. Our ability to offer quick sample analysis has provided increased business opportunities for release testing.

The increases in our services offerings as a result of both acquisition and internal development have resulted in our ability to provide a broader range of services to our clients, often using combined services of several disciplines to address client needs. Our ability to solve client problems by combining our knowledge base, services and products has been a factor in our selection by major pharmaceutical companies to assist in several preclinical through the post-approval phases.

Company Services and Products

Overview

We focus on developing innovative services and products that increase efficiency and reduce costs associated with taking new drugs to market. We operate in two business segments – contract research services and research products, both of which address the bioanalytical, preclinical, and clinical research needs of drug developers. Both segments arose out of our expertise in a number of core technologies designed to quantify trace chemicals in complex matrices.

Services

The contract research services segment provides screening and pharmacological testing, preclinical safety testing, formulation development, regulatory compliance and quality control testing. Revenues from the services segment were $25.6 million for fiscal 2011. The following is a description of the services provided by our contract research services segment:

- ***Product Characterization, Method Development and Validation****:* Analytical methods, primarily performed in West Lafayette, Indiana, determine potency, purity, chemical composition, structure and physical properties of a compound. Methods are validated to ensure that data generated are accurate, precise, reproducible and reliable and are used consistently throughout the drug development process and in later product support.

- ***Bioanalytical Testing****:* We analyze specimens from preclinical and clinical trials to measure drug and metabolite concentrations in complex biological matrices. Bioanalysis is performed at our facilities in Indiana, Oregon and the United Kingdom ("UK").

- ***Stability Testing****:* We test stability of drug substances and formulated drug products and maintain secure storage facilities in West Lafayette, Indiana to establish and confirm product purity, potency and shelf life. We have multiple International Conference on Harmonization validated controlled-climate GMP (Good Manufacturing Practices) systems in place, and the testing capability to complete most stability programs.

- ***In Vivo Pharmacology****:* We provide preclinical *in vivo* sampling services for the continuous monitoring of chemical changes in life, in particular, how a drug enters, travels through, and is metabolized in living systems. Most services are performed in customized facilities in Evansville, Indiana using our robotic Culex® APS (Automated Pharmacology System) system.

- ***Preclinical and Pathology Services****:* We provide pharmacokinetic and safety testing in studies ranging from acute safety monitoring of drugs and medical devices to chronic, multi-year oncogenicity studies in our Evansville, Indiana site. Depending on protocol, multiple tissues may be collected to monitor pathological changes.

Research Products

We focus our products business on expediting preclinical screening of developmental drugs. We compete in small niches of the multibillion dollar analytical instrument industry. The products business targets unique niches in life science research. We design, develop, manufacture and market state-of-the-art:

- *In vivo* sampling systems and accessories (including disposables, training and systems qualification)
- Physiology monitoring tools
- Liquid chromatography and electrochemistry instruments platforms

Revenues for our products segment were $7.5 million for fiscal 2011. We offer three (3) principal product lines: Analytical Products, In vivo Sampling Products and Vetronics' Products. The following is a brief description of the products offered:

- ***Analytical Products:*** The analytical products consist of our liquid chromatographic and electrochemical instruments with associated accessories. The critical component of these products is the Epsilon® electrochemical platform. This incorporates all the hardware capabilities needed for most electrochemical experiments but can be modified through software development. The market is principally academic institutions and industrial research companies.

- ***In vivo Sampling Products:*** The *in vivo* sampling products consist of the *Culex*® family of automated *in vivo* sampling and dosing instruments. These are used by pharmaceutical researchers to dose animals and collect biological samples (blood, bile, urine, microdialysate, feces or any bio-fluid) from the animals. Since dosing and sample collections are automated, animals are not manually handled, reducing stress on the animals and producing more representative pharmacological data. Behavior and other physiological parameters can also be monitored simultaneously. Compared to manual methods, the Culex® products offer significant reduction in test model use and comparable reduction in labor. The line also includes miniaturized *in vivo* sampling devices sold to drug developers and medical research centers to assist in the study of a number of medical conditions including stroke, depression, Alzheimer's and Parkinson's diseases, diabetes and osteoporosis.

- ***Vetronics' Products:*** The Vetronics' products consist of instruments and related software to monitor and diagnose cardiac function (electro-cardiogram) and measure other vital physiological parameters primarily in cats and dogs in veterinary clinics.

Clients

Over the past five years, we have regularly provided our services and/or products to most of the top 25 pharmaceutical companies in the world, as ranked by the number of research and development projects. Approximately 11% of our revenues are generated from customers outside of North America.

We balance our business development effort between large pharmaceutical developers and smaller drug development companies.

With the signing of the Preferred Provider Agreement ("PPA") with Pharmasset, Inc. in the first quarter of the current fiscal year, Pharmasset, Inc. has become our largest client, accounting for approximately 14.5% of our total revenues in fiscal 2011 and 6.3% of our total trade accounts receivable at September 30, 2011. Pfizer, Inc. remains a large client, accounting for approximately 5.2% and 7.0% of our total revenues in fiscal 2011 and 2010, respectively. Pfizer, Inc. accounted for 4.2% and 4.7% of total trade accounts receivable at September 30, 2011 and 2010, respectively.

Per the PPA with Pharmasset, we will provide services for toxicology studies, pharmaceutical analyses and bioanalytical services as needed by Pharmasset. We agree to assign a priority status to any Pharmasset study and to place the study in our schedule such that Pharmasset will be able to meet its timelines and requirements. Pharmasset agrees to use the Company as its provider of first choice for toxicology studies, but does not guarantee a specific level of projects. Pricing, per the PPA, is detailed in a pricing list accompanying the agreement and is based on study specifics. A volume discount will also be applied to incremental services provided and is based on annual billings. The PPA shall remain in effect for two years unless terminated earlier on mutual written agreement of the parties, or on 90 days' advance written notice by either party.

There can be no assurance that our business will not continue to be dependent on continued relationships with Pharmasset, Inc., Pfizer, Inc. or other clients, or that annual results will not be dependent on a few large projects. In addition, there can be no assurance that significant clients in any one period will continue to be significant clients in other periods. In any given year, there is a possibility that a single pharmaceutical company may account for 5% or more of our total revenue. Since we do not have long-term contracts with most of our clients, the importance of a single client may vary dramatically from year to year.

Sales and Marketing

With a primary focus on both large and small pharmaceutical and biotechnology companies, we promote our services through concentrated business development efforts, scientist-to-scientist communications and centralized corporate marketing programs. We recognize that our growth and customer satisfaction depend upon our ability to continually improve and create new client relationships.

Our new sales and global marketing initiatives include integrated campaigns designed to help differentiate and promote our products and services. Through trade events, online and print advertising in trade publications, direct communication, newsletters, and our website, we provide our perspective on current industry challenges or developments to create an ongoing dialogue with our clients and to promote our industry expertise, quality, technology and innovation. We reinforce key messages and selling points through client presentations, corporate material, at trade events and industry conferences.

We encourage and sponsor the participation of our scientific and technical personnel in a variety of professional endeavors, including speaking and the presentation of papers at national and international professional trade meetings and the publication of scientific articles in medical and pharmaceutical journals. Through these presentations and publications, we seek to further our reputation for professional excellence.

We currently have 16 employees on our sales and marketing staff based in our corporate headquarters located in West Lafayette, Indiana. We have a network of 11 established distributors covering Japan, the Pacific Basin, South America, the Middle East, India, South Africa and Eastern Europe. All of our distributor relationships are managed from the corporate headquarters in West Lafayette, Indiana.

Contractual Arrangements

Our service contracts typically establish an estimated fee to be paid for identified services. In most cases, some percentage of the contract costs is paid in advance. While we are performing a contract, clients often adjust the scope of services to be provided based on interim project results. Fees are adjusted accordingly. Generally, our fee-for-service contracts are terminable by the client upon written notice of 30 days or less for a variety of reasons, including the client's decision to forego a particular study, the failure of product prototypes to satisfy safety requirements, and unexpected or undesired results of product testing. Cancellation or delay of ongoing contracts may result in fluctuations in our quarterly and annual results. We are generally able to recover at least our invested costs when contracts are terminated.

Our products business offers annual service and maintenance agreements on most product lines.

Backlog

The contracts pursuant to which we provide our services are terminable upon written notice of 30 days or less. We maintain projections based on bids and contracts to optimize asset utilization. We have increased the use of sales forecasts in manufacturing our products, with the result that we rarely have a significant backlog for Products. For Services, backlog generally includes work to be performed under signed agreements (i.e., contracts and letters of intent). Once work under a signed agreement begins, net revenues are recognized over the life of the project. Some of our studies and projects are performed over an extended period of time, which may exceed several years. We maintain an order backlog to track anticipated net revenues yet to be earned for work that has not been performed.

Although backlog can provide meaningful information to our management with respect to a particular study, we believe that our backlog for Services as of any date is not necessarily a meaningful indicator of our future results for a variety of reasons. Studies vary in duration; the scope of studies may change, which may either increase or decrease their value; and studies may be terminated, or delayed at any time by the client or regulatory authorities.

Competition

Services

We compete with in-house research, development, quality control and other support service departments of pharmaceutical and biotechnology companies. There are also full-service Contract Research Organizations ("CROs") that compete in this industry. Several of our competitors have significantly greater financial resources than we do. The largest CRO competitors offering similar research services include:

- Covance, Inc.;
- Pharmaceutical Product Development, Inc.;
- Charles River Laboratories, Inc.;
- Parexel; and
- MDS Health Group Ltd.

CROs generally compete on:

- regulatory compliance record;
- reputation for on-time quality performance
- quality system;

- previous experience;
- medical and scientific expertise in specific therapeutic areas;
- scientist-to-scientist relationships;
- quality of contract research;
- financial viability;
- database management;
- statistical and regulatory services;
- ability to recruit investigators;
- ability to integrate information technology with systems to optimize research efficiency;
- quality of facilities;
- an international presence with strategically located facilities; and
- price.

Products

Founded as a provider of instrumentation and products utilized in life and physical sciences research laboratories, we continue to serve these product niches today. Though many global analytical instruments competitors exist, we have an extensive, long standing network of customers who are repeat buyers and recommend our products. In contrast, there are few competitors for our *in vivo* sampling products. The primary market is large pharmaceutical research departments. Our differentiators are high quality, flexibility to meet customers' specific needs and superior technical support and service. We provide equipment that enables our customers to attain premium scientific laboratory information on a reasonable operating investment. As customers' needs constantly change, we continually invest in the refinement of our products and in new product opportunities that meet our operating objectives.

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Government Regulation

We are subject to various regulatory requirements designed to ensure the quality and integrity of our data and products. These regulations are promulgated primarily under the Federal Food, Drug and Cosmetic Act, and include Good Laboratory Practice ("GLP"), Good Manufacturing Practice ("GMP"), and Good Clinical Practice ("GCP") guidelines administered by the FDA. The standards of GLP, GMP, and GCP are required by the FDA and by similar regulatory authorities around the world. These guidelines demand rigorous attention to employee training; detailed documentation; equipment validation; careful tracking of changes and routine auditing of compliance. Noncompliance with these standards could result in disqualification of project data collected by the Company. Material violation of GLP, GMP, or GCP guidelines could result in regulatory sanctions and, in severe cases, could also result in a discontinuance of selected operations. Since October 2004, we have been audited, on a routine basis, by the FDA and UK's MHRA twenty times. The FDA has visited seven times in West Lafayette, three times each at the Oregon and Evansville locations and twice at the UK location. MHRA has visited the UK facility five times. Of the fifteen FDA audits, seven were without findings. Where the FDA had findings, which have not been significant to our operations, we have taken actions to address the findings. The UK facility was found to be compliant with GLP and GCP.

We have not experienced any significant problems to date in complying with the regulations of such agencies and do not believe that any existing or proposed regulations will require material capital expenditures or changes in our method of operation.

Analytical Services

Laboratories that provide information included in INDs, NDAs and PLAs must conform to regulatory requirements that are designed to ensure the quality and integrity of the testing process. Most of our contract research services are subject to government standards for laboratory practices that are embodied in guidelines for GLP. The FDA and other regulatory authorities require that test results submitted to such authorities be based on studies conducted in accordance with GLP. These guidelines are set out to help the researcher perform work in compliance with a pre-established plan and standardized procedures. These guidelines include but are not restricted to:

- Resources – organization, personnel, facilities and equipment
- Rules – protocols and written procedures
- Characterization – test items and test systems

- Documentation – raw data, final report and archives

- Quality assurance unit – formalized internal audit function

We must also maintain reports for each study for specified periods for auditing by the study sponsor and by the FDA or similar regulatory authorities in other parts of the world. Noncompliance with GLP can result in the disqualification of data collected during the preclinical trial.

Preclinical Services

Our animal research facilities are subject to a variety of federal and state laws and regulations, including The Animal Welfare Act and the rules and regulations enforced by the United States Department of Agriculture ("USDA") and the National Institutes of Health ("NIH"). These regulations establish the standards for the humane treatment, care and handling of animals by dealers and research facilities. Our animal research facilities maintain detailed standard operating procedures and other documentation necessary to comply with applicable regulations for the humane treatment of the animals in our custody. Besides being licensed by the USDA as a research facility, we are also accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International ("AAALAC") and have registered assurance with the NIH.

Quality Assurance and Information Technology

To assure compliance with applicable regulations, we have established quality assurance programs at our facilities that audit test data, train personnel and review procedures and regularly inspect facilities. In addition, FDA regulations and guidelines serve as a basis for our Standard Operating Procedures ("SOPs") where applicable. On an ongoing basis, we endeavor to standardize SOPs across all relevant operations. In addition, we have both developed and purchased software to ensure compliant documentation, handling and reporting of all laboratory-generated study data. In fiscal 2004, we purchased similar 21 CFR Part 11 (FDA guidelines on electronic records and electronic signatures that define the criteria under which electronic records and electronic signatures are considered to be trustworthy, reliable and equivalent to paper records) compliant software for our preclinical research group. At the end of fiscal 2011, the majority of our laboratory operations in the U.S. were fully in compliance with 21 CFR Part 11, in our analytical, bioanalytical, toxicology, lab information management, and document management systems. Systems compliant with 21 CFR Part 11 were formally validated and released for use in regulated studies.

We manage our business systems through the use of an Enterprise Resource Planning ("ERP") system. We are continually refining and adjusting our ERP system to improve efficiency, provide better management tools and address changes in our business. These changes are appropriately documented and tested before implementation. We also test these systems in connection with management's annual review of our internal control systems. Management's assessment and report on internal controls over financial reporting is included in Item 9A.

Controlled, Hazardous, and Environmentally Threatening Substances

Some of our development and testing activities are subject to the Controlled Substances Act administered by the Drug Enforcement Agency ("DEA"), which strictly regulates all narcotic and habit-forming substances. We maintain restricted-access facilities and heightened control procedures for projects involving such substances due to the level of security and other controls required by the DEA. In addition, we are subject to other federal and state regulations concerning such matters as occupational safety and health and protection of the environment.

Our U.S. laboratories are subject to licensing and regulation under federal, state and local laws relating to hazard communication and employee right-to-know regulations, the handling and disposal of medical specimens and hazardous waste, as well as the safety and health of laboratory employees. All of our laboratories are subject to applicable federal and state laws and regulations relating to the storage and disposal of all laboratory specimens, including the regulations of the Environmental Protection Agency, the Department of Transportation, the National Fire Protection Agency and the Resource Conservation and Recovery Act. Although we believe that we are currently in compliance in all material respects with such federal, state and local laws, failure to comply could subject us to denial of the right to conduct business, fines, criminal penalties and other enforcement actions.

The regulations of the U.S. Department of Transportation, the U.S. Public Health Service and the U.S. Postal Service apply to the surface and air transportation of laboratory specimens. Our laboratories also comply with the International Air Transport Association regulations which govern international shipments of laboratory specimens. Furthermore, when materials are sent to a foreign country, the transportation of such materials becomes subject to the laws, rules and regulations of such foreign country.

Safety

In addition to comprehensive regulation of safety in the workplace, the Occupational Safety and Health Administration has established extensive requirements relating to workplace safety for health care employers whose workers may be exposed to blood-borne pathogens such as HIV and the hepatitis B virus. These regulations, among other things, require work practice controls, protective clothing and equipment, training, medical follow-up, vaccinations and other measures designed to minimize exposure to chemicals, and transmission of blood-borne and airborne pathogens. Furthermore, relevant employees receive initial and periodic training focusing on compliance with applicable hazardous materials regulations and health and safety guidelines.

HIPAA

The U.S. Department of Health and Human Services has promulgated final regulations under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") that govern the disclosure of confidential medical information in the United States. We have had a global privacy policy in place since January 2001 and believe that we are in compliance with the current European Union and HIPAA requirements. We continue to monitor our compliance with these regulations, and we intend to take appropriate steps to ensure compliance as these and other privacy regulations are revised or come into effect.

Product Liability and Insurance

We maintain product liability and professional errors and omissions liability insurance, providing approximately $3.0 million in coverage on a claims-made basis. Additionally, in certain circumstances, we seek to manage our liability risk through contractual provisions to be indemnified by the client or covered by the client's liability insurance policies. Also, in certain types of engagements, we seek to limit our contractual liability to clients to the amount of fees received. The contractual arrangements are subject to negotiation with clients, and the terms and scope of such indemnification, liability limitation and insurance coverage vary by client and project.

Research and Development

In fiscal 2011 and 2010, we spent $534 and $546, respectively, on research and development. Separate from our contract research services business, we maintain applications research and development to enhance our products business.

Expenditures cover hardware and software engineering costs, laboratory supplies, labor, prototype development and laboratory demonstrations of new products and applications for those products.

Intellectual Property

We believe that our patents, trademarks, copyrights and other proprietary rights are important to our business. Accordingly, we actively seek protection for those rights both in the United States and abroad. Where we deem it to be an appropriate course of action, we will vigorously prosecute patent infringements. We do not believe, however, that the loss of any one of our patents, trademarks, copyrights or other proprietary rights would be material to our consolidated revenues or earnings.

We currently hold three federally registered trademarks. We also have two pending patents, one on the Dried Blood Spot (DBS) sampling card for the Culex Automated Blood Sampling Instrumentation and the second for the No Blood Waste technology also for the Culex instrument. The former (DBS) reduces the cost of bio-sample collection, shipment and storage and the latter is important for the precise sampling of bio-fluids of very small volume from animals such as mice. We also generate client value through continuing client support, hardware and software upgrades, system reliability and accuracy. In addition to these formal intellectual property rights, we rely on trade secrets, unpatented know-how and continuing applications research which we seek to protect through means of reasonable business procedures, such as confidentiality agreements. We believe that the greatest value that we

generate for our clients comes from these trade secrets, know-how and applications research.

Raw Materials

There are no specialized raw materials that are particularly essential to our business. We have a variety of alternative suppliers for our essential components.

Employees

At September 30, 2011, we had 251 full-time employees and 16 part-time employees. All employees enter into confidentiality agreements intended to protect our proprietary information. We believe that our relations with our employees are good. None of our employees are represented by a labor union. Our performance depends on our ability to attract and retain qualified professional, scientific and technical staff. The level of competition among employers for skilled personnel is high. We believe that our employee benefit plans enhance employee morale, professional commitment and work productivity and provide an incentive for employees to remain with the Company.

Executive Officers of the Registrant

The following table illustrates information concerning the persons who served as our executive officers as of September 30, 2011. Except as indicated in the following paragraphs, the principal occupations of these persons have not changed in the past three years. Officers are elected annually at the annual meeting of the board of directors.

Name	Age	Position
Anthony S. Chilton, Ph.D.	55	President, Chief Executive Officer
Michael R. Cox	64	Vice President, Finance; Chief Financial and Administrative Officer; Treasurer
Alberto Hidalgo	46	Vice President, Business Development and Marketing
Craig S. Bruntlett, Ph.D.	62	Senior Vice President, Instruments Division
Lina L. Reeves-Kerner	60	Senior Vice President, Human Resources

Anthony S. Chilton, Ph.D. was named as the Chief Executive Officer, effective May 13, 2010. Dr. Chilton had previously served as Chief Operating Officer since December 1, 2008 and interim President since January 27, 2010. Dr. Chilton has over 30 years of experience as a scientist and executive in leading life sciences companies in England, Canada and the United States. For the two years prior to joining the Company, Dr. Chilton was in charge of early development programs at Atherogenics, Inc. of Alpharetta, Ga. In the two years prior to that, Dr. Chilton provided consulting and advisory services to various pharmaceutical companies. Prior to that, he was Vice President of the Biopharmaceutical Development Division of Cardinal Health Inc., which he joined through a predecessor company in 1998 that was acquired by Cardinal in 2002. Previously, Dr. Chilton spent three years with life sciences companies in Canada, prior to which he held positions in his native United Kingdom. Dr. Chilton received his bachelor’s degree in Chemistry from the University of East Anglia in 1981, and his Ph.D. in Analytical Chemistry from the University of Hertfordshire in 1993.

Michael R. Cox has been Vice President, Finance, Chief Financial Officer and Treasurer since April 2004. In October 2007, he assumed the additional duties of Chief Administrative Officer. He was Vice President, Finance and CFO of Integrity Pharmaceutical Corporation, a private specialty pharmaceutical company, from October 2003 until its acquisition and merger in March 2004. Prior to that he was Senior Vice President, Finance of Intergen Company, a private biotech manufacturing and research products company, from 1997 until its acquisition in 2001, and continued with the acquirer, Serologicals Corporation, on special projects until joining Integrity. Prior to that, Mr. Cox held various executive positions in two environmental services firms and an investment firm. He was a partner in Touche Ross & Co., where he began his career after obtaining a BS in business administration from the University of North Carolina. The Company notified Mr. Cox of its intention not to renew his contract on September 27, 2011. His amended agreement would have expired on December 31, 2011, but was extended until March 31, 2012.

Alberto Hildago was hired as the Vice President of Business Development and Marketing, effective August 18, 2010. Mr. Hidalgo has over 15 years of senior-level sales experience in both domestic and international markets including 13 years in the CRO Market. Most recently he consulted with companies to develop and implement new sales and marketing strategies. Prior to that he served as Area Director of Sales with Covance Central Laboratory Services and held various positions including Director of Sales, for Eli Lilly Export, Puerto Rico. He has a strong history of developing new business relationships and sales strategies resulting in exceptional sales growth.

Craig S. Bruntlett, Ph.D. has been Senior Vice President of the Instruments Division since September 2005. Prior to that, he was Senior Vice President of International Sales from 1999. From 1992 to 1999 he was Vice President, Electrochemical Products. From 1980 to 1990, Dr. Bruntlett was Director of New Products Development for the Company. Dr. Bruntlett has a Bachelor of Arts degree in Chemistry and Mathematics from St. Cloud State University in Minnesota and a Ph.D. in Chemistry from Purdue University.

Lina L. Reeves-Kerner has been Vice President, Human Resources since 1995 and is responsible for the administrative support functions of the Company, including shareholder relations, human resources and community relations. From 1980 to 1990, Ms. Reeves-Kerner served as an Administrative Assistant with the Company. Ms. Reeves-Kerner has a Bachelor of Science degree in Business Administration from Indiana Wesleyan University.

Investor Information

We file various reports with, or furnish them to, the Securities and Exchange Commission (the "SEC"), including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to such reports. These reports are available free of charge upon written request or by visiting www.BASinc.com/invest. Other media inquiries and requests for reports or investor's kits should be directed to:

BASi Investor Relations, Corporate Center

2701 Kent Avenue, West Lafayette, IN 47906 USA

Phone 765-463-4527, Fax 765-497-1102, basi@BASinc.com

Inquiries from shareholders, security analysts, portfolio managers, registered representatives and other interested parties should be directed to:

Neil G. Berkman Associates

11835 West Olympic Blvd., Suite 405E, Los Angeles, CA 90064

Phone 310-477-3118, nberkman@berkmanassociates.com

PART IV

ITEM 15-EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as part of this Report.

1. Financial Statements: See Index to Consolidated Financial Statements under Item 8 on Page 30 of this report.

2.

Financial Statement Schedules: Schedules are not required, are not applicable or the information is shown in the Notes to the Consolidated Financial Statements.

3. Exhibits: The following exhibits are filed as part of, or incorporated by reference into, this report:

Number		Description of Exhibits
(10)	10.30^	Preferred Provider Agreement between Bioanalytical Systems, Inc. and Pharmasset Inc., dated July 29, 2010 (filed herewith).
(31)	31.1	Certification of Chief Executive Officer (filed herewith).
	31.2	Certification of Chief Financial Officer (filed herewith).
(32)	32.1	Written Statement of Chief Executive Officer and Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350) (filed herewith).

^ Portions of this exhibit have been redacted pursuant to a request for confidential treatment filed separately with the Secretary of the Securities and Exchange Commission pursuant to Rule 406 under the Securities Act of 1933, as amended.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BIOANALYTICAL SYSTEMS, INC.
(Registrant)

By: /s/ Anthony S. Chilton

Date: May 2, 2012

Anthony S. Chilton
President and Chief Executive Officer

Date: May 2, 2012

By: /s/ Jacqueline M. Lemke

Jacqueline M. Lemke
Vice President, Finance, Chief Financial Officer

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