UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K/A
(Amendment No. 2)

(mark one)

Annual Report Pursuant To Section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended September 30, 2009

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 000-26285

CNS RESPONSE, INC.
(Exact name of registrant as specified in its charter)

Delaware	**87-0419387**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

85 Enterprise, Suite 410
Aliso Viejo, CA 92656
(Address of Principal Executive Offices)(Zip Code)

(714) 545-3288
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

None

Securities registered under Section 12(g) of the Exchange Act:

Common Stock, $0.001 par value

(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes ☐ No ☒

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 ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required 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 ☐ No ☒

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) 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.☐

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 the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☐ (Do not check if smaller reporting company)	Smaller reporting company ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act.)

Yes ☐ No ☒

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant on March 31, 2009, the last business day of the registrant's most recently completed second fiscal quarter was $13,555,818 (based on the closing sales price of the registrant's common stock on that date).

At December 28, 2009, the registrant had 51,747,729 shares of Common Stock, $0.001 par value, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

STATEMENT REGARDING AMENDMENT NO. 2

This Amendment No. 2 on Form 10K/A ("Amendment No. 2") amends our Annual Report on Form 10-K (the "Original Filing") for the fiscal year ended September 30, 2009, as filed with the Securities and Exchange Commission on December 30, 2009, as subsequently amended on January 25, 2010 by our Annual Report on Form 10-K/A ("Amendment No. 1"). We are filing Amendment No. 2 in response to comments received from the SEC to make the amendments described below to Item 1 of the Original Filing as amended by Amendment No. 1:

- We have deleted the findings of the Center for Health Economics, Epidemiology and Science Policy of United Biosource, which relate to our rEEG product which appeared on page 9 of the Original Filing, as amended by Amendment No.1; and

- We have deleted statements from Milliman Global relating to payer appeal which appeared on page 10 of the Original Filing, as amended by Amendment No. 1.

In addition to the revisions referred to above, as required by Rule 12b-15 promulgated under the Securities and Exchange Act of 1934, our principal executive officer and principal financial officer are providing new Rule 13a-14(a) certifications in connection with this Form 10-K/A. Because no financial statements are contained within this Amendment No. 2, we are not including certifications pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

The only changes to the Original Filing, as amended by Amendment No. 1 being made by this Amendment No. 2 are those described above. No attempt has been made in this Amendment No. 2 to modify or update disclosures in the Original Filing, as amended by Amendment No. 1 except as required to address the changes described above. This Amendment No. 2 does not reflect events occurring after the filing of the Original Filing or modify or update any related disclosures. Information not affected by Amendment No. 2 is unchanged and reflects the disclosure made at the time of the filing of the Original Filing, as amended by Amendment No. 1.

CNS RESPONSE, INC.

2009 FORM 10-K/A ANNUAL REPORT

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PART I

ITEM 1. Business

With respect to this discussion, the terms "we" "us" "our" "CNS" and the "Company" refer to CNS Response, Inc., a Delaware corporation and its wholly-owned subsidiaries CNS Response, Inc., a California corporation ("CNS California"), Colorado CNS Response, Inc., a Colorado corporation ("CNS Colorado") and Neuro-Therapy Clinic, Inc., a Colorado professional medical corporation and a wholly-owned subsidiary of CNS Colorado ("NTC").

Background

CNS Response, Inc. was incorporated in Delaware on July 10, 1984, under the name Mammon Oil & Gas, Inc. Prior to January 16, 2007, CNS Response, Inc. (then called Strativation, Inc.) existed as a "shell company" with nominal assets whose sole business was to identify, evaluate and investigate various companies to acquire or with which to merge. On January 16, 2007, we entered into an Agreement and Plan of Merger (the "Merger Agreement") with CNS Response, Inc., a California corporation formed on January 11, 2000 ("CNS California"), and CNS Merger Corporation, a California corporation and our wholly-owned subsidiary ("MergerCo") pursuant to which we agreed to acquire CNS California in a merger transaction wherein MergerCo would merge with and into CNS California, with CNS California being the surviving corporation (the "Merger"). On March 7, 2007, the Merger closed, CNS California became our wholly-owned subsidiary, and on the same date we changed our corporate name from Strativation, Inc. to CNS Response, Inc.

Overview

CNS Response is a life sciences company with two distinct business segments. Our Laboratory Information Services business operated by CNS California, which we consider our primary business, is focused on the research, development, and commercialization of a patented system that guides psychiatrists and other physicians/prescribers to determine a proper treatment for patients with behavioral (psychiatric and/or addictive) disorders. Our Clinical Services business operated by NTC is a full service psychiatric clinic.

Laboratory Information Services

Traditionally, prescription of medication for the treatment of behavioral disorders (such as depression, bipolar disorders, eating disorders, addiction, anxiety disorders, ADHD and schizophrenia) has been primarily based on symptomatic factors, while the underlying physiology and pathology of the disorder is rarely able to be analyzed, often resulting in multiple ineffective, costly, and often lengthy, courses of treatment before effective medications are identified. Some patients never find effective medications.

We believe that our technology offers an improvement upon traditional methods for determining a course of medication for patients suffering from nonpsychotic behavioral disorders because our technology is designed to correlate the success of courses of medication, with the neurophysiological characteristics of a particular patient. Our technology provides medical professionals with medication sensitivity data for a subject patient based upon the identification and correlation of treatment outcome information from other patients with similar neurophysiologic characteristics. This treatment outcome information is contained in a proprietary outcomes database that consists of over 17,000 medication trials for patients with psychiatric or addictive problems (the " *CNS Database* "). For each patient in the CNS Database, we have compiled electroencephalographic (" *EEG* ") scans, symptoms and outcomes often across multiple treatments from multiple psychiatrists and physicians. This patented technology, called "Referenced-EEG®" or "rEEG®" represents an innovative approach to identifying effective medications for patients suffering from debilitating behavioral disorders.

With rEEG®, physicians order a digital EEG for a patient, which is then evaluated with reference to the CNS Database. By providing this reference correlation, an attending physician can choose a treatment strategy with the knowledge of how other patients having similar brain function have previously responded to a myriad of treatment alternatives. Analysis of this complete data set yielded a platform of 74 quantitative biomarkers that have shown utility in characterizing patient response to diverse medications. This platform then allows a new patient to be characterized, based on these 74 biomarkers, and the database to be queried to understand the statistical probability of how patients with similar brain patterns have previously responded to the medications currently in the database. This technology allows us to create and provide simple reports ("*rEEG Reports*") to the prescriber that summarizes historical treatment success of specific medications for those patients with similar brain patterns. It provides neither a diagnosis nor specific treatment, but like all lab results, objective, evidenced-based information to help the prescriber in their decision-making.

Our Laboratory Information Services business is focused on increasing the demand for our rEEG Reports. We believe the key factors that will drive broader adoption of our rEEG Reports will be acceptance by healthcare providers and patients of their benefit, demonstration of the cost-effectiveness of using our technology, reimbursement by third-party payers, expansion of our sales force and increased marketing efforts.

In addition to its utility in providing psychiatrists and other physicians/prescribers with medication sensitivity guidance, rEEG provides us with significant opportunities in the area of pharmaceutical development. rEEG, in combination with the information contained in the CNS Database, has the potential to be able to identify novel uses for neuropsychiatric medications currently on the market and in late stages of clinical development, as well as aid in the identification of neurophysiologic characteristics of clinical subjects that may be successfully treated with neuropsychiatric medications in the clinical testing stage. We intend to enter into relationships with established drug and biotechnology companies to further explore these opportunities, although no relationships are currently contemplated. The development of biomarkers as the new method for identifying the correct patient population to research is being encouraged by both The National Institute of Mental Health (NIMH) and The Food and Drug Administration (FDA).

Clinical Services

In January 2008, we acquired our largest customer, NTC, located in Colorado. Upon the completion of the transaction, NTC became our wholly-owned subsidiary. At the time, NTC operated one of the largest psychiatric medication management practices in the state of Colorado, under contracts with national health plans. Daniel A. Hoffman, M.D. is the medical director at NTC, and, after the acquisition, became our Chief Medical Officer and more recently, our President.

NTC, having performed a significant number of rEEG's, serves as an important resource in our product development, the expansion of our CNS Database, production system development and implementation, along with the integration of our rEEG services into a medical practice. Through NTC, we also expect to successfully develop marketing and patient acquisition strategies for our Laboratory Information Services business. Specifically, NTC is learning how to best communicate the advantages of rEEG to patients and referring physicians in the local market. We will share this knowledge and develop communication programs which can be generalized to physicians using our services throughout the country, which we believe will help drive market acceptance of our services. In addition, we plan to use NTC to train practitioners across the country in the uses of rEEG technology.

We view our Clinical Services business as secondary to our Laboratory Information Services business, and we have no current plans to significantly expand this business.

Laboratory Information Services

The Challenge and the Opportunity

The 1990's were known as "the Decade of the Brain," a period in which basic neuroscience yielded major advances in drug discovery and neurotherapy. Several trends have emerged which may propel significant adoption of these advances over the next decade:

- Comparative Effectiveness Research is incorporated into the Obama health plan. The cost to treat Americans under care for depression and other mental illnesses rose by nearly two-thirds from $35 billion to $58 billion in the last 10 years, according to a recent report from the Agency for Healthcare Research and Quality. Finding more cost-effective treatment modalities in mental disorders will be critical to successful health care reform;

- Mental Health Parity Act (Parity Act) requires payers, beginning in 2010, to pay for behavioral medications and treatments using the same standards for evidence and coverage as they currently use for medical/surgical treatments;

- According to a recent RAND report, 275,000 returning military personnel from the Iraq and Afghanistan theatres suffer from Major Depression, Post Traumatic Stress Disorder (PTSD), traumatic brain injury; and

- Consumers have emerged as active decision makers in behavioral treatment, driven by over $4.8 billion in annual Pharma direct-to-consumer advertising and the internet. At the same time, media costs for reaching those consumers are at historic lows.

Today, there are over 100 prescription drugs available to patients suffering from a behavioral disorder, representing one of the largest and fastest-growing drug classes. Unfortunately, psychotropic drugs often do not work, or lose their effect over time, and over 17 million Americans who have failed two or more medication treatments are now considered "treatment resistant". For these patients, the conventional "trial and error" method of prescribing psychotropic drugs has resulted in low efficacy, high relapse and treatment discontinuation rates, significant patient suffering and billions in additional cost to payers.

We believe we are the first company to create a biomarker database that correlates a patient's response to major drug classes and specific medications with their individual brain physiology. We developed this tool to improve pharmacotherapy outcomes, particularly in treatment resistant patients, a particularly expensive patient population with profound unmet clinical needs. Our rEEG technology has been used by physicians to guide prescribing in behavioral disorders such as depression, anxiety, anorexia, OCD, bipolar, ADHD, addiction and others.

rEEG® was developed by a pathologist/psychiatrist who recognized that correlation of a patient's unique brain patterns to known long-term medication outcomes in similar patients might significantly improve therapeutic performance. This approach — commonly referred to as Personalized Medicine, and exemplified by biomarker companies such as Genomic Health (GHDX) — is in the process of transforming both clinical practice and the pharmaceutical industry. CNS Response brings this science to behavioral medicine, where the unmet clinical need is well-documented, expensive, and growing.

The rEEG® Method

rEEG® reports are offered as a service, much like a reference lab, in which standard electroencephalogram (EEG) readings are referenced to a biomarker database to suggest patient-specific probabilities of response to different medications. EEG recording devices are widely available, inexpensive to lease, and are available in most cities by independent mobile EEG providers.

The service works as follows:

- Patients are directed to a national rEEG® provider, who performs a standard digital EEG.
- EEG data is uploaded over the web to our central analytical laboratory.
- We analyze the data against the CNS Database for patients with similar brain patterns.
- We provide a report describing the probability of patient success with different medication options (much like an antibiotic sensitivity report commonly used in medicine).
- The rEEG® report is sent back to the doctor, typically the next day.

Treatment Decisions Made by Licensed Professionals

With the exception of our subsidiary, the Neuro-Therapy Clinic based in Denver, CO, we do not currently operate our own healthcare facilities, employ our own treating physicians or provide medical advice or treatment to patients. Physicians who contract for our rEEG Reports own their own facilities or professional licenses, and control and are responsible for the clinical activities provided on their premises. Patients receive medical care in accordance with orders from their attending physicians or providers. Physicians who contract for rEEG Reports are responsible for exercising their independent medical judgment in determining the specific application of the information contained in the rEEG Reports, and the appropriate course of care for each patient. Following the prescription of any medication, Physicians are presumed to administer and provide continuing care treatment.

Estimated Market for rEEG Reports

Currently, the wholesale (direct to physician) price for standard rEEG testing is $400 per test, and the retail (payer and consumer) price is approximately $800. Thus far, payments have typically been from psychiatrists whose patients pay privately for the rEEG® report. The National Institute of Mental Health (NIMH) estimates that only 12.7% of patients get minimally effective treatment, with over 17 million Americans now classified as “treatment resistant”, meaning they’ve failed to find relief after trying two or more medications.

We therefore estimate the potential market for our rEEG reports at $1.7 billion annually, based on an addressable market of 17 million Treatment Resistant patients, with only 12.5% of patients seeking care and complying with treatment. Now that we have completed our clinical trial (please see page 11 Laboratory Services Accomplishments for further information on our clinical trial), we intend to place greater emphasis on the marketing of our rEEG technology to physicians, consumers and payers.

Path to Adoption

Several biomarker firms have successfully commercialized products that predict medication response, including Genomic Health's OncotypeDx which predicts response to chemotherapy, and Roche/Affymetrix Cytochrome P450 test which shows how each patient is likely to metabolize a given antidepressant. We are following the paths to adoption used by these successful biomarker firms by focusing on growth in three stages:

(1) Private pay market.

Consumers and private-pay psychiatrists drive over 33% of the market for psychiatric visits, and a significant proportion of all licensed psychiatrists now describe themselves as private pay only. We believe consumers who have experienced treatment failure will seek out our network of physicians once they become aware of the successful outcomes demonstrated in our clinical trial.

During 2008, the recruiting for our Depression Efficacy Trial (the Depression Efficacy Trial is further described under the heading Laboratory Services Accomplishments on page 11) generated many important lessons about integrated marketing for our rEEG® service. By using a media mix of web, radio and TV, interested patients were delivered into the trial at an average cost of $40-$68 per contact. We will continue to pursue integrated consumer marketing as a means to introduce interested patients to our rEEG® provider network.

To drive growth in private pay, consumer-driven rEEG testing, we plan to do the following:

- Grow our focused physician network: We currently have 51 active practicing physicians utilizing rEEG in their practices, defined as having paid for testing within the last 12 months. An additional 52 physicians are currently involved in training or clinical trials utilizing rEEG. Physicians who become "power users" (which we define as physicians who conduct several tests per month) report significantly better results than casual users of rEEG technology, and have certain economies of scale in using the test in their practices. Similar to the adoption of LASIK technology in consumer-driven opthalmology, successful practices using rEEG have reported that as their word-of-mouth referrals increase, their procedure billings increase, and their average patient visits decrease (as patients improve). Accordingly, their patient turnover may increase over time, requiring additional marketing efforts to grow their practice volume.

  We plan to focus on supporting these power users through direct marketing, clinical practice support (patient intake, scheduling, washout support and reporting), and technical support. This focused network approach has been successful in other specialties (for example, in organ transplant networks and in disease management) because it is easier to sell to payers, facilitates data collection, and is more cost-effective in delivering care even at higher provider margins.

- Increase unit pricing: Currently, the wholesale (direct-to-physician) price for standard rEEG testing is $400 per test, and the retail (payer and consumer) is approximately $800. We anticipate that our pricing will be increased over time with greater acceptance of the test as a standard of care, rewarding power users for committed volume and affording improvement in test margins overall.

- Utilize our product laboratory: In 2008, we purchased the psychiatric clinic in Denver, CO founded by our Chief Medical Officer, Daniel Hoffman, MD. The clinic currently serves as a platform for perfecting rEEG workflow, information systems, product development and research. We also test local marketing strategies in Denver which can then be generalized to other rEEG® network clinics. The Denver clinic may ultimately become a national Center of Excellence for neuropsychiatry, where insurers may direct certain treatment-resistant patients.

- Scalable platform for delivery: During 2008, significant development effort was focused on production systems and lab infrastructure to accommodate potential growth in the production volume of our rEEG Reports. Our current production application is able to accommodate up to 100 tests per day without additional manpower. In addition to providing scalable capacity, the production system provides for online delivery of tests and delivery of test data to physicians' desktops. Currently, we are investing in projects to reduce or eliminate the remaining manual processes in test production: "artifacting" of EEG data and Neurologist review of each case. It is estimated that these processes will, over time, be replaced with validated algorithms and/or post-facto sampling for quality assurance.

(2) Payer economic trials.

Health plans currently spend over $30 billion on psychotropic medications each year according to the Substance Abuse and Mental Health Services Administration (SAMHSA), and most are aware that these agents only work on about 30% of patients who take them. The lack of medication adherence and poor treatment outcomes in behavioral health have been longstanding issues for payers, but they've lacked a targeted, cost-efficient approach to solve the problem.

Presently, rEEG is not a reimbursable procedure for most health care payers. Initially, payer response to most new technologies is a reflexive denial of coverage, regardless of the superiority of evidence or economics. Over time, however, certain payers may adopt technologies which confer a clear marketing or underwriting advantage, or which protect them from legal claims for reimbursement under new legislation (e.g. Parity). Because of this, it is possible that with sufficient marketing efforts, we may shift payer "fear of adoption" to "fear of not adopting" and increase the number of payers that approve our rEEG Reports as a reimbursable expense.

We intend to prove that our rEEG reports are a compelling value for payers through independent research, budget impact models, and payer pilots (economic trials):

- **Evidence for payers:** We will share well-designed research on rEEG® efficacy, showing the weight of superior evidence in controlled and real-world clinical trials and case series.

- **Parity:** In 2010, Mental Health Parity Act (Parity Act) will change all payers' coverage criteria, requiring equal coverage for behavioral and medical therapies, using the same coverage criteria and evidence. Milliman Global Actuarial Services estimates a 1-3% increase in overall health costs resulting from a significant increase in behavioral health expenditures driven by the Parity Act. Of particular interest to us, however, is the specific language in the Parity Act which requires that coverage of a scope-of-service for one type of diagnosis (for example: a Neurologist performing a diagnostic EEG for Epilepsy) be applied equally as the use of an EEG by a Psychiatrist for medication management.

- **Budget Impact Model:** A Budget Impact Model for rEEG® has been developed by Analysis Group Economics based on the published research of Kessler, Russell, and others covering the cost of treatment failure in mental disorders. Modeling the economic impact of rEEG® in a health plan with five million members, we estimate that full utilization of rEEG® in treatment-resistant depression, anxiety, bipolar and ADHD could save $8,500 per treatment resistant member for a savings of $45 million per year.

- **Economic Trials:** Economic Trials are intended to demonstrate the comparative effectiveness of rEEG versus prevailing Trial & Error medication management through pilot programs within a payer's own population. Although no payer is currently reimbursing physicians for the use of rEEG technology, we are currently negotiating pilot programs for reimbursement coverage with several of the nation's largest payers, representing over 80 million covered lives.

(3) Full payer coverage.

Full reimbursement of referenced-EEG is likely to follow successful direct-to-consumer adoption of the rEEG test, along with continued release of confirmatory rEEG research in peer-reviewed publications. Following the example of the biomarker firms discussed above, it appears possible to accelerate the effect of these initiatives in the following ways:

- **Patient Advocacy:** we believe that some components of the rEEG test may be billable to payers under Mental Health Parity Act. Historically, patients of our physician network providers, and those in our own clinic in Colorado, have paid out of pocket for rEEG testing and then sought reimbursement from their insurance carrier. Although these providers frequently furnish information to support these claims, the success of their prosecution by patients is unclear.

  Accordingly, we intend to follow the example of biomarker firms such as Genomic Health, which developed Patient Advocacy services where patient claims were documented and tracked, and the company helped organize the advocacy of each claim with third party payers. Using this approach, Genomic Health was able to win a retrospective reversal of claim denials for its test from Medicare (the Centers for Medicare and Medicaid Services) in 2006.

- **Guideline development :** we intend to continue internal and externally-sponsored clinical research to prove the efficacy of our technology to professional associations, such as the American Psychiatric Association. We believe that with strong clinical results, professional associations may endorse rEEG in their treatment guidelines, which may drive full payer coverage.

We also believe that the inclusion of historical and new rEEG research in Comparative Effectiveness studies conducted under the Agency for Healthcare Research and Quality (AHRQ) would be a significant milestone. As a consequence of this recent focus on cost-effective treatment, an unprecedented level of funding has been made available under the Economic Recovery Act, the budgets for NIH and AHRQ, and earmarked budgets for Defense and the Veterans Association (VA). We intend to pursue research opportunities with several external sponsors of research, including:

- the **National Institutes of Mental Health** , focusing on the cost-effectiveness of rEEG as a more deployable version of brain imaging to guide prescribing;

- the **Department of Defense and the Veterans Administration** , to address the potential for rEEG in treating returning soldiers with PTSD and Major Depression; and

- the **Centers for Medicare and Medicaid Services (CMS)** , as a mechanism for improving quality and cost performance in programs that spend billions on psychotropic medications.

Laboratory Services Accomplishments

Over the last few years, we have been primarily focused on proving the efficacy of rEEG-guided treatments through multiple clinical trials. The largest of these — the Depression Efficacy Trial — was a multi-center, randomized, parallel controlled trial completed this year at 12 medical centers, including Harvard, Stanford, Cornell, UCI and Rush. The study began in late 2007 and was completed in September of this year, screening 465 potential subjects with Treatment Resistant Depression and ultimately randomizing 114 participants to a 12-week course of treatment utilizing rEEG in the experimental group, and a modified STAR*D algorithm in the control group (STAR*D, or Sequenced Alternatives to Relieve Depression, was a large, seven-year study sponsored by the National Institute of Mental Health and completed in 2006). Top-line results were consistent with previous clinical trials of rEEG:

- The study found that rEEG significantly outperformed the modified STAR*D treatment algorithm from the beginning. The difference, or separation, between rEEG and the STAR*D control group was 50 and 100 percent for the study's two primary endpoints. By contrast, separation between a new treatment and a control group often averages less than 10 percent in antidepressant studies. Interestingly, separation was achieved early (week 2) and durable, continuing to grow through week 12.

- The control group in this case, STAR*D, was a particularly tough comparator, representing a level of evidence-based depression care that is available to only 10% of the US population, according to one of the study's authors.

- Statistical significance ($p < .05$) was achieved on all primary and most secondary endpoints.

In the course of undertaking the study, we also gained insights into marketing of the rEEG technology, highlighting aspects of marketing which proved to be more successful than others. Furthermore, we also developed a foundation for commercialization of the rEEG technology with insurance companies, and signing a payer group, Cal Optima (a Southern California health plan for Medicare/Medicaid enrollees), to run a pilot study with us. A second large insurer is in the process of negotiating a pilot study. Additionally, over the course of the last few years, much time has been spent securing sufficient financing to continue our operations and ensure that the clinical trial was completed.

Going forward, we plan to continue expanding the CNS Database with the addition of more pharmaceuticals and their respective outcomes. Additionally, we plan on improving the functionality and clinical utility of our rEEG reports, in order to improve adoption and compress the training period necessary for physicians to become proficient with the report. Finally, we plan to increase and refine our marketing efforts to consumers and psychiatrists, and expand our effort to obtain regular insurance reimbursement for rEEG-guided therapies.

Use of rEEG Technology in Pharmaceutical Development

In addition to its utility in providing psychiatrists and other physicians with medication sensitivity guidance, rEEG provides us with significant opportunities in the area of pharmaceutical development. In the future, we aim to use our propriety data and processes to advance central nervous system (CNS) pharmaceutical development and economics, in one or more of the following ways:

- **Enrichment :** selecting patients for clinical trial who not only have the symptoms of interest, but are shown by rEEG® screening to likely respond to the developer's drug. An oft-cited example is the antidepressant Prozac, which failed several clinical trials before it achieved success in two separate trials. The ability to design trials in which exclusion criteria identify and exclude patients who are clearly resistant, as determined by rEEG, has the potential to sharpen patient focus and productivity in clinical trials of psychotropic medications.

- **Repositioning :** rEEG® may suggest new applications/indications of existing medications. For example, Selective Serotonin Reuptake Inhibitors Antidepressants (SSRI's) are now commonly given by primary care physicians for depression and other complaints, but often produce unwanted side effects or inadequate results. The ability to biomarker patients who respond better to tricyclics (TCA's), or combinations of TCA's and stimulants, offers the potential for new indications for existing compounds.

- **Salvage :** resuscitation of medications that failed phase II or III studies. One example of this opportunity is Sanofi-Aventis' unsuccessful PMA filing for Rimonabant, a promising anti-obesity/cardiometabolic compound which was denied approval in the U.S. due to CNS side-effects in their clinical trial populations. Being able to screen out trial participants with resistance to a certain medication is an application for rEEG, and could create "theranostic" products (where an indication for use is combined with rEEG) for compounds which have failed to receive broader approval.

- **New Combinations :** unwanted adverse effects occur with medications in fields from cancer to hepatitis. The ability to improve these medications, in combination with psychotropics, may improve safety, compliance, and, sometimes, patient outcomes.

- **Decision Support :** improved understanding supports improved decision making at all levels of pharmaceutical development.

Competition

Comparable Biomarker Companies

Although there are no companies offering a service directly comparable to rEEG, the following companies might be noted as pursuing similar strategies:

- GENOMIC HEALTH (Nasdaq: GHDX) Genomic Health, Inc. is a life science company focused on the development and commercialization of genomic-based clinical laboratory services for cancer that allow physicians and patients to make individualized treatment decisions. The company was founded in 2000 and is based in Redwood City, California. In 2004, the company launched the Oncotype DX breast cancer test, which has been shown to predict the likelihood of chemotherapy benefit, as well as recurrence in early-stage breast cancer. By the end of 2008, the company reported that over 90% of health plans were reimbursing use of this test. In addition to its adopted Oncotype DX breast cancer test, Genomic Health is preparing to launch its Oncotype DX colon cancer test in early 2010.

- ASPECT MEDICAL SYSTEMS, INC. (Nasdaq: ASPM), an EEG anesthesia monitoring company, is developing a specific EEG measurement system that indicates a patient's likely response to some antidepressant medications. Its biomarker, based on research from the UCLA Neuropsychiatric Institute, is called Cordance.

  A 375-subject multi-site clinical trial on the efficacy of this biomarker in guiding treatment of treatment resistant depression — the BRITE trial — demonstrated positive predictive outcomes for a single antidepressant, escitalopram (Lexapro). Patients in the trial were measured prior to and after taking medication. Publicly available data suggests that the technology may validate a patient's treatment but does not guide specific treatment. Initial trials have shown efficacy in correlating a patient's ultimate response to antidepressants. The revenue model may involve sale of equipment and a per-patient charge, but the company does not currently appear to be close to a commercial release of its product. The company is now conducting trials.

- BRAIN RESOURCE COMPANY (Aust: BRRZF) (www.brainresource.com), is an Australian Clinical Research Organization (CRO) and biomarker company focused on personalized medicine solutions for patients, clinicians, pharmaceutical trials and discovery research. As a CRO, its main focus has been iSPOT, an $18 million international biomarker study with a private biotechnology company. Their revenue model includes physician services and sale of systems and services to pharmaceutical development companies in the CNS discovery field. As a biomarker provider, it signed a $6 million agreement last year with Optum (United Healthcare) to provide screening for plan members.

We believe that we have a competitive advantage with respect to the behavioral biomarker firms such as Aspect Medical or Brain Resource Company as we offer more comprehensive testing (e.g. to cover the full range of CNS medications, not just certain antidepressants in the case of Aspect Medical) and have conducted studies to validate the efficacy of our service. We also believe that we offer greater clinical utility (ease of use, rapid results) in day-to-day clinical practice than our competitors.

Emerging Medical Device Technologies .

The field of neuropsychiatry is undergoing dramatic change as a result of the introduction of new technologies. Many of these technologies are focused on the same treatment-resistant patient populations which are the focus of rEEG, and are priced from $10,000 to over $50,000 for a full course of treatment. Two of the three examples presented here are invasive, implantable devices.

- CYBERONICS, INC. (Nasdaq: CYBX) is a neuromodulation company, engages in the design, development, manufacture, and marketing of implantable medical devices that provide vagus nerve stimulation (VNS) therapy for the treatment of epilepsy and treatment-resistant depression. The VNS therapy system consists of an implantable generator that delivers an electrical signal to an implantable lead attached to the left vagus nerve, as well as a bipolar lead, a programming wand and software, and a tunneling tool.

  Cyberonics has developed an implantable Vagus Nerve Stimulation device approved for treatment-resistant depression. This device has received pre-market approval from the Food and Drug Agency for patients and is believed to be under reimbursement review by insurance payers.

- MEDTRONIC, INC. (NYSE: MDT). Medtronic has an implantable deep brain stimulation device (DBS) in development which is similar to their device approved for Parkinson's treatment. Deep brain stimulation uses an implanted electrode – essentially a pacemaker for the brain — to deliver electrical stimulation to specific structures within the brain. The Food and Drug Administration (FDA) approved DBS as a treatment for essential tremor in 1997, for Parkinson's disease in 2002, and dystonia in 2003. DBS is also routinely used to treat chronic pain and has been used to treat various affective disorders, including major depression. While DBS has proven helpful for some patients, there is potential for serious complications and side effects.

- NEURONETICS (Privately held) (www.neuronetics.com). Neuronetics has pioneered and refined the NeuroStar TMS Therapy system for non-invasive, non-systemic treatment for depression using a focused, pulsed magnetic field to stimulate function in targeted brain regions. NeuroStar TMS Therapy stimulates nerve cells in an area of the brain that is linked to depression by delivering highly focused MRI-strength magnetic field pulses.

TMS is performed in a physician's office with each treatment lasting about 40 minutes daily for four to six weeks. In an open-label clinical trial, which is most like real world clinical practice, approximately one in two patients experienced significant improvement in symptoms, and one in three experienced complete symptom resolution. NeuroStar TMS Therapy was cleared by the FDA in October 2008 for patients who have not adequately benefited from prior antidepressant medication. TMS Therapy is currently available at over 25 treatment locations in 15 states.

From a competitive standpoint, we view these emerging treatment options as expensive augmentations to existing therapies for treatment-resistant patients, and as competitive therapeutic options to medications. To the best of our knowledge, rEEG-guided therapy provides a higher probability of treatment success at a significantly lower cost than device-based solutions, which gives us a competitive advantage in the marketplace.

Intellectual Property

rEEG Patents

We have three issued U.S. Patents which we believe provide us with the right to exclude others from using our rEEG technology. In addition, we believe these patents cover the analytical methodology we use with any form of neurophysiology measurement including SPECT (Single Photon Emission Computed Tomography), fMRI (Functional Magnetic Resonance Imaging), PET (Positron Emission Tomography), CAT (Computerized Axial Tomography), and MEG (Magnetoencephalography)). We do not currently have data on the utility of such alternate measurements, but we believe they may, in the future, prove to be useful to guide therapy in a manner similar to rEEG. We have also filed patent applications for our technology in various foreign jurisdictions, and have issued patents in Australia and Israel.

rEEG Trademarks

“Referenced-EEG” and “rEEG” are registered trademarks of CNS California in the United States. We will continue to expand our brand names and our proprietary trademarks worldwide as our operations expand.

CNS Database

The CNS Database consists of over 17,000 medication trials across over 2,000 patients who had psychiatric or addictive problems. The CNS Database is maintained in two parts:

1. The QEEG Database

The QEEG Database includes EEG recordings and neurometric data derived from analysis of these recordings. This data is collectively known as the QEEG Data. QEEG or “Quantitative EEG” is a standard measure that adds modern computer and statistical analyses to traditional EEG studies. The Company utilizes two separate, FDA-approved external QEEG databases which provide statistical and normative information in the rEEG process.

2. The Clinical Outcomes Database

The Clinical Outcomes Database consists of physician provided assessments of the clinical long-term outcomes (average of 405 days) of patients and their associated medications. The clinical outcomes of patients are recorded using an industry-standard outcome rating scale, the Clinical Global Impression Global Improvement scale (“CGI-I”). The CGI-I requires a clinician to rate how much the patient's illness has improved or worsened relative to a baseline state. A patient's illness is compared to change over time and rated as: very much improved, much improved, minimally improved, no change, minimally worse, much worse, or very much worse.

The format of the data is standardized and that standard is enforced at the time of capture by a software application. Outcome data is input into the database by the treating physician or in some cases, their office staff. Each Physician has access to his/her own patient data through the software tool that captures clinical outcome data.

We consider the information contained in the CNS Database to be a valuable trade secret and are diligent about protecting such information. The CNS Database is stored on a secure server and only a limited number of employees have access to it.

Research and Development

In 2010, we plan to continue to enhance, refine and improve the accuracy of our CNS Database and rEEG through expansion of the number of medications covered by our rEEG Reports, expansion of our biomarkers, refinement of our biomarker system, and by reducing the time to turnaround a report to the physician.

Government Regulation

We do not believe that sales of our Laboratory Information Services, including our rEEG Reports, are subject to regulatory pre-market approval. However, on April 10, 2008 we received a “warning letter” from the FDA in which the FDA indicated it believed, based in part on the combination of certain marketing statements it read on our website, together with the delivery of our rEEG Reports, that we were selling a software product to aid in diagnosis, which constituted a “medical device” requiring pre-market approval or clearance by the FDA pursuant to the Federal Food, Drug and Cosmetic Act (the "Act"). We responded to the FDA on April 24, 2008 indicating that we believed it had incorrectly understood our product offering, and clarified that the Laboratory Information Services were not diagnostic and thus did not constitute a medical device. On December 14, 2008, the FDA again contacted us and indicated that, based upon its review of our description of our intended use of the rEEG Reports on our website, it continued to maintain that the rEEG Reports met its definition of medical devices. In response to of the FDA communications, we made a number of changes to our website and other marketing documents to reflect that rEEG is a service to aid in medication selection and is not a diagnosis aid. On September 4, 2009, through our regulatory counsel, we responded to the December 14, 2008 FDA letter explaining our position in more detail.

On December 28, 2009, the Company and Regulatory counsel received a response from the FDA indicating that it still believes referenced-EEG constitutes a “medical device” under the Act. In response to the most recent letter, we will request a meeting with FDA to discuss the scope of and requirements for 510(k) clearance, that they might require, if any. In any event, we will continue our ongoing dialogue with the FDA regarding our Laboratory Information Services, and we will take all action necessary and appropriate to support our position.

We cannot provide any assurance that additional FDA regulation, including PMA, will not be required in the future for referenced-EEG. It is also possible that legislation will be enacted into law and may result in increased regulatory burdens for us to continue to offer referenced-EEG testing.

If pre-market review is required, our business could be negatively impacted until such review is completed and clearance to market or approval is obtained, and FDA could require that we stop selling our test pending pre-market clearance or approval. If our test is allowed to remain on the market but there is uncertainty about our test, if it is labeled investigational by FDA, or if labeling claims FDA allows us to make are very limited, orders may decline. The regulatory approval process may involve, among other things, successfully completing additional clinical trials and submitting a pre-market clearance notice or filing a PMA application with the FDA. If pre-market review is required by FDA, there can be no assurance that our test will be cleared or approved on a timely basis, if at all. Ongoing compliance with FDA regulations would increase the cost of conducting our business, and subject us to inspection by FDA and to the requirements of FDA and penalties for failure to comply with these requirements.

Even if the sale of our Laboratory Information Services are not subject to regulatory approval, federal and state laws and regulations relating to the sale of our Laboratory Information Services are subject to future changes, as are administrative interpretations of regulatory agencies. In the event that we do not resolve the status of our Laboratory Information Services with the FDA, or in the event that federal and state laws and regulations change, we may need to incur additional costs to seek government approvals for the sale of our Laboratory Information Services.

In the future, we intend to seek approval for medications or combinations of medications for new indications, either with corporate partners, or potentially, on our own. The development and commercialization of medications for new indications is subject to extensive regulation by the U.S. Federal government, principally through the FDA and other federal, state and governmental authorities elsewhere. Prior to marketing any central nervous system medication, and in many cases prior to being able to successfully partner a central nervous system medication, we will have to conduct extensive clinical trials at our own expense to determine safety and efficacy of the indication that we are pursuing.

PART IV

ITEM 15. Exhibits, Financial Statement Schedules

(a) 3. The following exhibits are included herein:

Exhibit Number	Exhibit Title
31.1	Certification by Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2	Certification by Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934, 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.

CNS RESPONSE, INC.

By: /s/ George Carpenter
George Carpenter
Chief Executive Officer

Date: March 29, 2010

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ George Carpenter George Carpenter	Chief Executive Officer, Director (Principal Executive Officer)	March 29, 2010
/s/ Paul Buck Paul Buck	Chief Financial Officer (Principal Financial and Accounting Officer)	March 29, 2010
* David B. Jones	Director	March 29, 2010
* Jerome Vaccaro, M.D.	Director	March 29, 2010
* Henry T. Harbin, M. D.	Director	March 29, 2010
* John Pappajohn	Director	March 29, 2010

* By: /s/ George Carpenter
George Carpenter
As Attorney-In-Fact

INDEX TO EXHIBITS

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Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO SECURITIES EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a) AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, George Carpenter, certify that:

1. I have reviewed this annual report on Form 10-K/A of CNS Response, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 29, 2010

/s/ George Carpenter
George Carpenter
Principal Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECURITIES EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a) AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Paul Buck, certify that:

1. I have reviewed this annual report on Form 10-K/A of CNS Response, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 29, 2010

/s/ Paul Buck
Paul Buck
Principal Financial Officer